Defining the Addressable Market of OTC vs. Prescription Hearing Aids: Expanding the Market with Something for Everyone

Brent Edwards, PhD
National Acoustic Laboratories
Innovation in Hearing Healthcare

Clinical

Technology

Services

Channel

Consumer
Innovation in Hearing Healthcare

- Technology
- Services
- Channel

CLINICAL

CONSUMER
Innovation in Hearing Healthcare

Technology

Services

Channel
Innovation in Hearing Healthcare

Diagram showing the following:
- Technology
- Services
- Channel

Categories:
- CLINICAL
- CONSUMER
Consumer Expectations are Changing

- I have an interest in **health maintenance and lifestyle changes** 79%
- I do more **research online** to understand my symptoms and treatments 73%
- I expect **convenience** in addition to quality of care 72%
- I am informed about my disease and its treatment 68%
- I am interested in **lower-cost treatment** 62%
- I monitor my health using technology 61%
- I expect my doctor to **communicate with me digitally** 58%
- I schedule **appointments through mobile apps** 55%
Overview

• OTC Hearing Aids
  • What is it?
  • Who are they for?
  • Defining and diagnosing “perceived hearing loss”
  • Treatment strategies

• Consumer-friendly definitions of hearing technology
• Hearing difficulty with videoconferencing
• What does this mean for hearing healthcare practices
Over the Counter Hearing Aids
OTC Hearing Aids: Why was it created?

• Several influential studies argued that there are barriers to adults getting hearing aids
  – Affordability and accessibility the main reasons given
  – Stated that only 1 of 4 people who can benefit from a hearing aid have one

We’re protecting seniors’ life savings by cracking down on nursing homes that commit fraud, endanger patient safety, prescribe drugs that are not needed.

Millions of Americans can now save thousands of dollars because they can finally get a hearing aid over the counter without a prescription.

Look, capitalism without competition is not capitalism. It’s extortion. It’s exploitation.

President Joe Biden
State of the Union Address, 7th Feb 2023
OTC Hearing Aids: What are they?

- Government-regulated medical devices, just like traditional hearing aids, BUT:
  - Are only for adults with “perceived mild-moderate hearing loss”
  - Must not require a professional for fitting or use
  - Must have specific package labels and instructions about use, who they are for, warnings and signs to see a doctor

**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
Innovation in Hearing Healthcare

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Innovation in Hearing Healthcare

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CLINICAL

X

CONSUMER
Sonova Acquires Sennheiser Consumer Audio
Possible preparation for consumer hearing aids
Consumer Product Reviews of OTC Hearing Aids

BEST FOR SENIORS: Jabra Enhance™
- Rating: 4.2/5
- Visit Site

MOST AFFORDABLE: Audien Hearing
- Rating: 3.9/5
- Visit Site

BEST SELF-FITTING: lexis
- Rating: 4.5/5
- Visit Site

BEST INVISIBLE FIT: EARGO
- Rating: 3.9/5
- Visit Site
Approximate half of those with HL (n=3113) are uncomfortable doing tasks associated with OTC.
IS OTC a threat to hearing care professionals (HCPs)?

Most of those with HL (n=3113) believe HCPs are valuable for hearing aid success

HA owners (n = 967)

- Minimally, 6%
- Not at all, 1%
- Not sure, 3%
- Moderately, 21%
- A great deal, 69%

HA non-owners (n = 2141)

- Not at all, 3%
- Minimally, 21%
- Moderately, 28%
- Not sure, 10%
- A great deal, 38%

Edwards, 2020
Self-fitting hearing aids

- Device and controls
  - Form factor
  - Signal processing
  - User control interface

- Audiological specifications
  - Audiometric measurements
  - Fitting rationale

- Service delivery and support resources
  - User instructions
  - Personalised support

- Preferences, needs, and capabilities of the end user
  - Factors associated with successful self-fitting
  - Usability

Convery et al., 2017
COM-B Framework
COM-B Framework: OTC Success

**Capability**
- Able to select appropriate device
- Able to fit correctly on ear
- Able to manage app

**Motivation**
- Belief in self treatment
- No self-stigma
- Lifestyle need
- Supportive environment

**Opportunity**
- Socially acceptable
- Support from others
- Accessible
- Affordable
- Activity limitations

**Behaviour**
- Accept OTC Hearing Aid
Who Are The Customers for OTC Hearing Aids?
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 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
Who has a perceived mild-moderate hearing loss?
Survey of People with No Hearing Loss Who Come to a Hearing Clinic for Help

