

Over The Counter (OTC) HEARING AIDS

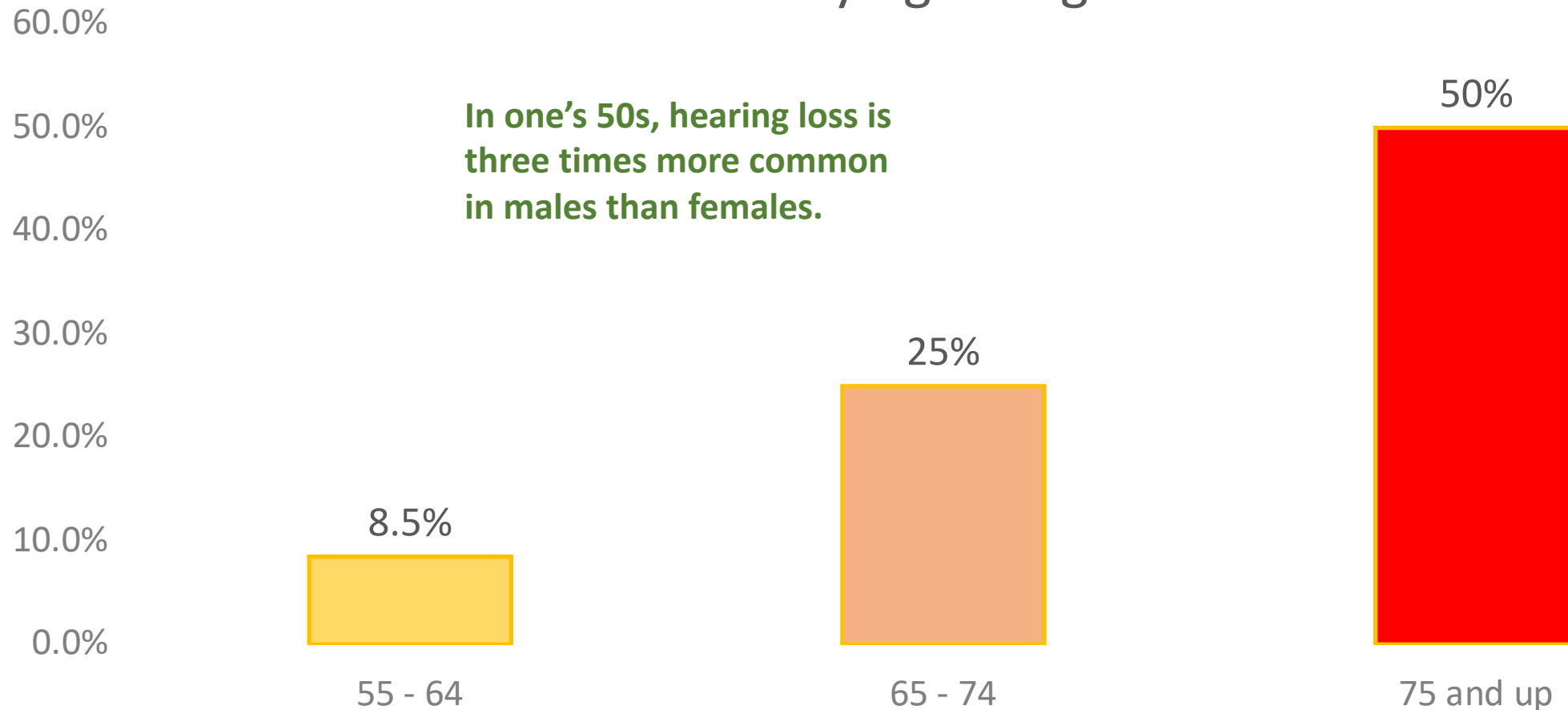
Considerations

The statistics

The (1999-2010 National Health and Nutrition Examination Survey (NHANES); 2010 (hearing loss = the level at which adults could generally benefit from hearing aids).

Over 80% in ages 80 and above.

Disabling Hearing Loss in U.S. by age ranges



NIDCD estimates that nearly 29 million ^(28.8) U.S. adults could benefit from using hearing aids but only 16 percent have ever used them.

(NIDCD Epidemiology and Statistics Program, based on December 2015 Census Bureau estimates of the noninstitutionalized U.S. population, personal communication; May 2016.

Correlations

Correlation between the progression of hearing loss and the risk of falls, depression, dementia and overall brain function.

“If you have hearing loss, you have a greater chance of developing dementia”

(Dementia Prevention, Intervention, and Care: vol. 396, Issue 10248, Aug. 2020 report of the *Lancet* Commission)

“... auditory deprivation, increased cognitive load, and depression”

(Lin FR, Albert M. (2014) “Hearing Loss and Dementia – Who’s Listening?” Aging and Mental Health, U.S. National Library of Medicine www.ncbi.nlm.nih.gov/pmc/articles/PMC4075051).

Amplification/Remediation

Amplification does help improve ability to hear - ability to hear is correlated with cognitive health.

It would make sense that those with hearing loss should utilize some type of amplification (hearing aids).

Hearing aids and regulations

Historical barriers for prescription hearing aids:

- ❖ Prescription hearing aids cost thousands of dollars
- ❖ Prescription hearing aids require medical clearance (or waiver)
- ❖ Prescription hearing aids must be professionally fit
- ❖ Potential users may have a self-perceived lack of disability or self-perceived likelihood of benefit or lack of benefit
- ❖ Potential users may have concerns over comfort and appearance

Opportunities to reduce barriers

- ❖ Hearing aids cost thousands of dollars (If more demand and more mfg. competition to meet demand = reduce cost?)
- ❖ Etiology of hearing loss in the older population (*Presbycusis* – aging of the auditory system) - cannot be “cured” medically (Why insist on medical clearance and prescription?)
- ❖ Technology has advanced to potentially allow end-user to “fit” amplification (Can “professional” intervention <costs> be reduced/eliminated?)
- ❖ Over 90% of individuals in the older generation that could benefit from amplification have high freq. mild to moderate hearing loss (Should not standardized specifications be adequate?)

