



# Applications of DTC Hearing Devices for Adults

**Brian Taylor**

# DISCLOSURES

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Note: I am employed by Signia which has a strategic partnership with Sony OTC

# Key Questions

- What is the patient journey and how might DTC/OTCs affect it?
- What are the various types of DTC/OTC devices sold in the US and how do they differ?
- Why OTC became a new FDA-regulated category?
- How OTC/DTC might fit into your practice as part of a broader patient engagement strategy?

# Two-parts

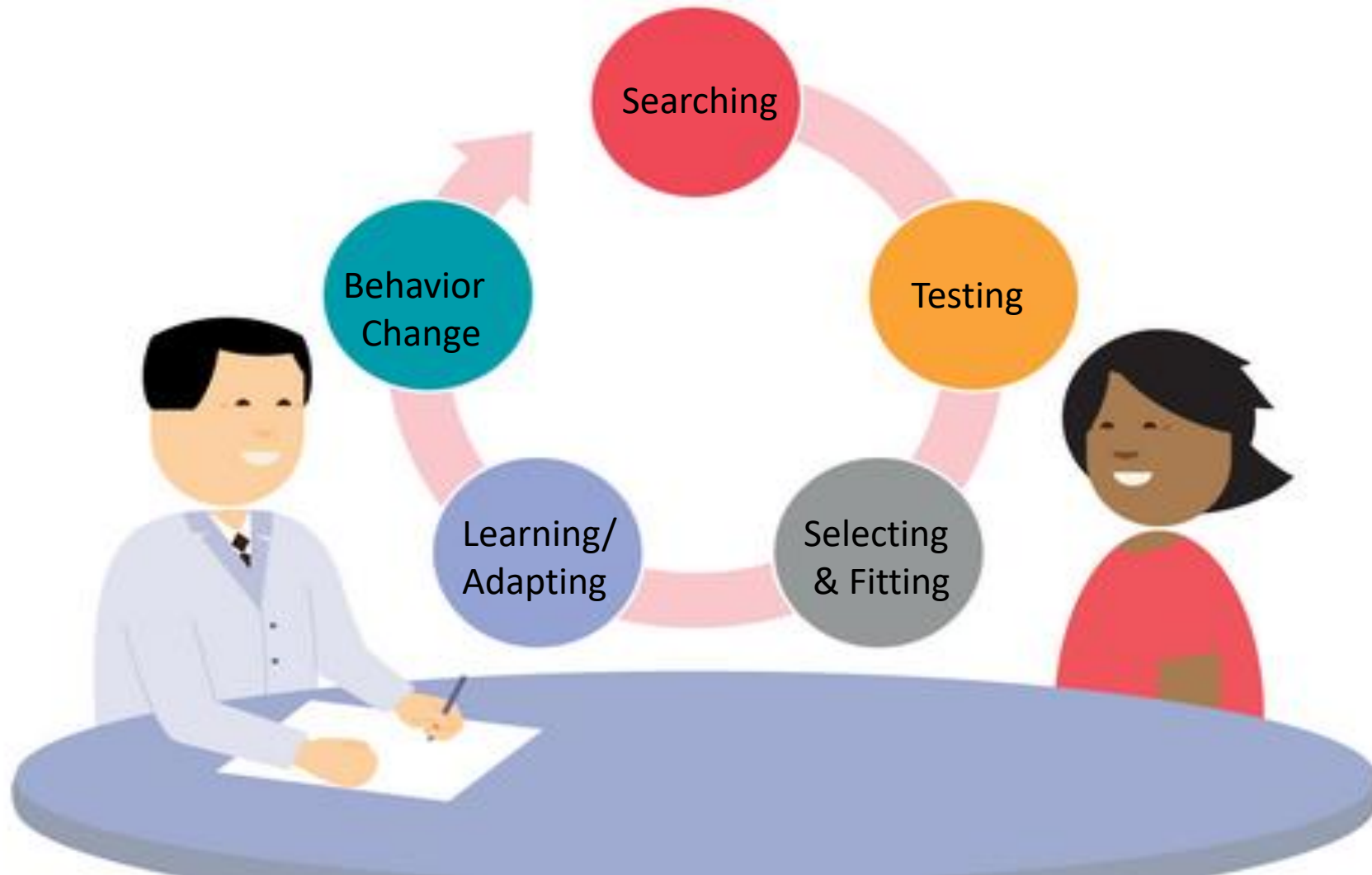
Part 1: The device landscape. Current status of OTC, 1-year post-FDA announcement

Part 2: Applications of OTC/DTC: How we can leverage OTC to improve the lives of more people with hearing loss

# Persons with hearing difficulties: Differ in many ways



# The Patient Journey



# What we know about the patient journey

No two journeys are the same

It's often complicated



# Some patients might choose a different pathway

No two journeys are the same

It's often complicated



Conventional “way of doing things” is in-person



# Augmented In-person and Self-directed Care

- Basic OTC devices target only the selecting/fitting leg of the journey
- Self-fitting OTC target only the testing and selecting/fitting leg of the journey
- For uptake to improve, other legs of the journey must be addressed
- Audiologists using new tools -- AI and OTC -- can provide a much different service experience

