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Beyond the Widget: OTC Hearing Aids and the Future of Audiology

Arizona Speech and Hearing Association 2023 Convention

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Associate Professor, University of Iowa



Financial: I am a salaried employee of the University of Iowa and my travel and lodging for this conference was paid for by ASHA.

Non-financial: ASHA Board of Directors

Acknowledgments



*Lindsay Creed, AuD, CCC-Aa
Associate Director, Audiology
Practices, ASHA*

Presentation agenda

- Introduction & disclosures
- Learning outcomes
- History of OTCs
- OTC hearing aids defined
- FDA regulations
- Incorporation of OTCs into clinical practice
- ASHA OTC toolkit

Learning Outcomes

Participants will be able to:

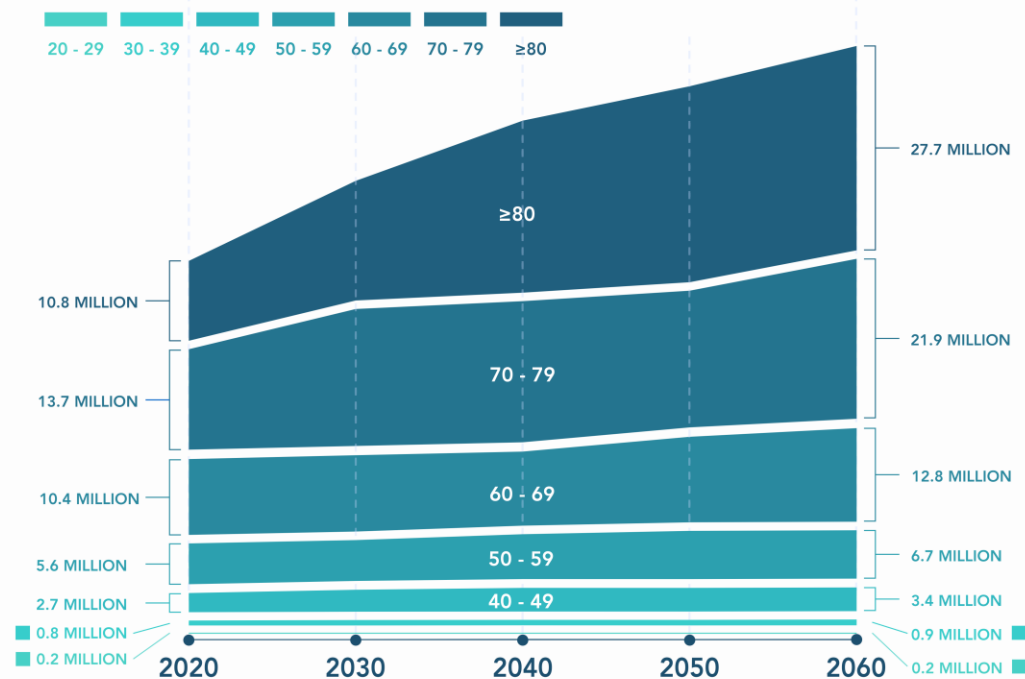
1. Summarize research and legislation resulting in the FDA's creation of OTC hearing aids
2. Define OTC and prescription hearing aids
3. Summarize OTC regulatory requirements
4. Plan for clinical integration of OTCs
5. Discover ASHA's OTC toolkit

Unaddressed hearing loss is a growing problem in the U.S.

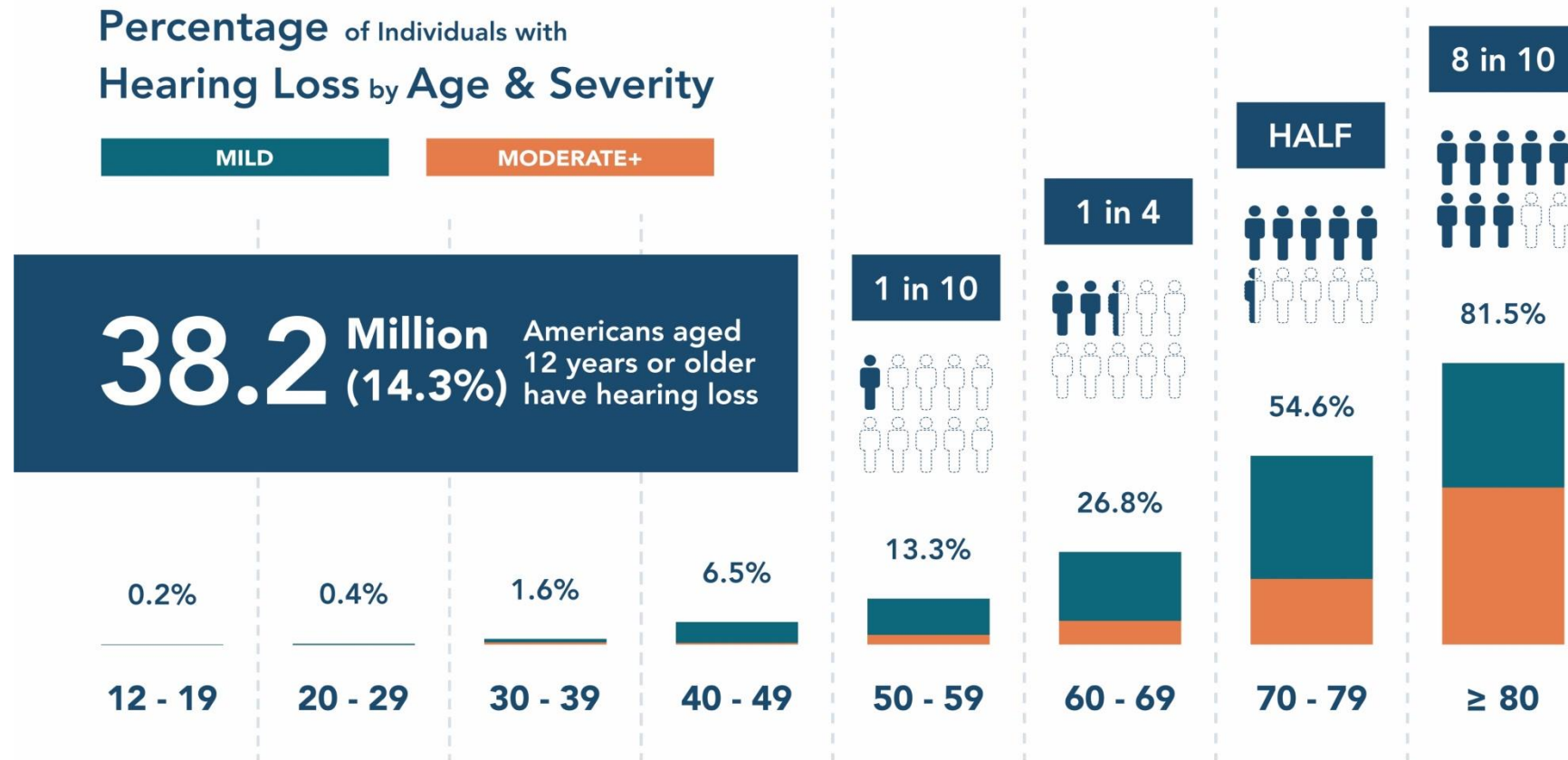
Estimated Number of Individuals with
Hearing Loss by Age

73.5 Million

American adults are expected to have
hearing loss in 2060



Most older adults have mild to moderate hearing loss



**Satisfaction with
hearing aids is
increasing but
the adoption
rate is still low**



Hearing Aid Adoption

Only ~15-30% of individuals
with hearing loss use a
hearing aid (*Reed et al., 2021*;
MarkeTrak 2022 data)



Satisfaction

83% of individuals are
satisfied with their hearing
aids (*MarkeTrak 2022 data*)



Trends in hearing aid ownership

Table. Weighted Number and Proportion of Adults 70 Years and Older Using Hearing Aids in the United States From 2011 to 2018^{a,b}

Characteristic	2011		2015		2018		Percentage change, 2011-2018
	No. (95% CI), millions	Percentage (95% CI)	No. (95% CI), millions	Percentage (95% CI)	No. (95% CI), millions	Percentage (95% CI)	
All	4.0 (3.7 to 4.2)	15.0 (14.0 to 15.9)	5.0 (4.7 to 5.3)	16.9 (15.9 to 17.9)	6.1 (5.7 to 6.6)	18.5 (17.2 to 19.7)	23.3
Race							
White	3.5 (3.3 to 3.8)	16.6 (15.5 to 17.7)	4.5 (4.2 to 4.8)	19.2 (18.0 to 20.4)	5.5 (5.1 to 5.9)	20.9 (19.4 to 22.4)	25.9
Black	0.1 (0.1 to 0.1)	5.1 (3.8 to 6.5)	0.1 (0.1 to 0.1)	4.7 (3.5 to 5.9)	0.1 (0.1 to 0.2)	5.9 (4.2 to 7.6)	15.2
Sex							
Male	2.0 (1.9 to 2.2)	18.7 (17.1 to 20.3)	2.8 (2.6 to 3.0)	21.9 (20.2 to 23.6)	3.4 (3.1 to 3.8)	24.1 (21.9 to 26.3)	28.6
Female	1.9 (1.7 to 2.1)	12.2 (11.1 to 13.3)	2.2 (2.0 to 2.4)	13.1 (12.0 to 14.2)	2.7 (2.4 to 2.9)	14.1 (12.6 to 15.6)	15.4
Income ^c							
Less than 100% of the poverty line	0.7 (0.6 to 0.8)	12.4 (10.7 to 14.1)	0.5 (0.4 to 0.6)	10.3 (8.6 to 11.9)	0.5 (0.4 to 0.7)	10.8 (8.4 to 13.1)	-13.0
100%-199% Of the poverty line	1.0 (0.8 to 1.1)	13.8 (12.2 to 15.5)	1.0 (0.9 to 1.1)	14.5 (12.7 to 16.3)	1.0 (0.8 to 1.2)	15.4 (12.9 to 17.9)	11.3
200% Or more of the poverty line	2.0 (1.8 to 2.2)	16.2 (14.8 to 17.7)	3.3 (3.0 to 3.5)	19.7 (18.2 to 21.1)	4.5 (4.1 to 4.8)	21.2 (19.5 to 23.0)	30.6

^a Data derived from the National Health Aging and Trends Study (NHATS) 2011, 2015, and 2018 cycles.

^b All proportions are age-adjusted according to the NHATS weighted sample

size and age distribution.

^c Poverty line for those 65 years and older in a 2-person household as defined by the US Census.

People wait on average 4-7 years to get a hearing aid



Why the wait?

