



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

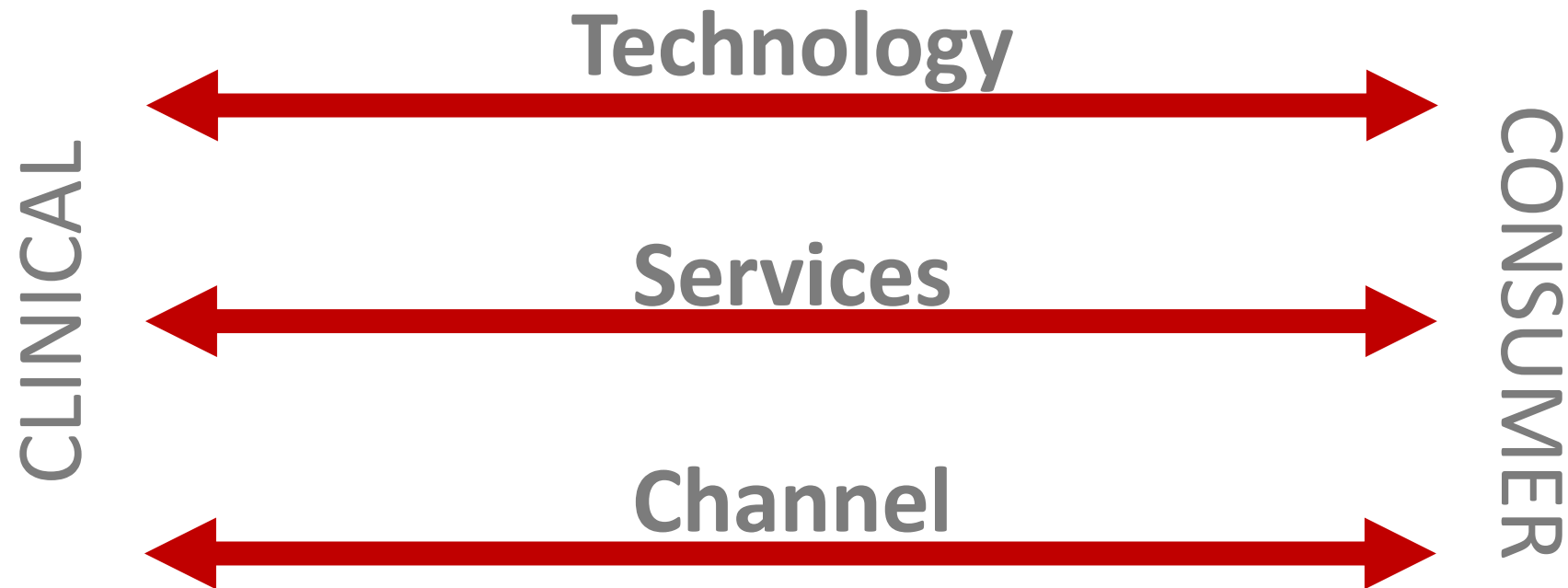
Brent Edwards, PhD

National Acoustic Laboratories

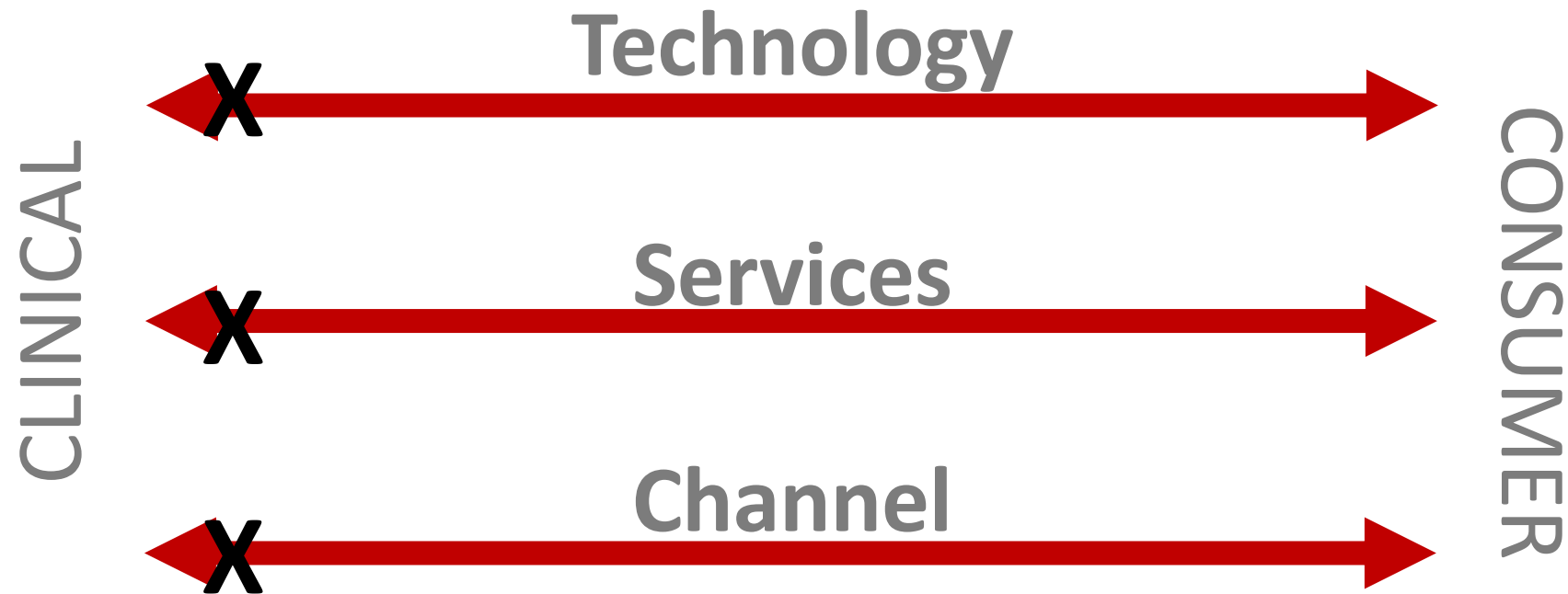




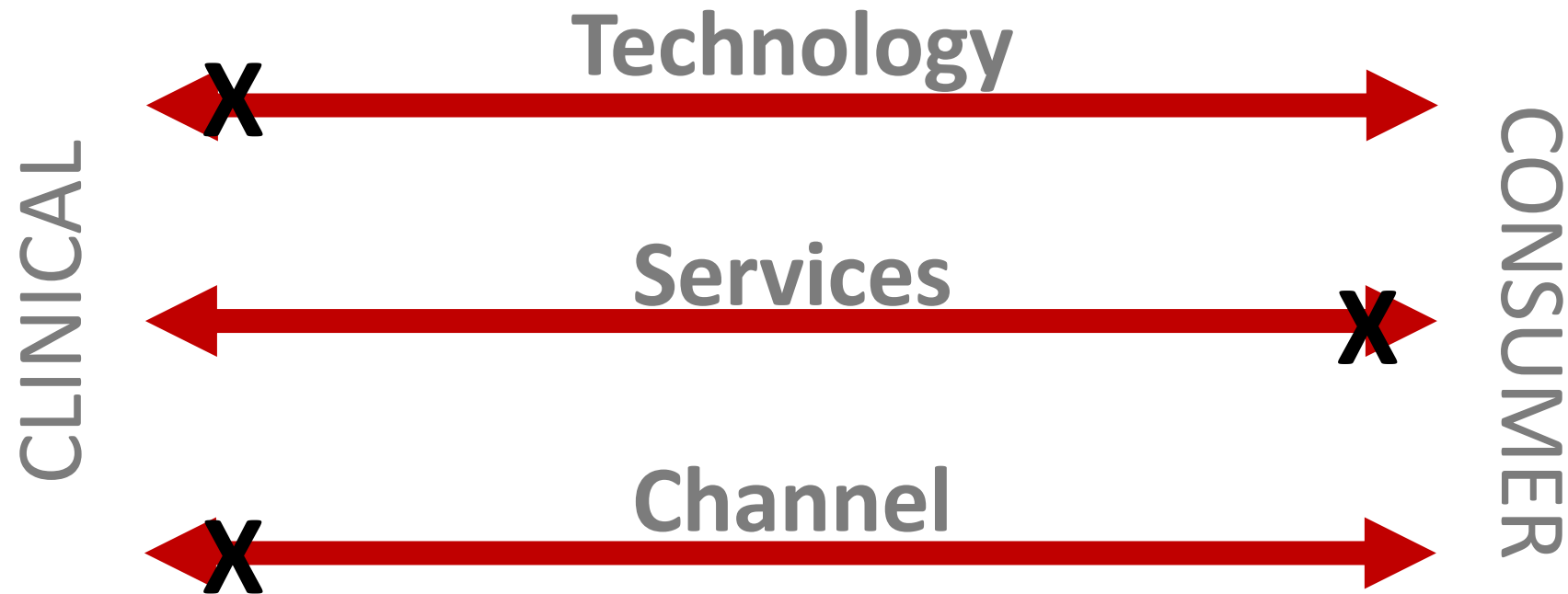
# Innovation in Hearing Healthcare



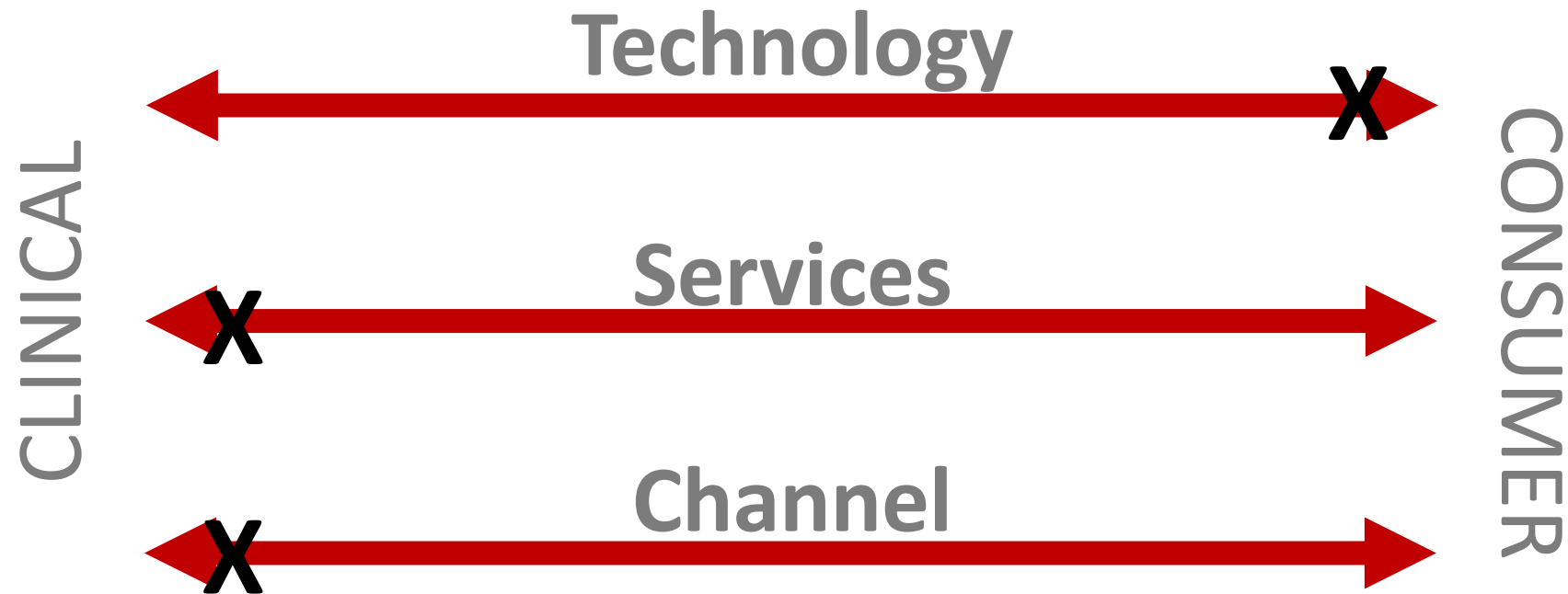
# Innovation in Hearing Healthcare



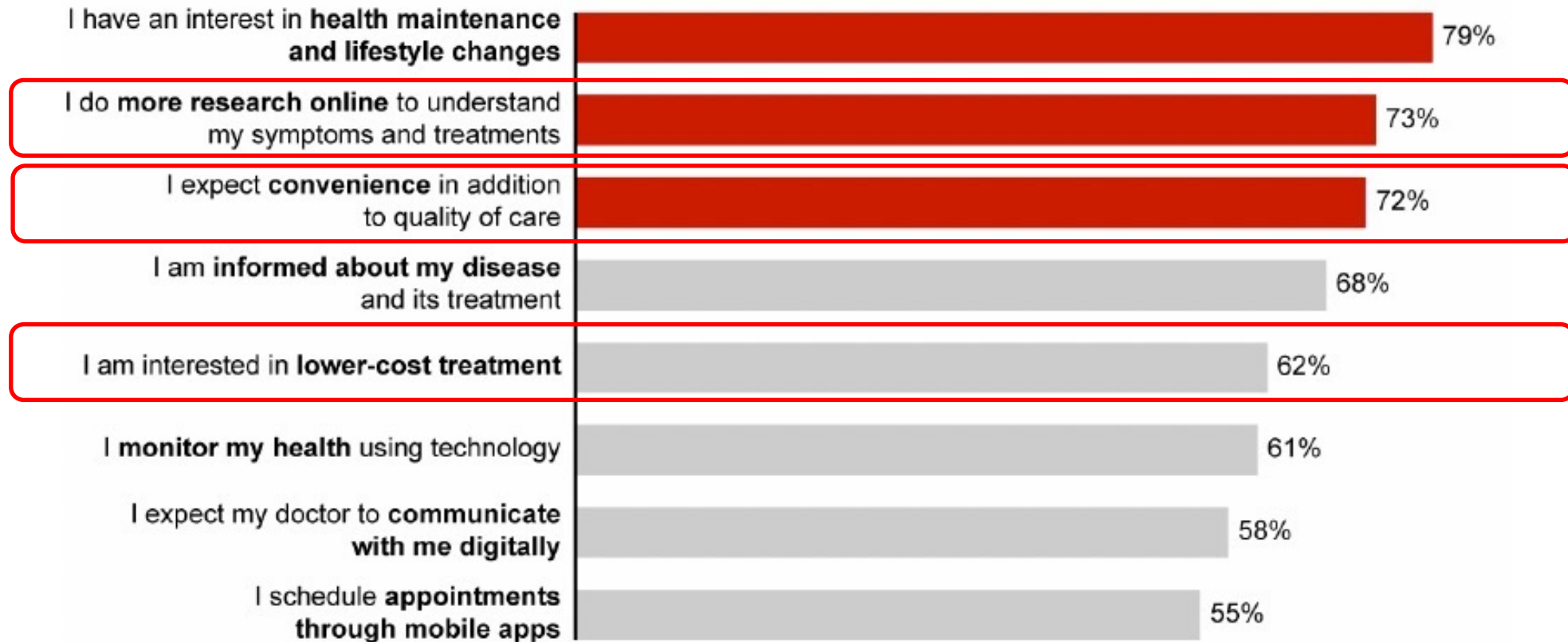
# Innovation in Hearing Healthcare



# Innovation in Hearing Healthcare



# Consumer Expectations are Changing



# 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, 7<sup>th</sup> Feb 2023



# OTC Hearing Aids: What are they?

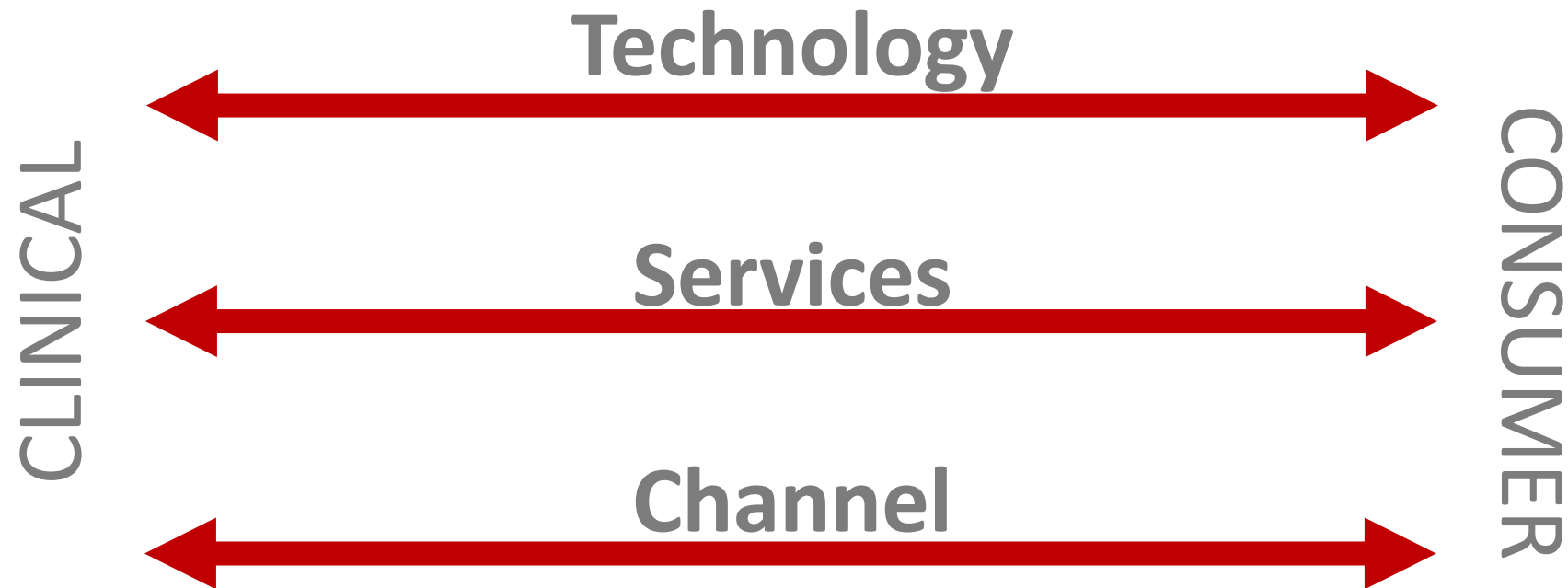
