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Ethical and legal aspects of
pediatric audiology: what could
go wrong?



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Adam Schefter reveals Jason
Pierre-Paul had a finger
amputated by tweeting private
medical record

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Children's
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Blazer's Edge
 @Blazersedge

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...how on Earth is this ethical? twitter.com/adamscheffer/s...

7:14 PM - 8 Jul 2015

7 10


Chris Long ✓
 @JOEL9ONE

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How does ESPN obtain and leak the pics of JPP medial charts? Is that even legal?

7:41 PM - 8 Jul 2015



191 275

At first people were concerned that Scheffer had violated the Health Insurance Portability and Accountability Act (HIPAA) a law that exists in part to protect the confidentiality and security of healthcare information. The law **does not apply directly to news media**, however.




What's the difference?

- Laws –obligatory; Black and white – not much gray
- Ethics –necessary; Continuum of black to white, including a lot of gray
- Morals – Hopefully; gray only

LAW

\ˈlō\

Noun: the principles and regulations established in a community by some authority and applicable to its people, whether in the form of legislation or of custom and policies recognized and enforced by judicial decision.

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Applicable Laws

- **False Claims Act** - illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.
- **Anti-Kickback Statute** – prohibits individuals or entities to offer, pay, solicit or receive remuneration in order to induce business reimbursed under federal programs
- **Stark Law** - prohibits a physician who has a "financial relationship" with an entity from referring patients to that entity for services covered by Medicare
- **HIPAA** – Regulates the use and disclosure of protected health information (PHI), including medical records and billing/payment history.

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Case Example: OCR

- **Private Practice Implements Safeguards for Waiting Rooms**
- A staff member of discussed HIV testing procedures with a patient in the waiting room, thereby disclosing PHI to several other individuals. Among other corrective actions to resolve the specific issues in the case, OCR required the provider to develop and implement policies and procedures regarding appropriate administrative and physical safeguards related to the communication of PHI. The practice trained all staff on the newly developed policies and procedures.

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Legal Challenge #1

A mature minor patient of yours requests copies of her medical records. When she shows up to receive the records, no one asks her for her ID to verify her identity. Is this a HIPAA violation?

No. It is not a HIPAA violation to receive you own medical records. The patient is the patient.

The same patient requests copies of her medical records. She asks her mother to get her records? When the mother shows up to receive the records, no one asks her for her ID to verify her identity. Is this a HIPAA violation?

Yes. This is not the patient. The patient would have to provide permission for her mother to pick up the records, and ID would have to be verified.

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Legal Challenge #2

Your son gives you permission to assist in resolving the bill from the hospital where you work. As an employee of that hospital, can you enter the billing records without violating HIPPA privacy rules?

No, if the child is under 18.

Yes, if the child is over 18. Written permission must reside in the medical records giving you permission.

However, this might be a violation of company policy....

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Legal Challenge #3

A parent requests copies of their child's medical records be mailed to them. Several weeks later, that parent comes into your office with those records and shows you that two pages are actually records from another patient. Is this a HIPAA violation?

Yes. It is one of the most common violations. Corrective action is required.

Could the patient whose medical records have been accidentally been released sue you for violating their rights under HIPAA?

HIPAA law does not include civil actions. Currently being tested in courts?

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Legal Challenge #4

As an employee of a hospital, a friend asks you to review her daughters audiologic medical records to assure she understands all the recommendations. Is this a HIPAA violation?

Yes. It is a violation unless written permission exists in the record allowing you to access the records.

What if you were the grandfather of a child seen for a vestibular evaluation and the mother signed a release of information request with your name on it? Could you access the records?

No. It is a violation unless written permission exists in the record allowing you to access the records. A release of information is not the same as accessing medical records.

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Additional legal obligations

- State laws
 - Licensing
 - Medical services
 - Fraud and Abuse
 - Anti-Discrimination laws
 - Child abuse reporting
- Patient Protection and Affordable Care Act
- CMS Regulations (e.g. Medicare and Medicaid)
- FDA Regulations (e.g. hearing aid delivery)
- Department of Education (e.g. IDEA)

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Example: Ohio Licensing Laws

- Audiologist
 - Requirements for license
 - Maintaining license
- Audiology Assistant
- Research
- Telepractice
- Ethical Practices

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Affordable Care Act



Audiologists must also follow the ethical guidelines and rules of payers.