Cost

Lack of
insurance
coverage

Hearing loss not
bad enough

Still gathering
information

Stigma

Not a priority

Not ready to
admit having
trouble hearing

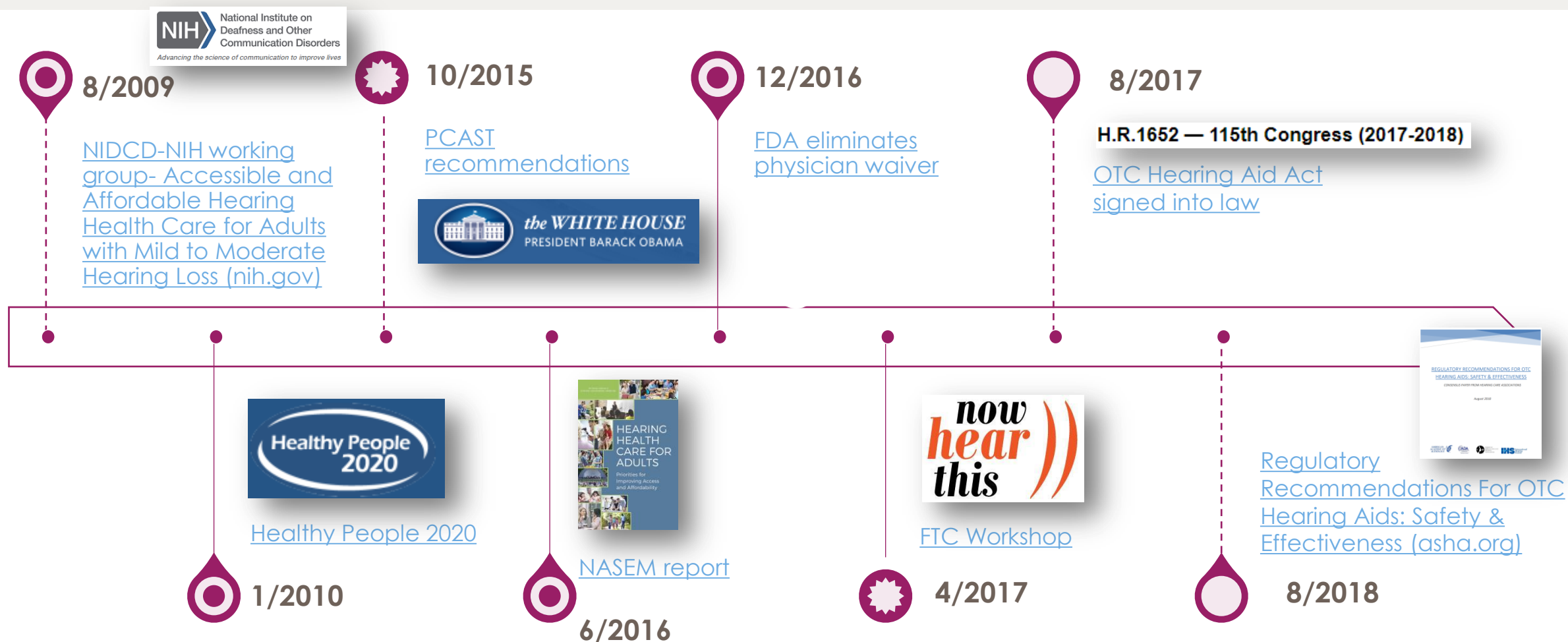
Physical
discomfort

Why do we care?

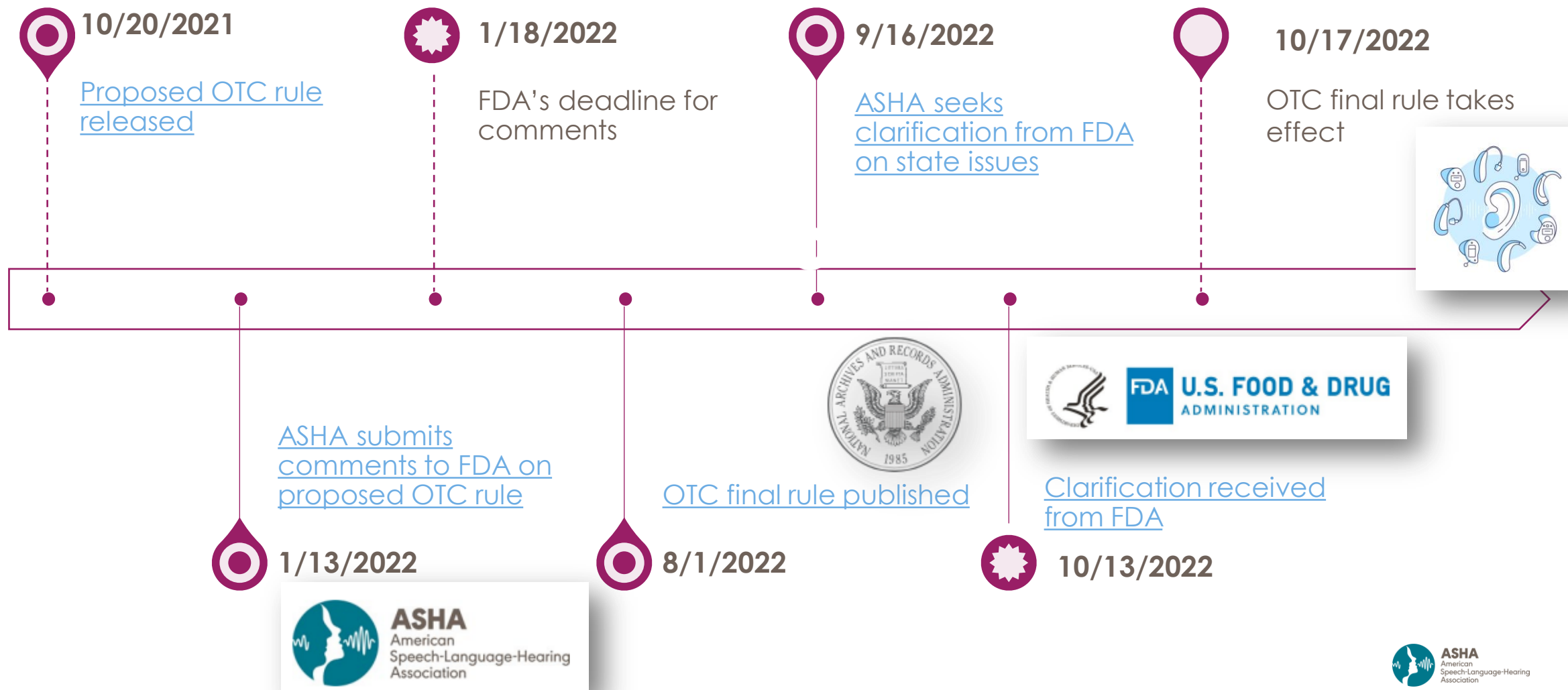
- Untreated hearing loss is associated with:
 - Depression (Lawrence et al., 2020)
 - Social isolation (Nachtegaal et al., 2009)
 - Reduced quality of life (Ciorba et al., 2012)
 - Dementia (Huang et al., 2023)
 - Falls (Jiam et al., 2016)
 - High healthcare costs and utilization patterns (Reed et al., 2019)



How did we get here?



How did we get here?



Implications of the FDA's final rule

- Establishes a new regulatory category for **OTC hearing aids**
 - Defining and establishing applicable requirements
- Designates hearing aids that do not meet the requirements for the OTC category as **prescription hearing aids**
- **Repeals the conditions for sale** applicable to hearing aids
- **Amends existing labeling requirements** for hearing aids
- Updates regulations relating to decisions on applications for exemption from **Federal preemption** that will become obsolete as a result of changes to the hearing aid requirements.

ASHA seeks clarification from FDA on state level impact

- ASHA has been active in helping our members and state affiliates understand the implications of two critical components of the FDA rule:
 - The designation of traditional (non-OTC) hearing aids as “prescription devices”
 - The repeal of federal medical evaluation requirements



Rx

ASHA seeks clarification from FDA on state level impact



September 16, 2022

Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

Sincerely,

A handwritten signature in black ink, reading "Judy Rich", is positioned above the typed name and title.

Judy Rich, EdD, CCC-SLP, BCS-CL
2022 ASHA President

Status of Non-OTC Hearing Aids as Prescription Devices

To help remedy this issue, **ASHA strongly urges the FDA to confirm through additional guidance that reclassifying non-OTC hearing aids as “prescription devices” is not intended to prevent licensed practitioners—who are authorized to order the use of these devices—from continuing to do so.**

Status of Medical Evaluations Under § 801.421

To help address this concern, **ASHA strongly urges the FDA to confirm through additional guidance that the OTC hearing device rule does not require states to implement medical evaluation requirements for prescription hearing aids for adults. Furthermore, ASHA urges the agency to consider establishing new conditions for the use of prescription hearing aids that only allows for a medical evaluation requirement with the option for the consumer to opt-out via a waiver.**

OTC Rule Impact on States



U.S. FOOD & DRUG
ADMINISTRATION

We clarify below that the final rule:

October 13, 2022

Dear State Official:

- Does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting, and dispensing of these devices;
- Does not require an additional professional to take actions, for example, does not in any way require a physician's involvement prior to fitting these devices; and
- Does not require an examination of any kind to obtain a prescription hearing aid.

FDA: Hearing Aids and Personal Sound Amplification Products: What to Know

	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

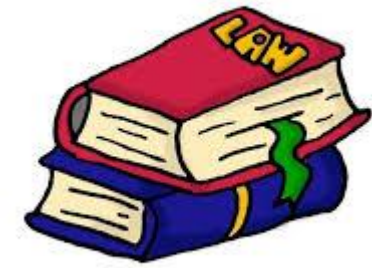
[Hearing Aids and Personal Sound Amplification Products: What to Know | FDA](#)

Defining OTC hearing aids

- “An over-the-counter (OTC) hearing aid is an
 - **air conduction hearing aid** that does not require implantation or other surgical intervention, and
 - is intended for use by a person age **18 or older** to compensate for **perceived mild to moderate hearing impairment**.
 - The device, through **tools, tests, or software**, allows the user to control the hearing aid and customize it to the user’s hearing needs.
 - The device may use wireless technology or may include tests for self-assessment of hearing loss.
 - The device is available over-the-counter, **without** the supervision, prescription, or other order, involvement, or intervention of a **licensed person**, to consumers through **in-person transactions, by mail, or online**, provided that the device **satisfies the requirements** in this section.” p.50749

What are those requirements?

- Labeling
- Output limits
- Electroacoustic performance limits
- Design requirements
- Conditions for sale
- Effect on state law



Labeling

- Outside package labeling
- Labeling, inside the package
- Labeling on the device
- Technical specifications
- Software device labeling

Outside package labeling

- Warnings and other important information
- Statement of build condition
- Statement of OTC availability
- Indication of battery information
- Indication of control platform



Warnings

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This hearing aid is for adults with signs of mild to moderate hearing loss. How do you know if you have this?

- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain it's too loud

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] or write to [email address] or [postal address] to request a paper copy of this information and other labeling.