# Why OTC/DTC devices are needed?

3 possibilities

# 1. Shortage of Audiologists

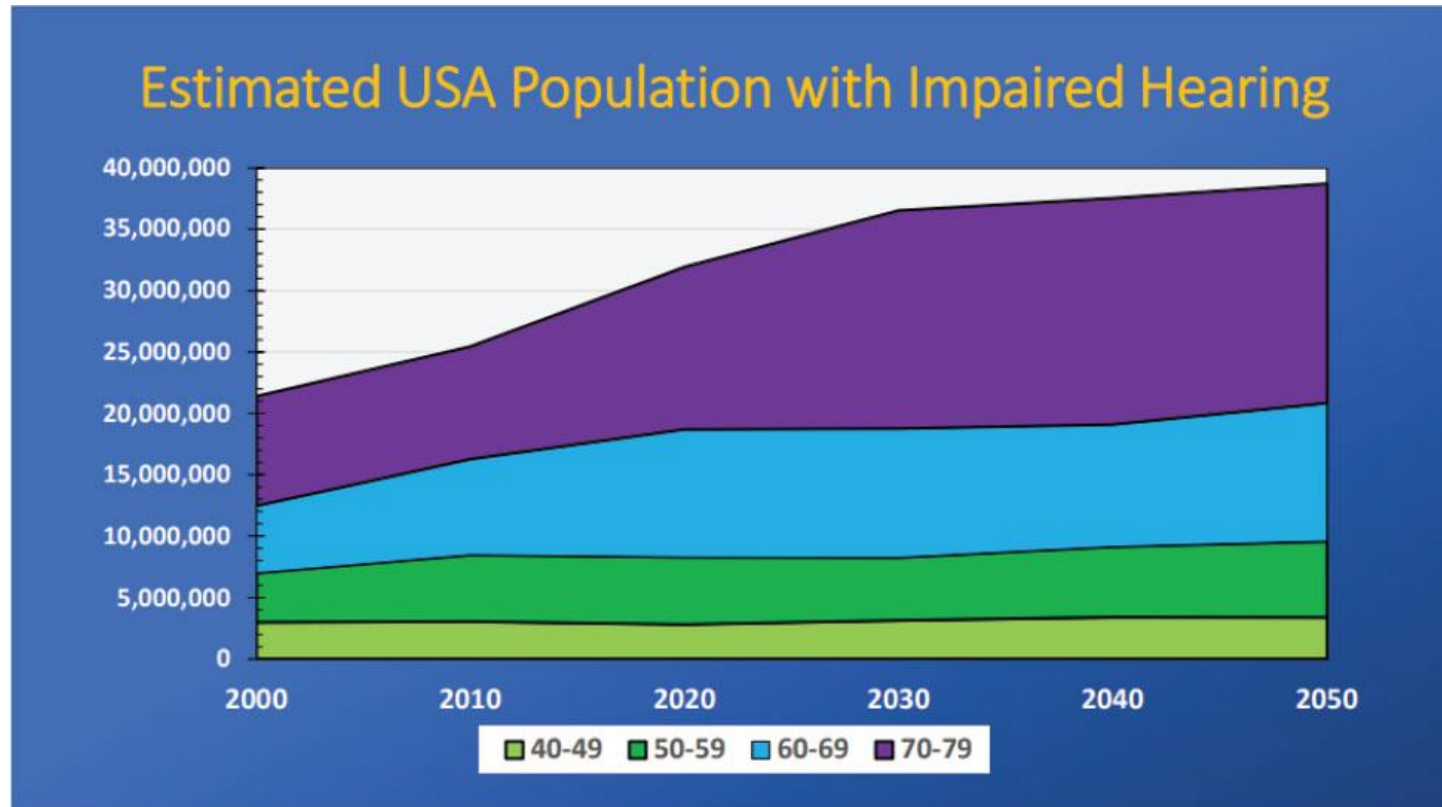


Figure 8. Graying of America: Predicted number of persons in the USA with impaired hearing (ages 40 to 79) between 2000 and 2050.

# Shortage of Audiologists

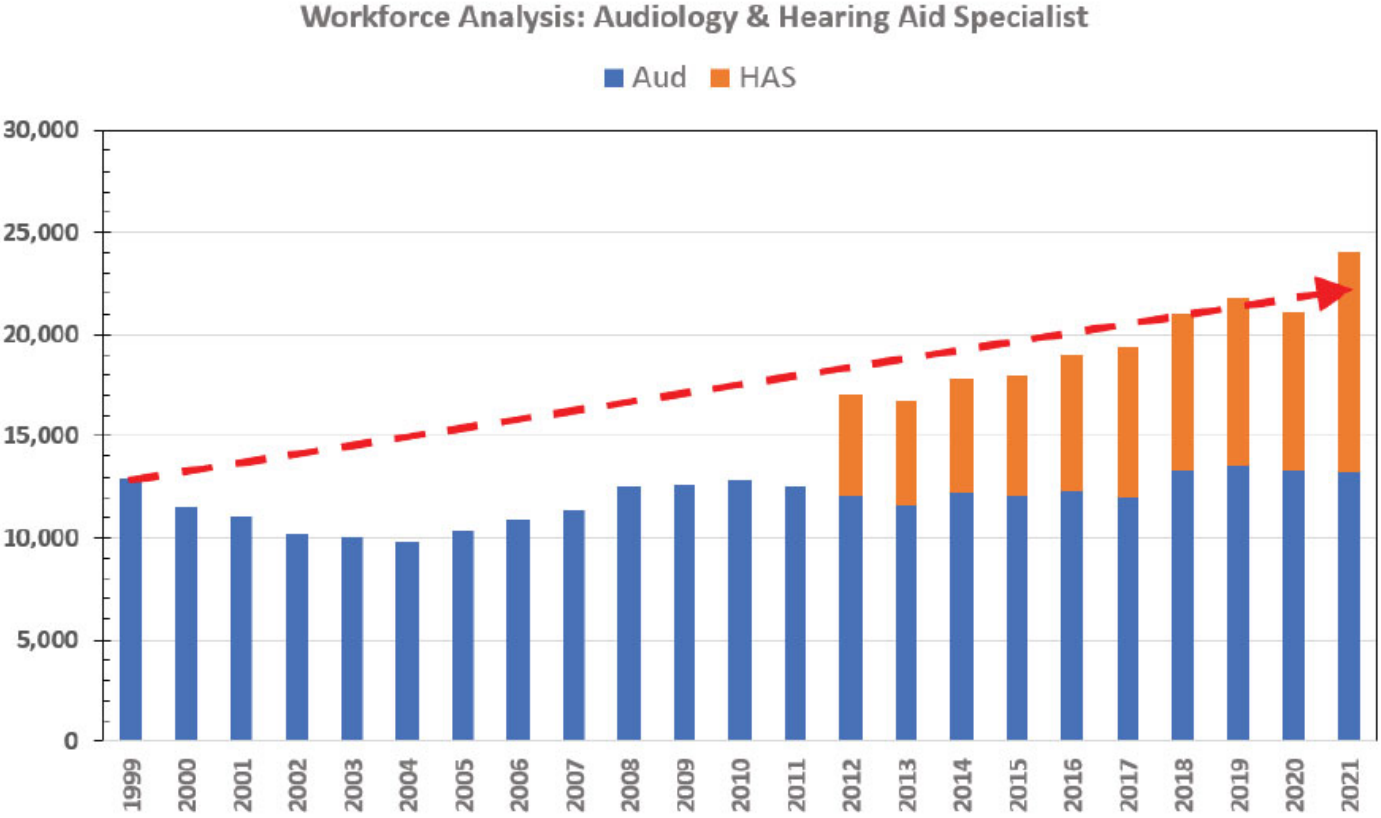


Figure 6. Predicting hearing healthcare workforce that is expected in 2021 (re: 1999, depicted as red dashed line), and workforce estimates of Audiology (i.e., blue bars) and Hearing Aid Specialist (i.e., orange bars)

# By 2030, it is projected...

- 37,000,000 adults between 40 and 79 with hearing loss
- 22,000 licensed hearing care professionals
- 1,682 persons with hearing loss per licensed professional
- 32 new patients per week with no vacation or sick time!