October 2022 FDA finalized OTC hearing aid guidance

Intention – make air conduction hearing aids more accessible:

- ❖ Increase manufacturers innovation and competition
- ❖ Lower instrument cost by volume production
- ❖ Reduce regulatory barriers
- ❖ ALSO: Differentiate between true hearing aids vs PSAP (Personal Sound Amplification Products). *A bit more on this later*

METHOD - make air conduction hearing aids more accessible:
Take those prescription hearing aids built and intended for mild/moderate hearing loss out of the prescription category.

RULING

- ❖ Hearing test/evaluation/prescription/fitting no longer needed for adults with **mild to moderate hearing loss**. (Obvious objective is to address hearing loss needs in the older generation.)

note: Pediatric (birth up to 18 yrs.) and all ages with severe to profound hearing losses still require professional evaluation/fitting.

However, a professional evaluation for any perceived hearing loss is still a strong recommendation

Hearing evaluation cost covered with medical referral

“Medicare covers audiologic diagnostic testing provided by an audiologist when a physician or non-physician practitioner (nurse practitioner, clinical nurse specialist, or physician’s assistant) orders the evaluation for the purpose of informing the physician's diagnostic medical evaluation or determining appropriate medical or surgical treatment of a hearing deficit or related medical problem.”

HHS: [Medicare Benefit Policy Manual at Chapter 15, Section 80.3](#)

note: If eligible for VA medical benefits, then testing, hearing aids, batteries, fitting , f/u all covered.

If a retiree is eligible for medical care at an MTF (not under USFHS), then eligible for RACHAP/RHAPP.
Retiree-At-Cost Hearing Aid Program/Retiree Hearing Aid Purchase Program. (pay “at-cost”)

Other than cost, two practical reasons to get a full evaluation

- If a medical issue is discovered through the diagnostic test results, the audiologist will advise and refer (back or on) appropriately.
- If no medical issues are found, you'll have the completed diagnostic test results that will be used to select appropriate amplification characteristics (based upon degree and configuration of hearing loss).
 - Audiologist will also be able to recommend the best amplification option(s)

FDA Stipulations for OTC hearing aids

- *Must be controllable by the user and customizable to the user's hearing needs.*
- *Controls must allow the user to select the output volume and profile according to preference.*
 - *note: restricted maximum sound output*
- *Insertions depth no closer than 10 mm from eardrum (tympanic membrane)*
- *“Simplified” language to be used for warnings and other important information and shall appear outside and inside the packaging.*
- *For adults with “mild” to “moderate” hearing losses*

Mild / Moderate hearing loss?

- **Mild** - *“Audiometric pure tones between **25 and 35 dB**”*
“Some difficulties keeping up with conversations, especially in noisy surroundings.”
- **Moderate** – *“Audiometric pure tones between **35 and 50 dB**”*
“Difficulty keeping up with conversations in many/most situations.”

Presbycusis

Features of presbycusis

- ❖ Sensorineural

note: The term is not restricted to the cochlear (inner ear / sensory hair cells)

- ❖ Develops slowly

note: if rapid onset or fluctuating then something else is going on

- ❖ Symmetrical

note: asymmetrical: recreational/occupational noise exposure or medical considerations

Features of presbycusis

- ❖ High frequency

note: can progress to low and/or mid-range frequencies depending on site of lesion. Most often – high freq.

- ❖ Mild to Moderate degree of loss

note: can progress

- ❖ Tinnitus is common

Manifestations

Problems hearing (understanding) in crowds (*cocktail party syndrome*)

Upward spread of masking

Problems hearing (understanding) TV without volume being too loud for others with “normal” hearing Narrower frequency transmission, quality of TV voices, competing music, et... (note: see if TV has a “user” mode to adjust freq.)

Problems understanding accents Lower linguistic redundancy and central processing & encoding

Manifestations

Problems hearing (understanding) when someone talks from another room **High frequencies don't go around corners well**

Problems hearing (understanding) on the phone, especially with someone else in the room talking or TV/radio on **Narrow transmission/masking**

Greater problems understanding (hearing) children's voices or women's voices **Higher freq.**

Narrowed dynamic range - **"recruitment" an unnatural loudness growth**

Sensing a pattern here?

- Hearing loss from presbycusis is typically a loss in the high freq. ranges
- High freq. speech sounds provides majority of speech “understanding”
- High freq. sounds are easily weakened/covered up or lost in competing sounds
- High freq. sounds are easily attenuated with simple barriers, e.g., around corners
- Vowels and voiced consonants are in lower frequency ranges and provide much less information than voiceless consonants and can cover up high freq. sounds