- Government-regulated medical devices, just like traditional hearing aids, BUT:
  - Are only for adults with “perceived mild-moderate hearing loss”
  - Must not require a professional for fitting or use
  - Must have specific package labels and instructions about use, who they are for, warnings and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

**WARNING: When to See a Doctor**

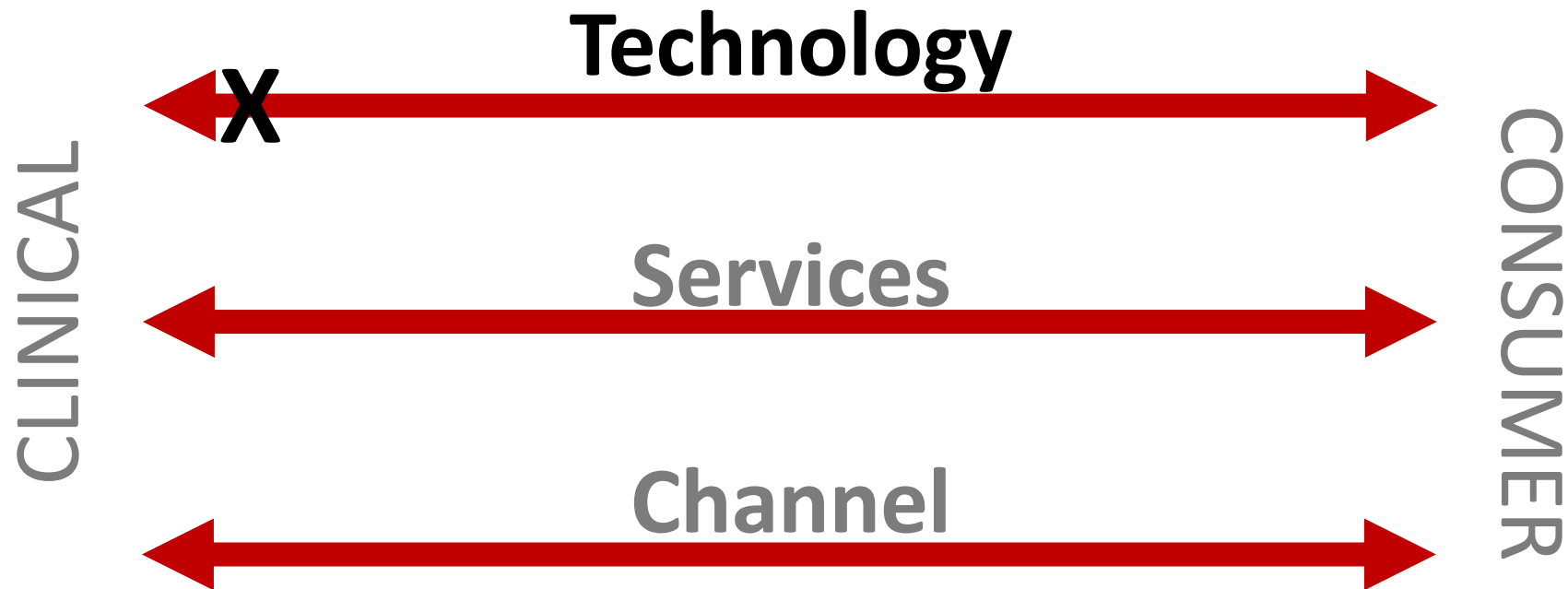
If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- 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