## 2. Insidious Effects of Untreated Hearing Loss



- Loneliness and Social Isolation
- Listening-related Fatigue
- Impact work performance, physical activity levels, social connections and quality of life

# Cascading Effects of Hearing Loss and Aging

**Gradual Hearing Loss**



**Fatigue & Frustration**



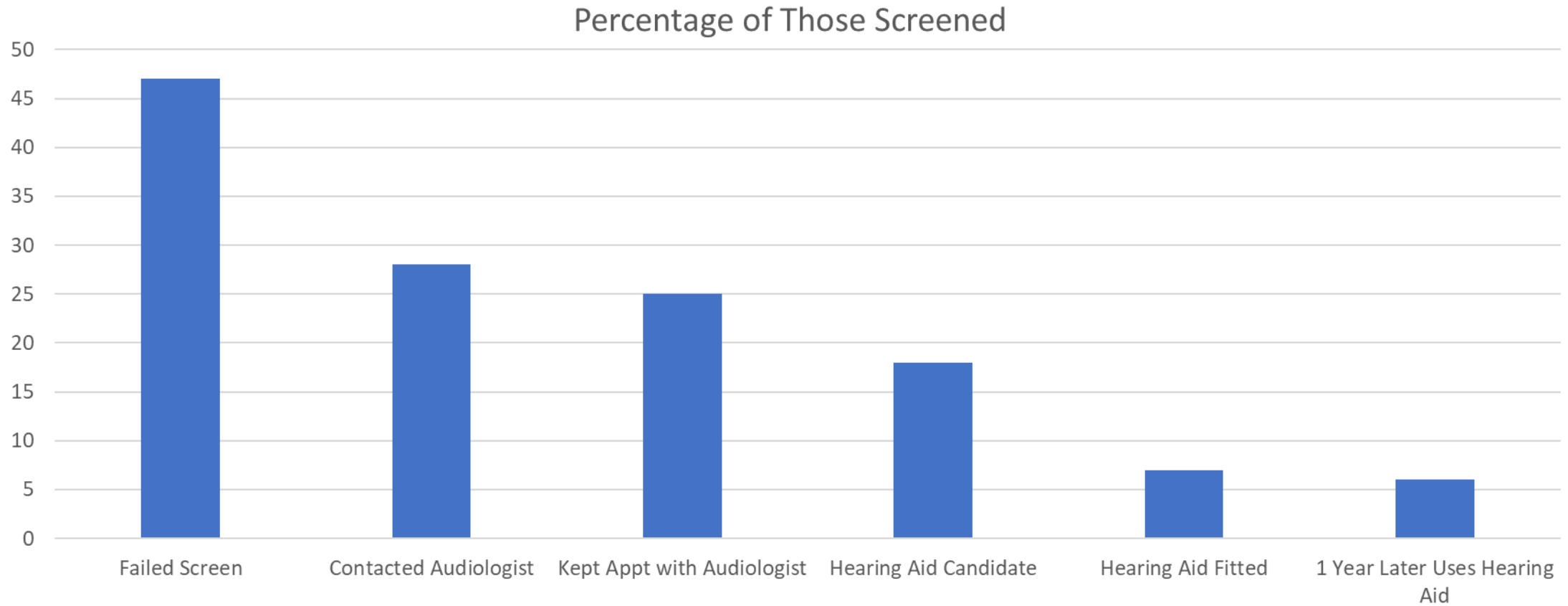
**Withdrawal & Isolation**



**Loneliness**



# 3. Low Uptake Rates



Dubno JR, Majumder P, Bettger JP, et al. A pragmatic clinical trial of hearing screening in primary care clinics: cost-effectiveness of hearing screening. *Cost Eff Resour Alloc.* 2022;20(1):26.  
Folmer RL, Saunders GH, Vachhani JJ, et al. Hearing Health Care Utilization Following Automated Hearing Screening. *J Am Acad Audiol.* 2021;32(4):235-245  
Smith SL, Francis HW, Witsell DL, et al. A Pragmatic Clinical Trial of Hearing Screening in Primary Care Clinics: Effect of Setting and Provider Encouragement [published online ahead of print, 2023 Aug 21]. *Ear Hear.* 2023;10.  
Yueh B, Collins MP, Souza PE, et al. Long-term effectiveness of screening for hearing loss: the screening for auditory impairment--which hearing assessment test (SAI-WHAT) randomized trial. *J Am Geriatr Soc.* 2010;58(3):427-434.  
Zazove P, Plegue MA, McKee MM, et al. Effective Hearing Loss Screening in Primary Care: The Early Auditory Referral-Primary Care Study. *Ann Fam Med.* 2020;18(6):520-527.



# The Changing Landscape



# Device Landscape 1970s to 2022



**“Medical Grade”  
Hearing Aids**



**Non-custom  
amplifiers:**

**PSAPs**

**ALDs**

**Hearables**

**Apps**

# “Medical Grade” Hearing Aids

- Regulated by FDA as medical device since 1973
  - Manufacturing process
  - Advertising claims
  - Labeling requirements
  - Also regulated by FTC
- Require involvement of licensed professional in acquisition process
  - Licensing is done by each state

# Personal Sound Amplification Devices (PSAPs)

- 2013 FDA Draft Guidance, clarified in the 2022 FDA OTC Regulations:
  - Accentuate sounds in specific listening situations for individuals with normal hearing
  - Not intended to be used by people with hearing loss
  - Cannot be labeled as an over-the-counter hearing aid
  - Not a medical device