Audiologists are required to participate in the ACA and are required to report data. According to the ACA, audiologists will be penalized for noncompliance.

Audiologists must document improvement/outcomes for services billed. The outcome measured can include functional outcome measure, questionnaires or therapy progress notes.

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Audiologists are currently eligible to report on six PQRS measures

- Documentation of current medications in the medical record (Measure #130)
- Preventive care and screening: Screening for clinical depression and follow-up plan (Measure #134)
- Falls: Risk assessment (Measure #154)
- Falls: Plan of care (Measure #155)
- Preventative care and screening: Tobacco use: screening and cessation intervention (Measure #226)
- Referral for otologic evaluation for patients with acute or chronic dizziness (Measure #261)

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Free Hearing Test

- Under CMS rules a provider cannot charge Medicare for a procedure or device that would be given to others for free; including hearing testing.
- Audiologists can provide hearing screenings at no charge because that is not a covered service according to CMS.



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Soliciting Patients

- CMS has strict rules on soliciting patients.
 - Audiologists attending health fairs cannot solicit patients. They must provide patients with a list of local providers but can list themselves first.
 - Audiologists cannot provide referral pads to other hearing healthcare professionals.
 - If reminder cards are sent to a patient, it should be disclosed on the card that it may not be covered and may not be deemed medically necessary to have an annual hearing test.

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Legal Responsibilities in Service Delivery

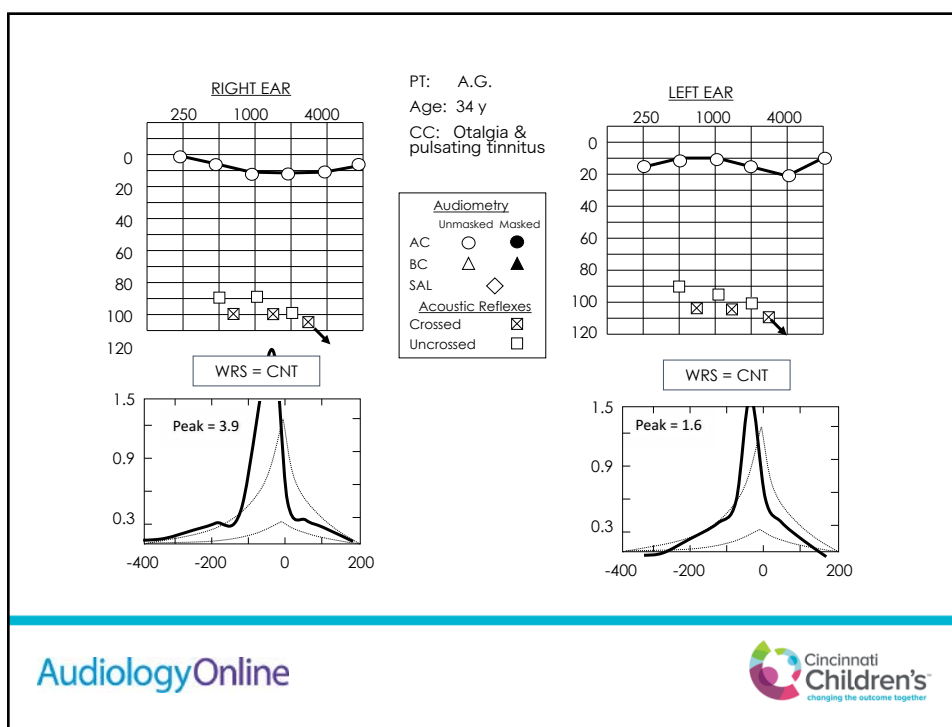
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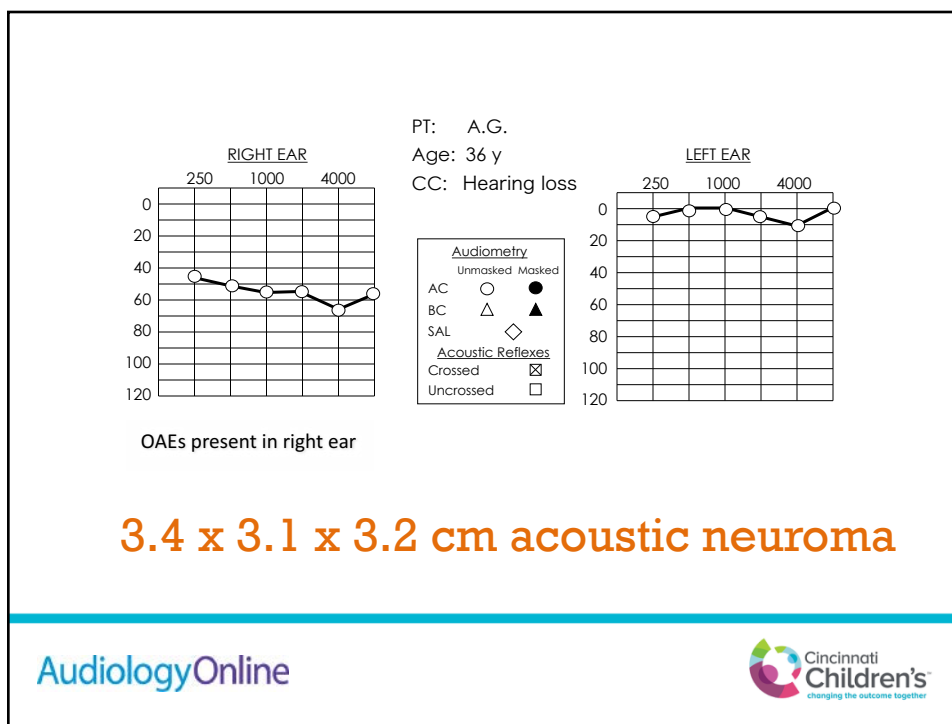
Case: A.G.