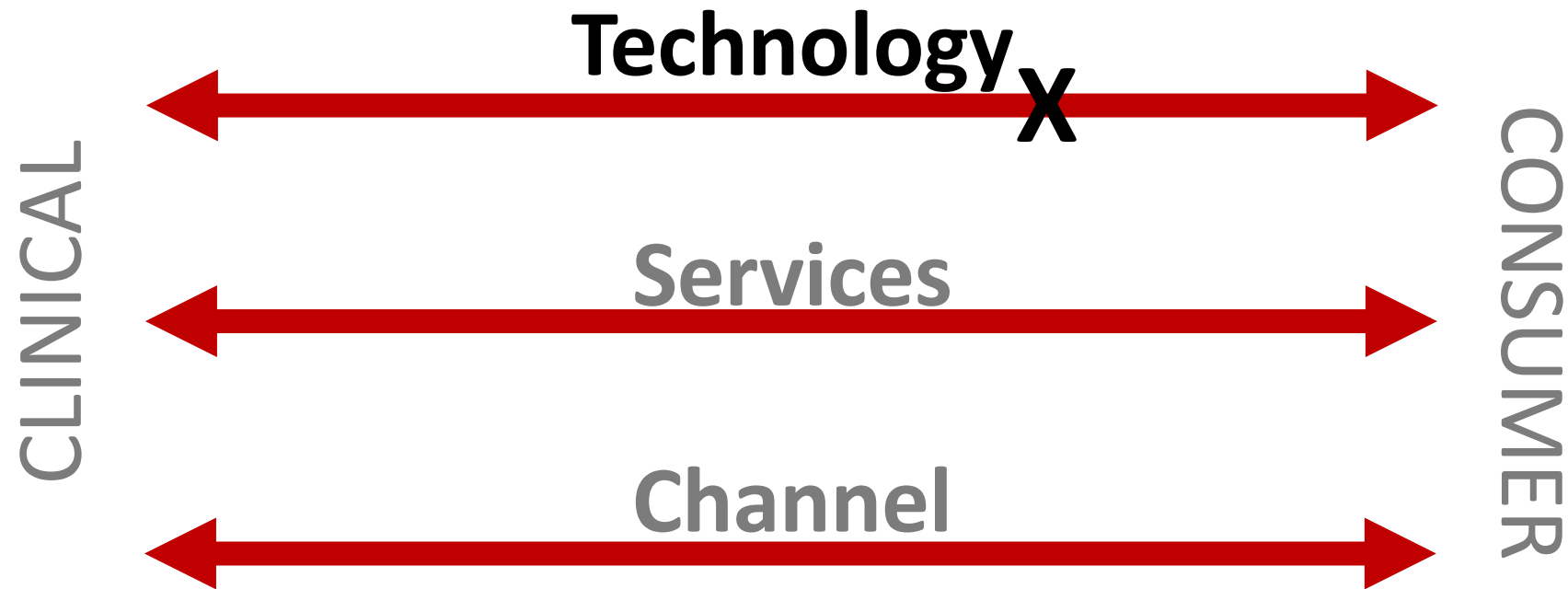
# Innovation in Hearing Healthcare



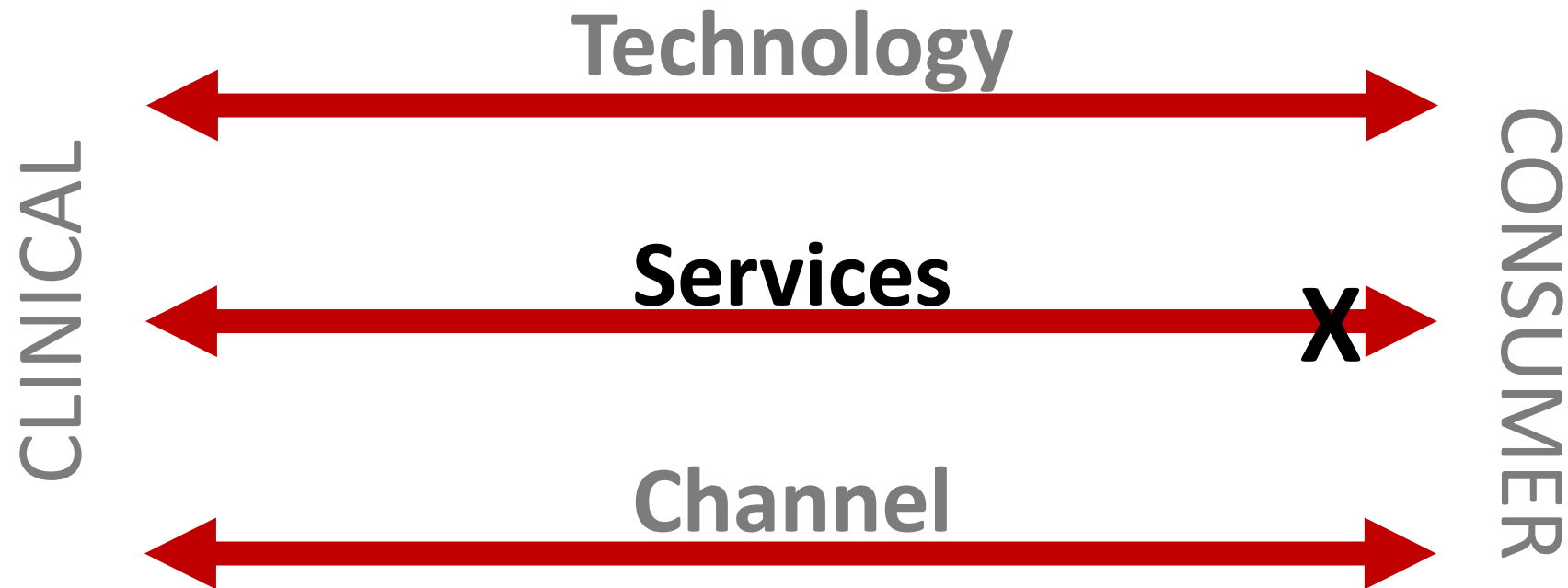
# Innovation in Hearing Healthcare



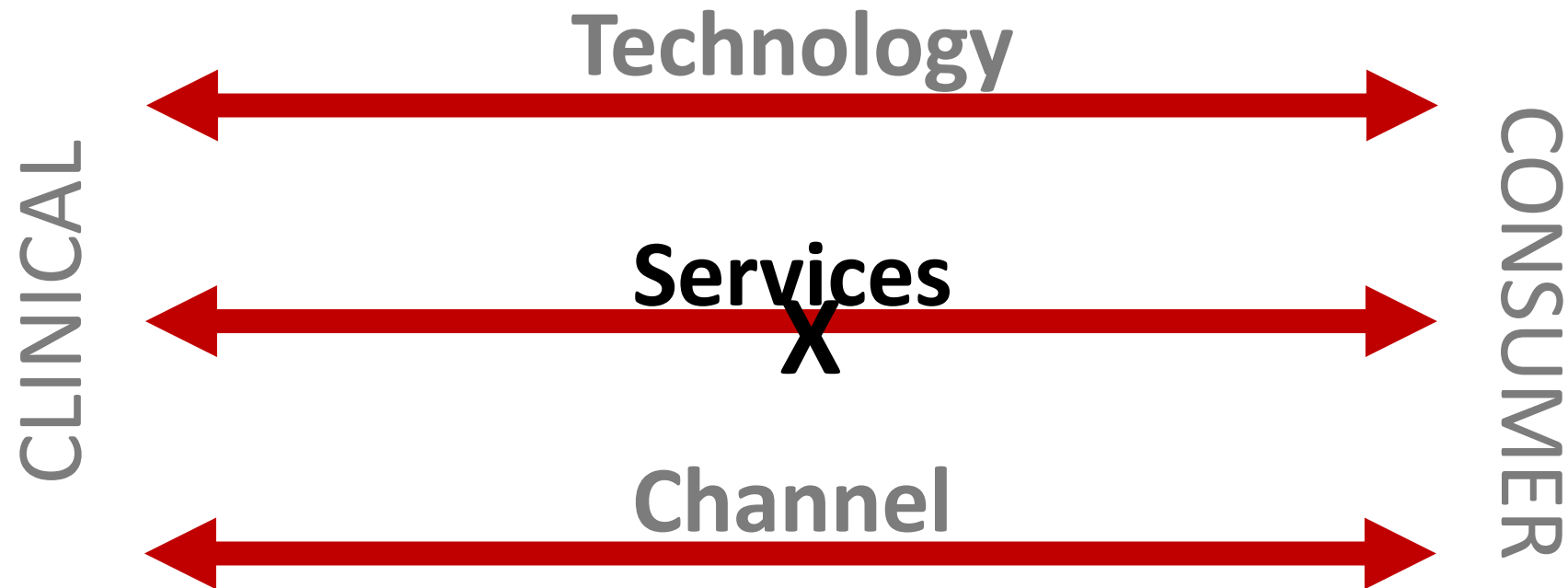
# Innovation in Hearing Healthcare



# Innovation in Hearing Healthcare

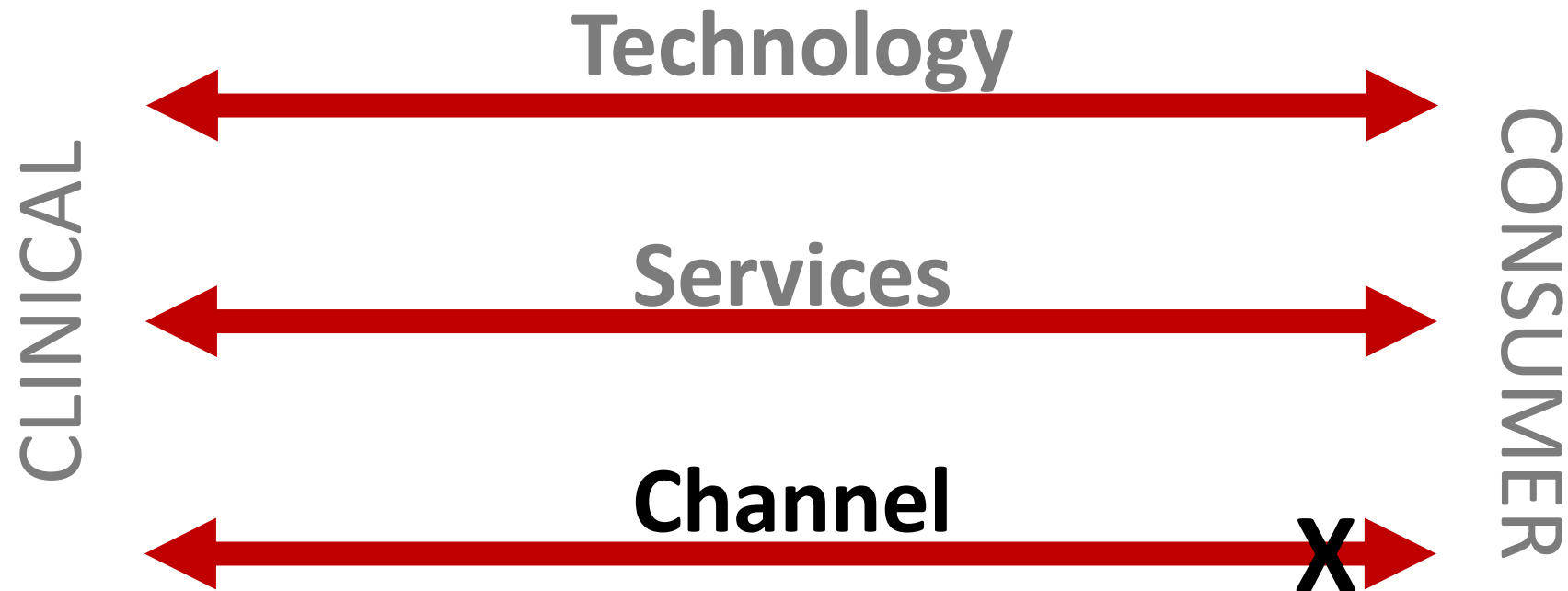


# Innovation in Hearing Healthcare

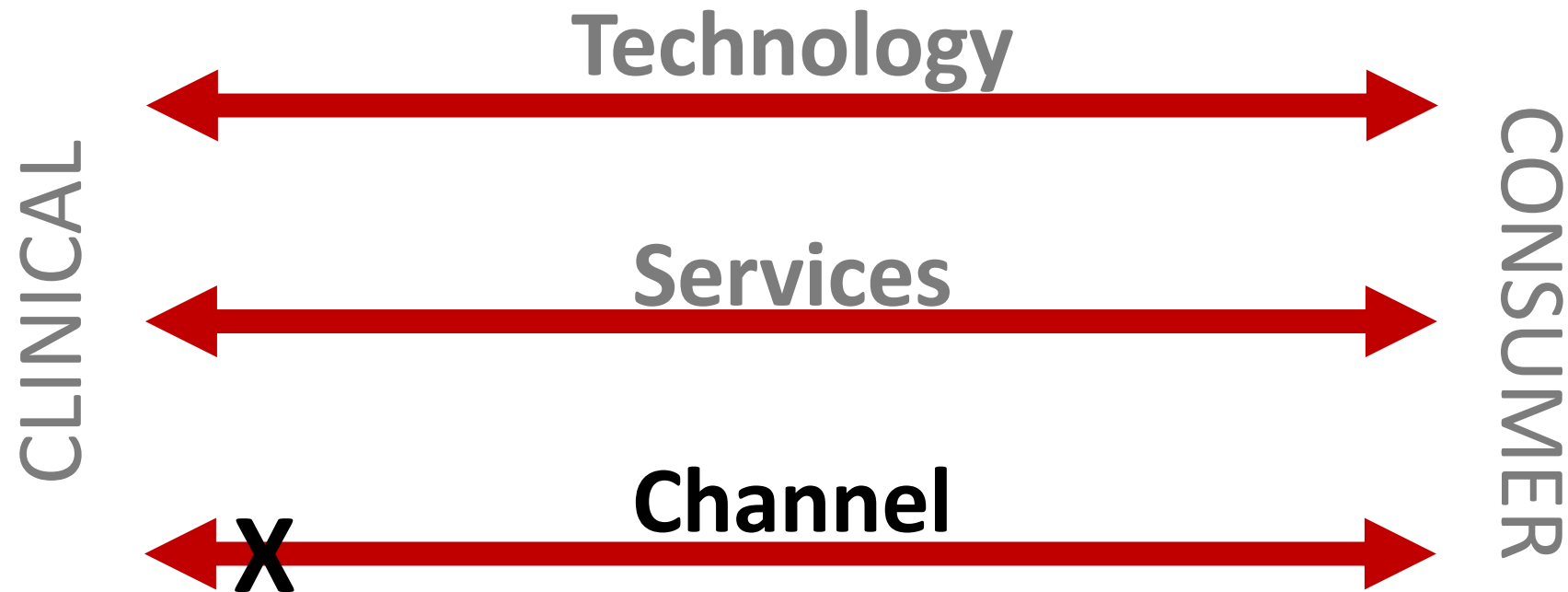




# Innovation in Hearing Healthcare



# Innovation in Hearing Healthcare



**SONOVA**  **SENNHEISER**

HEAR THE WORLD

# Sonova Acquires Sennheiser Consumer Audio

Possible preparation for consumer hearing aids





**SONY** × **WSAudiology**




lexie®

POWERED BY

BOSE

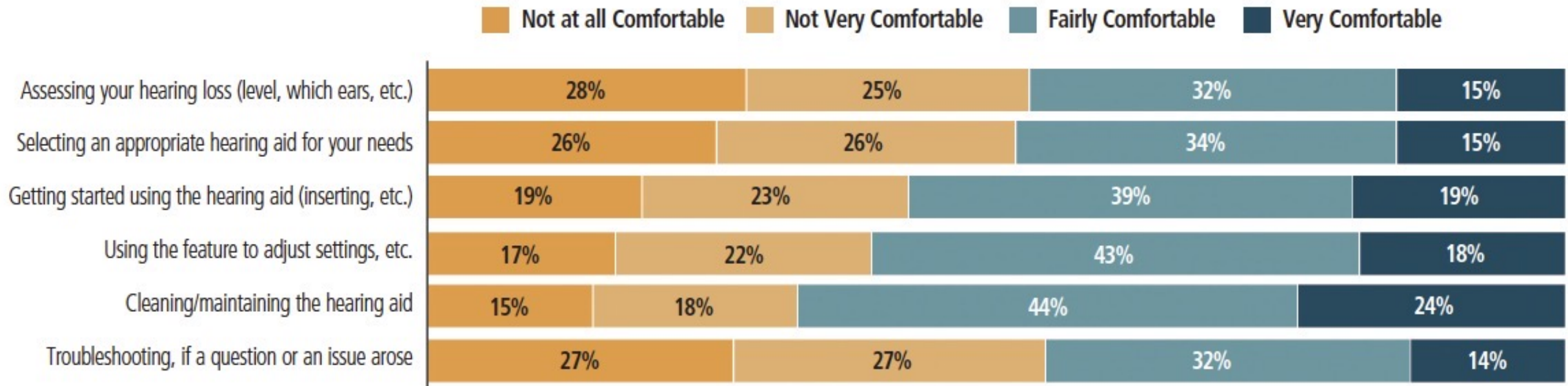