Image of audiogram from Google images

20 Hz.

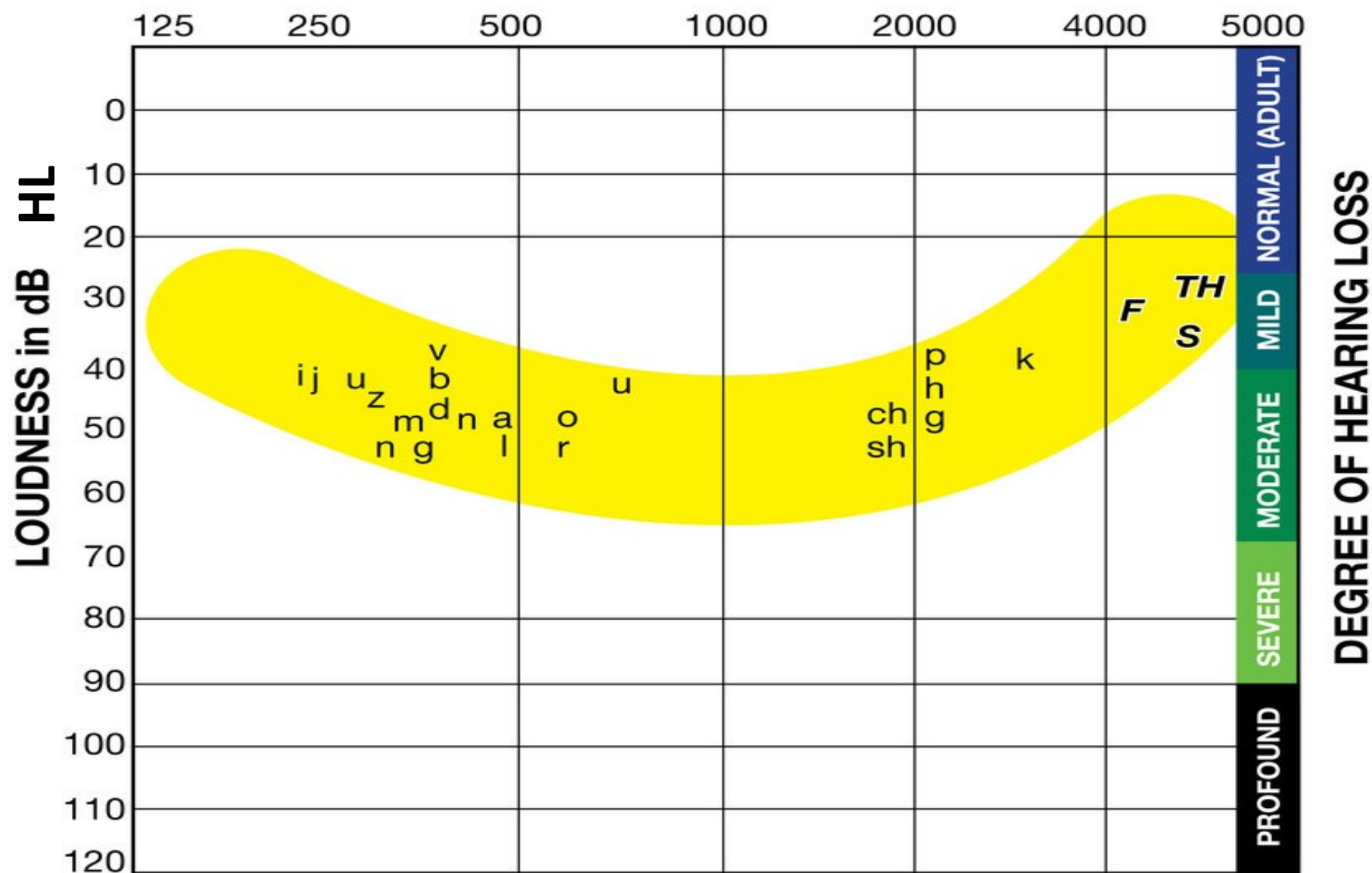
20,000 Hz



"THE SPEECH BANANA"

RANGE OF AVERAGE HUMAN SPEECH

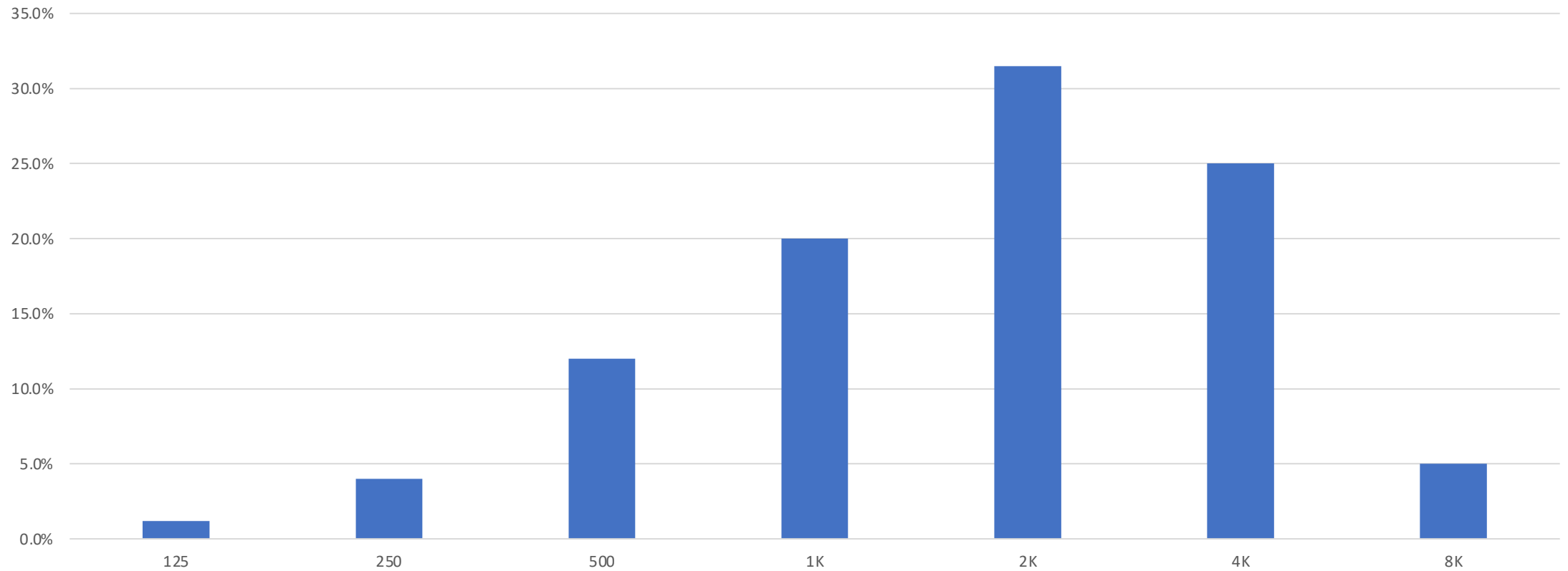
FREQUENCY in Hz



FACTS ABOUT SPEECH INTELLIGIBILITY

N.R. French & J.C. Steinberg: Factors governing the intelligibility of speech sounds. JASA vol. 19, No 1, 1947