Distribution of sample by age group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 years or under</td>
<td>4.5%</td>
</tr>
<tr>
<td>26 - 45 years</td>
<td>4.5%</td>
</tr>
<tr>
<td>46 - 65 years</td>
<td>18.2%</td>
</tr>
<tr>
<td>Over 65 years</td>
<td>70.5%</td>
</tr>
</tbody>
</table>

Self-reported level of hearing loss

<table>
<thead>
<tr>
<th>Hearing Loss Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>6.8%</td>
</tr>
<tr>
<td>Mild</td>
<td>47.7%</td>
</tr>
<tr>
<td>Moderate</td>
<td>29.5%</td>
</tr>
<tr>
<td>Severe</td>
<td>13.5%</td>
</tr>
<tr>
<td>Profound</td>
<td>13.5%</td>
</tr>
</tbody>
</table>

Armita Adily, PhD
### Factors influencing help seeking of clients with no hearing loss

#### Help seeking factors

1. Self-assessment - Perceived value of hearing assessment
2. Self-assessment - Noticeable changes in mood
3. Self-assessment - Perceived limitations in daily life due to hearing problem
4. Self-assessment - Tinnitus
5. Social norms - Family and friends
6. Social norms - General population
7. Marketing/promotional campaigns
8. Feedback on client’s hearing ability - Family and friends
9. Feedback on client’s hearing ability - GP/other health professionals
10. Requirements (occupation/health)
11. Non-hearing problems (e.g., vertigo, infection, exostosis, blocked ear, feel something in the ear, pain)

#### Distribution of help seeking factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>35</td>
</tr>
<tr>
<td>4</td>
<td>25</td>
</tr>
<tr>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>5</td>
</tr>
</tbody>
</table>

![Distribution of help seeking factors](image-url)
What can Hearing Care Professionals do for people with “perceived hearing loss” but no measurable hearing loss?
Patient Journey

Devi et al., 2020
How can you diagnose a hearing problem when they have a normal audiogram?
Diagnostic Test Kit

• Develop tools for clinicians to validate the hearing needs of someone with hearing difficulty but minimal hearing loss

Jessica Monaghan, PhD
Methodology

• A test group who reported having hearing problems in noise and a control group who reported no problems took part in a battery of tests to assess:
  • Hearing thresholds
  • Spatial hearing
  • Auditory nerve function
  • Speech-in-noise understanding
  • Processing speed
  • Sustained attention
Results

• Responses to the HHIE questionnaire were able to identify the participants with speech-in-noise difficulties with 95% accuracy

• Questionnaire responses were significantly correlated with measures of loss of hair-cells (OAEs, PTA) as well as measures of damage to the auditory nerve (MEMR, ABR, EFR)
Hearing Handicap Inventory for the Elderly – Short version (HHIE-S)

1. Does a hearing problem cause you to feel embarrassed when you meet new people?
2. Does a hearing problem cause you to feel frustrated when talking to members of your family?
3. Do you have difficulty hearing when someone speaks in a whisper?
4. Do you feel handicapped by a hearing problem?
5. Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?
6. Does a hearing problem cause you to attend religious services less often than you would like?
7. Does a hearing problem cause you to have arguments with family members?
8. Does a hearing problem cause you difficulty when listening to TV or radio?
9. Do you feel that any difficulty with your hearing limits or hampers your personal or social life?
10. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?

Answer: No, Sometimes, Yes
What solution can you recommend for someone with *perceived* hearing loss but no *measurable* hearing loss?
### EXPERIMENTAL