# Consumer Product Reviews of OTC Hearing Aids

<p><b>BEST FOR SENIORS</b></p> <p>Jabra Enhance™</p> <p>★★★★☆ 4.2/5</p> <p><a href="#">VISIT SITE</a></p>	<p><b>MOST AFFORDABLE</b></p> <p> Audien Hearing</p> <p>★★★★☆ 3.9/5</p> <p><a href="#">VISIT SITE</a></p>	<p><b>BEST SELF-FITTING</b></p> <p>lexie®</p> <p>★★★★☆ 4.5/5</p> <p><a href="#">VISIT SITE</a></p>	<p><b>BEST INVISIBLE FIT</b></p> <p><b>EARGO</b></p> <p>★★★★☆ 3.9/5</p> <p><a href="#">VISIT SITE</a></p>
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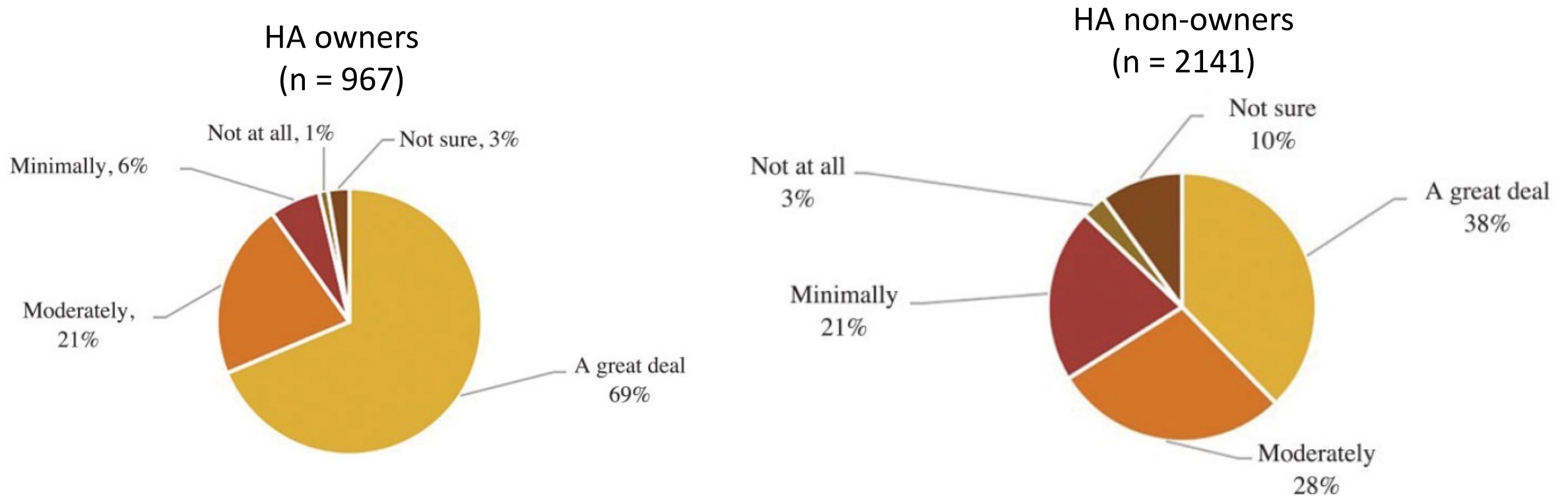
# IS OTC a threat to hearing care professionals (HCPs)?

Approximate half of those with HL (n=3113) are uncomfortable doing tasks associated with OTC



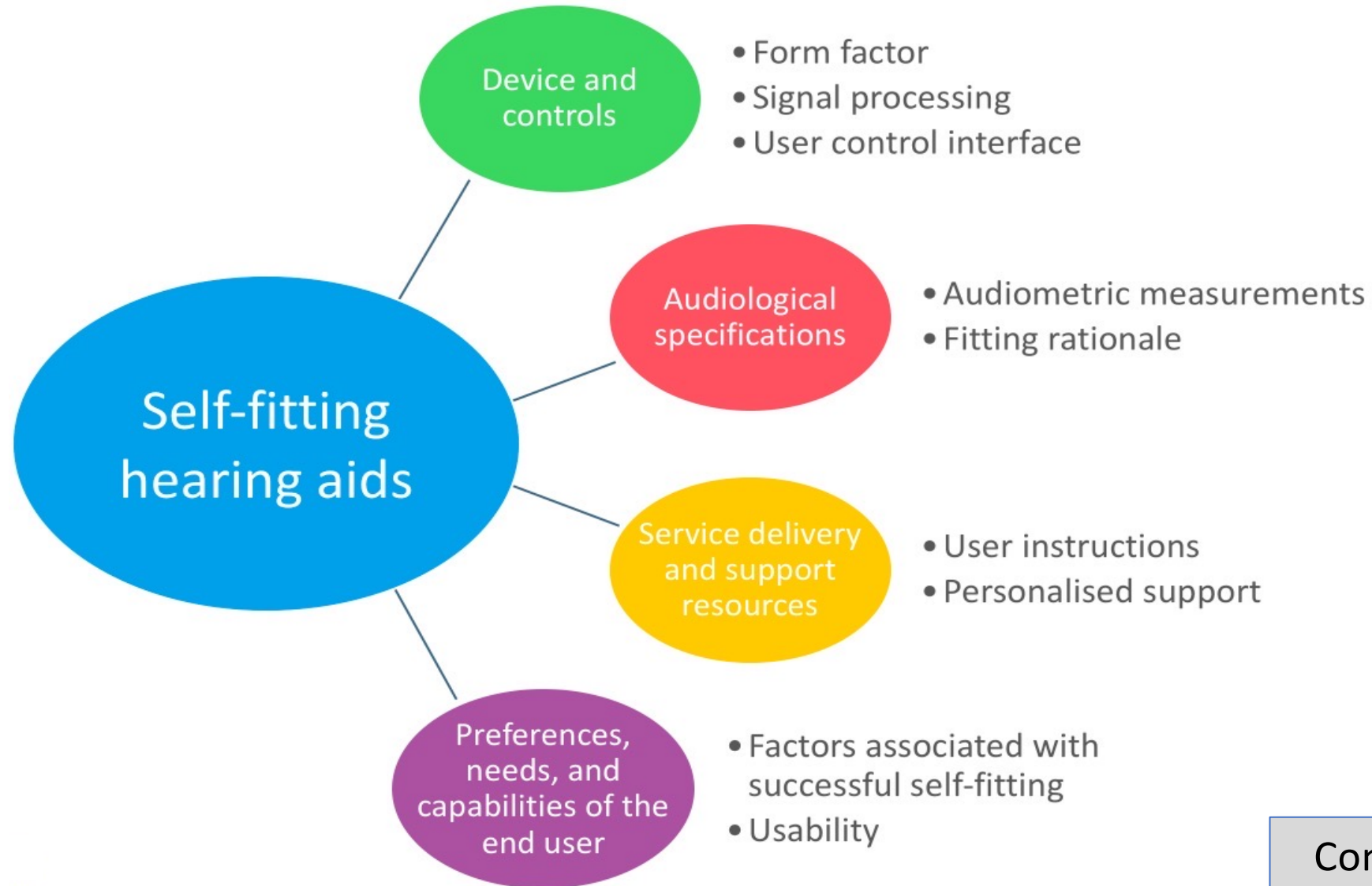
# IS OTC a threat to hearing care professionals (HCPs)?