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

Some people with hearing loss may need help from a hearing healthcare professional. How do you know if you need to see one?

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, for example, you don't hear loud music, power tools, engines, or other very noisy things

If your hearing loss makes it hard to hear loud noises, this hearing aid may not be your best choice without help from a professional. If this hearing aid does not help you enough, ask for help from a hearing healthcare professional.

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

Outside package labeling

- Warnings and other important information
- Statement of build condition
- Statement of OTC availability
- Indication of battery information
- Indication of control platform



Statement of build condition

- “If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.” p. 50751
- Rebuilt hearing aid: “An OTC hearing aid is “rebuilt” if the manufacturer has inspected and tested the device, made any necessary modifications to ensure it meets applicable regulatory requirements, including the requirements in this section to be available OTC, and adequately reprocessed the device for the next user.” p. 50749

Outside package labeling

- Warnings and other important information
- Statement of build condition
- Statement of OTC availability
- Indication of battery information
- Indication of control platform



Statement of OTC availability

- “The principal display panel shall bear the marks “OTC” and “hearing aid” with the same prominence required in § 801.61 (c) of this chapter for the device’s statement of identity. The device’s common name on the principal display panel may satisfy all or part of this requirement to the extent the common name includes the marks.” p.50751



Outside package labeling

- Warnings and other important information
- Statement of build condition
- Statement of OTC availability
- Indication of battery information
- Indication of control platform



Indication of battery information & control platform

- Indication of battery information: “The outside package shall indicate the type and number of batteries and whether batteries are included in the package.”
- Indication of control platform: “The outside package shall indicate whether a mobile device or other non-included control platform is required. The indication must include the type of platform and how the platform connects to the device.” p.50751



Labeling

- Outside package labeling
- Labeling, inside the package
- Labeling on the device
- Technical specifications
- Software device labeling

Labeling, inside the package

- Warnings
- Cautions
- Illustration of OTC hearing aid
- Information on function of all controls
- Description of any necessary accessories
- Instructions for sizing & inserting eartip, tools, tests, and software, use of OTC hearing aid with any accessories, maintenance and care, battery replacement or recharging, expected battery life
- Technical specifications
- Commonly occurring, avoidable events
- Warnings re: wireless technology if necessary
- How and where to obtain repair services (*at least one specific address*)
- Clinical or non-clinical studies performed by manufacturer

Warnings

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

Cautions

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Labeling

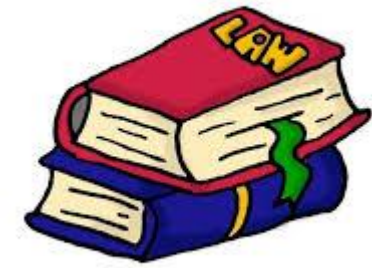
- Outside package labeling
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Labeling on the device

- The serial number
- If the battery is removable, “+” symbol to indicate positive terminal for battery
- Removeable tag indicating hearing aid is rebuilt, if applicable

What are those requirements?

- Labeling
- Output limits
- Electroacoustic performance limits
- Design requirements
- Conditions for sale
- Effect on state law



Output limits & electroacoustic performance limits

Max OSPL90 of 111 dB SPL or 117 dB SPL in device with activated input-controlled compression

Total harmonic distortion not to exceed 5%*

Self generated noise shall not exceed 32 dBA

Latency shall not exceed 15 ms.

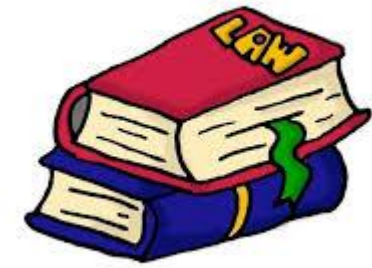
≤ 250 Hz- ≥ 5000 Hz frequency bandwidth

No single peak in one-third-octave frequency response shall exceed 12 dB

Acoustic coupler choice: 2cm³ or a scientifically valid and technically equivalent alternative

What are those requirements?

- Labeling
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Design requirements

Most medial component must remain ≥ 10 mm away from tympanic membrane

Use of atraumatic materials

Customized, acoustically favorable, and comfortable physical fit

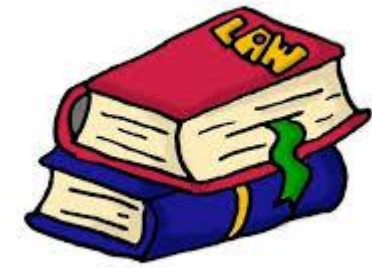
Through tools, tests, and software, allow “lay user” to control and customize device

User-adjustable volume control

Adequate reprocessing if rebuilt

What are those requirements?

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Conditions for sale

Age minimum of 18

Sale of an OTC hearing aid without “statement of OTC availability” is prohibited



Pediatric & Educational Audiologists: AKA-Freakin' Miracle Workers

Private group · 3.0K members



Seeing a 14 (almost 15) year old young man today, who wants desperately to get rid of his ear molds and get RICs. Hey then proceeded to tell me that he was saving up money so he could go buy them now over the counter 🙄



4

6 comments

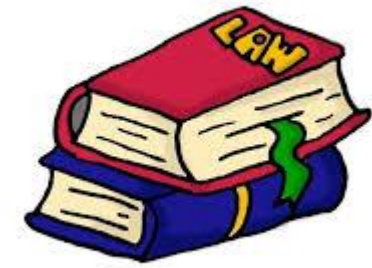
 Like

 Comment

 Send

What are those requirements?

- Labeling
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Effect on state law

- Preemption
 - No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids...
- Professional requirements
 - The sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity...shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification...

Bad actors

**CONSUMER ALERT: Attorney General James Issues Alert
to Warn New York Consumers to Be Cautious of Companies
Marketing Over-the-Counter Hearing Aids**



Welcome to the Office of the Attorney General Online Submission Form
Health Care Complaint Form



Hearing Aids - What to Know

New informational video about the new category of OTC hearing aids, prescription hearing aids, and how they are different from personal sound amplification products.



Amazon clamps down on rogue OTC hearing aid sellers

Allegations of Regulatory Misconduct Form



<https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form>

Types of OTCs

“...customization need not entail self-fitting but self-fitting is a form of customization.” p. 50703