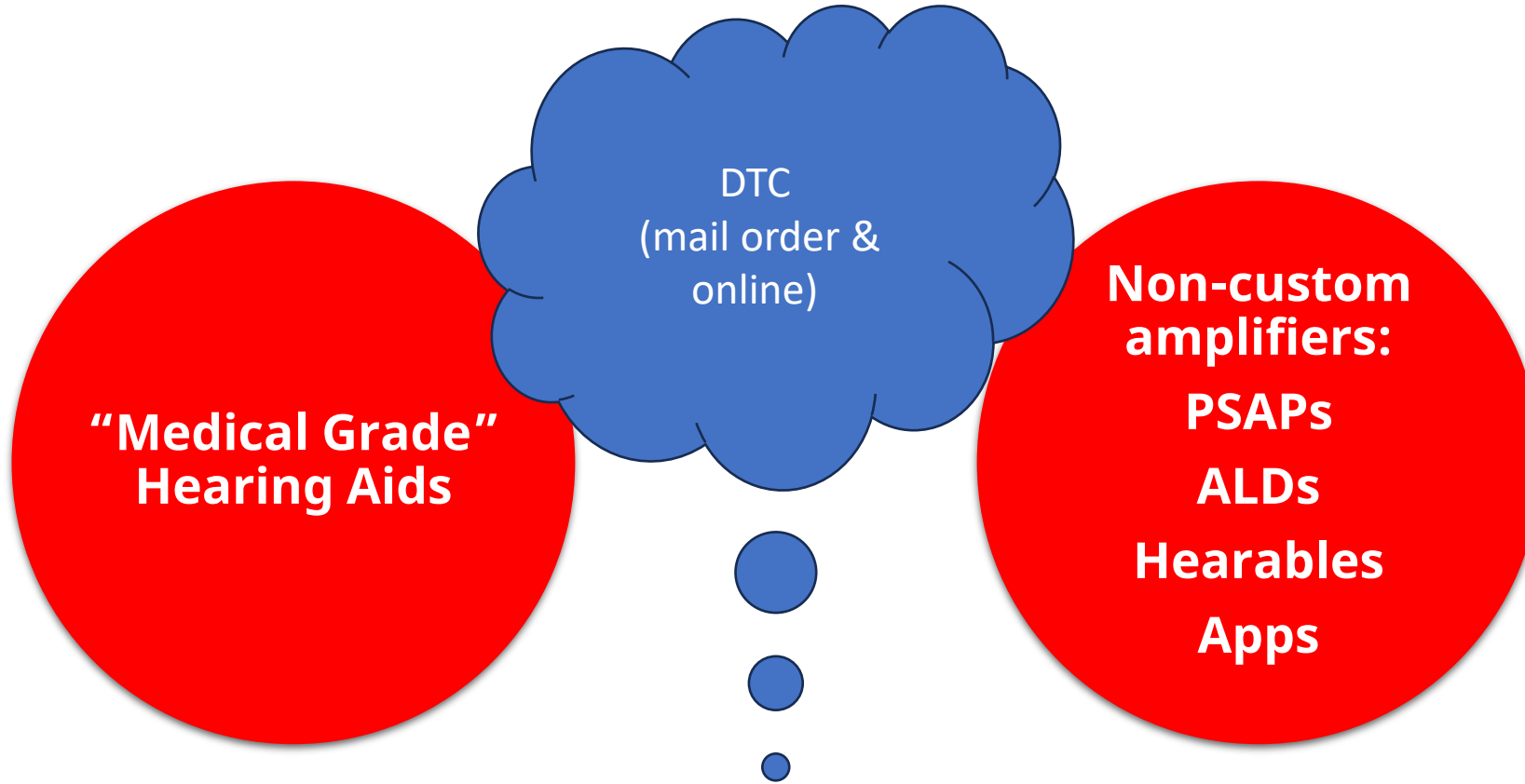
# Hearables -- Consumer Earbuds

- A marketing term
- Coined by Nick Hunn, circa 2010
- Consumer earbuds that provide amplification, denoising, or extended bandwidth/frequency shaping
- “Multi-taskers”



See NAL's Nicky Chong White's work at Hearing Review

# Device Landscape 1970s to 2022



As RICs have become more popular, DTC hearing aids look more like "medical grade" devices



# DTC hearing aids are not new



# DTC hearing aids are not new



Dear Friend,

I would like to let you in on two secret facts the rest of the hearing aid industry was hoping you would never discover.

**\*Fact #1: The overall user satisfaction rate of people purchasing hearing aids from regular dealer offices and audiology clinics is only 58%. Not really very good.**

**\*Fact #2: The overall satisfaction rate amongst Lloyd's customers is 86%. This is substantially higher than any other area of hearing aid dispensing.**

MarkeTrak I  
1989



# Direct-to-Consumer (DTC) Devices

- Hearing aids programmed by licensed hearing professionals (using online hearing test results) and shipped to customers
- DTC options:\*

Pre-Sale Vetting Process	Limited Vetting Process, Pre-sale**
Hear.com	Audicus
Hearing Planet	Eargo
JabraEnhance	Lloyd's
	Nano
	Online Hearing
	MD Hearing
	Blaid's Hearing
	Neosonic

25 \*Not a complete list, excludes companies selling OTC devices. Search conducted, January 2023

\*\* Often use the term "FDA-registered"

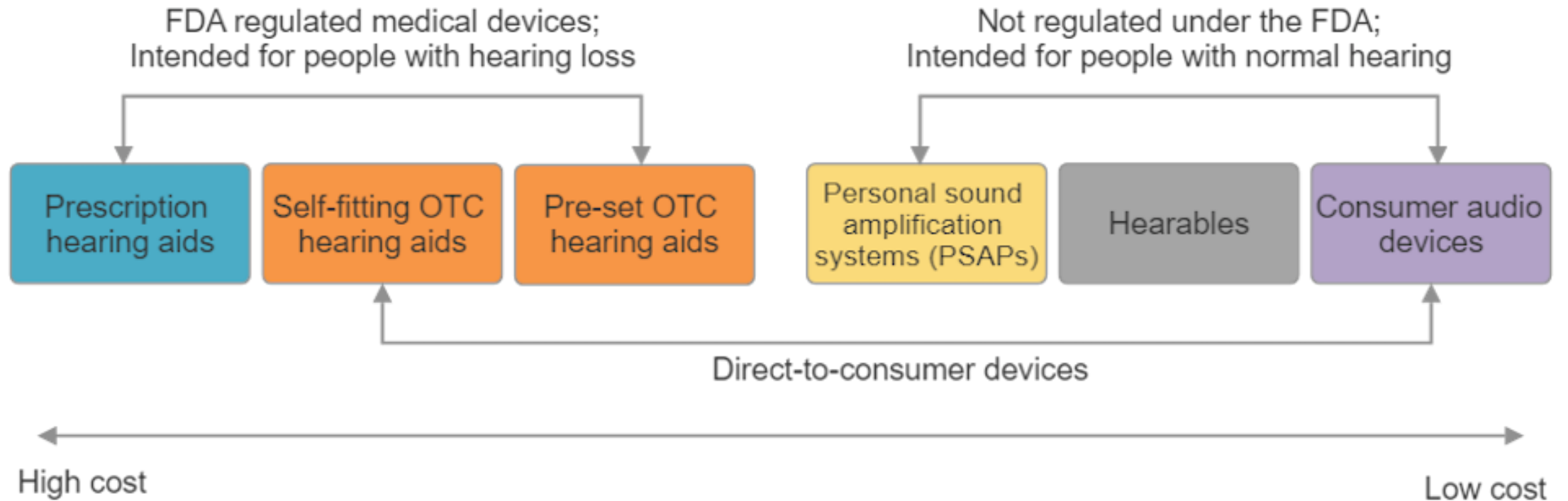
# OTC: a disruption 10+ years in the making



It all officially changed on this date

OCTOBER 2022						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
25	26	27	28	29	30	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

# Current Hearing Device Landscape



# What is the intent of the OTC regulations?

7 Reasons

1. Spur competition
2. Reduce prices for consumers
3. Increase access in places where it might be hard to find a licensed provider (internet, drug stores)
4. Reduce stigma
5. Empower consumers to take ownership of their condition
6. Make the buying process easier
7. Provide more consumer choice
8. Agitate audiologists with new form factors, fine-tuning interfaces, spec sheets, etc.