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

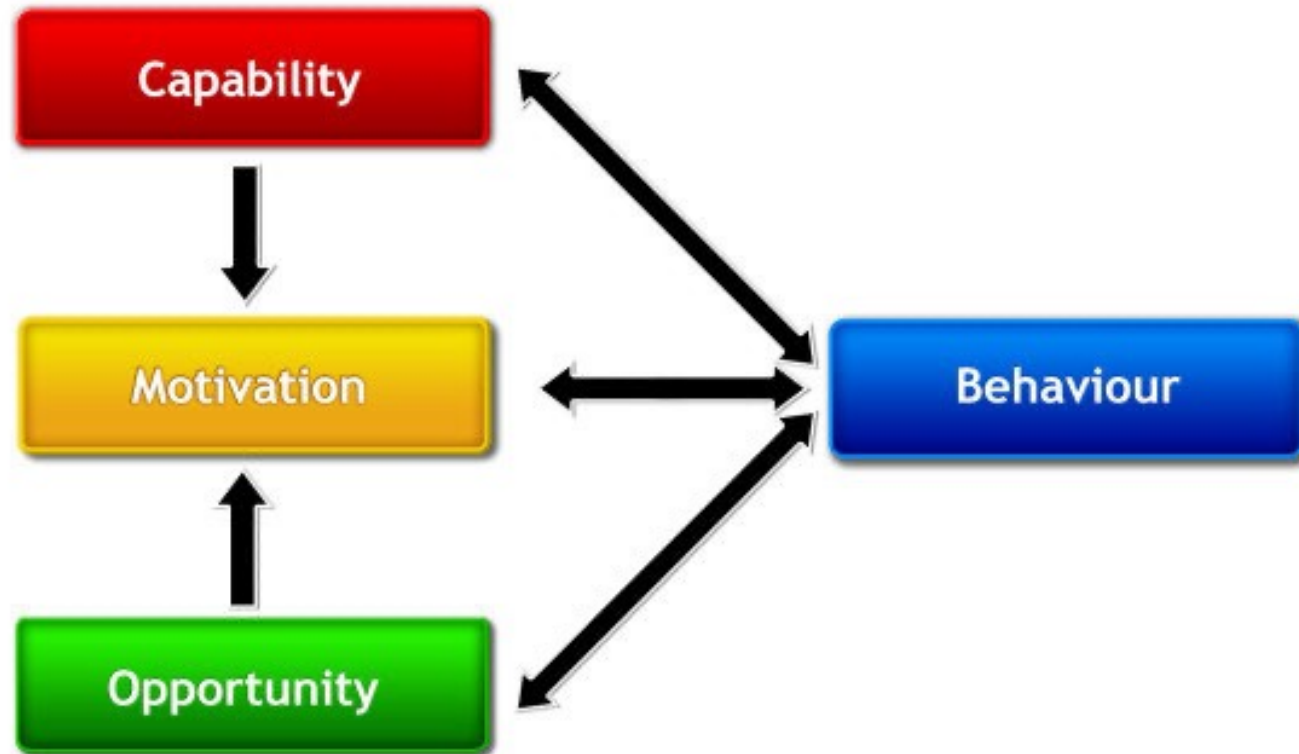




# OTC Hearing Aids have many challenges to success



# COM-B Framework



# COM-B Framework: *OTC Success*

Able to select appropriate device  
Able to fit correctly on ear  
Able to manage app

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

Socially acceptable  
Support from others  
Accessible  
Affordable  
Activity limitations

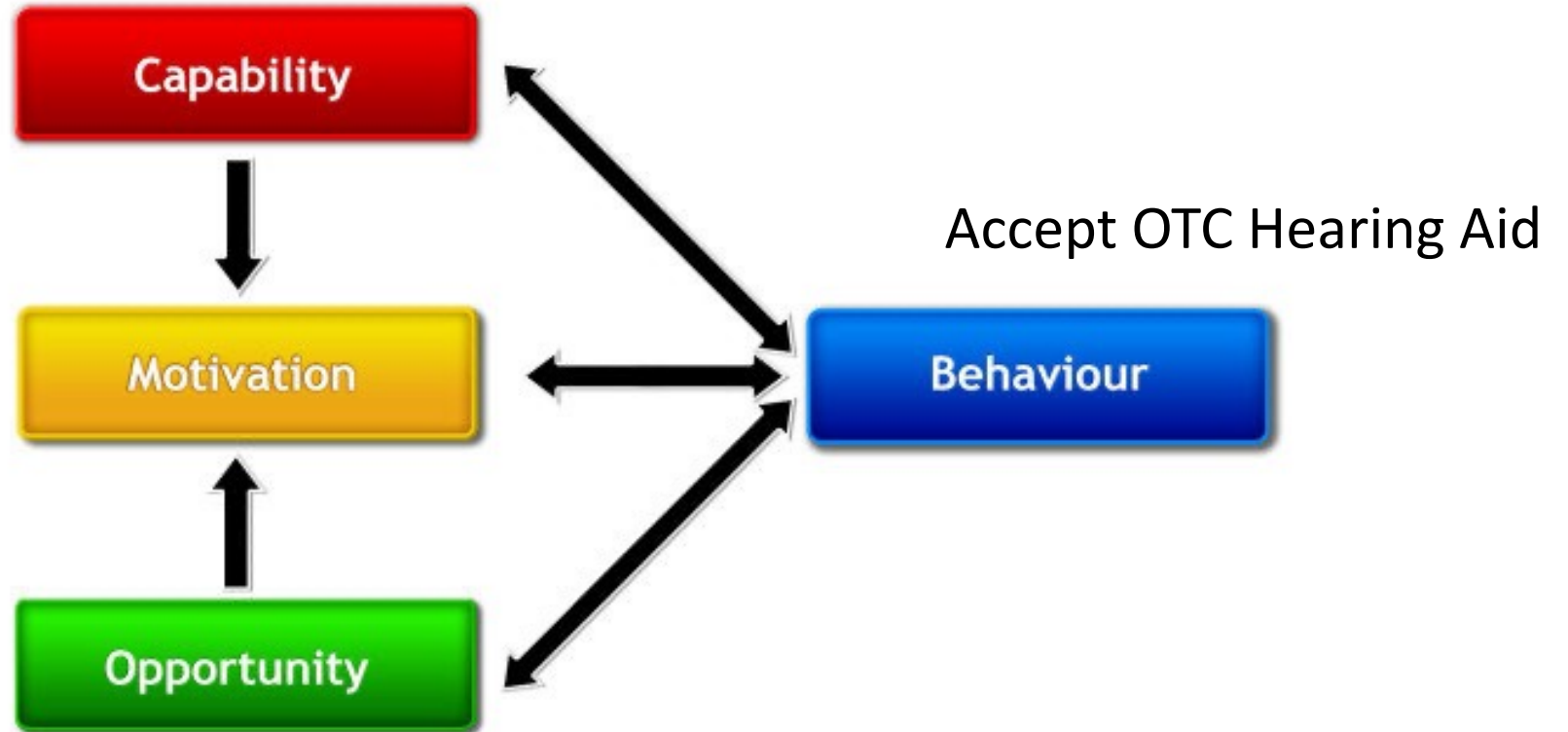
Capability

Motivation

Opportunity

Behaviour

Accept OTC Hearing Aid



Who Are The Customers for OTC Hearing Aids?

# FDA Required Labeling

**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

	No Hearing Loss	Hearing Loss	
No Hearing Difficulty	<p>A</p> <p>NHD-NHL</p>	<p>B</p> <p>NHD-HL</p> <p><b>26 M</b></p>	
Hearing Difficulty	<p>C</p> <p>HD-NHL</p> <p><b>25.3 M</b></p>	<p>D</p> <p>HD-HL Owner</p> <p><b>8.7 M</b></p>	<p>E</p> <p>HD-HL Non-Owner</p> <p><b>3.4 M</b></p>

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

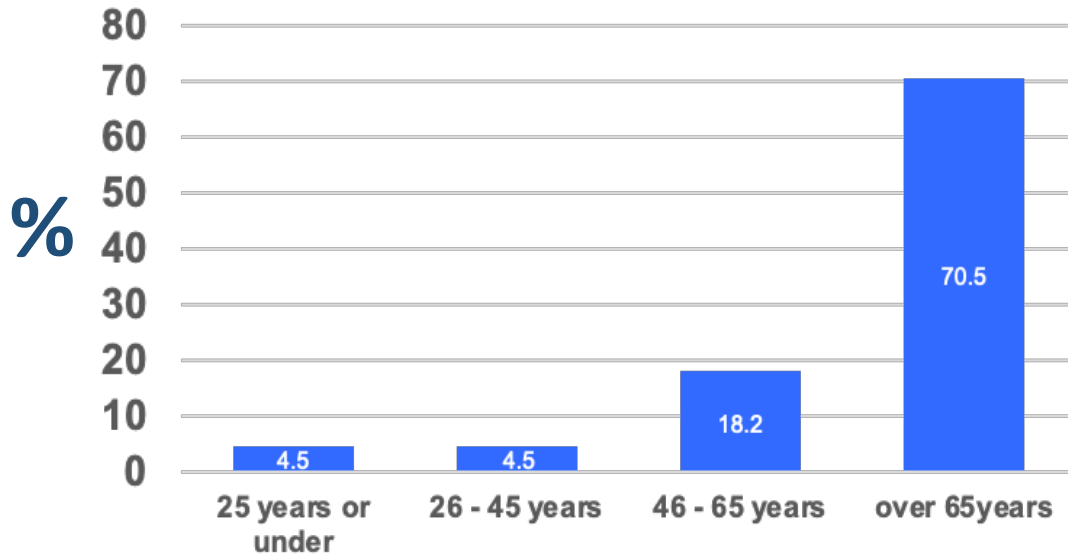
- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain it's too loud