Self-fitting OTCs

Non-self-fitting
OTCs

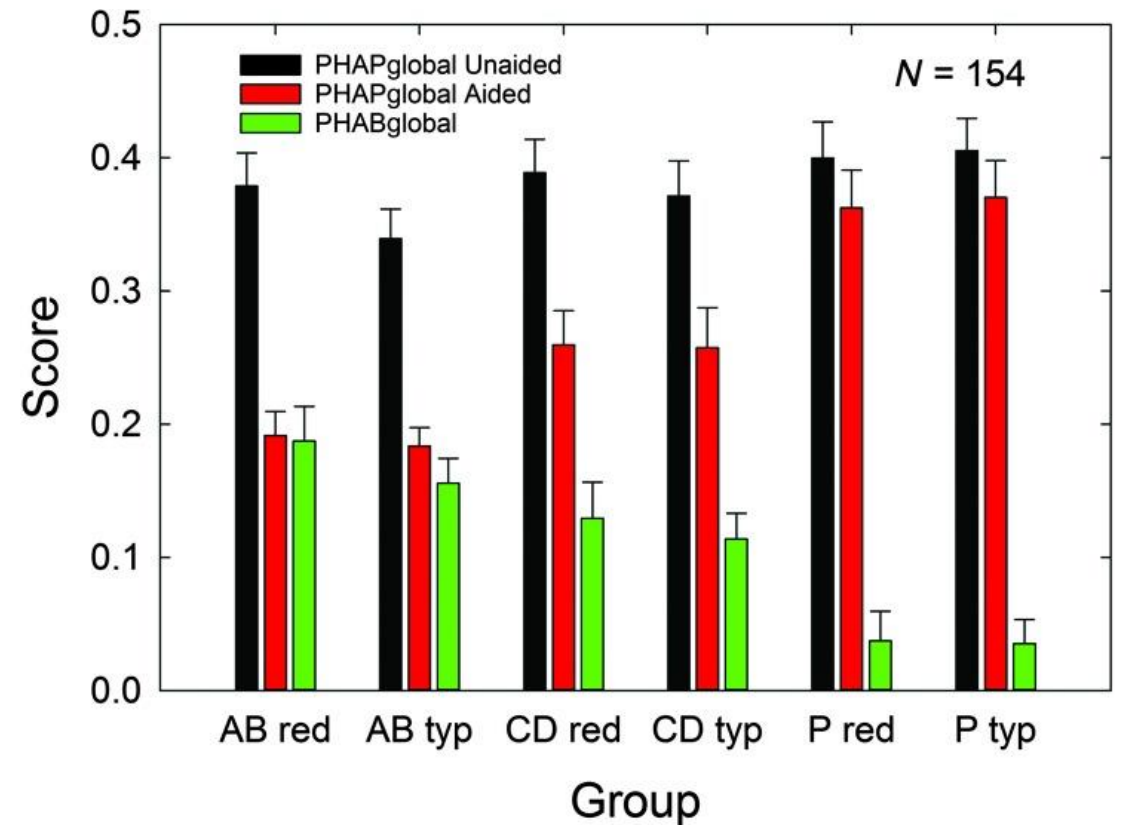
Disruption



An OTC delivery model can be efficacious

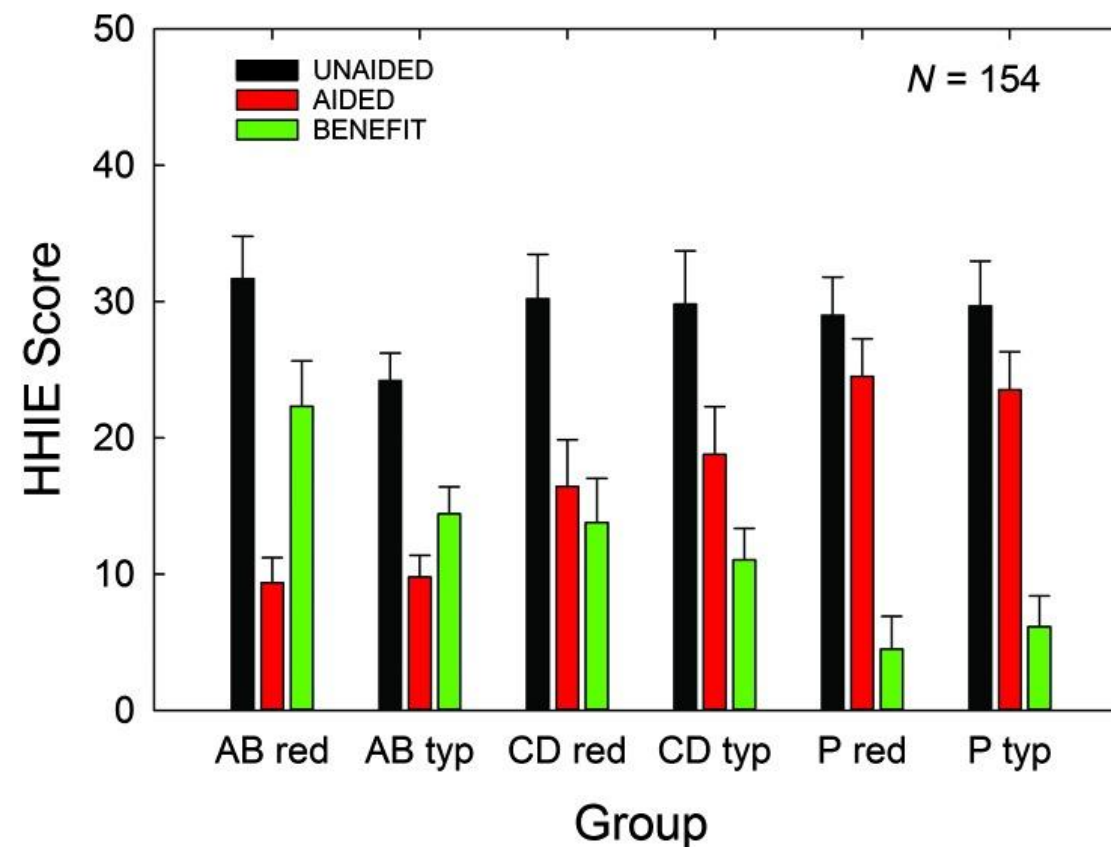
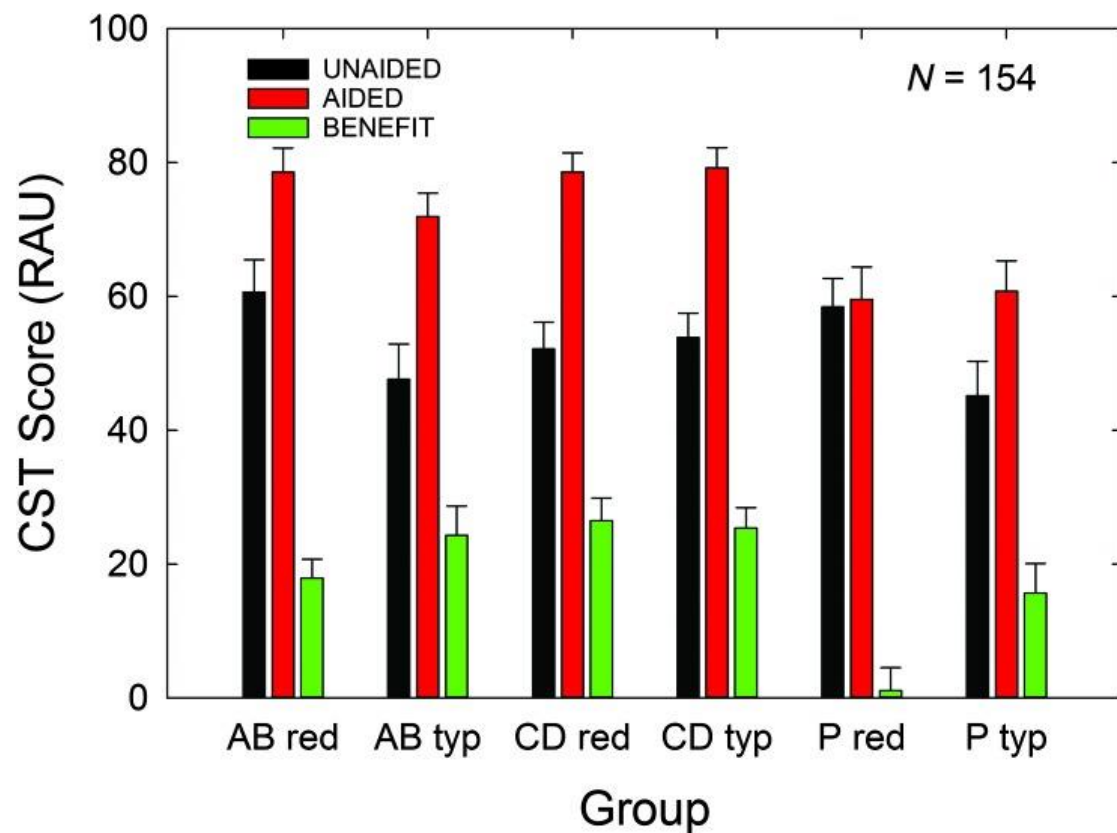
Humes et al., 2017 performed the first ever placebo-controlled double-blind randomized clinical trial of hearing aid outcomes

- AB participants: best practice services from audiologists
- CD participants: self-selection of hearing aids, virtually no contact with professional
- P participants: same services as AB group but devices were programmed to be acoustically transparent



Humes, L. E., Rogers, S. E., Quigley, T. M., Main, A. K., Kinney, D. L., & Herring, C. (2017). The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *American journal of audiology*, 26(1), 53–79. https://doi.org/10.1044/2017_AJA-16-0111

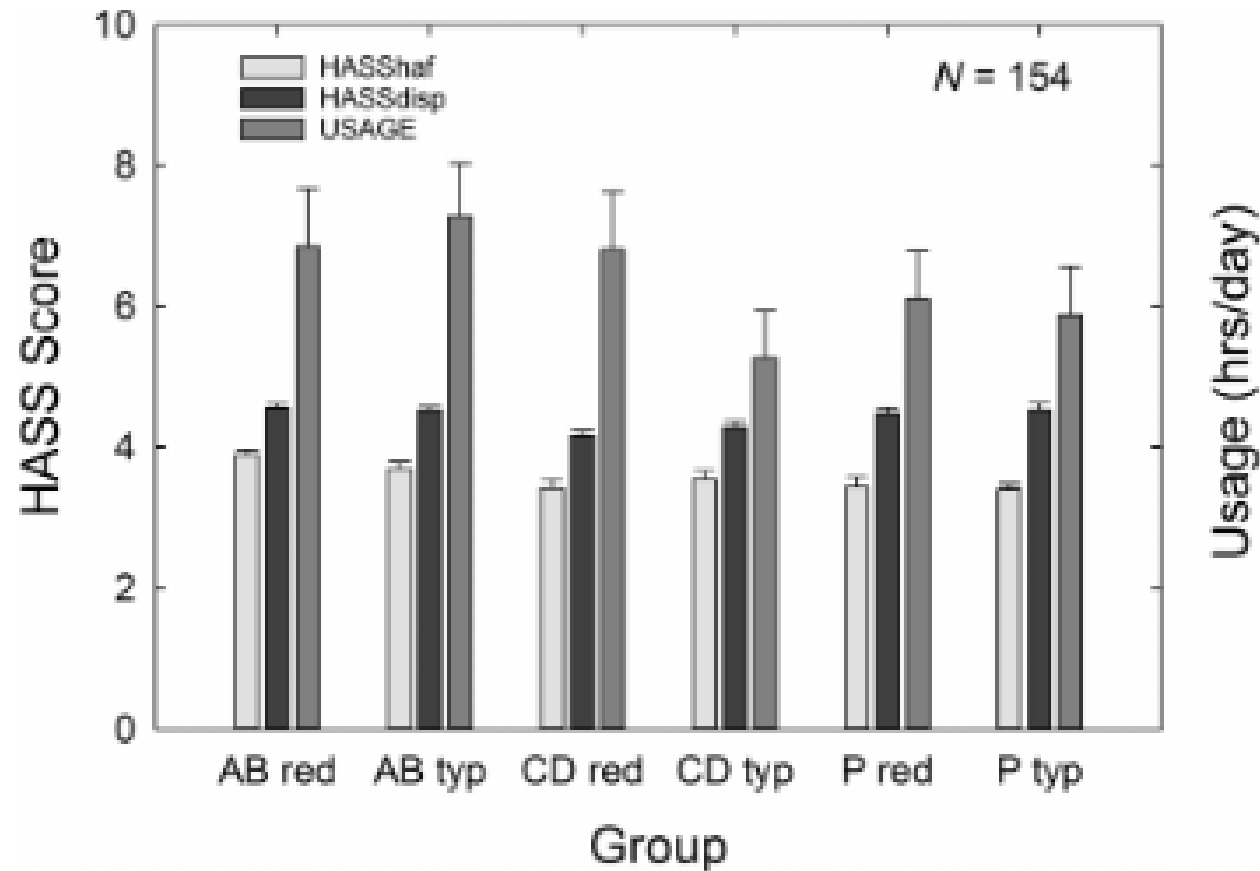
An OTC delivery model can be efficacious



But audiology best practices led to higher satisfaction...

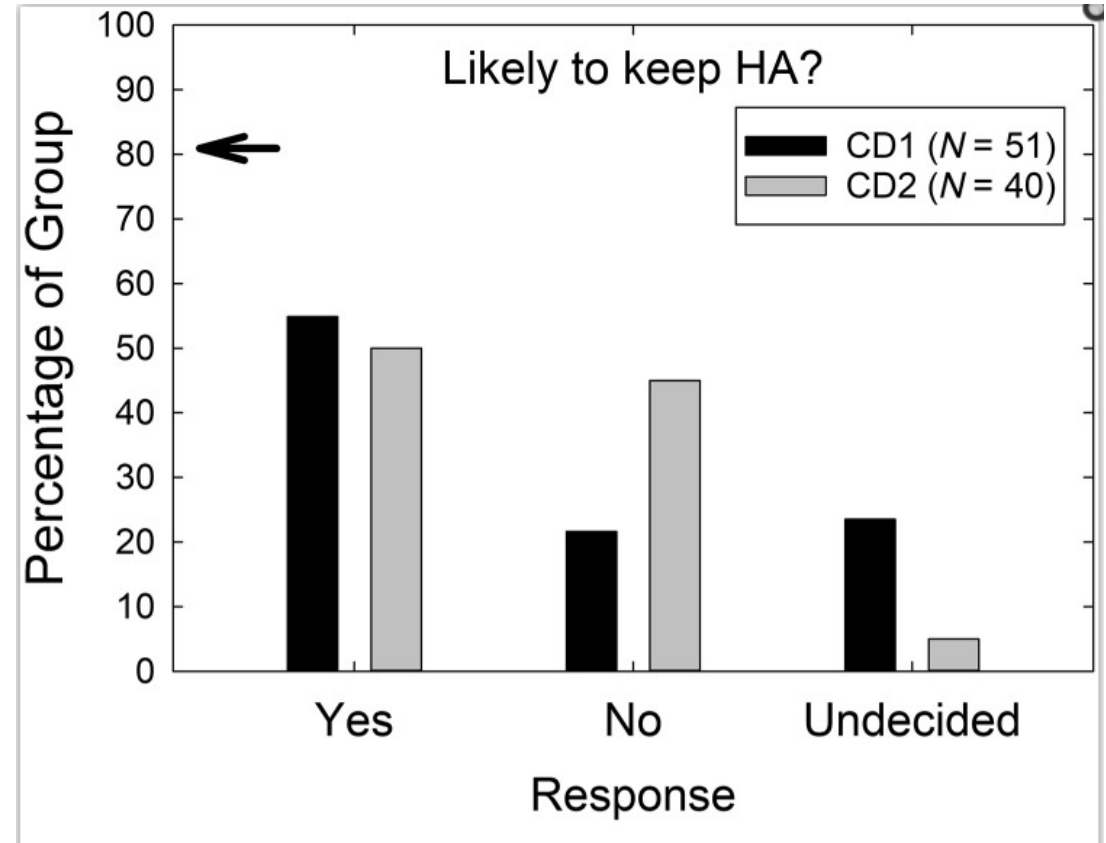
- The CD (consumer decides) participants demonstrated significantly lower satisfaction (HASS) than AB (audiology best practices) participants.
- A significantly smaller % of CD participants indicated that they planned to keep their hearing aids at the end of the initial trial than the AB participants.
- 6/10 of the CD participants that indicated that they were not likely to keep their hearing aids at the end of the initial trial decided to keep them after an additional trial period with audiology best practices. Additionally, their PHAB and HASS improved.