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes but it does appear to have improved my condition</td>
<td></td>
</tr>
<tr>
<td>No because I don't think I need them at this stage and they're a bit</td>
<td></td>
</tr>
<tr>
<td>awkward (slightly itchy, tickly and make it harder to change glasses</td>
<td></td>
</tr>
<tr>
<td>especially if also wearing a mask and earrings). I don't like hearing</td>
<td></td>
</tr>
<tr>
<td>myself eat</td>
<td></td>
</tr>
<tr>
<td>Currently, I would only want to wear the hearing aids in particular,</td>
<td></td>
</tr>
<tr>
<td><strong>controlled environments</strong> where there may need to be a lot of</td>
<td></td>
</tr>
<tr>
<td>listening or conversation - this would help reduce fatigue/frustration</td>
<td></td>
</tr>
<tr>
<td>Yes, would be a useful option to have when going into noisy</td>
<td></td>
</tr>
<tr>
<td>social/talking envs</td>
<td></td>
</tr>
<tr>
<td>Not at this stage. I am still able to moderately participate in</td>
<td></td>
</tr>
<tr>
<td>conversations in a noisy situation. Carrying and wearing the hearing</td>
<td></td>
</tr>
<tr>
<td>aid, still feels a hassle comparing the advantage I am getting. Though</td>
<td></td>
</tr>
<tr>
<td>in future, when my hearing abilities weaken further, I will surely</td>
<td></td>
</tr>
<tr>
<td>consider using hearing aids</td>
<td></td>
</tr>
<tr>
<td>Yes I would in social situations. It makes engaging in conversations</td>
<td></td>
</tr>
<tr>
<td>easier</td>
<td></td>
</tr>
<tr>
<td>Yes. The benefit that I gain from them is too great to not use them</td>
<td></td>
</tr>
</tbody>
</table>
AirPods Pro Can help

<table>
<thead>
<tr>
<th>Question</th>
<th>CTR</th>
<th>EXP</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: Compared to using no hearing aid at all, do your hearing aids help you understand the people you speak with most frequently?</td>
<td>2.3</td>
<td>3.5</td>
<td>0.13</td>
</tr>
<tr>
<td>Q2: Are you frustrated when your hearing aids pick up sounds that keep you from hearing what you want to hear?</td>
<td>2.7</td>
<td>2.9</td>
<td>0.86</td>
</tr>
<tr>
<td>Q3: Are you convinced that obtaining your hearing aids was in your best interests?</td>
<td>1.6</td>
<td>3.7</td>
<td>0.015</td>
</tr>
<tr>
<td>Q4: Do you think people notice your hearing difficulties more when you wear your hearing aids?</td>
<td>1.8</td>
<td>1.1</td>
<td>0.32</td>
</tr>
<tr>
<td>Q5: Do your hearing aids reduce the number of times you have to ask people to repeat?</td>
<td>1.8</td>
<td>3.1</td>
<td>0.076</td>
</tr>
<tr>
<td>Q6: Do you think your hearing aids are worth the trouble?</td>
<td>1.5</td>
<td>3.4</td>
<td>0.011</td>
</tr>
<tr>
<td>Q7: How content are you with the appearance of your hearing aids?</td>
<td>3.7</td>
<td>4.5</td>
<td>0.17</td>
</tr>
<tr>
<td>Q8: Does wearing your hearing aids improve your self-confidence?</td>
<td>1.3</td>
<td>1.7</td>
<td>0.56</td>
</tr>
<tr>
<td>Q9: How natural is the sound from your hearing aids?</td>
<td>3.0</td>
<td>3.9</td>
<td>0.13</td>
</tr>
<tr>
<td>Q10: Do you think wearing your hearing aids makes you seem less capable?</td>
<td>1.3</td>
<td>0.8</td>
<td>0.41</td>
</tr>
<tr>
<td>Q11: How comfortable are your hearing aids?</td>
<td>2.5</td>
<td>3.7</td>
<td>0.049</td>
</tr>
<tr>
<td>Q12: How easy to use are your hearing aids?</td>
<td>3.8</td>
<td>4.8</td>
<td>0.056</td>
</tr>
<tr>
<td><strong>GLOBAL SCORE</strong></td>
<td>2.28</td>
<td>3.08</td>
<td>0.0006</td>
</tr>
</tbody>
</table>
How to Use AirPods Pros for hearing help

https://www.youtube.com/watch?v=w9tt5iHY1g8

Nicky Chong-White, PhD
Jorge Mejia, PhD
What can you do when someone presents at your clinical with perceived hearing loss but no measurable hearing loss?