**Who has a perceived mild-  
moderate hearing loss?**

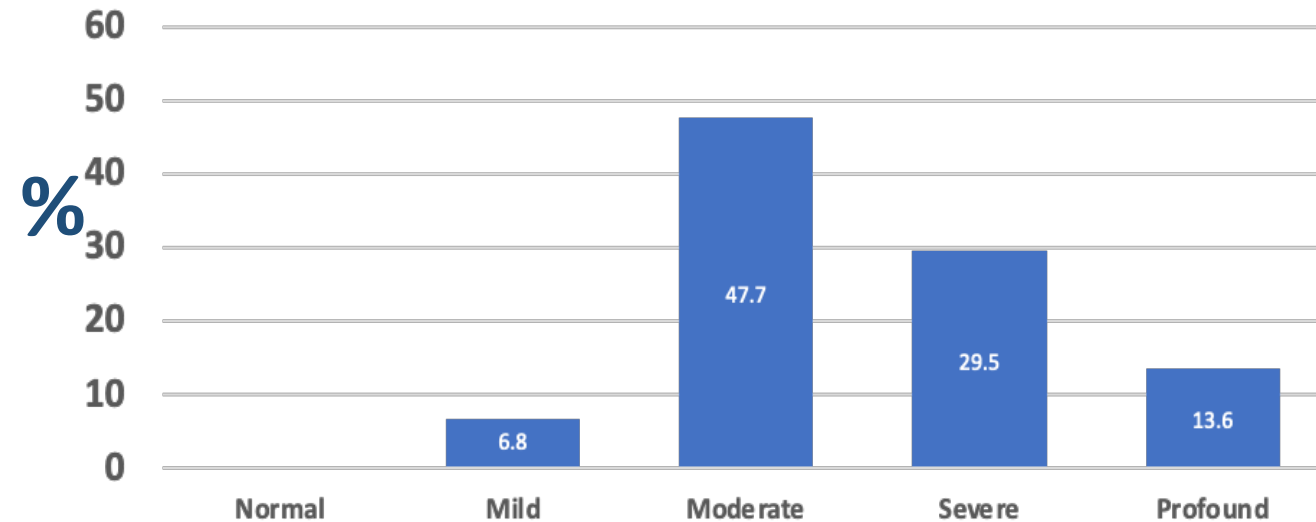


# Survey of People with No Hearing Loss Who Come to a Hearing Clinic for Help

Distribution of sample by age group



Self-reported level of hearing loss



Armita Adily, PhD

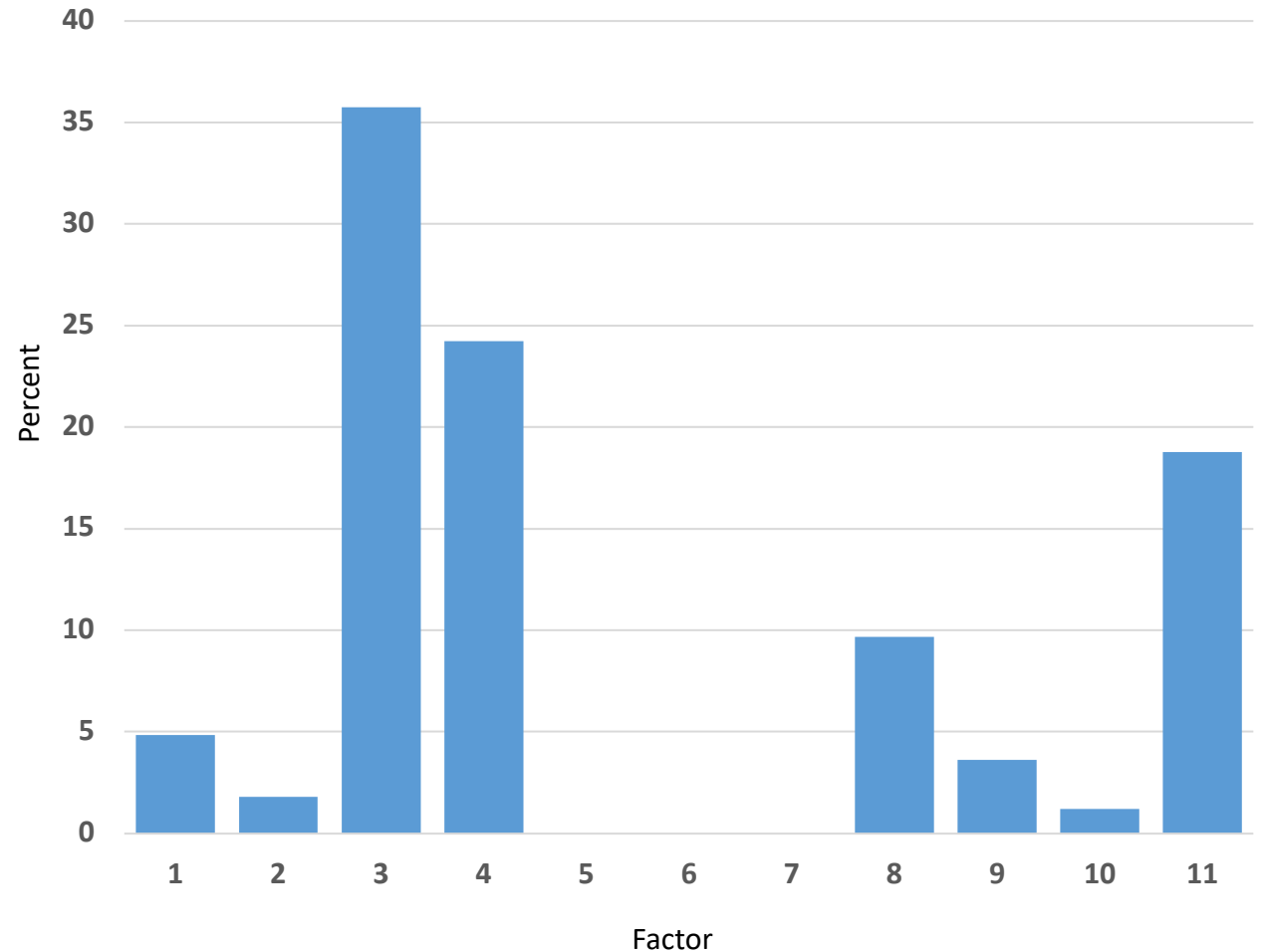


# Factors influencing help seeking of clients with no hearing loss

## 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



What can Hearing Care Professionals do for people with “perceived hearing loss” but no measurable hearing loss?

# Patient Journey



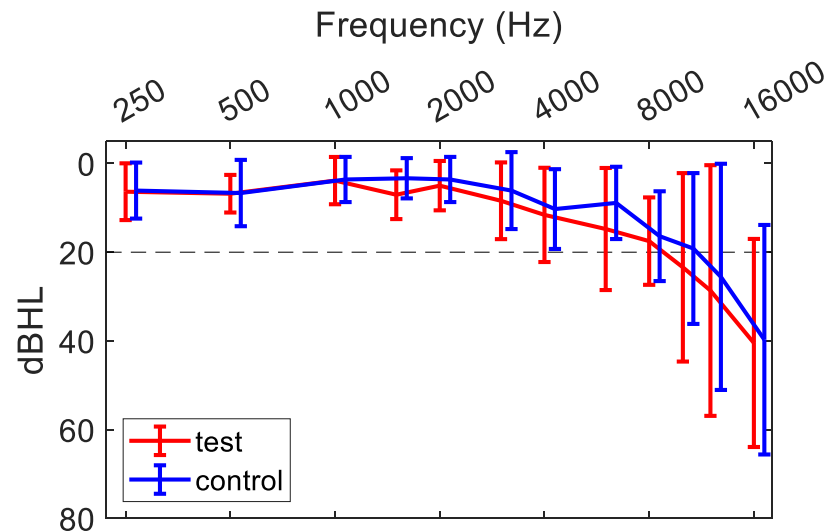
**How can you diagnose a hearing problem when they have a normal audiogram?**

# 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?

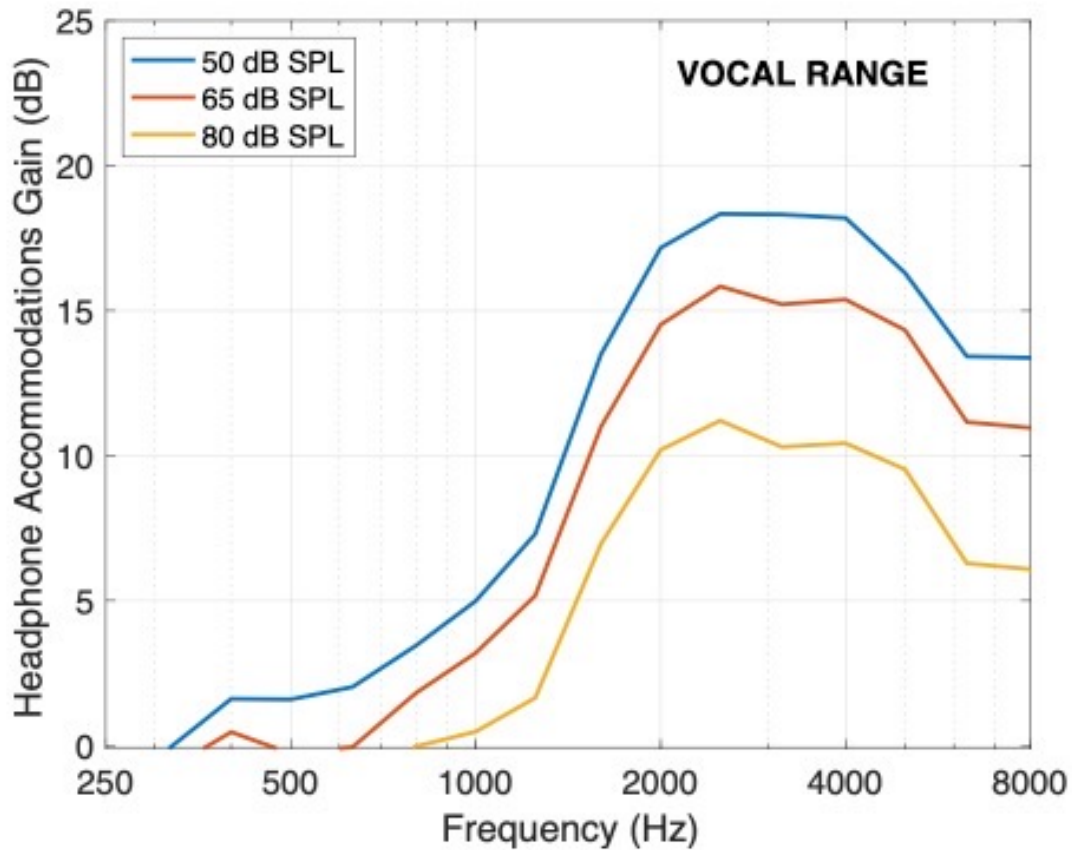
**Answer: No, Sometimes, Yes**

**What solution can you recommend for someone with *perceived* hearing loss but no *measurable* hearing loss?**

# Hearing aids can help this group

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

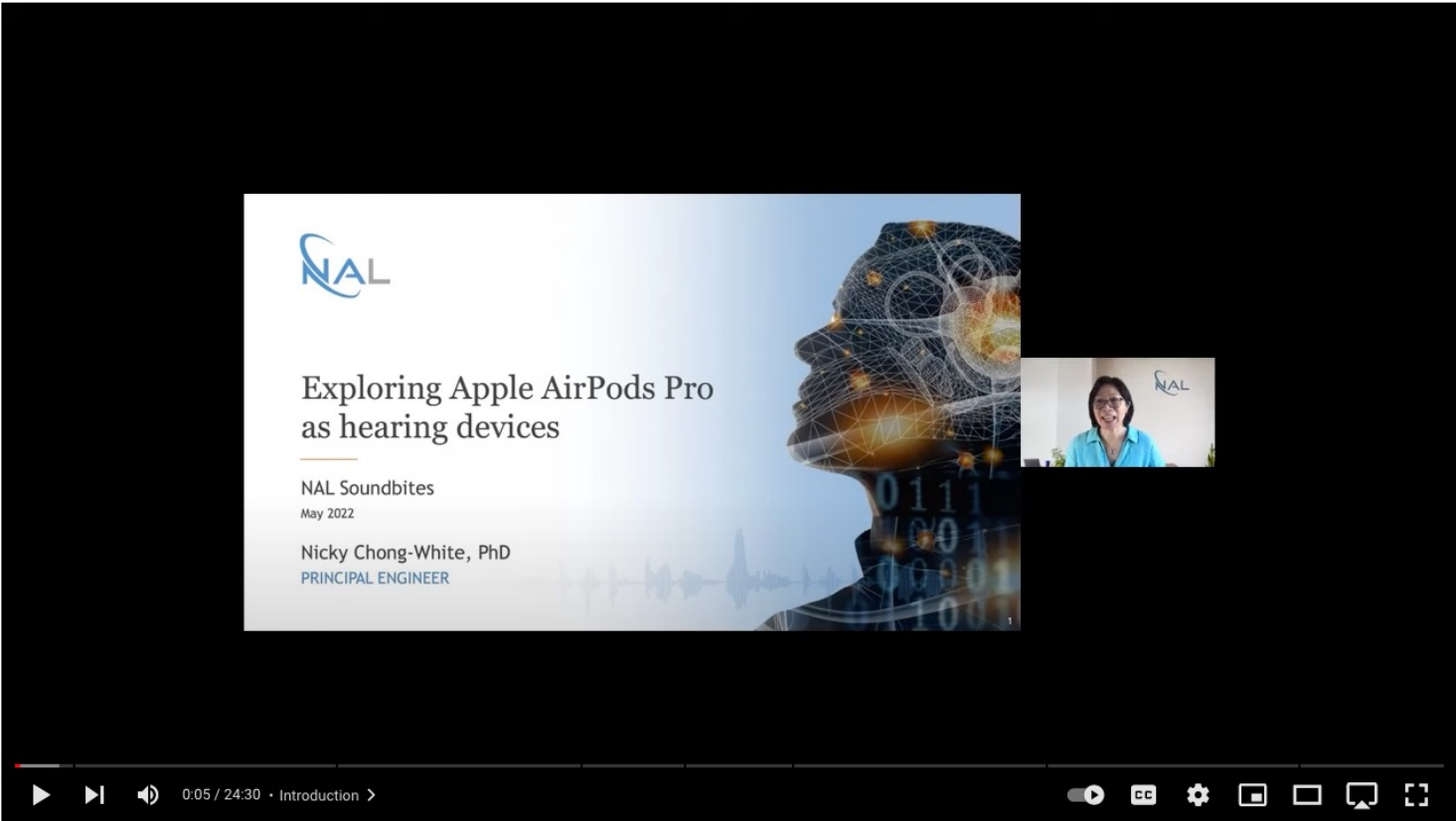
# AirPods Pro Can help



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

# How to Use AirPods Pros for hearing help

national acoustic laboratories



Exploring Apple AirPods Pro as hearing devices

NAL Soundbites  
May 2022

Nicky Chong-White, PhD  
PRINCIPAL ENGINEER

0:05 / 24:30 · Introduction >

Soundbites S03E02 - Exploring Apple AirPods Pro as hearing devices

National Acoustic Laboratories  
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<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