- 34 year old immigrant from Bosnia with limited English
- Sinus congestion
- “sudden onset, constant R ear pain with pulsing sound and decreased hearing”
- Mild discomfort to palpitation of R postauricular area
- Referred to audiology for diagnostic workup

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Follow-up

- Total nerve excision 2 months later
- Surgical complications; Slow to wake; CT revealed bleeding into brainstem; poor prognosis
- Defendants - Surgery Chair, ENT faculty, ENT resident, audiologist, audiology director
- Negligence; loss of consortium
 - Failure to diagnose acoustic neuroma
 - Failure to follow protocols

Outcomes - Legal

- Case Resolution
 - Three years
 - Final disposition
 - Settlement
- Legal questions
 - Responsibilities with licensure
 - Professional standards
- Clinical concerns

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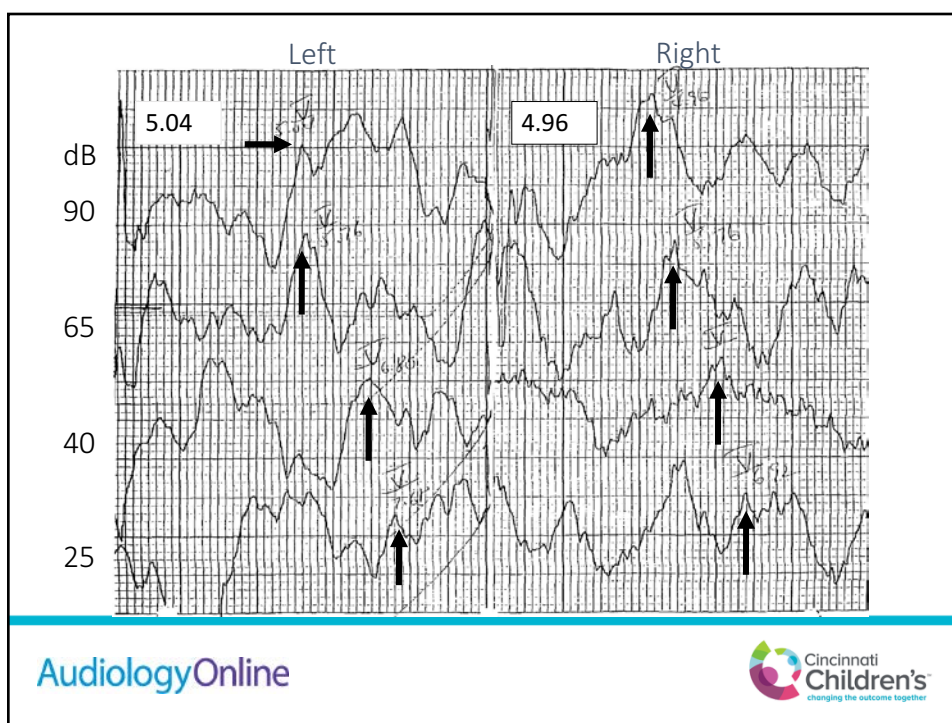


Case: W.V. – prior Hx

- Hearing evaluation requested by mother
- First tested at two months with sound field
 - Single response noted at 60 dB @ 2K
 - SAT of 60-65 dB
- Retested at 5 months with ABR
 - “Absolute Wave V present at 90 dB, 65 dB, 40 dB and 25 dB. Levels below 25 dB were not attempted since the infant was awake and active.”
 - Conclusion: Normal hearing bilateral

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Case: W.V.