# What the OTC regulations do?

- Makes OTC hearing aids available for sale to adults, aged 18 and older who have a self-perceived mild to moderate hearing loss, even if they have not had a hearing exam.
- Fitting of OTC devices in the clinic still requires state licensure for the provider
- Establishes specific labeling requirements for consumers
- Establishes specific technical requirements (gain/output, etc) for manufacturers

# FDA OTC Technical Requirements

Measure		Proposed ANSI-CTA 2017
Maximum Power Output (OSPL90)		120 dB SPL
Full-on Gain (FOG 50)		No limit
Total Harmonic Distortion (THD)		$\leq 5\%$
Self-generated internal noise floor		$\leq 32\text{dBA}$
Bandwidth		$< 250$ to $5000$ Hz or greater
Latency		$\leq 15\text{msec}$
Smoothness of frequency response		No peak in $1/3$ octave $> 12\text{dB}$ above average levels of adjacent $1/3$ octaves

# FDA OTC Technical Requirements

Measure	OTC Technical Requirement 2022	Proposed ANSI-CTA 2017
Maximum Power Output (OSPL90)	111 dB SPL (linear) 117 dB SPL (input compression)	120 dB SPL
Full-on Gain (FOG 50)	No limit	No limit
Total Harmonic Distortion (THD)	</= 5%	</= 5%
Self-generated internal noise floor	</= 32dBA	</= 32dBA
Bandwidth	<250 to 5000 Hz or greater	<250 to 5000 Hz or greater
Latency	</= 15msec	</= 15msec
Smoothness of frequency response	No peak in 1/3 octave > 12dB above average levels of adjacent 1/3 octaves	No peak in 1/3 octave > 12dB above average levels of adjacent 1/3 octaves



# Other OTC Technical Standards

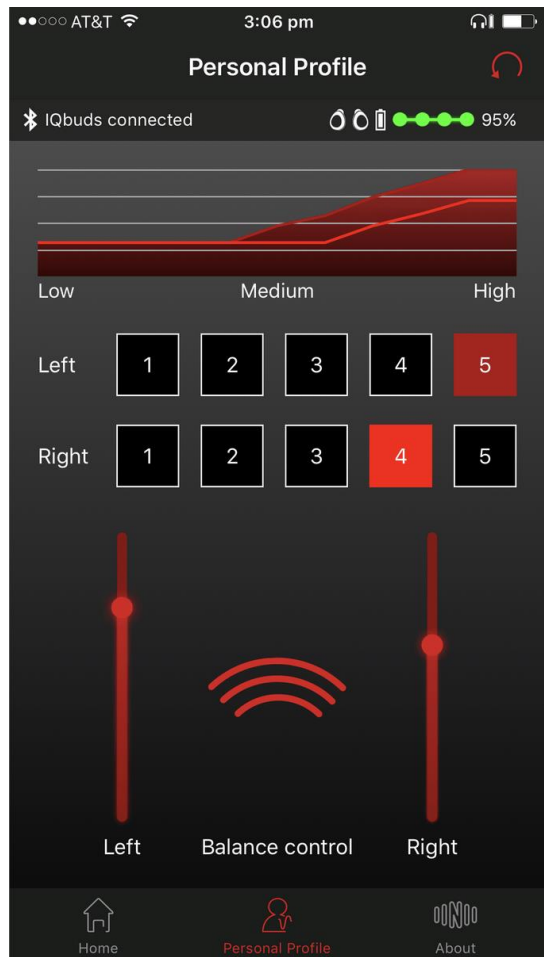
- User adjustable volume control
- Software/interface to control & self-test
- Insertion depth  $\geq$  10 mm from eardrum
- Proper physical fit
- Required labeling
  - Age (18+)
  - Medical red flags
  - Usage cautions/When to seek professional help

# Preset OTC vs. Self-fit OTC

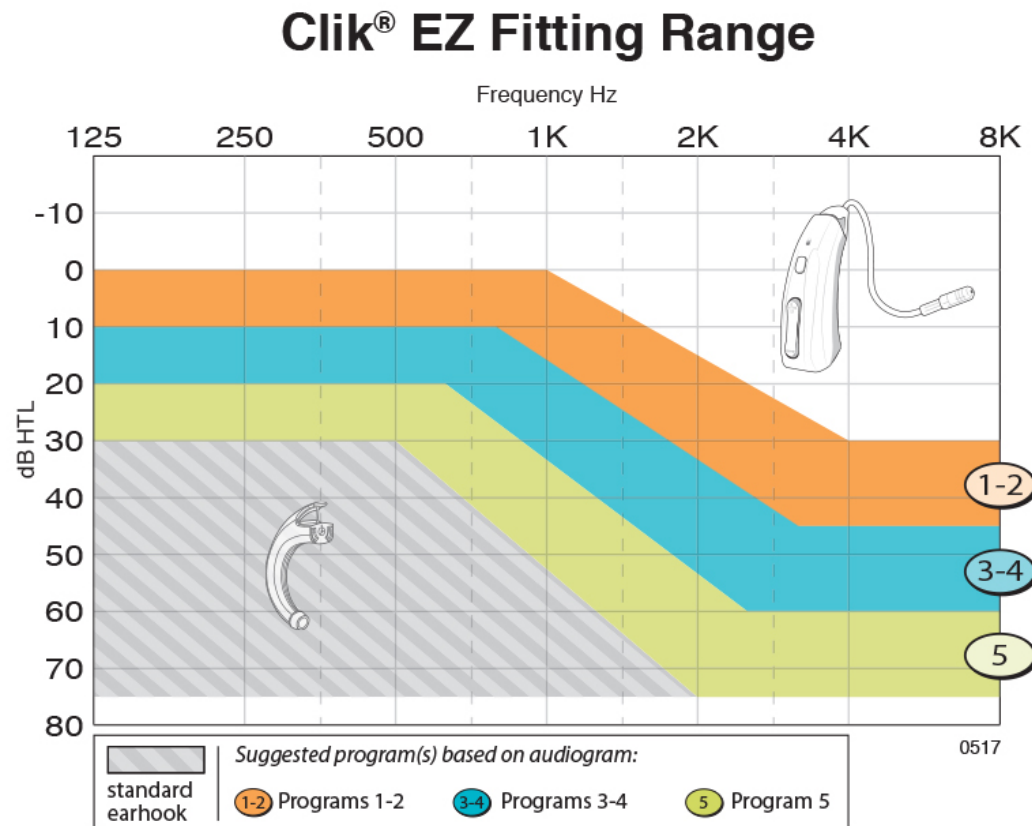
- **Preset OTC devices** are any air-conduction hearing aid for mild-to-moderate hearing loss that includes “tools, tests, or software” to allow the user to “control or customize” the hearing aid and is available without the intervention of a licensed person.
- **Self-fitting OTC devices** are wireless air-conduction hearing aids that incorporate technology, including software, that ***allows users to program hearing aids, that integrates user input with a self-fitting strategy***, and that enables users to independently derive and customize their hearing aid fittings and settings.....