Satisfaction and HA usage



Less homogenous study sample

- In 2019, Humes and colleagues replicated the 2017 trial using less restrictive inclusion criteria. Overall, findings were similar.
- 33/40 CD participants chose to do a second trial period and better outcomes were noted after provision of audiology best practices.
- Across both studies, 50-60% of CD participants were planning to keep their HAs after the initial trial. This rose to ~85% after the additional trial with best practices.



Data with PSAPs

Keidser & Convery (2018) examined effect of fitting procedures (user driven vs. clinician driven) and found no significant differences on HHIE, APHAB, SADL, or speech recognition in noise.

Hearing aid fittings with professional support led to higher scores on evaluation and management of hearing aids and participants rated the sound quality more natural (perhaps due to domes that were too occluding).

Keidser G, Convery E. Outcomes With a Self-Fitting Hearing Aid. Trends Hear. 2018 Jan-Dec;22:2331216518768958. doi: 10.1177/2331216518768958. PMID: 29716438; PMCID: PMC5991196.

Data with PSAPs cont.

- Common inquiries/communications with clinical assistants showed ~50% of inquiries were related to **Bluetooth/mobile device function**. Second most common was “**behaviors of hearing aid**” and then other issues included **feedback, dome discomfort, tube setting stability, HA functionality, battery life, and rehabilitation expectations**.

Keidser G, Convery E. Outcomes With a Self-Fitting Hearing Aid. Trends Hear. 2018 Jan-Dec;22:2331216518768958. doi: 10.1177/2331216518768958. PMID: 29716438; PMCID: PMC5991196.

Audiology support services

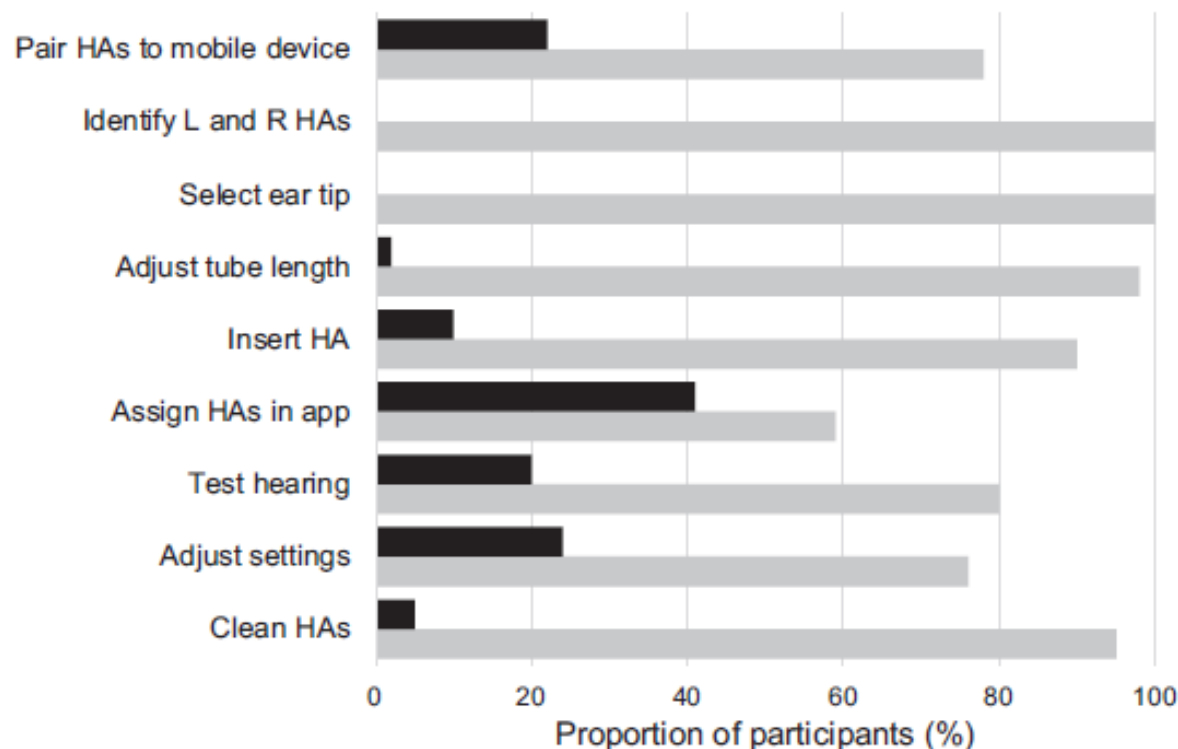


Figure 2. The proportion of participants who successfully self-fit (N = 41) who completed each step in the self-fitting procedure independently (gray bars) and with CA support (black bars).

Convery E, Keidser G, Hickson L, Meyer C. Factors Associated With Successful Setup of a Self-Fitting Hearing Aid and the Need for Personalized Support. *Ear Hear*. 2019 Jul/Aug;40(4):794-804. doi: 10.1097/AUD.0000000000000663. PMID: 30285978.

Potential application for audiology assistants

- “An audiology assistant is a person who, after appropriate training and demonstration of competency, performs delegated tasks that are prescribed, directed, and supervised by a certified and/or licensed audiologist...”
ASHA



Audiology assistant responsibilities

- performing checks on hearing aids and other amplification devices
- performing troubleshooting and minor repairs to hearing aids, earmolds, and other amplification devices
- cleaning hearing aids and other amplification devices
- performing electroacoustic analysis of hearing aids and other amplification devices
- instructing patients in proper use and care of hearing aids and other amplification devices
- demonstrating alerting and assistive listening device
- interacting with hearing instrument manufacturers/suppliers regarding status of orders/repairs

What role will audiologists play for these patients?

- ASHA respects the professional autonomy of audiologists to make decisions about their practice, which includes what devices they offer and what services they provide to their patients.
- Our goal at ASHA is to help our members pre-position themselves and their practices to navigate these changes in a way that best aligns with their values and goals.



Clinical integration of OTCs

Discuss them or recommend them to patients

Support OTC users

Sell OTC hearing aids with support

Sell OTC hearing aids without support

Factors to consider

- Patient population
- Setting
- Billing model
- State practice act/requirements
- Bandwidth



Evaluating OTC hearing aids

Cost

Electroacoustic
capabilities

Manufacturer
support

User
customization

Additional
technology
required

Design

Wireless
streaming

Features

Brand
recognition

Return policy

Shipping
policies

Ability to
negotiate with
vendor

Unbundled delivery model

Pros

Cost transparency
Shows value of professional services
Lowers upfront cost of hearing aids
Accessible to patients who purchased HAs elsewhere

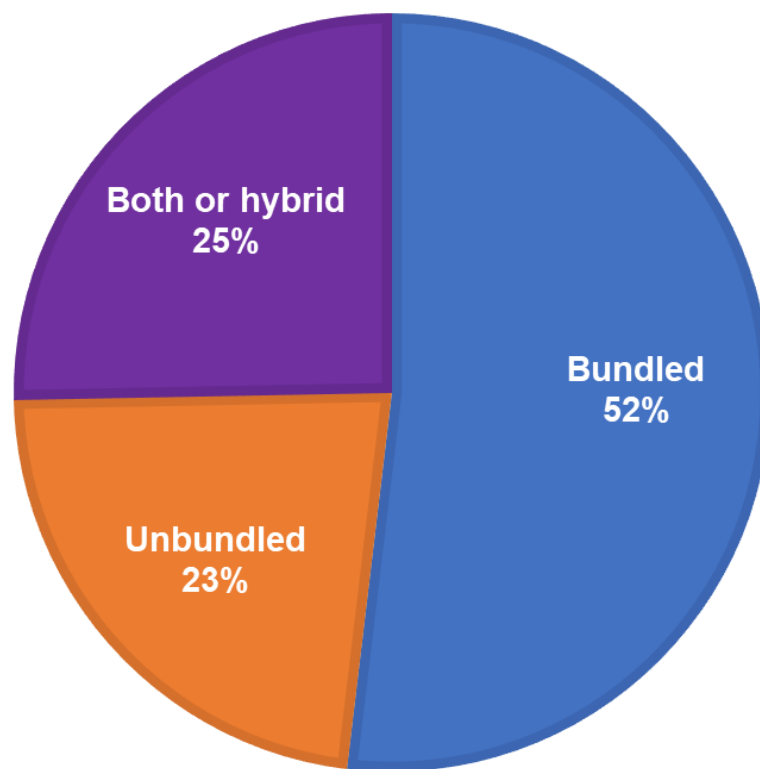
May deter patients from seeking follow-up services
Follow-up services not covered by insurance
May increase billing and administrative burden