- Mother continued expressing concern regarding hearing
 - Fluid present bilateral
 - Pressure equalizing tubes inserted
 - Persistent clear drainage from both ears since surgery
- No action on hearing concerns

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Cincinnati Children's
changing the outcome together

Case: W.V.

- Admitted to the hospital with meningitis at 14 months of age
 - Audiologic evaluation requested by attending physician (I.D.) and mother
 - Tubes present and continued clear drainage from both ears
- Audiologic evaluation
 - No response to click ABR bilateral
 - No response to DPOAE bilateral

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Case: W.V. Outcomes

- CT Scan - Mondini Malformation
- Bilateral congenital hearing loss
- Incorrect conclusion with subsequent inappropriate management
- Physical, intellectual and emotional states of parent and child
- Legal ramifications - began with ENT; expanded to audiologist

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Medicolegal perspectives...

- Missing a significant pathology (e.g. vestibular schwannoma)
- Failure to identify hearing loss, particularly in the newborn
- Failure to identify central auditory disorders – with subsequent educational delay
- Inappropriate treatment (e.g. hearing aids; cochlear implants, etc.)
- Failure to refer to other specialists

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Medical (Audiologic) Malpractice

Medical malpractice describes any treatment, lack of treatment, *departure from accepted standards of care* or safety by a health care provider that causes harm to a patient. Medical malpractice includes misdiagnosis, delay in diagnosis, delay in treatment or failure to perform appropriate follow-up.

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moral

[mawr-uh l]

Adjective: of, relating to, or concerned with the principles or rules of right conduct or the distinction between right and wrong. *moral attitudes.*

About morals, I know only that
what is moral is what you feel
good after and what is immoral
is what you feel bad after.

[Ernest Hemingway](#)

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Morals vs Ethics

Morals define personal character, while ethics stress a social system in which those morals are applied. In other words, ethics point to standards or codes of behavior expected by the group to which the individual belongs.

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[eth-iks]

Noun: the rules of conduct recognized in respect to a particular class of human actions or a particular group, culture, etc.: *medical ethics*; *Christian ethics*.

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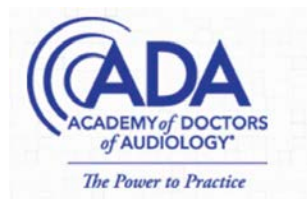


Ethical Standards

- Professional organizations
- Research
- Higher education
- Students Code of Conduct
- Licensing Laws

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Code of Ethics

AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

Code of Ethics



Code of Ethics

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Ethical Challenge #1

Cincinnati Children's Hospital wants to host a two-day conference on the the business of pediatric audiology. The speakers include top names in pediatric audiology. Is this CE content ethical? Is the conference? Are the attendees?

What if the same conference is sponsored by Phonak – but held at Cincinnati Children's Hospital?

What if the same conference is sponsored by Phonak - but held in Cancun?

What if the manufacturer wanted to pay the airfare for the attendees?

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Ethical Challenge #2

A diagnostic technique being used at a clinic is discovered to have low to no reimbursement. The director, in an attempt to meet the adage of “no margin, no mission” indicates that the clinic should switch to another technique that has better reimbursement? Is this ethical?

What if the second technique actually had more evidence to support its inclusion?

But the charge was 5 times higher?

Do clinicians have the right/obligation to assess a patients ability to pay before deciding on which procedures to perform?

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Ethical Challenge #3

A parent brings a child in for a hearing test and is discovered to have a mild bilateral hearing loss. The patient feels as though the low-cost PSAP devices purchased at the local outdoors store might work just as well as the high priced hearing aids. What would you do?

What if a probe mic evaluation showed the PSAPs provide about the right amount of gain and have an appropriate frequency response?