# 3 Self-Fitting Approaches

# 1. Audiogram-based



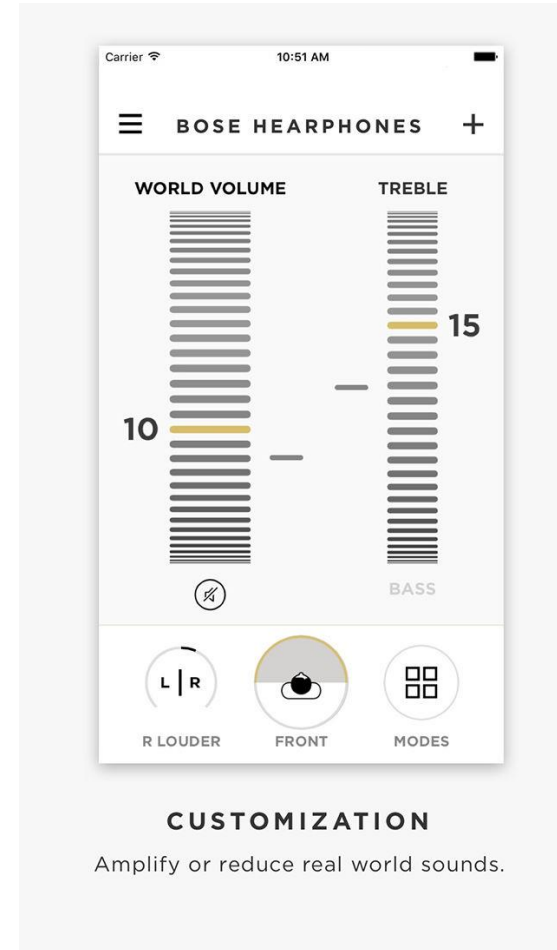
## 2. Pre-set Programs



- Stores 3 to 5 different combinations of gain and frequency response “programs”

# 3. Direct Adjustment

- No hearing test required



# OTC 1 year later: Where are we?

- 54 companies list a pre-set OTC and 18 companies list a self-fitting OTC with the FDA
- SRP range from \$90.00 to \$5,500.00 (usually sold in pairs)
- Still dozens of PSAPs and hearables on the market
- OTC represents about 1-2% of total hearing device sales (some say OTCs are under-reported, % could be higher)
- Average age of first-time buyer is 5-10 years younger than prescription hearing aids
- Return rates are estimated at about 35% and higher

# What's in a name, anyway?

- OTC vs. Prescription vs. PSAP
- There is still a lot to be confused about....  
for both consumers and professionals



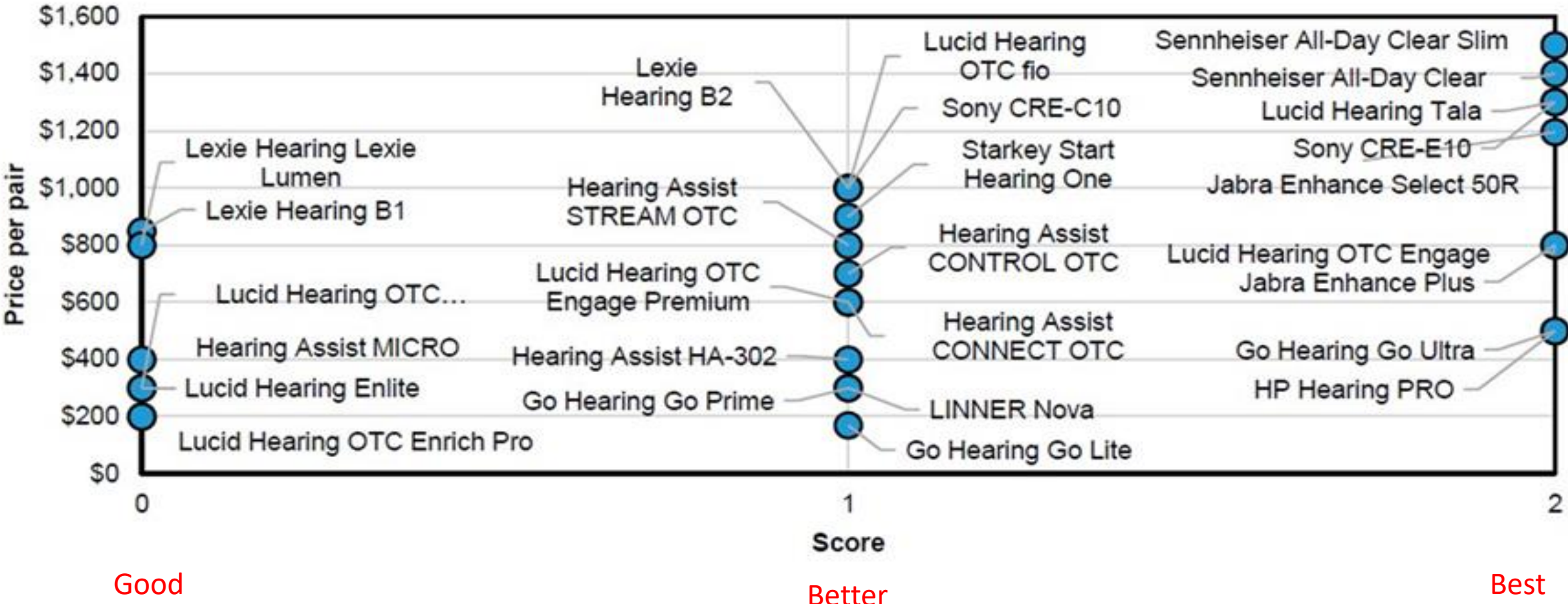


	Over-the-Counter Hearing Aids
Type of Product	Medical device
Intended User	Adults, aged 18 and older with perceived mild to moderate hearing loss
Conditions for Sale	No medical exam, no hearing test needed. Must be 18 years or older
Standards	ANSI CTA 2051 (2017) <b>Specifies device performance for consumers</b>

	Over-the-Counter Hearing Aids	Prescription Hearing Aids
Type of Product	Medical device	Medical device
Intended User	Adults, aged 18 and older with perceived mild to moderate hearing loss	Any age, any degree of hearing loss
Conditions for Sale	No medical exam, no hearing test needed. Must be 18 years or older	Purchase from a licensed professional
Standards	ANSI CTA 2051 (2017) <b>Specifies device performance for consumers</b>	ANSI S3.22 2014 (R2020) <b>Specifies test methods and tolerances for professionals who compares to specs</b>

	Over-the-Counter Hearing Aids	Prescription Hearing Aids	Personal Sound Amplification Products (PSAPs) and Hearables
Type of Product	Medical device	Medical device	Consumer electronic
Intended User	Adults, aged 18 and older with perceived mild to moderate hearing loss	Any age, any degree of hearing loss	Persons with normal hearing who want enhancement of sounds in their environment
Conditions for Sale	No medical exam, no hearing test needed. Must be 18 years or older	Purchase from a licensed professional	No conditions for sale per FDA
Standards	ANSI CTA 2051 (2017) <b>Specifies device performance for consumers</b>	ANSI S3.22 2014 (R2020) <b>Specifies test methods and tolerances for professionals who compares to specs</b>	No required standards

**EXHIBIT 11: Devices offering both streaming connectivity and rechargeability tend to be priced above \$1,000**



Devices with a score of 2 points offer both streaming connectivity and a rechargeable battery while those with a score of 1 point offer only one of those two features. We have excluded Eargo given size constraints rather other factors limit the potential to have connectivity.