• Apply the HHIE questionnaire or something similar to validate their difficulty

• Recommend options based on their needs
  • Don’t be afraid to suggest hearing aids or other technologies
Videoconferencing
More people are using videoconferencing and many are struggling to understand.
Hearing Loss and Videoconferencing

Speech Reception Threshold (dB)

-4 -3 -2 -1 0 1 2 3

Unaided Aided F2F

Sentence Score (% Correct)

0 10 20 30 40 50 60 70 80 90

Unaided Aided F2F

Vicky Zhang, PhD

Padraig Kitterick, PhD
Hearing Loss and Videoconferencing

Perceived Listening Effort

- Unaided
- Aided
- F2F
Hearing Loss and Videoconferencing

• What can you do?
  • Talk to your clients about how they may have difficulty with Zoom
  • Hearing aids help with Zoom, but they may still have difficulty
  • Try headphones or apps like Sonicloud
How it Works

Let's explore how to properly take the hearing assessment, how to stream media on your computer, and how to make clearer calls on your smartphone.

The Hearing Assessment

Streaming Media

Making Phone Calls
Helping Consumers Understand Hearing Aid Technology
Key Objective

Develop a consumer-friendly terminology for the features of contemporary hearing devices
Design Goals

• Consumer friendly and easy to understand

• Avoids technical jargon but covers widely-used terms

• Not specific to any manufacturer/brand/model

• Describes potential benefits to consumers
Features

- Adaptive directional microphone
- Automatic directional microphones
- Binaural directionality - Super directional microphone or Binaural beamformer
- Binaural directionality - Better-ear effect
- FM systems
- Table and remote microphones
- Bands or Channels
- Wide Dynamic Range Compression
- Music Program
- Extended frequency range
- Extended dynamic range
- Spatial Cue preservation

Features

- Wind reduction features
- Notch sound therapy
- Acclimatization management
- Occlusion effect processing
- Environmental classifiers
- Automatic environment
- Advanced sensors
- Bilateral synchronisation
- Binaural communication
- Rechargeability
- Smartphone app
- On-device control

Feature Family

Feature
- Intended Purpose

Feature
- Intended Purpose
Client Benefit

- Speech understanding
- Sound Quality
- Audibility
- Localisation
- Comfort
- Usability
- Personalisation
- Connectivity

Feature Family

- Feature
  - Intended Purpose
- Feature
  - Intended Purpose
Why should you care

• These are consumer-friendly descriptions that you could use with your clients

• While this might mostly benefit people getting OTC hearing aids, if this were on an official website:
  • You could refer it to your clients and their families to better understand what you have recommended for them
  • Your clients *might* be better informed in their visits
  • Your clients *might* have a better idea of what they want
  • You can use it to help describe what you are recommending
What does chatGPT think about OTC hearing aids?
What things do you think audiologists should do to stay relevant with the advent of OTC hearing aids?

- Audiologists should be open to incorporating new technologies into their practice such as tele-audiology
- Audiologists can differentiate themselves by providing value-added services such as customized fittings, follow-up care and counseling, and rehabilitation services
- Audiologists should build relationships with other healthcare professionals such as primary care physicians and otolaryngologists
- Audiologists can increase awareness and education about the importance of hearing health, the services they provide and the limitations of OTC hearing aids
- Audiologists should consider new business models, such as direct-to-consumer sales, or subscription-based services
- Audiologists can emphasize the importance of professional evaluations for the diagnosis and management of hearing loss
Conclusion
What does OTC mean for your clinic?

• You need to be able to clearly explain to clients the value that you bring to success with hearing aids
  – Make your differentiated value clear to every client you see
  – Be ready to help people who got an OTC device and are struggling

• Develop a treatment strategy for those with hearing difficulty but no measurable hearing loss
Population with Auditory Dysfunction

<table>
<thead>
<tr>
<th>No Audiometric Hearing Loss</th>
<th>Audiometric Hearing Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>A  NHD-NHL</td>
<td>B  NHD-HL</td>
</tr>
<tr>
<td>C  HD-NHL</td>
<td>D  HD-HL Owner</td>
</tr>
<tr>
<td>E  HD-HL Non-Owner</td>
<td></td>
</tr>
</tbody>
</table>
Where Will You Focus Your Opportunity?

CLINICAL

Technology

Services

Channel

CONSUMER
Thank you!

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https://www.linkedin.com/in/brentedwards/

https://chat.openai.com/chat