Cons

Bundled delivery model

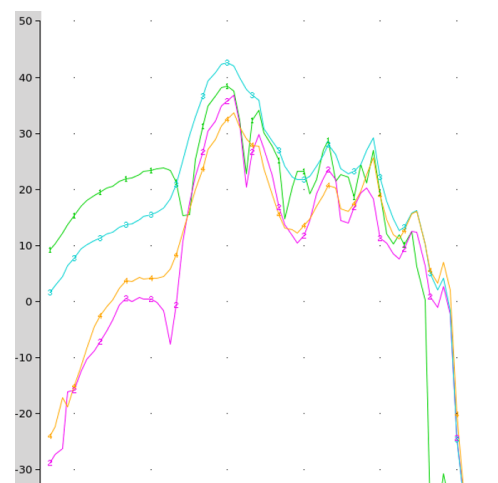
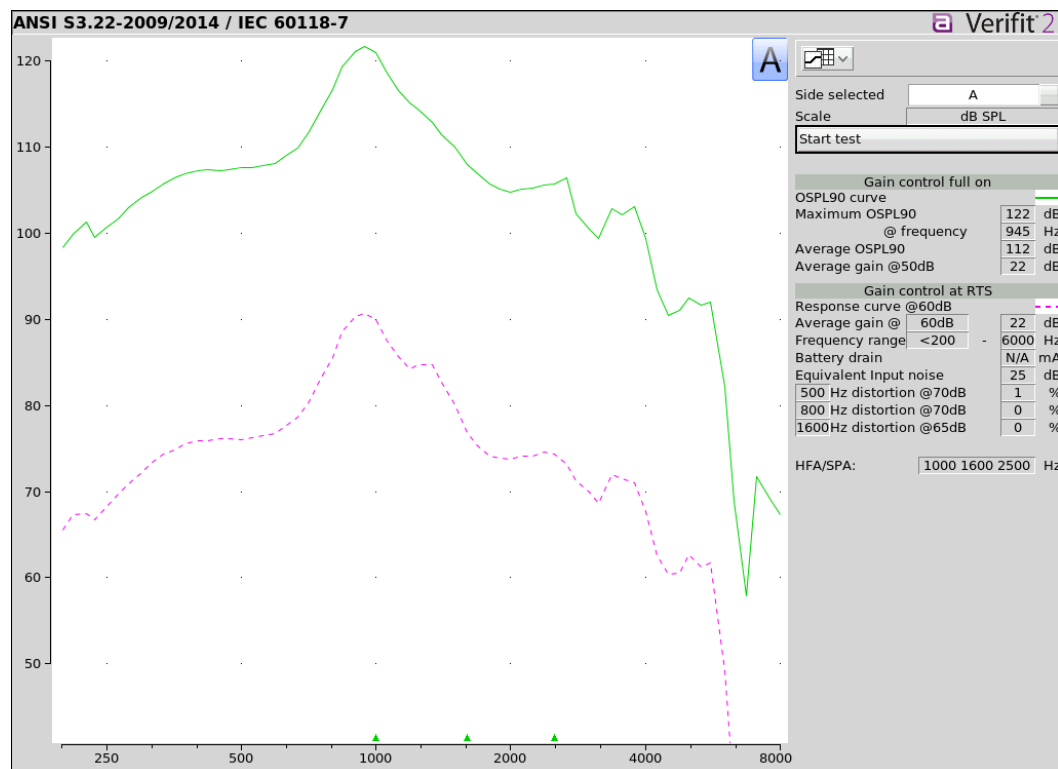


Pre-ASHA convention survey



Electroacoustic analysis

Coupler: 2cm³ acoustic coupler OR one that is “a scientifically valid and technically equivalent alternative.”

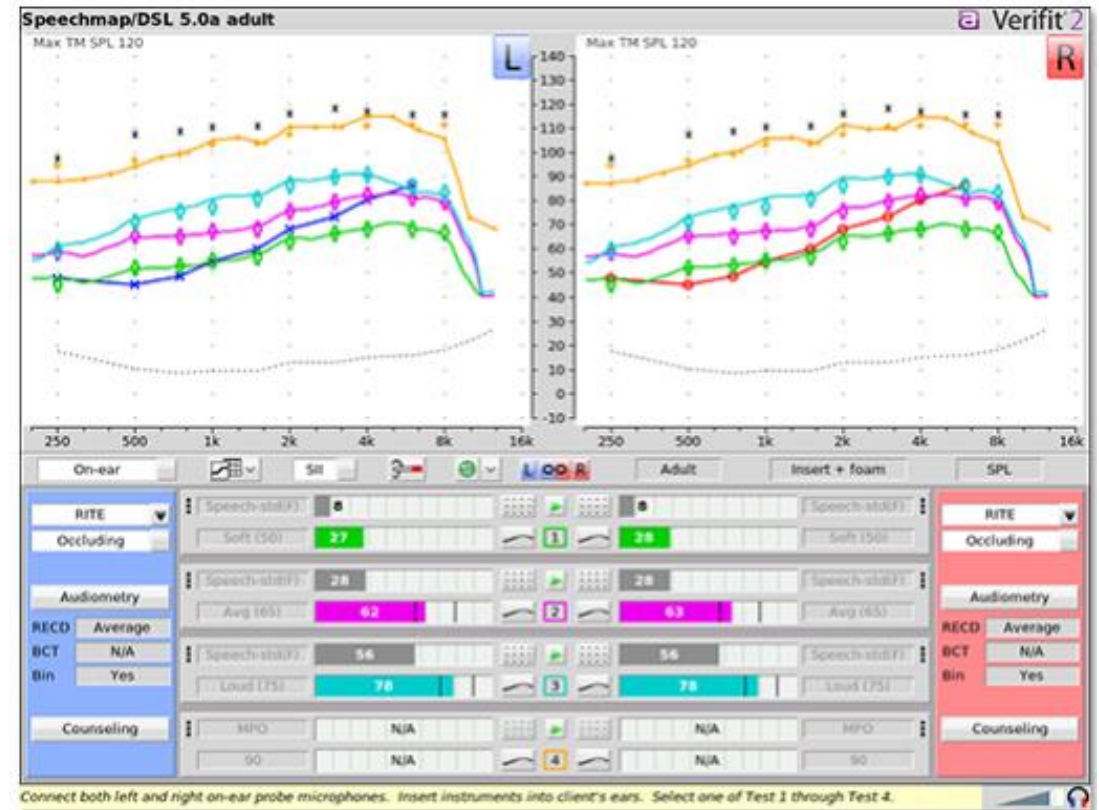


CTA Workbook



Real ear measurements

- Counseling
- Inform user-adjustments
- Demonstrate benefit or inappropriate fit
- Comparative measurements between OTC and prescription hearing aid

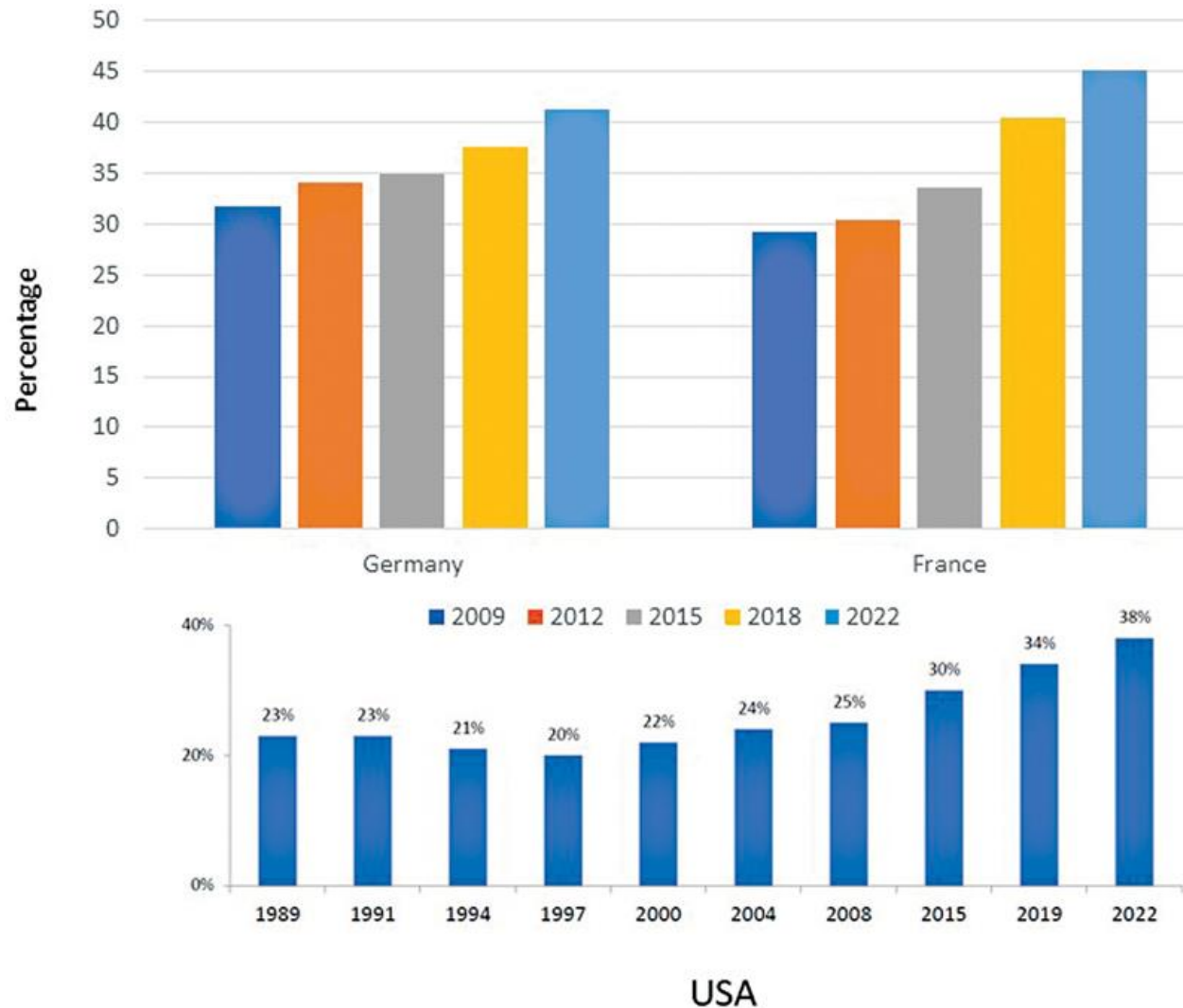


Practicing at the top of our license

What are audiology best practices?