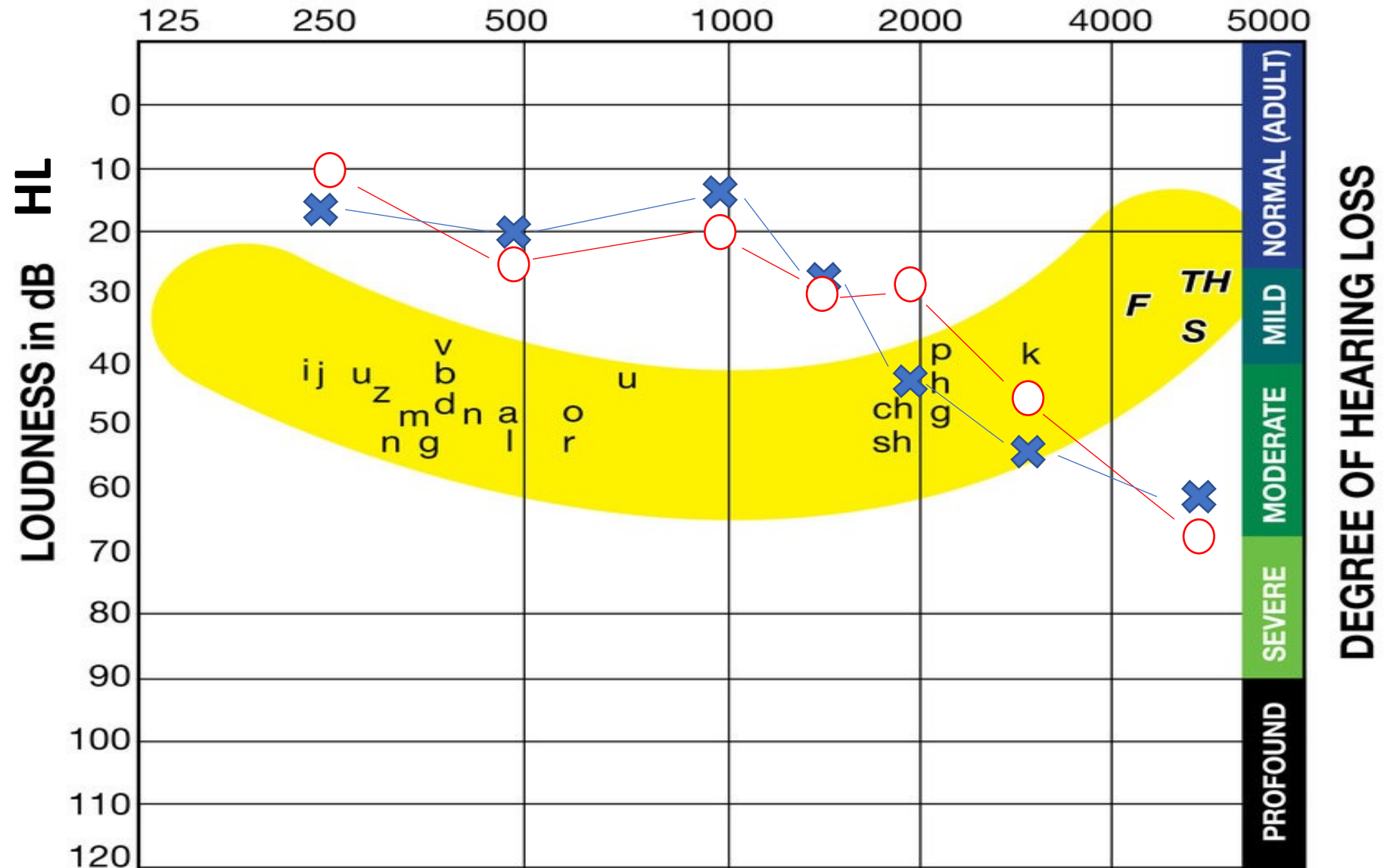
Intelligibility by Frequency



“THE SPEECH BANANA”

RANGE OF AVERAGE HUMAN SPEECH

FREQUENCY in Hz



Different amplification needs depending on
type and amount of hearing loss

FDA

Over-the-Counter
(OTC) Hearing Aids

Prescription
Hearing Aids
(Any hearing aids that do not meet OTC requirements)

