

Lecturers and Biographic Summaries PSHS 2023



Lindsay S. Creed, AuD, CCC-A

Associate Director, Audiology Practices
American Speech-Language-Hearing Association (ASHA)

Lindsay S. Creed, AuD, CCC-A is an Associate Director of Audiology Practices at ASHA. She serves as the team lead on OTC policy work and is the Ex Officio (liaison) of ASHA's Technology Member Advisory Group. Other focus areas include educational audiology and auditory rehabilitation. Prior to joining ASHA, Dr. Creed worked at an ENT practice, where she specialized in pediatric diagnostics and amplification.



Marquitta Merkison, AuD, CCC-A

Associate Director, Audiology Practices
American Speech-Language-Hearing Association (ASHA)

Marquitta Merkison, AuD, CCC-A is an Associate Director of Audiology Practices at ASHA. She is the Ex Officio (liaison) of ASHA's Practice Management Member Advisory Group. Her other focus areas include implantable hearing devices and public health. Dr. Merkison has experience working for a cochlear implant manufacturer as well as working as a clinical audiologist in various medical settings.

Title: Over-the-counter (OTC) Hearing Aids: a brief history and potential trajectory

This course will focus on clinical and research updates on Over-the-Counter (OTC) hearing aids. Presenters will review the history of OTC hearing aids, current regulatory requirements, recent advances in research on OTCs, and the role of audiologists in the implementation of OTC hearing aids. The session will conclude with a discussion of resources, including materials that can be used to educate the public and health care professionals on appropriate use of OTC hearing aids and the importance of audiologic support services. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment

In what year was the OTC Hearing Aid Act signed into law?

- 2015
- 2017
- 2019
- 2021

What is the statement of OTC availability that must be printed on the outside packaging of OTC hearing aids?

- The words "OTC" and "hearing aid" must be included on the principal display panel
- "This device is only appropriate for individuals age 18+"
- A statement indicating the return policy



“This device is FDA approved”

The ASHA OTC Hearing Aid Toolkit contains resources for audiologists, _____, and _____.

students and audiology assistants

SLPs and students

teachers and primary care physicians

pharmacists and primary care physicians

Disclosures

Check one	
X	The presenter has nothing to disclose (skip to section #3)
	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
	Consultant	
	Speakers bureau/ Honoraria	
	Stockholder/Ownership	
	Employment	
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1.

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.

Lindsay S. Creed, AuD, CCC-A and Marquitta Merkison, AuD, CCC-A

Date: August 14, 2023



Lindsey E. Jorgensen AuD PhD

Professor and Chair

University of South Dakota Department of Communication Sciences and Disorders

Clinic Director USD Speech-Language and Hearing Clinics

Lindsey E. Jorgensen is a Professor and serves as Department Chair and Clinic Director in the Communication Sciences and Disorders Department at the University of South Dakota; she also holds a position as a Research Audiologist for the Department of Veterans affairs. At the University of South Dakota Lindsey teaches, conducts research, and provides clinical services in the area of hearing aids and hearing assistive technology. Her research focuses on how to best personalize hearing technologies for patient individual cognitive, psychological, physical,

and social needs.

Title: OTC from clinical trial to clinical care

This lecture will provide a summary of the current peer review research examining OTC hearing aids performance with an emphasis in comparing OTC and conventional hearing aids. The history of OTC hearing aids approval process by the Federal Drug Administration (FDA) will also be discussed. Finally, a practical guide to managing patients who either already have, or want to purchase OTC hearing aids will be discussed. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

What is the FDA criteria for approving a 510k application of a self-fitting hearing device?

No more harmful

The OTC has better perceived benefit than the comparative hearing aid

The OTC has better outcomes than the comparative hearing aid

The OTC is closer to meeting the specifications on the spec sheet than the comparative hearing aid

Which of the following do not need FDA approval

Self-fitting hearing aids

Audiologist fit hearing aids

Aids with multiple programs that have varied volumes

Aids that do an in situ audiogram

Which of the following could you do when someone walks in with an OTC?

Nothing, send them away

Clean & check (service fee), conformity evaluation (REAR)

Check ANSI settings

Tell them how awful the OTCs are at meeting their needs

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
x	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
x	Consultant	Various hearing aid manufacturers and verifications manufacturers for research
s	<u>Speakers</u> bureau/ Honoraria	Hear U is providing honorarium for this presentation
	Stockholder/Ownership	
	Employment	
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1.