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Ethical Challenge #4

The test protocols at your facility include the requirement to conduct a comprehensive history, otoscopy, air and bone conduction tests, SRT and WRS, tympanograms and OAEs on all patients over the age of 10. The next patient is complaining of difficulty hearing speech in noise. Is it ethical to explicitly follow protocols when some procedures may not contribute to understanding the patient complaint?

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Ethical Challenge #5

A 7 month old child of normal hearing parents is discovered to have a moderate to severe hearing loss. As part of the post-identification counseling process, you suggest options for communication. The parents ask your advice on which option they should consider. Is it ethical to offer your advice and suggest an auditory/oral approach?

What if the parents are both deaf and use sign language? Is this still an ethical approach?

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Ethical Challenge #6

A parent brings a six month old into your private audiologic practice for a hearing evaluation due to a failed newborn screening. You have OAE and click ABR, but not frequency specific stimuli. Is it ethical to provide this evaluation?

The mother insists that they do not have the financial resources to travel the two hours to the big city to get the test and is willing to accept the test results. Is it ethical to consider the financial resources of a patient when making a decision regarding care?

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Ethical Challenge #7

A parent brings their 14 year old child with a mild bilateral loss in for an annual check-up, including hearing aid cleaning. The child expresses frustration about having to wear hearing aids and does not wish to continue with them. Is it ethical to consider the child's wishes?

What if the child was 17 years old and a senior in high school?

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Ethical Challenge #8

You inform parents that their 10 month old child has a moderate to severe bilateral hearing loss. You indicate that the child needs amplification fit as soon as possible but the parents indicate they want to consult their pastor and pray about the situation? What is the ethical response to these parents?

What should you do if they refuse treatment for their child?

How do we ethically balance “best interests” with “beneficence”?

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Ohio Licensing Law

- Chapter 4753-9 Code of Ethics
- Includes (e.g.)
 - Relationships to patients; Discrimination
 - Public statements
 - Substance Abuse
 - Fees, Medical Records, and Prognosis
 - Infection Control
 - Referrals
 - Supervision of students and assistants
 - Credit for publications
 - Honoraria
 - Telepractice
 - Kickbacks

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Ohio Ethics Laws: Case Studies

An audiologist contacts the Licensing Board and asks about how long to retain patient files (paper). He needs to clear out space for more files and wants to dispose of old, inactive files. Is this an ethical issue?

According to the Ohio License Board, it is an ethical question.

???

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Ohio Ethics Laws: Case Studies

A patient receives hearing aids from the VA, and loses them six months later. He receives a replacement set from the VA. Two years later, the aids are found. He requests that the aids be programmed for his wife's hearing loss. Is this an ethical issue?

What if the VA has no issue with the aids being used by the wife?

According to the Ohio license law, it is ethical so long as the aids are "sold" as reconditioned.

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What could go wrong??

- Laws –Obligatory
- Ethics –Necessary
- Morals – Hopefully

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Sources

- Ethical Standards of professional organizations
- State licensing agencies
- Organizational sources
 - Legal and compliance
 - Human Resources
- Medical attorneys
- Federal and state agencies
 - Compliance
 - CMS

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Other pediatric ethical/legal issues

- Early identification of hearing loss
- Failure to recommend treatment in a timely manner (amplification, accessories, CI, etc.)
- Recommendations/decisions regarding communication modality
- Student supervision
- Ethics in documentation
- Recording provider/patient interactions
- Relationships to industry and commercial interests

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Ethical Challenge #9

During a hearing aid fitting on a child, a mother asks if she can film the session on her phone so she can use it to instruct the child's father on proper care and use of the hearing aid. Would you permit this to occur?

What if you found out that the mother was recording you without your permission?

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CCHMC Guidelines on Relation to Industry

- ***Can we accept food/nominal gifts from industry?***
- Meals: Only if the meals are associated with events that are educational or research based, offer CEUs and are open to the public.
- Items: May accept gifts with vendor logo in conjunction with educational conference, contains the name of the conference, and is provided to all attendees

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CCHMC Guidelines on Relation to Industry

- ***Can we accept travel for manufacturer sponsored events?***
- Yes – provided that travel is not contingent upon device sales

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CCHMC Guidelines on Relation to Industry

- ***Can we participate in manufacturer promotions?***
- No – and it's written into vendor contracts

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CCHMC Guidelines on Relation to Industry