Personal Sound Amplification Products

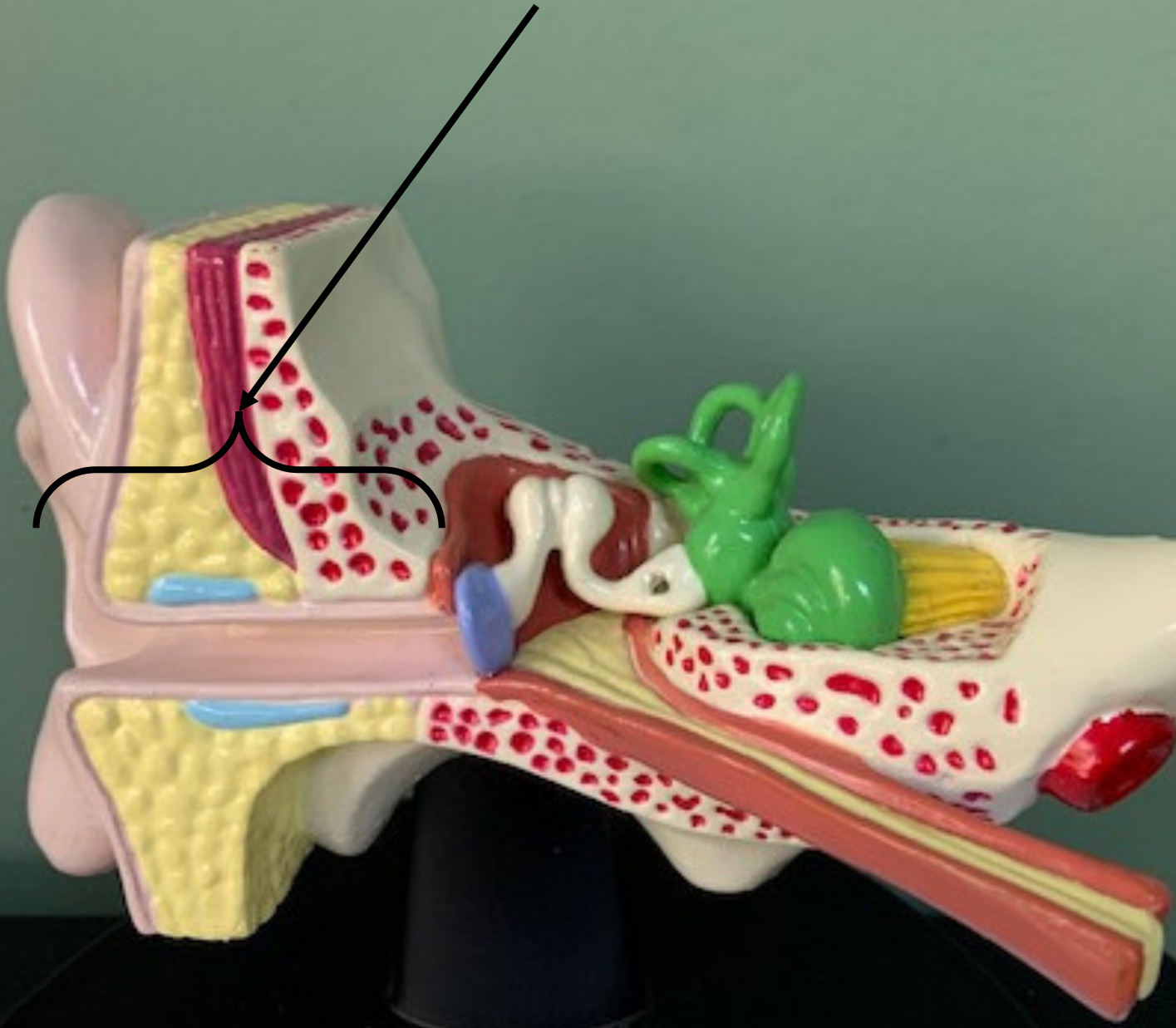
Type of Product	Medical device Electronic product	Medical device Electronic product	Electronic product
Intended Users	<ul style="list-style-type: none">•People 18 years and older•For those with perceived mild to moderate hearing loss	<ul style="list-style-type: none">•People of any age, including those younger than 18 years•For people with any degree of hearing loss, including severe	<ul style="list-style-type: none">•People of any age with normal hearing to amplify sounds in certain environments
Conditions for Sale	<ul style="list-style-type: none">•Purchaser must be 18 years or older•No medical exam•No prescription•No fitting by audiologist•No need for licensed seller	<ul style="list-style-type: none">•Prescription needed•Must purchase from licensed seller in some states	No applicable FDA requirements regarding conditions for sale

OTC hearing aid vs Personal Sound Amplification Products (PSAP)

- **OTCs** are meant for someone with a **mild to moderate** hearing loss
- **PSAPs** are meant for “normal” hearing sound enhancement

Need to do a brief review of the ear

Outer Ear



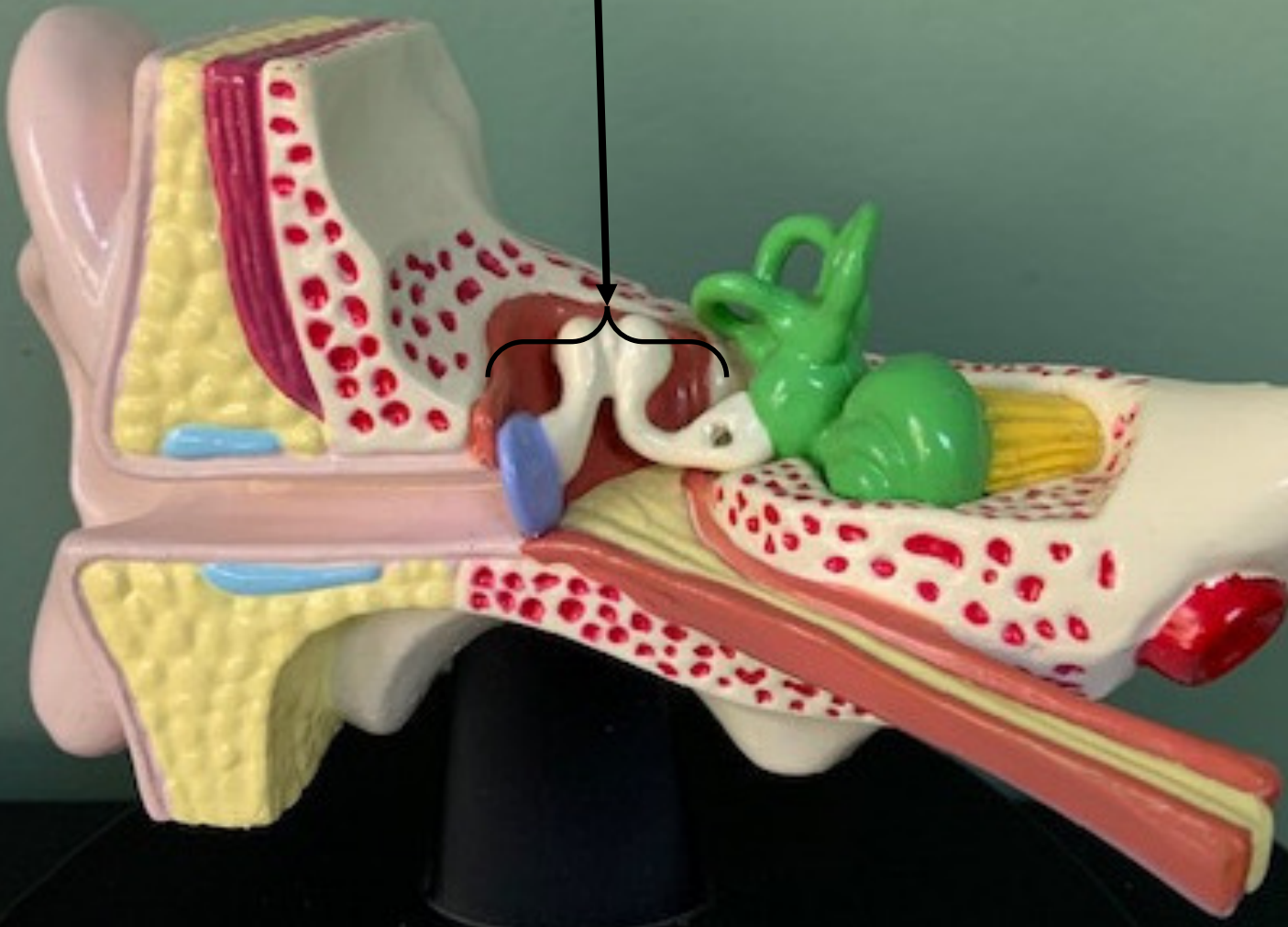
The **outer** ear:

Collects and funnels the sound down the ear canal.