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Date: August 14, 2023



Vinaya Manchaiah, AuD, PhD, MBA

University of Colorado School of Medicine, University of Colorado Anschutz Medical Campus, Aurora, Colorado
University of Colorado Hospital (UCHealth), Aurora, Colorado

Dr. Vinaya Manchaiah, AuD, MBA, PhD serves as the Professor of Otolaryngology-Head & Neck Surgery at the University of Colorado School of Medicine and as the Director of Audiology at the University of Colorado Hospital (UCHealth). He is the Principal Investigator at the Virtual Hearing Lab (www.virtualhearinglab.org). He also has a position as an Extraordinary Professor at the University of Pretoria, South Africa, and an Adjunct Professor at the Manipal Academy of Higher Education, India. He has authored over 200 scientific manuscripts and 5 textbooks.

Full bio is available on: www.vinayamanchaiah.com.



Title: Factors influencing hearing help-seeking and hearing aid uptake in adults

This lecture will describe intrinsic factors expressed by those of our patients who seek help with their hearing impairment. Learners will be able to, describe benefits of hearing aid use in adults with hearing loss, discuss the reasons why people may or may not seek hearing help, and discuss the factors influencing the hearing aid uptake in adults with hearing loss. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

What percentage of individuals with hearing loss in the US own hearing aids?

- 10%
- 25%
- 40%
- 50%

Which of the following factors has the highest evidence towards hearing aid uptake, use and satisfaction?

- Insurance coverage
- Hearing sensitivity
- Self-reported hearing disability
- Attitude towards hearing loss

Which of the following has no relation to hearing aid uptake, use and satisfaction?

- Gender
- Hearing sensitivity
- Self-reported hearing disability
- Attitude towards hearing loss

Title: Neurophysiological perspective on OTC hearing aid outcomes

This lecture will describe neurophysiological factors that are associated with successful hearing aid performance. Learners will be able to describe consequences of age-related hearing loss, describe neurocognitive changes in age-related hearing loss, and discuss the effects of early intervention with hearing aids on behavioral, self-reported, cognitive and neurophysiological outcomes. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

Which of the following is not a hearing device classified under the FDA?

- Prescription hearing aid
- Bone conduction hearing aid
- OTC hearing aid
- Personal Sound Amplification System (PSAP)

OTC hearing aids are appropriate for which of the following condition?

- Individuals with perceived mild to moderate hearing loss
- Individuals with tinnitus
- Individuals with active ear infections



All of the above

How long after OTC hearing aid use we start seeing cortical plasticity reversal as a result of hearing aid use?

- 3 weeks
- 3 months
- 6 months
- 1-year

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
x	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
x	Grant/research support	William Demant Foundation
x	Consultant	Scientific Advisor for hearX SA (Pty) Ltd
x	Speakers bureau/ Honoraria	Reimbursed for this event
	Stockholder/Ownership	
	Employment	
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1. Serve on Executive Committee of the International Society of Audiology (ISA)

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.



Date: August 14, 2023



Dr Karina C. De Sousa

Postdoctoral Research Fellow in Audiology
University of Pretoria, South Africa

Dr Karina De Sousa is an audiologist by training and a postdoctoral research fellow at the University of Pretoria in South Africa. Her expertise draws on applied research techniques to investigate novel methods to improve access to hearing care. Specifically, she has done work in developing a speech recognition in noise test to screen for hearing loss using a smartphone. The version of the digits-in-noise test has been used by the World Health Organization, called the hearWHO app. Furthermore, her work investigated how this test can be used to categorize types and degrees of hearing loss. Recently, she has shifted

toward the study of OTC hearing aids. Her ongoing research assesses the performance of the devices against audiologist-fitted hearing aids, adding critical insights to the discourse of these new category of hearing devices.

Title: Perceptions and Performance: Professionals views and effectiveness of OTC vs professionally-fitted hearing aids

This presentation navigates the complex new landscape of over the counter (OTC) hearing aids, a topic of growing significance in audiology and related fields. We will first delve into the prevalent concerns of hearing healthcare professionals regarding OTC hearing aids, outlining the potential risks and shortcomings of these devices may present to hearing-impaired individuals, in comparison to professionally-fitted hearing aids. We will shortly address the regulatory role of the FDA, clarifying how they measure and assess both effectiveness and usability of OTC hearing aids, and their mechanisms to ensure consumer safety. The final segment of this lecture pivots to the latest research in this field. Based on research, we will discuss the effectiveness of self-fitting OTC hearing aids drawing from the findings of a recent randomized control trial. The aim is to provide an evidence-based perspective that informs the current debate on these accessible, yet controversial devices. Attendees will gain a nuanced understanding of the OTC hearing aid landscape, empowering them to make more informed decisions and better serve their patients. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

How does the FDA measure the clinical effectiveness of OTC self-fitting hearing aids?