More work to be done



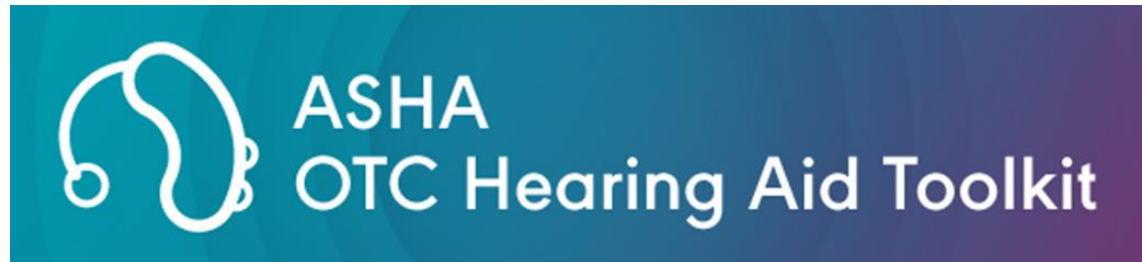
Adoption rates are only slightly better in countries where hearing aids are covered by insurance confirming there are other barriers to uptake

Powers, T. A., & Bisgaard, N. (2022). MarkeTrak and EuroTrak: What We Can Learn by Looking Beyond the U.S. Market. *Seminars in hearing*, 43(4), 348–356. <https://doi.org/10.1055/s-0042-1758361>

Ongoing advocacy

- Enhance Medicare access to audiology services through passage of the Medicare Audiology Access and Services Act
 - Expanding coverage to include treatment services
 - Removing physician referral requirement completely
- Enhance older adult access to telehealth services
 - Permanent congressional authority for audiologists to be telehealth providers under Medicare
- Reduced Medicare part B cuts
 - ASHA is committed to more fully stopping payment cuts and developing a solution that provides longer-term payment stability

ASHA's OTC toolkit



ASHA has compiled the following resources to help you

- Educate patients about OTC hearing aids
- Promote the continued value of an audiologist
- Collaborate with and market your practice to other trusted professionals influencing OTC hearing aid decisions

Resources

TOOLS FOR AUDIOLOGISTS

RESOURCES FOR
PHARMACISTS

RESOURCES FOR PRIMARY
CARE PHYSICIANS

Tools for audiologists



Tools for Educating Patients



Collaborating with Pharmacists



Collaborating with Primary Care Physicians (PCPs)



Other Resources

Tools for audiologists

	OTC HEARING AIDS	VS. PRESCRIPTION HEARING AIDS
SELECTION PROCESS	Self-selection; however, consumers may choose to consult with a licensed audiologist or hearing instrument specialist or non-licensed support personnel.	Functional communication assessment with a licensed audiologist or hearing instrument specialist.
FIT BY	Self, licensed audiologist or hearing instrument specialist, or non-licensed support personnel.	Licensed audiologist or hearing instrument specialist.
PRICE	Estimated to be less than \$1,500/pair-consult vendor or retailer for exact pricing.	~\$1,000-\$7,000/pair-varies based on what services or warranties are included in the cost.
AGE	18+	0+
HEARING LOSS DIAGNOSIS	Purchase <u>does not require a hearing test</u> ; hearing levels may be approximated through self-reflection, self-administered tools, tests, or software, or through a hearing test with a licensed audiologist or hearing instrument specialist.	Pre-purchase audiologic assessment required.
HEARING LOSS SEVERITY	Self-perceived mild to moderate.	All degrees.
DESIGN	One-size-fits-most or semi-custom; hearing aid must sit >10 mm from eardrum.	Not limited by depth or design; includes custom-molded and invisible in the canal options.
RETURN POLICY	Not required by the FDA; determined by manufacturer and state of sale; this information must be on the hearing aid packaging.	Required in most states.
VERIFICATION OF AMPLIFICATION LEVELS	Users seeking care from a licensed audiologist or hearing instrument specialist can inquire about verification measures compatible with their OTC hearing aids.	Best practices include real-ear measurements (REMs) at the time of hearing aid fitting.

Tools for audiologists

AUDIOLOGIST AND HEARING AID DISPENSER: WHAT IS THE DIFFERENCE?



Audiologist		Hearing Aid Dispenser
<input checked="" type="checkbox"/>	State licensure required	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Degree requirement: master's or doctorate in audiology	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Degree requirement: high school diploma or associate's degree	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Clinical education training: 1,800+ hours of hands-on experience	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Hearing aid fitting and dispensing: adult population	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Hearing aid fitting and dispensing: pediatric population	<input type="checkbox"/>
<input checked="" type="checkbox"/>	May bill insurance, including Medicare, for medically necessary hearing and balance evaluations	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Performs diagnostic hearing evaluations on children and adults	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Serves as part of a medical team to conduct pre- and post-operative hearing evaluations	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Evaluates and monitors patients who are at risk for ototoxicity (hearing and balance loss due to certain medications)	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Evaluates and treats patients with dizziness and balance disorders	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Evaluates and treats patients with tinnitus (ringing in the ears) and hyperacusis (sensitivity to sounds)	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Evaluates and treats patients with cochlear implants or other implantable hearing devices	<input type="checkbox"/>
<input checked="" type="checkbox"/>	Performs hearing testing for the purposes of dispensing hearing aids	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Performs hearing evaluations for the purposes of diagnosing and treating hearing loss	<input type="checkbox"/>

*States may use a title other than hearing aid dispenser when referring to a nonaudiologist who is licensed to dispense hearing aids. Other similar titles are hearing instrument specialist, hearing aid specialist, hearing aid fitter, and hearing aid dealer.

Please visit [ASHA.ORG/OTC-HEARING-AID-TOOLKIT](https://www.asha.org/OTC-HEARING-AID-TOOLKIT) for more information.

WHEN TO STOP USING AN OVER-THE-COUNTER (OTC) HEARING AID



Do you have difficulty understanding conversations with your over-the-counter hearing aid?

Are you experiencing dizziness or a feeling of imbalance?

Are you having pain or debilitating discomfort in one or both ears?

Do you have ringing in one or both ears?

Are there any sudden changes in hearing in one or both ears (threshold shift)?

Do you have drainage of any kind from one or both ears?

If you are experiencing any of the symptoms above, your hearing difficulties are likely not appropriately treated by an over-the-counter hearing aid, and you should stop using the OTC hearing aid. Seek help from a certified and licensed audiologist to treat your hearing difficulties. Looking for an audiologist in your area? Find a provider by contacting ASHA Audiology Practices at audiology@asha.org.

Please visit [ASHA.ORG/OTC-HEARING-AID-TOOLKIT](https://www.asha.org/OTC-HEARING-AID-TOOLKIT) for more information.

Is an OTC Hearing Aid Right for Me?

An overview of the importance of hearing loss treatment and a quick guide to selecting the best type of hearing device

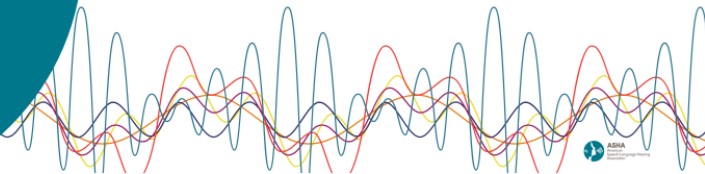


Collaboration with PCPs

PATIENT HEARING CHECKLIST

ASHA Over-the-Counter (OTC) Hearing Aid Toolkit

A Quick Reference for Primary Care Physicians



Collaboration with pharmacists

PATIENT HEARING CHECKLIST



Please check all items that apply to you:

- ☐ I am younger than 18 years old.
- ☐ I hear much better in one ear than in the other ear.
- ☐ In the last 6 months, I suddenly cannot hear out of one or both ears as well as I used to.
- ☐ I have ringing, roaring, or beeping in one or both of my ears.
- ☐ I have a history of taking medication that causes hearing loss.
- ☐ I have a history of chemotherapy and/or radiation in the head and neck region.
- ☐ In the last 6 months, I have noticed active drainage from one or both of my ears.
- ☐ I have constant pain or discomfort in one or both of my ears.
- ☐ I experience dizziness.

If you check any one of the boxes above, an OTC hearing aid may not work for you. Consult with an audiologist. Please see pharmacist for recommendation.

Reflect on your hearing in quiet and noisy environments, and check the column that best describes you:

This Best Describes Me	Quiet Environments	Noisy Environments
<input type="checkbox"/>	I have good to excellent hearing.	I have good hearing; I rarely have difficulty following/participating in a conversation.
<input type="checkbox"/>	I do not have problems hearing what people say.	I may have difficulty following/participating in a conversation.
<input type="checkbox"/>	I have difficulty hearing a normal voice.	I have difficulty hearing and participating in a conversation.
<input type="checkbox"/>	I can hear speech if it is loud speech.	I have great difficulty hearing and participating in a conversation.
<input type="checkbox"/>	I can hear loud speech if it is directly in my ear.	I have very great difficulty hearing and participating in a conversation.
<input type="checkbox"/>	I have great difficulty hearing.	I cannot hear any speech.
<input type="checkbox"/>	I cannot hear any speech or loud sound.	I cannot hear any speech or sound.

If you have selected an option above where writing is highlighted in red, an OTC hearing aid may not work for you. Consult with an audiologist. Please see pharmacist for recommendation.

Collaboration with pharmacists



Dear <insert name here>,

Greetings! We hope that this letter finds you well.
I'm [insert first name or first + last name], an audiologist.

As you may know, over-the-counter (OTC) hearing aids are expected to hit the pharmacy shelves soon. We understand and highly respect that, as pharmacists, you may be the first or last (prior to purchase) health-care provider that a patient approaches for advice on their hearing difficulties. I am writing to invite you to collaborate with me so that, together, we can provide high-quality patient-centered hearing health care. OTC hearing aids, just like any other OTC product, may be appropriate for some but not all patients who come through the pharmacy door.

Refer to an audiologist when the patient reports:

- being younger than 18 years of age (OTC hearing aids are intended for patients 18+ only);
- asymmetrical hearing;
- a sudden onset of hearing loss in one or both ears (see ENT referral below);
- ringing, roaring, or beeping in one or both ears (tinnitus);
- a history of exposure to ototoxic medications;
- a history of chemotherapy and/or radiation to the head and neck region (hearing loss related to chemotherapy often occurs closer to treatment, whereas hearing loss related to radiation can have a delayed onset); and/or
- experiencing greater than a perceived mild to moderate hearing loss.

AUDIOLOGIST AND ENT REFERRAL GUIDE



What is an audiologist?

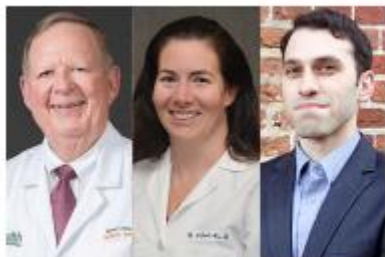
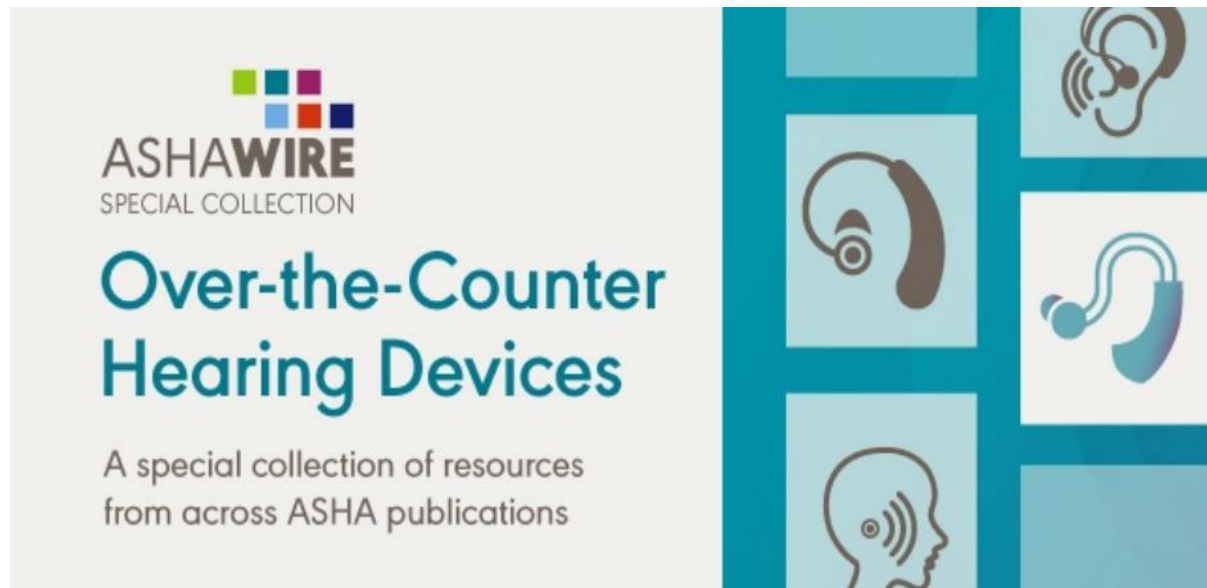
An audiologist is a hearing health-care expert who helps prevent, diagnose, and manage hearing and balance disorders for people of all ages. An audiologist holds either a master's (MS) or a doctoral level degree in audiology (AuD/PhD/ScD), completes a fellowship or externship year, and is licensed to practice state by state. An audiologist helps patients understand what part of their hearing system may be causing a breakdown, conducts a functional communication assessment to identify a patient's hearing needs, and helps guide patients through the process of selecting the most appropriate level and type of hearing technology to address their hearing needs. It is recommended anyone with concerns about their hearing get evaluated by a licensed audiologist as the first step, even if they intend to purchase an OTC hearing aid.