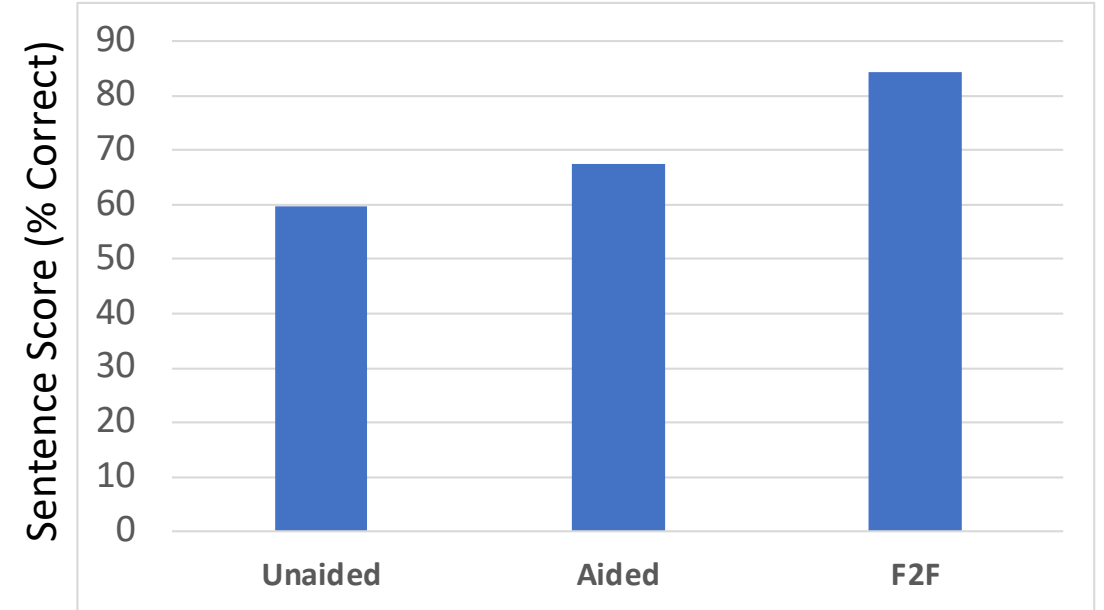
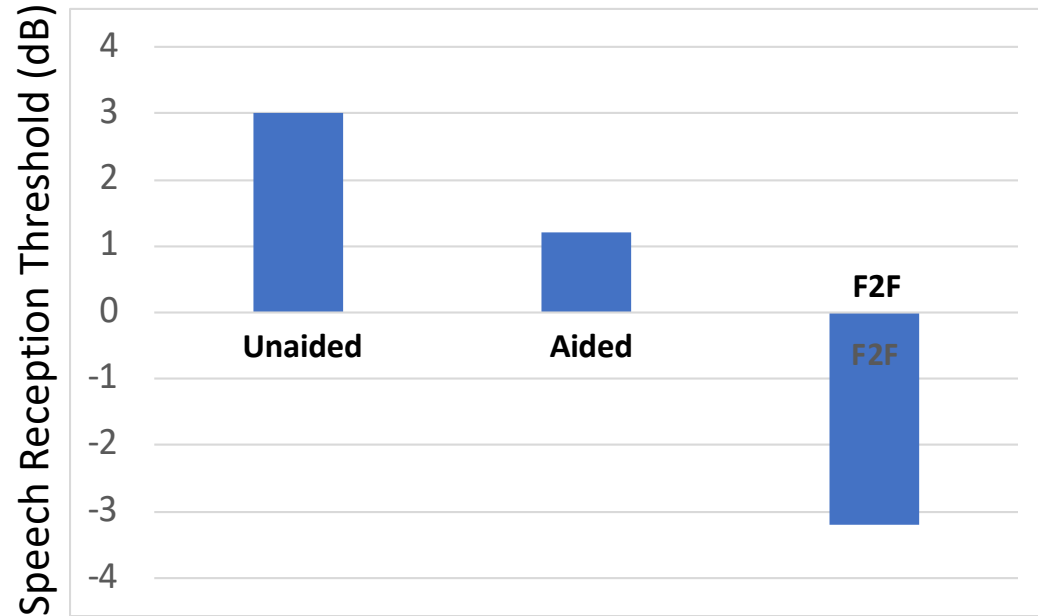
# Videoconferencing