- Monitoring and conducting market surveys to examine consumer satisfaction and perceptions.
- Checking and regulating the maximum power output of the device
- Checking evidence of clinical efficacy and studies on usability.
- Tracking the number of units sold.

According to recent research, how does the effectiveness of an OTC self-fitting hearing aid compare to that of a professionally fitted hearing aid?

- OTC hearing aids are not effective and fall well below the acceptable range of outcomes.
- Professionally fitted hearing aids are always more effective.



Effectiveness of a self-fitting OTC can perform similar to an audiologist-fitted hearing aid for people who qualify

Both types of hearing aids perform equally in all hearing conditions.

Which of the following best describes a major concern expressed by hearing healthcare professionals about OTC self-fitting hearing aids?

They are too expensive.

They might lead to incorrect self-diagnosis of hearing problems.

They provide better sound quality than professionally-fitted hearing aids.

They do not require adjustment over time.

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
X	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
X	Grant/research support	University of Pretoria
X	Consultant	hearX Group
	Speakers bureau/ Honoraria	
	Stockholder/Ownership	
	Employment	
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1.

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.

Date: August 14, 2023



Lucas A. Berenbrok, PharmD, MS

Associate Professor of Pharmacy and Therapeutics
University of Pittsburgh School of Pharmacy

Dr. Lucas Berenbrok is an Associate Professor at the University of Pittsburgh School of Pharmacy. In collaboration with audiology colleagues, Luke created pharmacist competencies for over-the-counter hearing aids and the nation's first OTC hearing aid training program for community pharmacists.

Title: Establishing Collaborative Working Relationships with Pharmacists: Secrets to success for audiologists and hearing aid dispensers

This presentation will review a framework for building collaborative working relationships with pharmacists. Bidirectional referrals, OTC hearing aids, and other opportunities for collaborations will be covered. Examples of existing relationships and secrets for building new relationships with pharmacists will be highlighted. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

The scope of pharmacy is best described as which of the following?

- Diagnosing and treating disease
- Providing direct patient care and assessments
- Ensuring appropriate, effective, safe, and convenient use of medications
- Prevent, identify, assess, diagnose, and treat impairment of auditory and vestibular function

Which of the following is the lowest level of collaboration between pharmacists and other healthcare professionals?

- Professional awareness
- Professional recognition
- Exploration and trial
- Professional relationship expansion

A recent study by Midey et al found that which of the following would likely support integration of OTC hearing aids into pharmacy practice?

- Affiliation with research institutions
- Culture or mission of place of employment
- Professional connections to hearing healthcare professionals like audiologists
- Supportive leadership from place of employment

Title: Pharmacy Implementation of Over-the-Counter and Direct-to-Consumer Hearing Aid Devices: Expanding public access to hearing aids

Past, current, and future implementation models for OTC and DTC hearing aids sold at community pharmacies will be outlined. Emphasis will be placed on how audiologists and hearing aid dispensers can work collaboratively with pharmacies to reach populations underserved by existing hearing aid dispensing



locations. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

Which of the following locations in the pharmacy would require a conversation with a pharmacy employee?

- On the shelf, unsecured
- On the shelf, secured
- Behind the front register
- Behind the pharmacy counter

During “Assess”, pharmacists evaluate patients for red flag conditions, also known to pharmacists as which of the following?

- Boxed warnings
- Contraindications
- Exclusions for self-care
- Precautions

Audiologists and hearing aid dispensers may refer patients to pharmacists for which of the following?

- Patient dissatisfaction with OTC hearing aids
- Self-treatment of dermatitis of the external ear
- Refined customizations of OTC hearing aids
- Conditions excluding patient use of OTC hearing aids

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
X	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
	Consultant	
	Speakers bureau/ Honoraria	
X	Stockholder/Ownership	Embarx, LLC
X	Employment	University of Pittsburgh
	Intellectual property rights	
X	Royalty	American Pharmacists Association
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1.

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.