Things can get in the way of sound being “conducted”. If so, it is a **“conductive”** hearing loss.

- Usually taken care of medically
- Making it louder will help (PSAP)
- Condition can obstruct fitting and comfort of amplification devices.

Middle ear

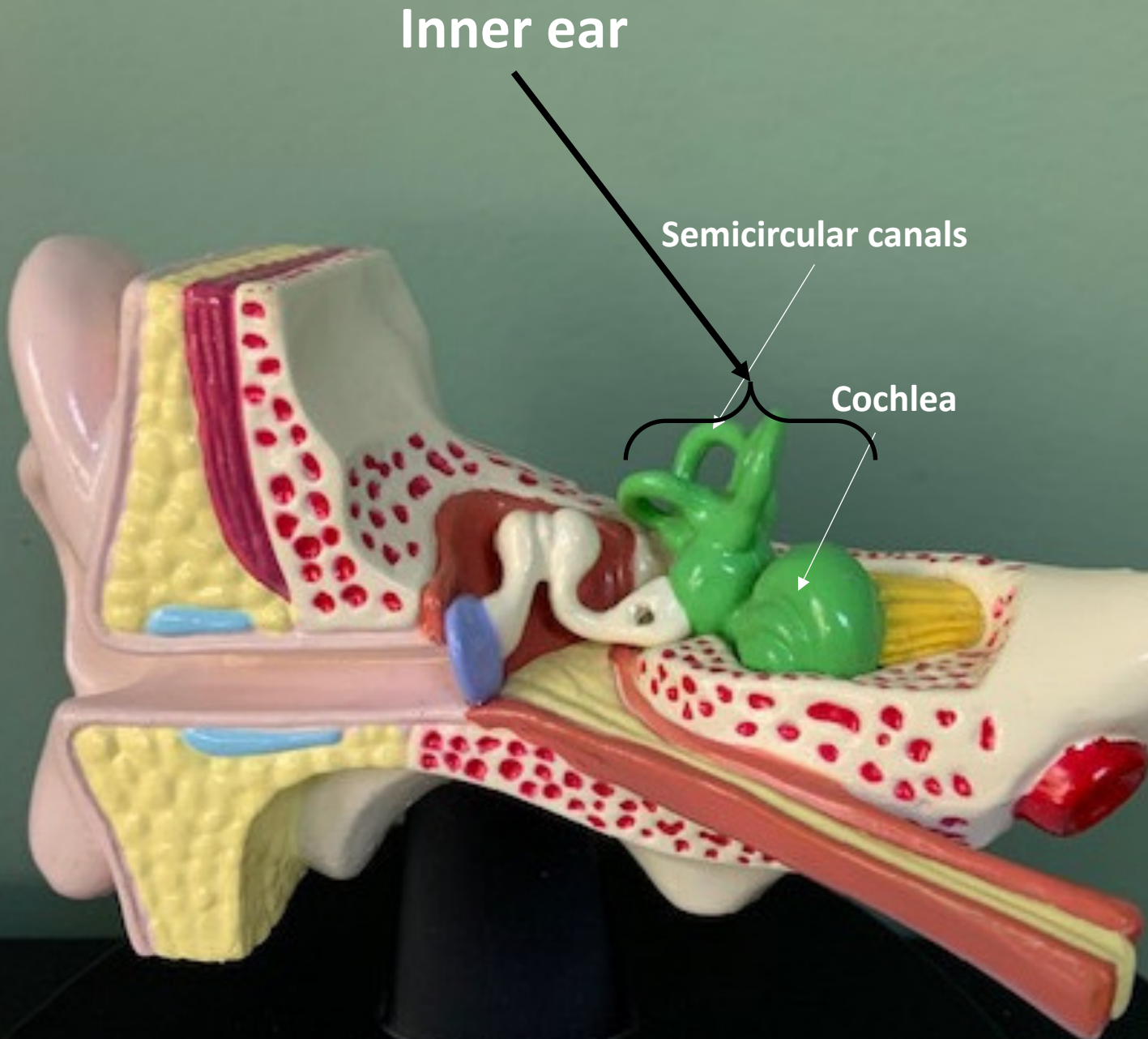


The middle ear

Vibrations hit the TM transferred to the ossicles (mechanical action).