**More people are using videoconferencing  
and many are struggling to understand**





# Hearing Loss and Videoconferencing



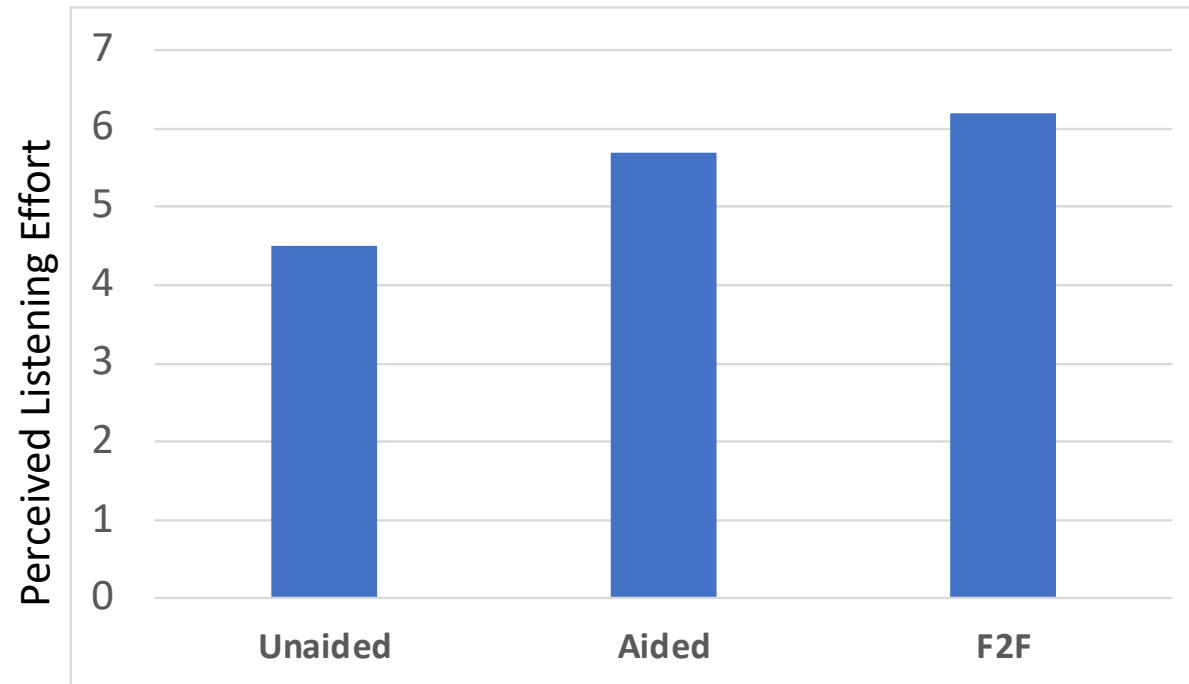
Padraig Kitterick, PhD



Vicky Zhang, PhD



# Hearing Loss and Videoconferencing

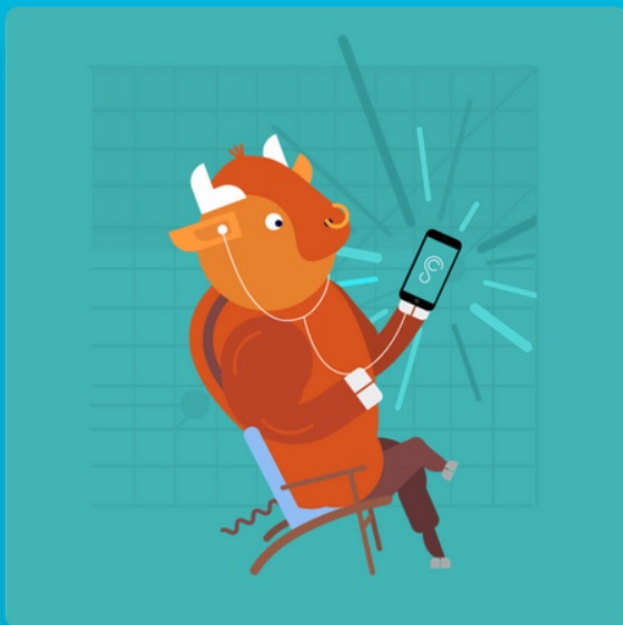


# Hearing Loss and Videoconferencing

- 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 Soniccloud

# 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

# Overview

## Key Objective

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



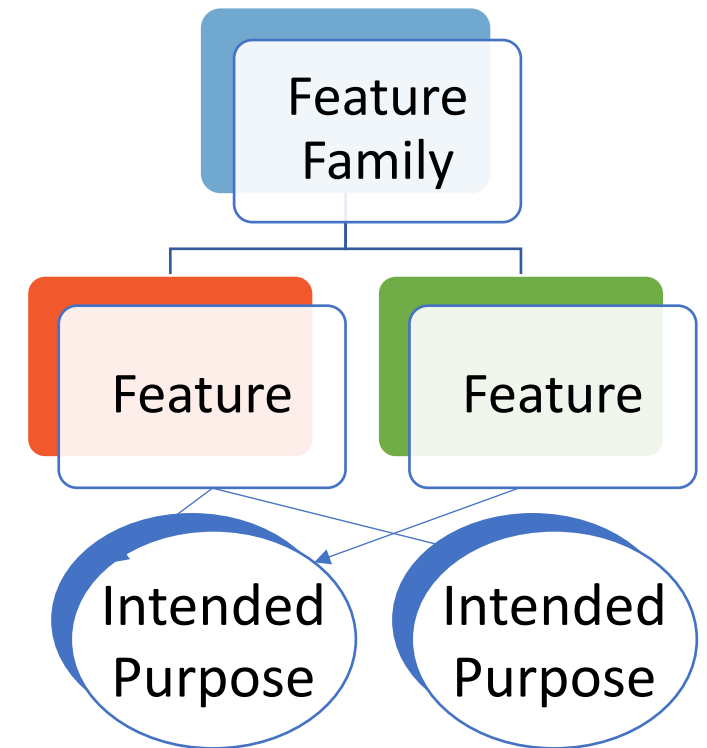
# Design Goals

- 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

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

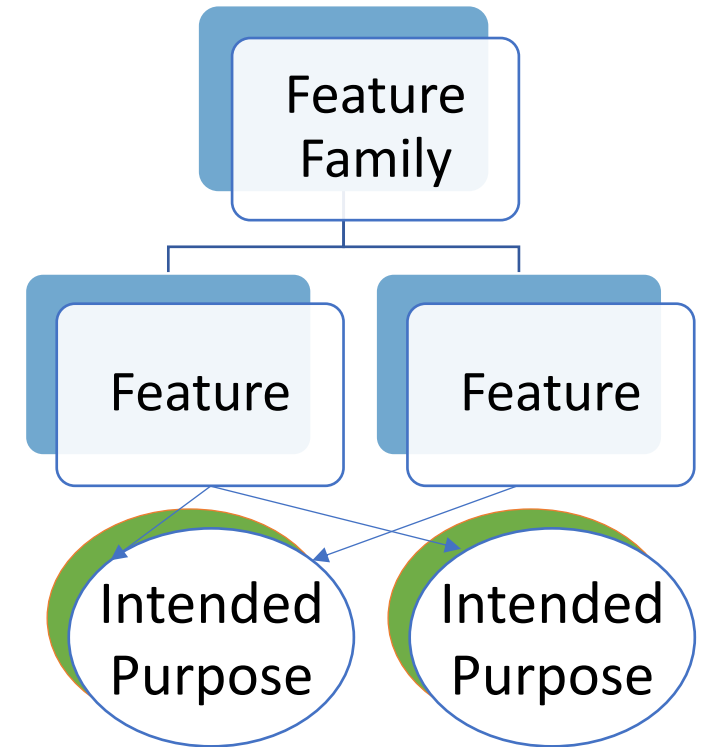
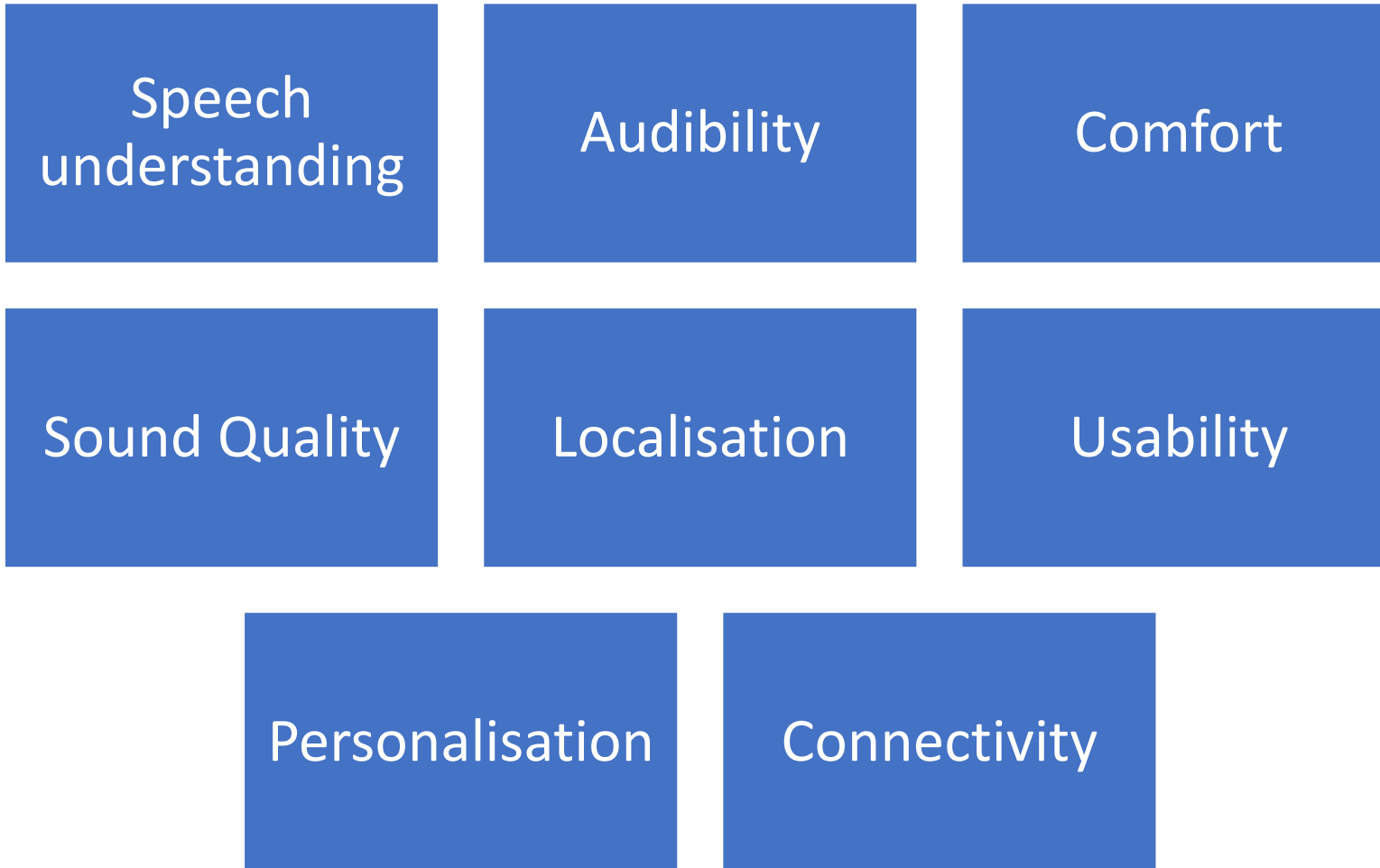
Features
Wind reduction features
Notch sound therapy
Acclimatization management
Occlusion effect processing
Environmental classifiers
Automatic environment
Advanced sensors
Bilateral synchronisation
Binaural communication
Rechargeability
Smartphone app
On-device control





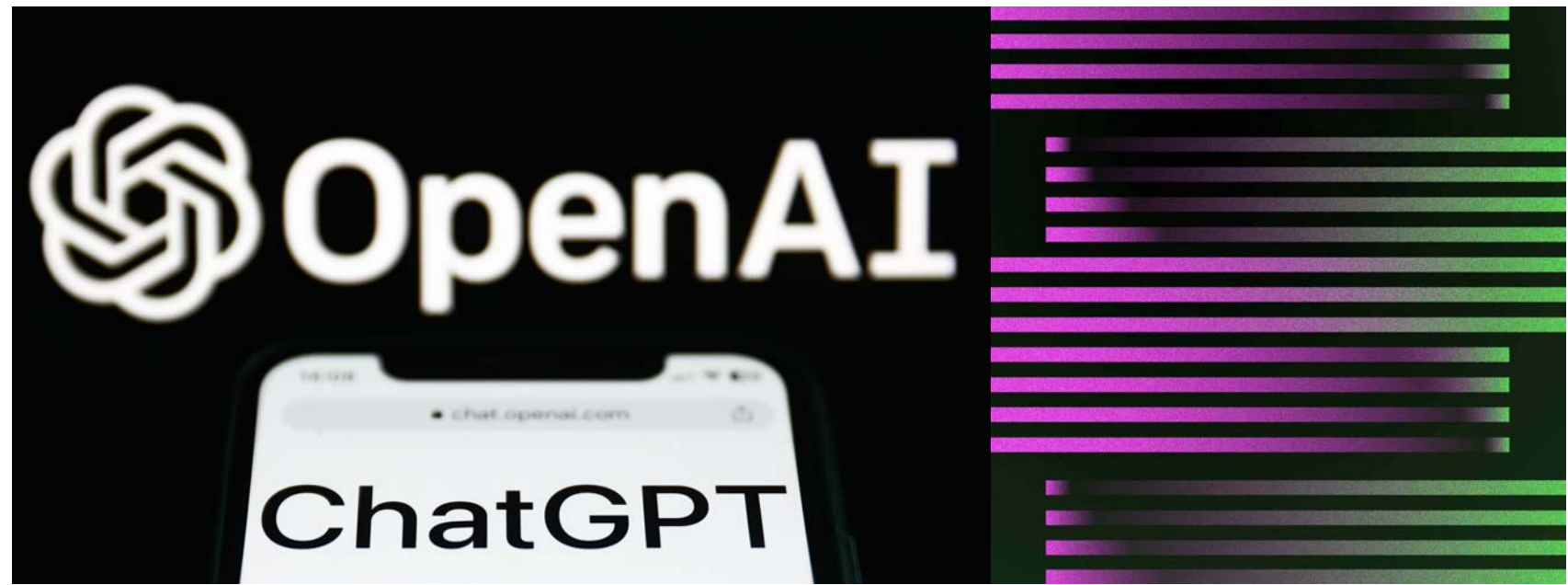
# Client Benefit

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# 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

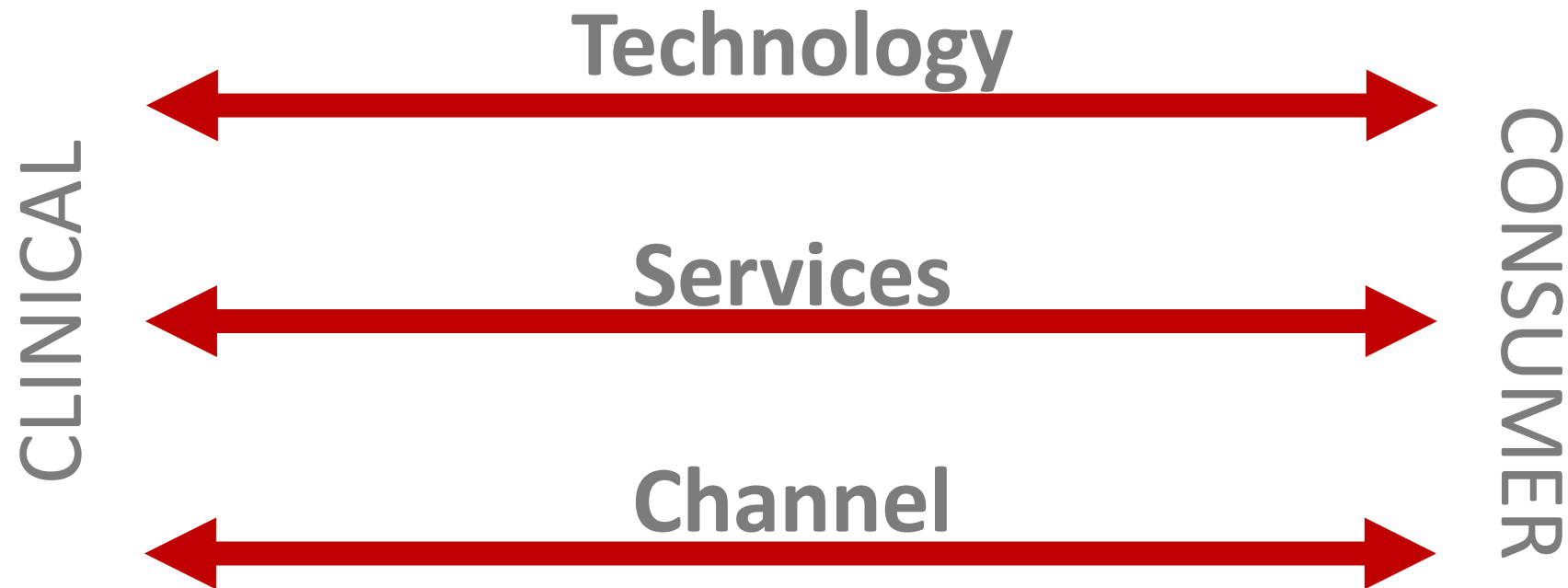
# What does OTC mean for your clinic?

- 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

	No Audiometric Hearing Loss	Audiometric Hearing Loss	
No Hearing Difficulty	A NHD-NHL	B NHD-HL	
Hearing Difficulty	C HD-NHL	D HD-HL Owner	E HD-HL Non-Owner

# Where Will You Focus Your Opportunity?





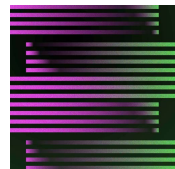
# Thank you!



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