Date: August 14, 2023



Mark A Parker PhD

Director of Audiology, Steward St. Elizabeth’s Medical Center
Assistant Professor of Otolaryngology, Boston University School of Medicine

Dr. Parker holds a PhD in Neuroscience and is a licensed and practicing Audiologist. Dr. Parker currently serves as the Director of Audiology at Steward St. Elizabeth’s Medical Center and as an Assistant Professor at Tufts University School of Medicine. In this capacity, Dr Parker sees patients, manages the audiology, balance, hearing aid, and newborn hearing screening programs, and conducts both basic and clinical research in hearing loss and hearing restoration.

Title: Breakout Session: Listening OTC and traditional hearing aids

Manufacturers will demonstrate basic and advanced features of their OTC and conventional hearing aids, including live listening stations, to the attendees. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

Name of manufacturer and product reviewed:

List 3 ways in which this product could be used to improve customer performance:

Describe two features the differentiate this product from the others you have evaluated:

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
x	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
	Consultant	
	Speakers bureau/ Honoraria	
x	Stockholder/Ownership	I am on the BOD of Hearing University (HearU), the parent company of PSHS
	Employment	
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1.

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.

Mark A Parker PhD

Date: August 14, 2023



Brian Taylor, AuD

Senior Director, Audiology
Signia

Brian Taylor, AuD is the senior director of audiology for Signia. Additionally, he serves as editor-at-large for Hearing Health and Technology Matters, a leading professional blog, and editor of Audiology Practices, the quarterly publication of the Academy of Doctors of Audiology. He is also an adjunct professor at the University of Wisconsin. Dr. Taylor has authored numerous peer reviewed articles and books on topics ranging from hearing aids to practice management. His latest textbooks, *Selecting and Fitting Hearing Aids* and *Relationship-Centered Communication for Audiologists* were published in 2021.

Title: Applications of direct-to-consumer hearing devices for adults with hearing loss: a review

This course reviews how OTC devices and other direct-to-consumer amplifiers differ from prescription hearing aids. Additionally, this course provides ideas, based on the most current published evidence, on how various direct to consumer devices can be successfully integrated into clinical practice to address the unmet need of untreated hearing loss.

Title: Applications of direct-to-consumer hearing devices for adults with hearing loss: a review

This lecture will describe a recently published systematic literature review aimed at investigating applications of direct-to-consumer hearing devices for adults with hearing loss. This review discusses three categories of direct-to-consumer hearing devices: 1) personal sound amplification products (PSAPs), 2) direct-mail hearing aids, and 3) over-the-counter (OTC) hearing aids. A literature review was conducted using EBSCOhost and included the databases CINAHL, MEDLINE, and PsycINFO. After applying prior agreed inclusion and exclusion criteria, 13 reports were included in the review. The results showed that electroacoustic characteristics of these devices vary significantly with some meeting the stringent acoustic criteria used for hearing aids, while others producing dangerous output levels (ie, over 120-dB sound pressure level). Low-end (or low-cost) devices were typically poor in acoustic quality and did not meet gain levels necessary for most adult and elderly hearing loss patterns (eg, presbycusis), especially in high frequencies. Despite direct-mail hearing aids and PSAPs being associated with lower satisfaction when compared to hearing aids purchased through hearing health care professionals, consumer surveys suggest that 5%–19% of people with hearing loss purchase hearing aids through direct-mail or online. Studies on outcome evaluation suggest positive outcomes of OTC devices in the elderly population. Of note, OTC outcomes appear better when a hearing health care professional supports these users.

The conclusions are that while some direct-to-consumer hearing devices have the capability to produce adverse effects due to production of dangerously high sound levels and internal noise, the existing literature suggests that there are potential benefits of these devices. Research of direct-to-consumer hearing devices is limited, and current published studies are of weak quality. Much effort is needed to understand the benefits and limitations of such devices on people with hearing loss. The target audience



are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

Over-the-counter hearing device officially become an FDA regulated product category in

Oct 2022

Oct 2017

April 2021

They are still not an officially FDA regulated device

The new FDA-sanctioned name for medical grade hearing aids is

Prescription hearing aids

Medical hearing aids

Custom hearing devices

Hearables

The type different maximum output limits placed on OTC devices are

120 and 115dB SPL

117 and 111dB SPL

110 and 105dB SPL

105 and 95dB SPL

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
x	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
	Consultant	
	Speakers bureau/ Honoraria	
	Stockholder/Ownership	
x	Employment	
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1. Employed by WS Audiology

3. Attestation Statement

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Brian Taylor

Date: August 14, 2023



Amy Bishop Au.D., CCC-A

Corporate Audiologist
Lucid Hearing

Amy Bishop, Au.D., CCC-A, is a distinguished corporate audiologist at Lucid Hearing. Dr. Bishop spent six years as a patient-facing audiologist in both a private practice and retail setting before joining Lucid Hearing, where she has now been providing training as well as clinical and technical support to hearing care professionals and their patients for the past three years. She obtained her undergraduate degree in Education of the Deaf and her Doctor of Audiology from the University of Southern Mississippi. With nearly a

decade of experience in the field, Dr. Bishop has made it her mission to help people enhance their hearing abilities and elevate their overall quality of life.

