

OTC Hearing Aids and Auditory Wellness

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Agenda

- Age-related hearing loss and dementia
- Does hearing-aid use benefit cognitive health?
- OTC hearing aids
- Who may benefit from OTC hearing aids?
- Limitations of the current OTC delivery models

Age-Related Hearing Loss is Highly Prevalent Public Health Issue



Proportion of population with hearing loss



Impact of Age-Related Hearing Loss Beyond Hearing

The audiogram or speech recognition performance do not represent the full impact of age-related hearing loss. Untreated hearing loss is statistically associated with

- higher risks of social isolation;
- depression;
- dementia;
- falls with injury; and
- inability to work, travel, or be physically active



Age-Related Hearing Loss as a Risk Factor for Dementia

- People who develop hearing problems during mid-life (aged 40–65) have an increased risk of developing dementia.
- Hearing loss is estimated to account for 8% of dementia cases ~800,000 of the nearly 10 million new cases of dementia diagnosed each year.

Livingston, G., Huntley, J., Sommerlad, A., Ames, D., Ballard, C., Banerjee, S., ... & Mukadam, N. (2020). Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *The lancet*, *396*(10248), 413-446.



Age-Related Hearing Loss as a Risk Factor for Dementia – Global Data



See, R. S., Thompson, F., Russell, S., Quigley, R., Esterman, A., Harriss, L. R., ... & Strivens, E. (2023). Potentially modifiable dementia risk factors in all Australians and within population groups: an analysis using cross-sectional survey data. *The Lancet Public Health*, *8*(9), e717-e725.

Mukadam, N., Sommerlad, A., Huntley, J., & Livingston, G. (2019). Population attributable fractions for risk factors for dementia in low-income and middle-income countries: an analysis using cross-sectional survey data. *The Lancet Global Health*, 7(5), e596-e603.

Does Hearing-Aid Use Benefit Cognitive Health?

The ACHIEVE (Aging and Cognitive Health Evaluation in Elders) study:

- **Objective**: To determine whether treating hearing loss can reduce the risk of cognitive decline in older adults.
- **Participants**: The study involves older adults aged 70-84 with untreated hearing loss.
- **Intervention**: Participants are randomly assigned to receive either hearing intervention (hearing aids and counseling) or a health education control.
- **Duration**: The study spans three years, with regular assessments of cognitive function.
- **Outcomes**: The primary outcome is the rate of cognitive decline, measured through standardized cognitive tests.

Lin, F. R., Pike, J. R., Albert, M. S., Arnold, M., Burgard, S., Chisolm, T., ... & Coresh, J. (2023). Hearing intervention versus health education control to reduce cognitive decline in older adults with hearing loss in the USA (ACHIEVE): a multicentre, randomised controlled trial. *The Lancet*, *402*(10404), 786-797.

Does Hearing-Aid Use Benefit Cognitive Health?



- ARIC group: recruited from an on-going study of cardiovascular health, i.e., high-risk group
- **De Novo group**: volunteers responding to ad, i.e., lowrisk group
- Benefits of hearing-aid use was observed after 3 years for the high-risk group.

Lin, F. R., Pike, J. R., Albert, M. S., Arnold, M., Burgard, S., Chisolm, T., ... & Coresh, J. (2023). Hearing intervention versus health education control to reduce cognitive decline in older adults with hearing loss in the USA (ACHIEVE): a multicentre, randomised controlled trial. *The Lancet*, *402*(10404), 786-797.

Emerging Evidence for the Benefit of Hearing-Aid Use on Cognitive Health?

	Participan	ts (n)				Hazard ratio (95% C
Amieva et al (2018) ¹⁰⁴	3588			-		0.86 (0.59–1.26)
Bucholc et al (2021) ¹⁰⁵	939			÷		0.73 (0.60-0.88)
Davies et al (2017) ¹⁰⁶	8651		_	++	_	0.99 (0.65–1.51)
Lin et al (2011) ⁹¹	605					0.97 (0.47–2.00)
Lin et al (2013) ¹⁰⁷	1984					0.82 (0.58–1.16)
Mahmoudi et al (2019) ¹⁰⁸	114862					0.82 (0.76–0.89)
Sugiura et al (2022) ⁹⁷	1193			$\frac{1}{2}$		0.68 (0.43–1.07)
Tai et al (2021) ¹⁰⁹	709			÷		0.82 (0.61–1.10)
Overall (J²=0·0%; p=0·88)				♦		0.81 (0.76–0.87)
		0.2	0.5	! 1·0	2.0	5.0
		Favours	hearing aid	use Fav	ours no heai	ring aids

Livingston, G., Huntley, J., Liu, K. Y., Costafreda, S. G., Selbæk, G., Alladi, S., ... & Mukadam, N. (2024). Dementia prevention, intervention, and care: 2024 report of the Lancet standing Commission. *The Lancet*, *404*(10452), 572-628.

Only a Minority of Older Americans With Hearing Loss Seek Out and Use Assistive Hearing Technologies



Why Aren't Older Americans Seeking Hearing Healthcare?



Lack of Access for Hearing Healthcare

Finding an audiologist?



https://www.bls.gov/oes/2019/may/oes291181.htm



https://www.bls.gov/oes/current/oes291051.htm

Lack of Affordability

Average price per hearing aid by technology level



Average Price Paid Per Hearing Aid

Excludes prices paid when insurance covered part or all of the cost.



https://www.hearingtracker.com/how-much-do-hearing-aids-cost

Over the Counter Hearing Aids (Oct 2022 -)











The New Landscape of Hearing Devices following FDA Ruling



Examples of OTC Hearing Aids on the market (~\$200 - \$2000 a pair)





Who may benefit from OTC hearing aids?