Source: Best Buy, Amazon, Bernstein analysis

Will OTC open the floodgates?



# After all, OTCs are Technically Feasible

- In double-blinded placebo-controlled studies, “self-fit” devices yielded similar benefit as clinician-fitted devices. (Humes, et al, 2017 and De Souza et al. 2023)
- When given user-control via a smartphone app, participants could successfully self-select gain (and report similar outcomes) similar to those fit by clinicians following best-practices. (Sabin, et al 2020)
- 4 pre-set gain programs match prescribed gain targets for 68% of mild to moderate hearing losses and result in outcomes similar to clinically fitted hearing aids. (Urbanski, et al 2021)
- About one-third of older users could successfully self-assemble (self-fit) without any professional support. (Convery, et al, 2019)

Will OTC open the floodgates?



# Why the floodgates remain closed?

- Unfamiliar with on-line buying process, in general and OTC as a product category.
- Patient journey has remained largely unchanged
- An in-person inquiry to an audiologist usually leads to purchase of prescription devices (audiologists don't carry OTC or sell similarly priced devices with service included)
- Uncomfortable buying healthcare products online. Chandra & Searchfield, 2016.
- Uncomfortable acquiring hearing aids without seeing a professional and getting a test first. Singh & Dhar, 2023



# Part 2

- Applications of OTC/DTC: How we can leverage OTC to improve the lives of more people with hearing loss

# Different Ways to Think About OTC and How It Might Fit into Your Practice

- Patient Segmentation “medical model”
- Customer Archetypes “retail profiles”
- A tool that speeds the journey:
- Empowerment and confidence
- Overcome apathy and indifference

# OTC: A tool to speed the journey

## ROAD TRIP TIPS WITH HEARING LOSS

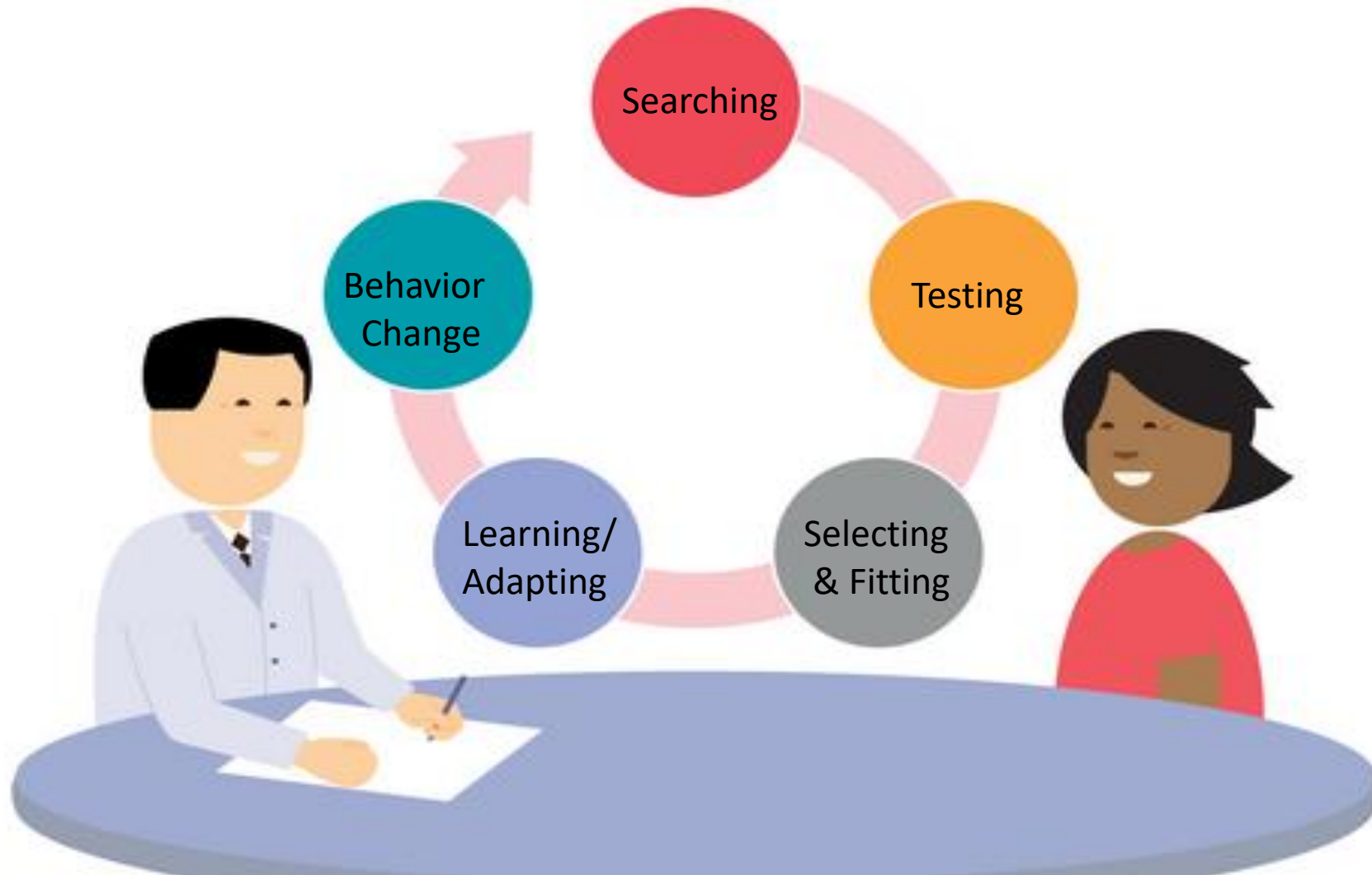
Prepare to hit the road on your next adventure with these useful travel hints.