- ***Can we accept speaker honoraria?***
- Yes – so long as it is education and not product endorsement. If it includes travel and overnight accommodations it must be approved in advance and arranged through hospital

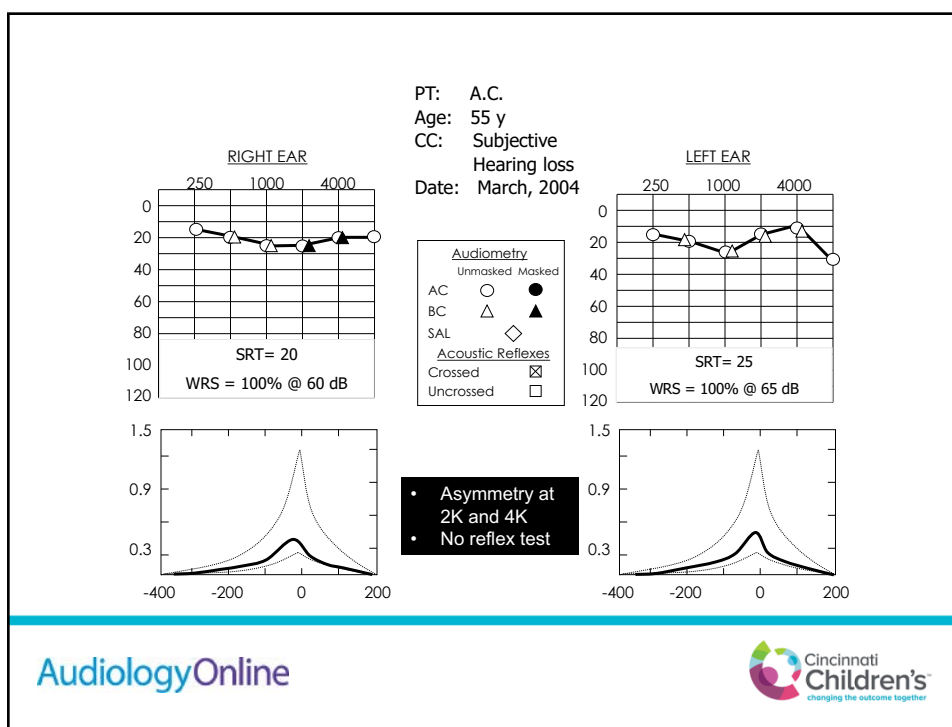
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Another legal/ethical case...

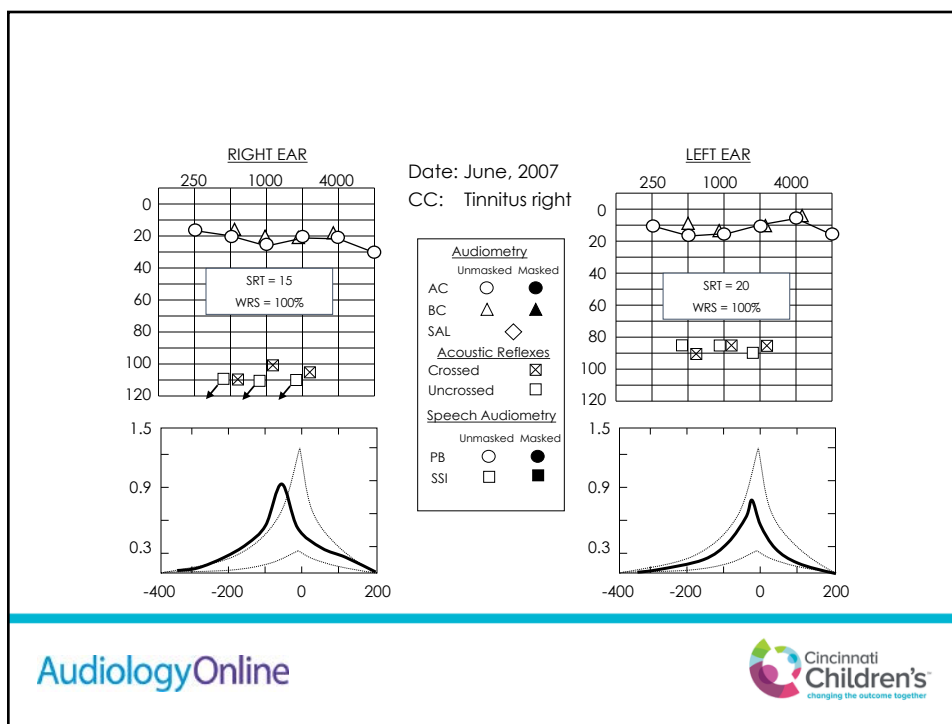
- Patient presented to ENT
 - Aural fullness (stuffy ear)
 - Tinnitus
 - Subjective hearing loss
- Referred to audiologist in practice
 - No additional history beyond chief complaint
 - Test battery based on “stuffy ear”

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Testimony...