Title: Challenges, Opportunities, and Ethical Considerations Between Traditional and OTC Hearing Aids

In today's era of advanced technology, the field of hearing aids has witnessed a significant transformation. As the landscape of hearing aids continues to evolve, it is crucial to recognize and appreciate the strengths and limitations of both traditional and Over-the-Counter options. With the implementation of OTC hearing aids comes new ethical considerations regarding our role as providers. How do OTC hearing aids fit into the code of ethics and providers' obligations to help patients find solutions to treat their hearing loss?

Traditional hearing aids offer unparalleled personalized programming and support as well as the best technology available and will always be the gold standard for treating hearing loss. OTC alternatives provide cost-effective accessibility and convenience. Data from Lucid Hearing's hearing centers shows that by embracing the potential of OTC products, providers can unlock new avenues to reach individuals who may have otherwise been hesitant to seek help. They also provide a solution for those who are unable to complete the testing required for traditional hearing aids. Together, the traditional and OTC approaches can transform the lives of more individuals with hearing loss, ensuring a win for both patients and the business. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

Which of the following individuals would not be an appropriate candidate for an OTC product?

- Someone who is unable to have a hearing test performed
- Someone who has a severe to profound hearing loss
- Someone with normal hearing thresholds, but who has significant difficulty in noise
- Someone with borderline thresholds, who's chief complaint is tinnitus

Which of the following statements is false regarding the benefits of traditional hearing aids

- They are programmed specifically to the patient's hearing loss
- They typically come with a high level of support and follow up care
- They are the most cost effective option



They can fit a wide range of hearing losses including severe to profound losses

Which of the following statements is true regarding the ethics surrounding OTC hearing aids

OTC hearing aids are always unethical

There are no ethical considerations when it comes to OTC hearing aids

OTC hearing aids are always ethical

It is important to consider how OTC hearing aids fit into our code of ethics and standards of practice

Disclosures

Check one	
	The presenter has nothing to disclose (skip to section #3)
x	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
	Consultant	
	Speakers bureau/ Honoraria	
	Stockholder/Ownership	
x	Employment	Lucid Hearing
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1. I am currently employed as the Corporate Audiologist for Lucid Hearing

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.

Amy Bishop, Au.D., CCC-A

Date: August 14, 2023



Tim Trine PhD

Chief Technology Officer

Eargo

Tim is the Chief Technology Officer at Eargo where he leads an interdisciplinary team of scientists, engineers, and clinicians in developing disruptive innovation for the direct-to-consumer hearing aid market. He returned to Eargo in September 2022 after previously serving in the same role from 2017 to 2020. Prior to returning to Eargo, Tim served as President & CEO of Noopl, a consumer audio startup. From 1998 to 2017, Tim held several management roles at Starkey Hearing Technologies, spending 12 of those years as Starkey's CTO and SVP of Research & Development. Prior to his tenure at Starkey, he was an Assistant Professor and Director of Audiology at Vanderbilt University. Tim holds a bachelor's degree in Communication Disorders from California State University-Northridge, a M.S. in Audiology from Vanderbilt University, a Ph.D. in Hearing Science from the University of Minnesota, and an M.B.A. from the Kellogg School of Management at Northwestern University.

Title: Integrating Over the Counter Hearing Aids with Audiology Practice: Opportunities and Challenges

Recently, the United States Food and Drug Administration (FDA) issued final regulations for over the counter (OTC) hearing aids, aimed at making hearing aids more affordable and accessible for millions of Americans living with untreated mild-to-moderate hearing loss. Such devices may change how the patients with hearing loss, clinicians, and the industry operate and interact with each other in the future. OTC hearing aids, generally, have self-adjustment algorithms as an integral part of their technology. Questions remain, however, about end users' ability to fit gain profiles appropriately to achieve satisfactory outcomes and clinical efficacy. One such device is Eargo's hearing aid that allows end users to program devices by performing in-situ hearing screening and self-adjustments using a smartphone application. In this talk, we will first review clinical evidence validating the effectiveness of Eargo's hearing aids self-fit by the users relative to the same devices fit professionally by an audiologist following clinical best practice methods. We will also discuss some of the opportunities and challenges in integrating OTC hearing aids with clinical practice. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

The statistical design demonstrating clinical equivalence between self-fit and audiologist-fit hearing aid outcomes with the Eargo hearing aids was:

- A double-blind crossover randomized clinical trial.
- A single-blind crossover randomized clinical trial.
- A non-blinded, non-randomized clinical trial.
- Based on anecdotal clinical observation.