**PHARMACIST LEARNING COURSE
FOR OTC HEARING AIDS**
Created by an Audiologist and Pharmacist

Refer to Ear, Nose, and Throat (ENT) physician when the patient reports:

- a sudden onset of hearing loss or fluctuating hearing loss in one or both ears (seek help as soon as possible; treatment for sudden sensorineural hearing loss is most effective **within 48 hours** of the onset of symptoms);
- a pulsing tinnitus;
- active fluid from one or both ears within the past 90 days;
- pain or discomfort in one or both ears;
- a feeling that one or both ears are clogged;
- visible congenital or traumatic deformity of the ear or surgically altered ears; and/or
- dizziness.

Other ASHA resources



ASHA Voices: OTCs on the Horizon

By J.D. Gray | September 16, 2021

[Educational Presentation for Audiology Students \[PPTX\]](#)

This PowerPoint presentation covers information about OTC hearing aids and the role of audiologists.

ASHA Voices: When OTCs Arrive, Pharmacists Could Be Key Allies for Audiologists

By J.D. Gray
April 29, 2022

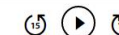


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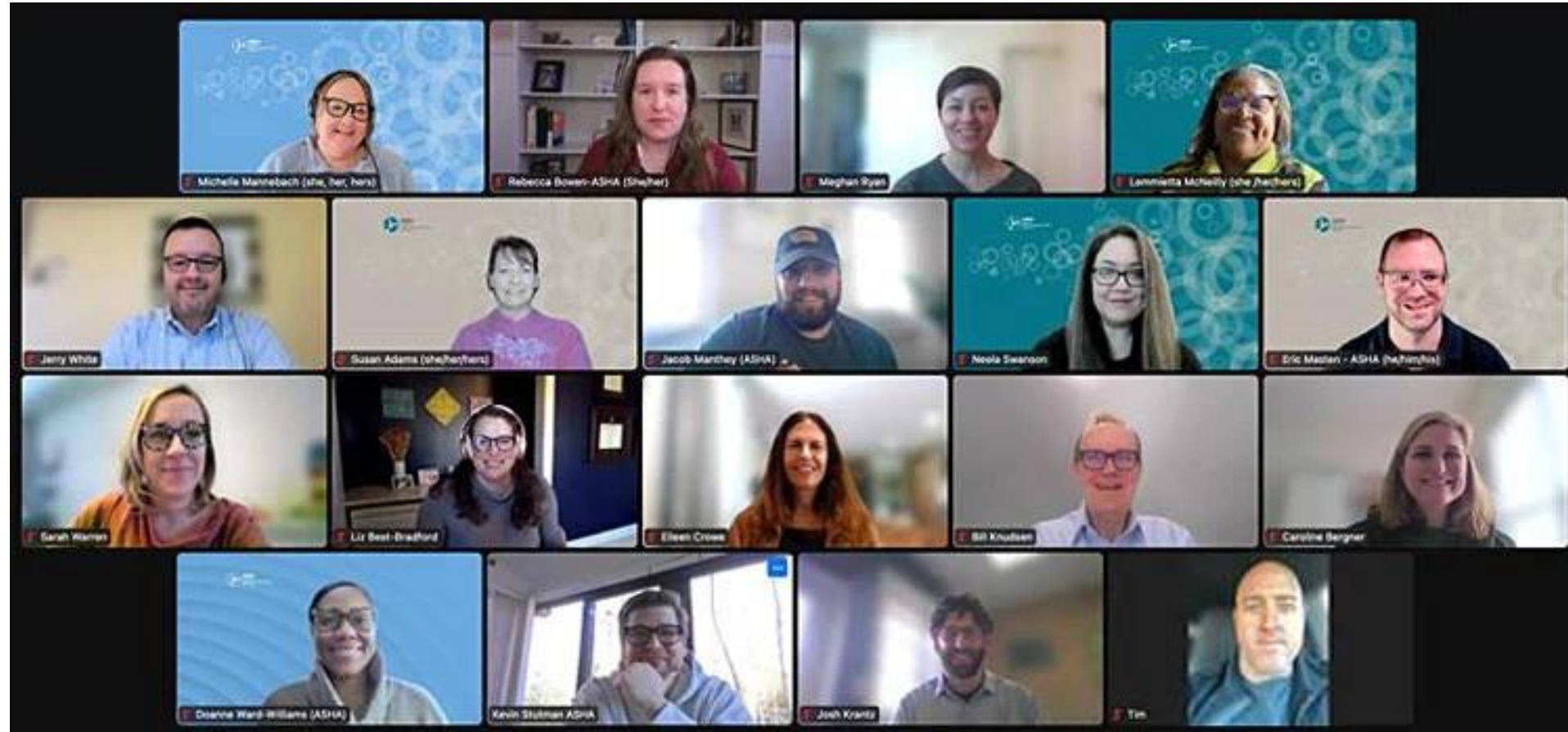
IE ASHA LEADER JOURNALS PERSPECTIVES OF THE ASHA SPECIAL INTEREST GROUPS TOPICS SPECIAL



When OTCs Arrive, Pharmacists Could Be Key Allies for ...
ASHA Voices



Spotlighting ASHA's GAPP unit



References

- Ciorba A, Bianchini C, Pelucchi S, Pastore A. The impact of hearing loss on the quality of life of elderly adults. *Clin Interv Aging*. 2012;7:159-63. doi: 10.2147/CIA.S26059. Epub 2012 Jun 15. PMID: 22791988; PMCID: PMC3393360.
- Goman, A. M., & Lin, F. R. (2016). Prevalence of Hearing Loss by Severity in the United States. *American journal of public health*, 106(10), 1820–1822. <https://doi.org/10.2105/AJPH.2016.303299>
- Goman AM, Reed NS, Lin FR. Addressing Estimated Hearing Loss in Adults in 2060. *JAMA Otolaryngol Head Neck Surg*. 2017;143(7):733–734. doi:10.1001/jamaoto.2016.4642
- Huang AR, Jiang K, Lin FR, Deal JA, Reed NS. Hearing Loss and Dementia Prevalence in Older Adults in the US. *JAMA*. 2023;329(2):171–173. doi:10.1001/jama.2022.20954
- Humes, L. E., Kinney, D. L., Main, A. K., & Rogers, S. E. (2019). A Follow-Up Clinical Trial Evaluating the Consumer-Decides Service Delivery Model. *American journal of audiology*, 28(1), 69–84. https://doi.org/10.1044/2018_AJA-18-0082
- Humes LE, Rogers SE, Quigley TM, Main AK, Kinney DL, Herring C. The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *Am J Audiol*. 2017 Mar 1;26(1):53-79. doi: 10.1044/2017_AJA-16-0111. Erratum in: *Am J Audiol*. 2019 Sep 13;28(3):730. PMID: 28252160; PMCID: PMC5597084.
- Jiam NT, Li C, Agrawal Y. Hearing loss and falls: A systematic review and meta-analysis. *Laryngoscope*. 2016 Nov;126(11):2587-2596. doi: 10.1002/lary.25927. Epub 2016 Mar 24. PMID: 27010669.
- Keidser G, Convery E. Outcomes With a Self-Fitting Hearing Aid. *Trends Hear*. 2018 Jan-Dec;22:2331216518768958. doi: 10.1177/2331216518768958. PMID: 29716438; PMCID: PMC5991196.
- Blake J Lawrence, PhD, Dona M P Jayakody, PhD, Rebecca J Bennett, PhD, Robert H Eikelboom, PhD, Natalie Gasson, PhD, Peter L Friedland, MBBCh, FRACS, Hearing Loss and Depression in Older Adults: A Systematic Review and Meta-analysis, *The Gerontologist*, Volume 60, Issue 3, April 2020, Pages e137–e154, <https://doi.org/10.1093/geront/gnz009>
- Nachtegaal J, Smit JH, Smits C, Bezemer PD, van Beek JH, Festen JM, Kramer SE. The association between hearing status and psychosocial health before the age of 70 years: results from an internet-based national survey on hearing. *Ear Hear*. 2009 Jun;30(3):302-12. doi: 10.1097/AUD.0b013e31819c6e01. PMID: 19322094.
- Reed NS, Altan A, Deal JA, Yeh C, Kravetz AD, Wallhagen M, Lin FR. Trends in Health Care Costs and Utilization Associated With Untreated Hearing Loss Over 10 Years. *JAMA Otolaryngol Head Neck Surg*. 2019 Jan 1;145(1):27-34. doi: 10.1001/jamaoto.2018.2875. PMID: 30419131; PMCID: PMC6439810.
- Reed NS, Garcia-Morales E, Willink A. Trends in Hearing Aid Ownership Among Older Adults in the United States From 2011 to 2018. *JAMA Intern Med*. 2021;181(3):383–385. doi:10.1001/jamainternmed.2020.5682
- Powers, Thomas & Bisgaard, Nikolai. (2022). MarkeTrak and EuroTrak: What We Can Learn by Looking Beyond the U.S. Market. *Seminars in Hearing*. 43. 348-356. 10.1055/s-0042-1758361.
- Powers TA, Carr K. MarkeTrak 2022: Navigating the changing landscape of hearing healthcare. *Hearing Review*. 2022;29(5):12-17



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HAVE A QUESTION?
ASHA Audiology is here to assist.



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Audiology
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the Profession of Audiology