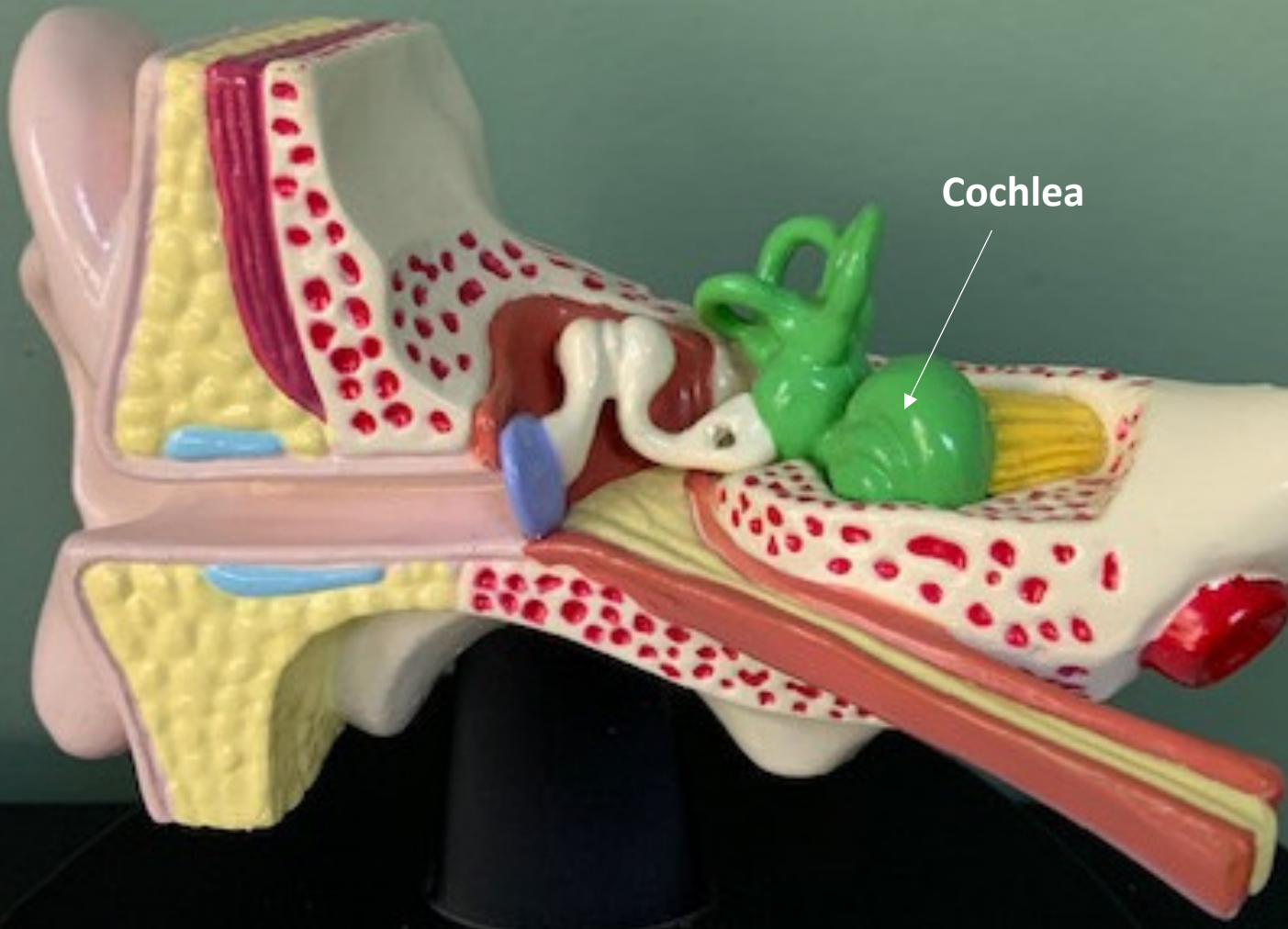
- Things can get in the way of sound being conducted through the middle ear too, so also a *conductive* loss.
- Also, usually taken care of medically (not always)
- Making it louder will help (PSAP)

Semicircular canals and cochlea



- ***semicircular canals*** (balance)
- ***cochlea*** (processing and conversion of auditory signals)

Inner ear



Cochlea - Sense organ

Nerves or beyond - Neural

- ***Sensorineural hearing loss (SNHL)***

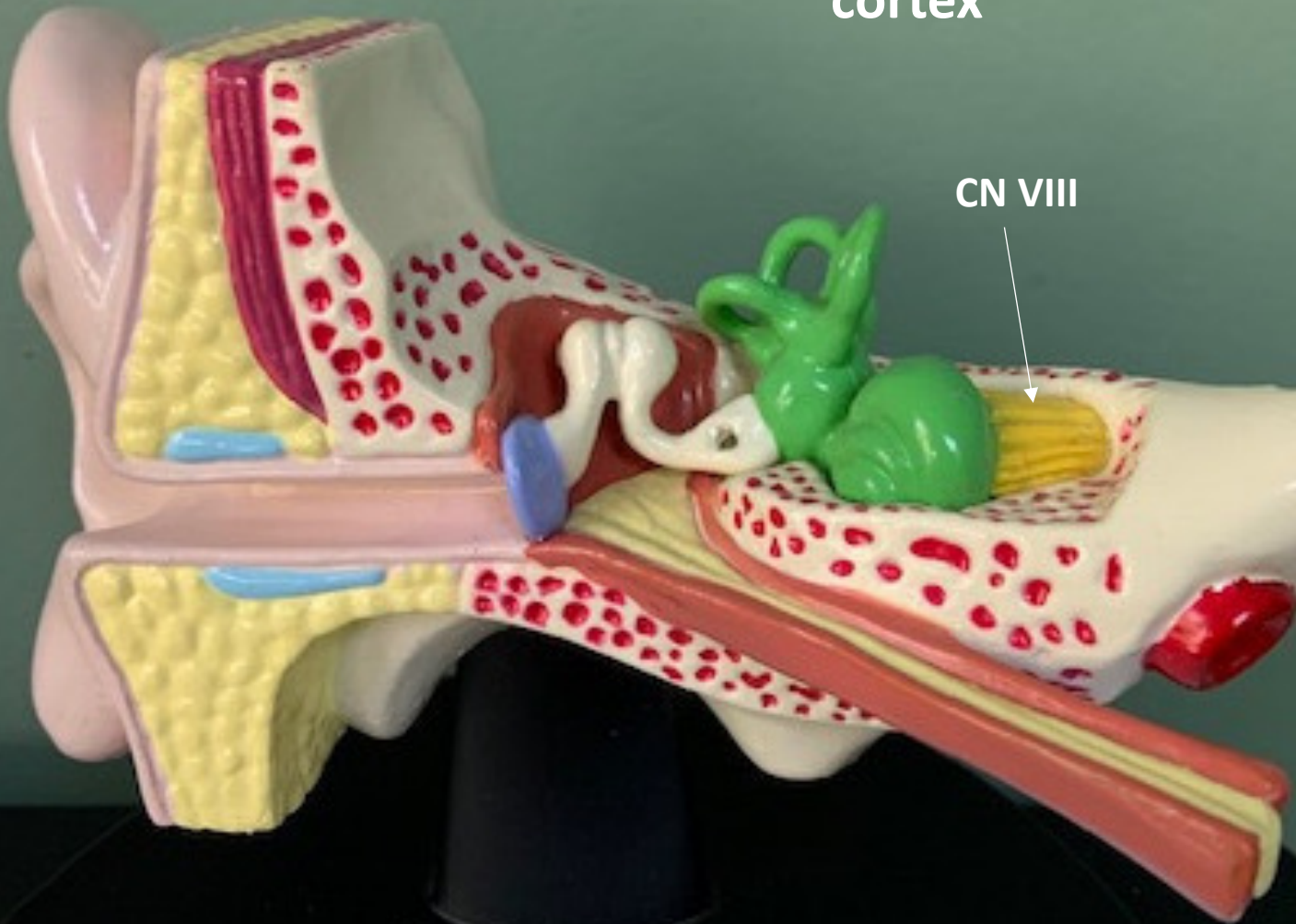
- *Many conditions – some but not all sensitive to medical intervention, e.g., **Presbycusis**.*