- “There is a national standard of care for an audiologist...”
- “...breach of standard of care caused harm to plaintiff in that it contributed to delay in diagnosis.”
- “...without history the audiologist can not design a test battery strategized to patient complaint.”
- “Whether to progress to further tests is left to the discretion of the audiologist.”

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Telling accusation...

“...acting as a mere technician, rather than an audiologist, who should act as a hearing professional with considerable diagnostic acumen.”

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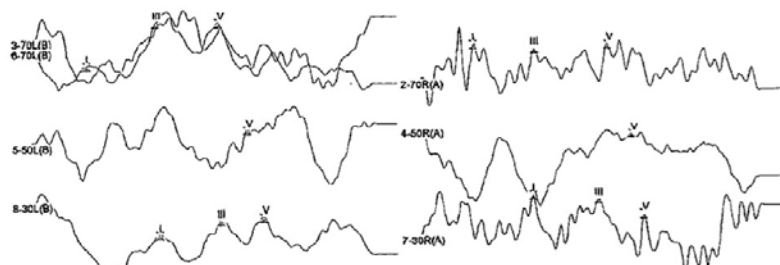
Case: C.S.

- Failed newborn screening
- Evaluated by audiologist/ENT
 - Normal results
 - Results reviewed by ENT – normal
- Referred to pediatric ENT due to ongoing concerns
- Initial test
 - Absent OAEs; Normal tymps
 - No reaction in soundfield

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Case: C.S.



Num	Int	Ear	Peaks: Latency(ms) Amp(μV) (AR=Amp Ratio)					
2	70	R	I: 1.88 0.00	II: 4.03 0.00	V: 6.60 0.00	III-I: 2.15	V-III: 2.57	V-I: 4.72
3	70	L			V: 7.43 0.00			
4	50	R			V: 7.48 0.00			
5	50	L						
6	70	L	I: 1.88 0.00	II: 4.35 0.00	V: 6.48 0.00	III-I: 2.37	V-III: 2.13	V-I: 4.50
7	30	R	I: 3.93 0.00	II: 6.20 0.00	V: 7.80 0.00	III-I: 2.28	V-III: 1.80	V-I: 3.88
8	30	L	I: 4.43 0.00	II: 6.53 0.00	V: 8.05 0.00	III-I: 2.10	V-III: 1.59	V-I: 3.63

Initial ABR; 7 weeks old

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Case: C.S.

The ABR test protocol was completed this day. I have reviewed the test data with the following results:

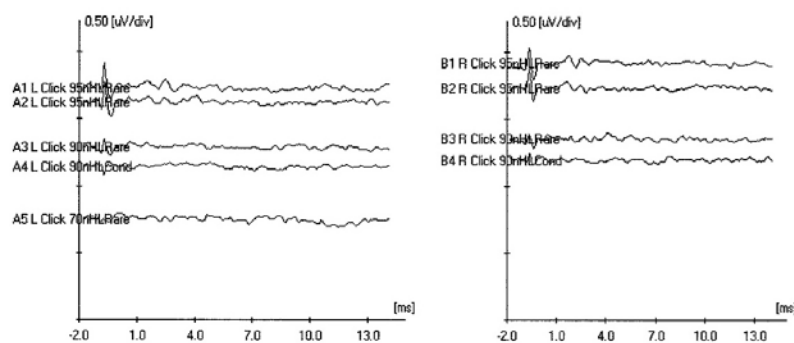
- ☒ Passed both ears
- ☐ Passed right ear/Referred left ear
- ☐ Passed left ear/Referred right ear
- ☐ Referred both ears

COMMENTS: Passed all levels tested, bilaterally. Tympanograms: Type A (normal), bilaterally.

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Case: C.S.



Sedated ABR; 13 months old

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Thankyou for Attending!
Questions or comments?

Ethical

Legal

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continuedTM