The primary and secondary outcome measures from the study conducted by the University of Minnesota shared in this presentation were:

The Abbreviated Profile of Hearing Aid Benefit (APHAB) and speech recognition in noise for AzBio sentences.

The APHAB and the speech reception threshold (SRT) in noise for spondaic words.

The Client Oriented Scale of Improvement (COSI) and speech recognition in quiet for NU-6 words.

The APHAB and the COSI.

The proportion of audiometric thresholds at 1, 2, 3, and 4 kHz that fell within test-retest reliability criteria when comparing clinically administered audiometry to self-administered in-situ audiometry was:

>60%

>70%

>80%

>90%

100%

Disclosures

Check one	
<input type="checkbox"/>	The presenter has nothing to disclose (skip to section #3)
<input checked="" type="checkbox"/>	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

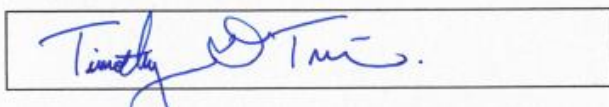
Check all that apply	Type of Financial Relationship	Company Name (list all)
<input type="checkbox"/>	Grant/research support	
<input type="checkbox"/>	Consultant	
<input type="checkbox"/>	Speakers bureau/ Honoraria	
<input checked="" type="checkbox"/>	Stockholder/Ownership	EARGO, INC.
<input checked="" type="checkbox"/>	Employment	EARGO, INC.
<input type="checkbox"/>	Intellectual property rights	
<input type="checkbox"/>	Royalty	
<input type="checkbox"/>	Patents on equipment/service	
<input type="checkbox"/>	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1. N/A

3. Attestation Statement

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Date: July 13, 2023



Aysel Cengiz

Director, Global PR and Communication
GN Group

Aysel is the Director of Global PR and Communication for the GN Group, which is the parent company of GN ReSound, Beltone, Danavox, and now Jabra which is GN's new OTC product line. Aysel has over 15 years of managerial and marketing experience across a wide range of industries.

Title: Reaching the unreachable: How GN's Jabra Enhance can fit the unmet need of the vast majority of our hearing impaired

Data has long shown that 89% of those persons who need hearing aids don't have them. Clearly, our hearing healthcare delivery model needs to change to help those patients who aren't coming to our practices. This lecture will introduce the audience to GN's new OTC hearing aid, Jabra Enhance, and its hearing healthcare delivery model, which includes online services and value-driven results. Jabra and our delivery model will be compared and contrasted to other OTC hearing aids currently on the market. The target audience are hearing healthcare professionals (i.e. hearing instrument specialists, dispensing otolaryngologists, audiologists, students in related fields, etc.).

Learning Assessment:

All of the following are included in Jabra Enhance's hearing healthcare delivery model except?

- OTC Hearing Aids
- Remote Care with a hearing healthcare professional
- Resources for the hearing impaired
- A free hearing test in an audiometric test suite

How many days is the trial period for Jabra Enhance?

- 30
- 60
- 90
- 100

Check one	
	The presenter has nothing to disclose (skip to section #3)
x	The presenter has disclosure(s) to report (complete sections #1, 2, & 3)

1. Financial Disclosure Information

Check all that apply	Type of Financial Relationship	Company Name (list all)
	Grant/research support	
	Consultant	
	Speakers bureau/ Honoraria	
	Stockholder/Ownership	
x	Employment	Employed by Jabra GN
	Intellectual property rights	
	Royalty	
	Patents on equipment/service	
	Other financial support (not listed above)	

2. Non-financial Disclosure Information (advisory committee, review panel, board, etc.)

Nature of financial/non-financial disclosure (list all)
1.

3. Attestation Statement

By signing this box with my electronic signature, I attest that all information above is true and correct.

Aysel Cengiz

Date: August 14, 2023