❖ *Hearing aids are needed to bring “hearing” remediation, once the loss is permanent.*

- ❖ Consideration of frequency response and gain.

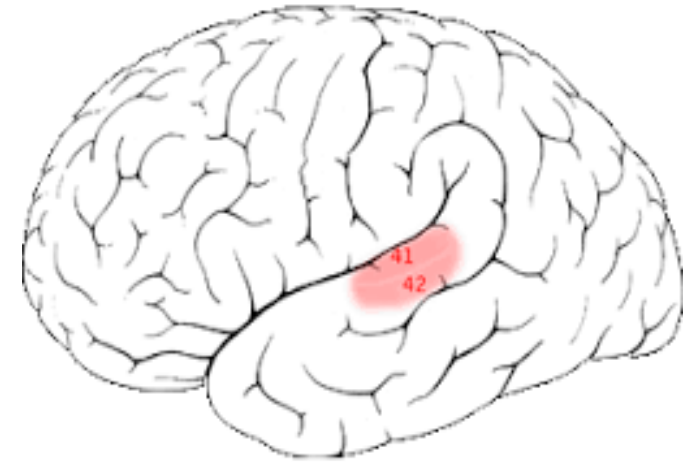
- ***note:** Can have combination of a conductive and sensory-neural loss (**mixed loss**)*

Auditory Nerve on
up to the auditory
cortex



CN VIII

Primary auditory cortex



- multiple stages and junctions throughout the neural auditory pathway (afferent and efferent)
- signals reach the ***auditory cortex*** of the brain for processing (True hearing).

Neural loss

Medical issues. Get a professional opinion(s)!

- SUDDEN HEARING LOSS (medical emergency)
- r/o treatable impairments, e.g., conductive losses
- r/o, be aware of any other medical issues (Ménière's disease, acoustic neuroma, autoimmune disorders, ototoxic meds., circulatory disorders, viruses, etc.)

Practical considerations with different types
of amplification

Electro-acoustical considerations with OTC

Technology:

1.Freq. settings

- Shaping responses, e.g., matching audiogram to freq. response of instrument

2.Intensity settings – gain is restricted to avoid hearing damage and “recruitment” but still may be too loud or not loud enough

3.Coupling (insertion gain/loss, venting, etc..)

EXPECTATIONS with Presbycusis and other SNHL

Hearing is no longer “normal”

- You can amplify but still will not sound the same as when you were 20 yrs. old
- It takes time to get used to hearing aids
- Keep in mind the cognitive impairment issue, there is a correlation but it's complicated.

Amplification characteristics that could influence cognition:

- amount of gain
- spectral bandwidth
- frequency transposition
- compression
- attack and release times
- noise reduction
- signal-to-noise ratio
- directional or omni or beam-former microphones
- real-ear characteristics
- hours of use
- etc..

For any hearing aid purchase

- Check insurance.

- **Contact plan provider e.g., ages covered, provider qualifications, benefit period, deductibles, etc.**
BTW: A New Hampshire law requires insurance companies to cover the cost of a hearing aid, for each ear, up to \$1,500, plus the related fitting and dispensing services.

- Make sure there is a trial period (how long).

- 30 days

- What's the warranty period?

- What's the total price and cost of repair(s)?

- Type of customer support (fit, adjustment, use, etc..)?

- Is it rechargeable or need to replace batteries?

- Batteries are usually very small (arthritis)

Use and function considerations with OTC

- Are you comfortable with installing the controller app on smartphone
 - Do you have a smartphone?
 - Is the app compatible with android / iPhone, both?
- Is it Bluetooth compatible (phone calls, TV, music, etc..)?
- Does it allow you to enter hearing test to tune the OTC device to better match hearing.

Suggestions for enhancing the listening environment

Hints to maximize the communication environment

Be in the same room (3-6 ft.) with light on the speaker's face and remove / reduce competing sounds.

- . Face the listener**
- . Get the listener's attention before speaking**
- . Don't cover your mouth, or have anything in your mouth**
- . Speak at a normal rate (naturally)**
 - . Use pauses rather than slow speech (processing time)**
- . Substitute a word / rephrase if not understood**
- . Don't shout**

Consider a communication app



Presbycusis: most common cause of hearing loss worldwide, estimated to affect approximately two-thirds of Americans aged 70 or older.

The hallmark of presbycusis: impaired ability to understand high-frequency components of speech, especially in background noise.

Reduced hearing is highly correlated with cognitive decline.

- * Get an evaluation, find out what you need.***
- * If you try amplification, give yourself at least a month to get used to it.***



Thanks for ***“LISTENING”!***



QUESTIONS?

COMMENTS?

Related topic web links

Funding for audiology services and hearing aids

ASHA (American Speech-Language-Hearing Association)

<https://www.asha.org/public/coverage/consumerchecklist/>

AAA (American Academy of Audiology) <https://www.audiology.org/>

State coverage for hearing aids:

https://www.asha.org/advocacy/state/issues/ha_reimbursement/

RACHAP/RHAPP (*Retiree-At-Cost Hearing Aid Program/Retiree Hearing Aid Purchase Program*)

<http://militaryaudiology.org/rachap-rhapp-locations/>

Speech to txt apps:

<https://www.techradar.com/news/best-speech-to-text-app#mobile-speech-to-text-apps-to-consider>