OTC Hearing Aids are intended for adults who:

are 18 years or older

have perceived mild-to-moderate hearing loss

Who may benefit from OTC hearing aids?

Article

May 20, 1988

Validation of Screening Tools for Identifying Hearing-Impaired Elderly in Primary Care

Michael J. Lichtenstein, MD; Fred H. Bess, PhD; Susan A. Logan, MSc

» Author Affiliations

JAMA. 1988;259(19):2875-2878. doi:10.1001/jama.1988.03720190043029

Interpretation:

- 0-8 = no hearing handicap
- 10-25 = mild-to-moderate handicap
- 26 to 40 = severe handicap

OTC Rule of Thumb: scores from 10 to 25 suggest potentially good OTC hearing aid candidates.

Hearing Handicap Inventory for the Elderly-Screening (HHIE-S)

E = Emotional; S = Social

	Item	Yes (4 pts)	Sometimes (2 pts)	No (0 pts)
E	Does a hearing problem cause you to feel embarrassed when meeting new people?			
E	Does a hearing problem cause you to feel frustrated when talking to members of your family?			
S	Do you have difficulty hearing when someone speaks in a whisper?	·	<u></u>	
E	Do you feel handicapped by a hearing problem?			
S	Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?			
S	Does a hearing problem cause you to attend religious services less often than you would like?			
E	Does a hearing problem cause you to have arguments with family members?			
S	Does a hearing problem cause you difficulty when listening to TV or radio?			
E	Do you feel that any difficulty with your hearing limits or hampers your personal or social life?			_
s	Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?			

Who may NOT be a candidate for OTC hearing aids?

on the package of an OTC OTC Hearing Aids are **NOT** for: hearing aid 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-thecounter hearing aids are only for users who are age 18 or older. More-than-moderate This hearing aid is for adults with signs of mild to moderate hearing Children (<18 y/o) degrees of hearing loss. How do you know if you have this? You have trouble hearing speech in noisy places loss 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 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 Asymmetric hearing deformed in an accident Treating tinnitus • You saw blood, pus, or fluid coming out of your ear in the past 6 months Your ear feels painful or uncomfortable 055 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

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Example elements of labeling

You hear ringing or buzzing in only one ear

When Does My Patient Need to See a Hearing Healthcare Professional?





https://sites.northwestern.edu/cedra/

CEDRA: A research validated questionnaire to help consumers decide if they should seek medical evaluation before purchasing and/or using hearing devices (Klyn et al. Ear and Hearing, 2019)

Where Can I Learn More About OTC Hearing Aids?



OTC Hearing Aids Are Available, But...

- Hearing healthcare professionals are still concerned about the lack of in-person care and professional safeguards for OTC customers (Manchaiah et al., 2023).
- Most customers (84%) still demonstrate a preference for inperson service (Singh and Dhar, 2023).

Manchaiah, V., Sharma, A., Rodrigo, H., Bailey, A., De Sousa, K. C., & Swanepoel, D. W. (2023). Hearing healthcare professionals' views about over-the-counter (OTC) hearing aids: analysis of retrospective survey data. *Audiology Research*, *13*(2), 185-195.

Singh, J., & Dhar, S. (2023). Assessment of consumer attitudes following recent changes in the US hearing health care market. *JAMA Otolaryngology–Head & Neck Surgery*, *149*(3), 247-252.

Questions to be Addressed:

- Is there a sustainable path to provide "in-person" care to OTC customers without undermining the affordability and accessibility that OTC hearing aids are designed to address?
 - > Who should provide "in-person" care to OTC customers?
 - > Who should pay for "in-person" care to OTC customers?

Role of Academic Training Programs

The academic programs have great access to both students and communities:

- Undergraduates.
- Interprofessional training.
- Continuous education.
- Community outreach programs.
- Community-based research
 programs.







Pilot Events (Summer 2024 -)

	Event 1	Event 2	Event 3
Community info			
Name of the partner/facility/community	Greenwood Senior Center	Aegis Living Issaquah	Franke Tobey Jones Tacoma
A brief description of the facility	Neighborhood community senior center providing social, physical, and educational activities	Senior living community focusing on assisted living, memory care, respite care, transitional care, and end-of-life care	Not-for-profit senior Continuing care Retirement Community (CCRC), including independing living, assisted living, memory care, and skilled nursing care
Event facts			
Date	6/21/24	1/29/25	2/27/25
# of clinician	1	1	1
# of students/postdocs	3	7	6
# of attendees	40-50	15	15

Budget per event:

- Car rental: \$60
- Clinician's time: ~\$200
- Printing: \$20



Potential Benefits of High-Throughput Community-Based Care/Training:

For students	•	Hands-on experience interacting with the local community Additional time-efficient learning and practice performing hearing tests, handling OTC hearing aids, and conducting research questionnaires/survey
For the community	•	Access to hearing care & wellness awareness and education Direct handling and experimentation with OTC hearing aids
For manufacturers	•	Exposure for new potential OTC hearing aid customers Increased community knowledge about OTC hearing aid use
For academic programs	•	Time- and cost-efficient student training and community outreach

Summary

- Addressing hearing loss is crucial for healthy aging.
- OTC hearing aids improved the accessibility and affordability of hearing healthcare, to a degree.
- Adequate care pathways incorporating OTC hearing aids are still emerging.

We would love to meet you at your local communities!

Email me: shenyi@uw.edu