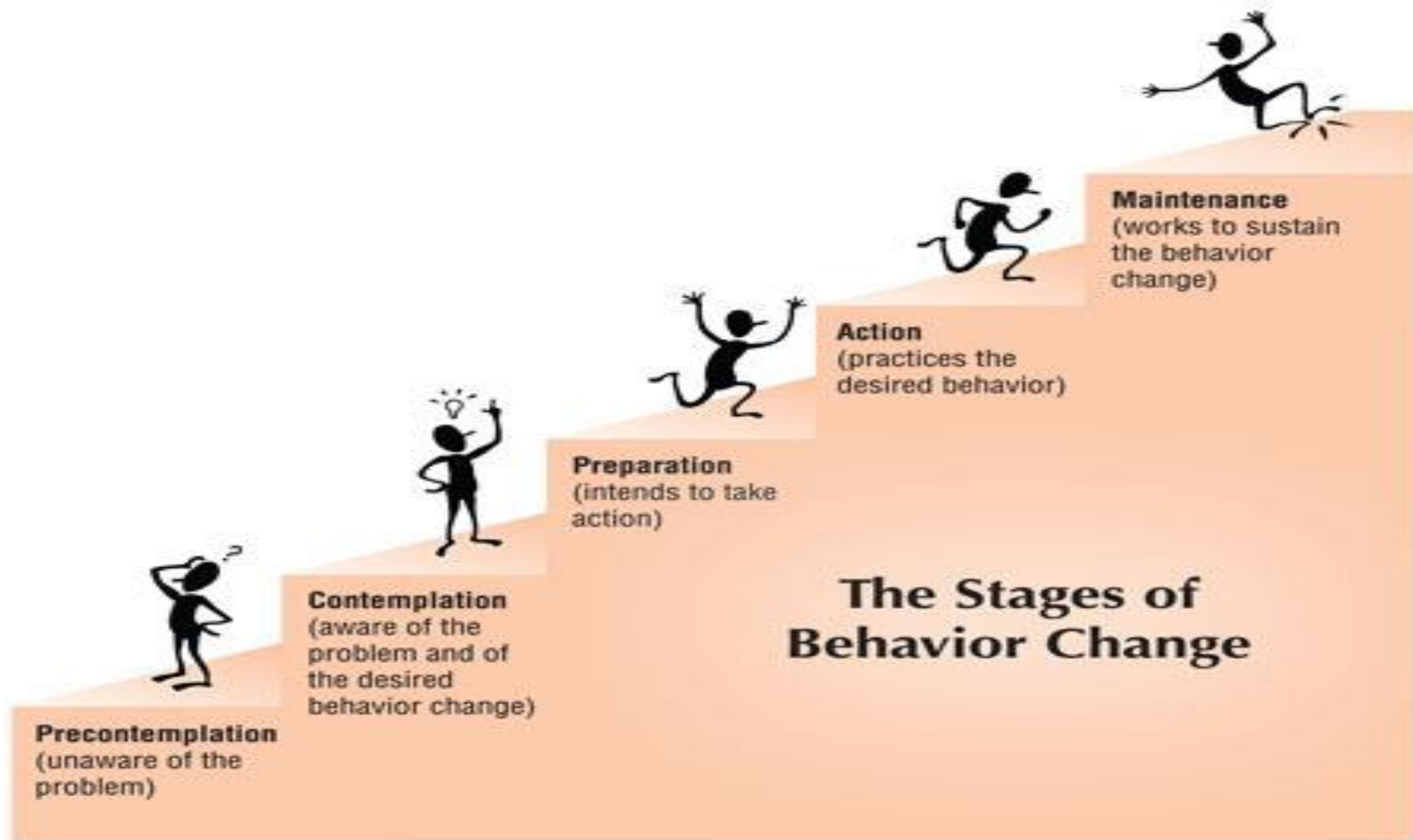
- 1** **Set up a road-friendly care routine for assistive hearing devices**  
Pack a cleaning kit, batteries or chargers, and storage case, and keep them cool and dry.
- 2** **Mind the music volume**  
Try a decibel-measuring app to keep sound at safe and comfortable levels.
- 3** **Let companions know your communication preferences**  
Ask your travel partners to speak clearly or write things down.
- 4** **Reduce background noise when needed**  
Keep the windows closed when traveling at high speeds; when they're open, turn off hearing devices on that side.
- 5** **Know your route**  
Have an idea of where you'll need to turn or have a copilot inform you of GPS audio alerts.
- 6** **Consider Bluetooth GPS or an FM transmitter**  
These technologies can help deliver directions and conversation directly to your device.
- 7** **Play hearing loss-friendly road trip games**  
Bring a small whiteboard to support word games or play visual games (passengers only - not while driving!).
- 8** **Look for hearing assistance signs at the venues you visit**  
Places like museums and theaters often display signs to help you know that assistive listening technology is available there.

Learn how captioned telephones can help you catch every word at [CapTel.com](http://CapTel.com).



# The Patient Journey





Sources: Grimley 1997 (75) and Prochaska 1992 (148)

# Why a 7-10 year wait?

- “Hearing aids are expensive”
- “I don’t know where to get tested”
- “I have to wait 3 weeks to get an appointment”
- “My hearing is normal for my age”
- “I can get by with help from my wife and kids”
- Apathy and Indifference!

# It starts with addressing apathy and indifference

- Just how big of a problem is apathy....



Imagine 100 adults, aged 50+ in the community you serve



What do we know about them?



“Within the past year, have you.....”

Type of visit	%
Seen your primary care physician	86%
Had an eye exam	71%
Gone to the dentist	71%
Had a hearing test	18%

Survey of 1000 adults aged 45+, Hearing Review March 3, 2023

It gets worse....

Original Study

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OPEN

**Awareness, Perceptions, and Literacy Surrounding Hearing Loss  
and Hearing Rehabilitation Among the Adult Population in the  
United States**

\*Matthew L. Carlson, \*Ashley M. Nassiri, †John P. Marinelli, ‡Christine M. Lohse,  
and §Sarah A. Sydlowski, Hearing Health Collaborative<sup>§</sup>

\*Department of Otolaryngology – Head and Neck Surgery, Mayo Clinic, Rochester, Minnesota; †Department of Otolaryngology –  
Head and Neck Surgery, San Antonio Uniformed Services Health Education Consortium, San Antonio, Texas; ‡Division of Clinical  
Trials and Biostatistics, Department of Quantitative Health Sciences, Mayo Clinic, Rochester, Minnesota; and §Cleveland Clinic –  
Head and Neck Institute, Cleveland, Ohio

1250 respondents aged 50 to 80. 500 wore hearing aids, 750 denied hearing loss

# “Knowledge of link between hearing loss and other health conditions and social outcomes”


Responses	All	With hearing loss	Without hearing loss
Linked to increased risk of depression	23%	35%	19%
Linked to reduced income/job opportunities	22%	35%	18%
Linked to increased risk of falling	18%	28%	15%
Linked to increased risk of dementia	10%	18%	7%
Linked to increased risk of Type 2 diabetes	6%	9%	4%

# “Likelihood of prioritizing health condition or life activity in next year”

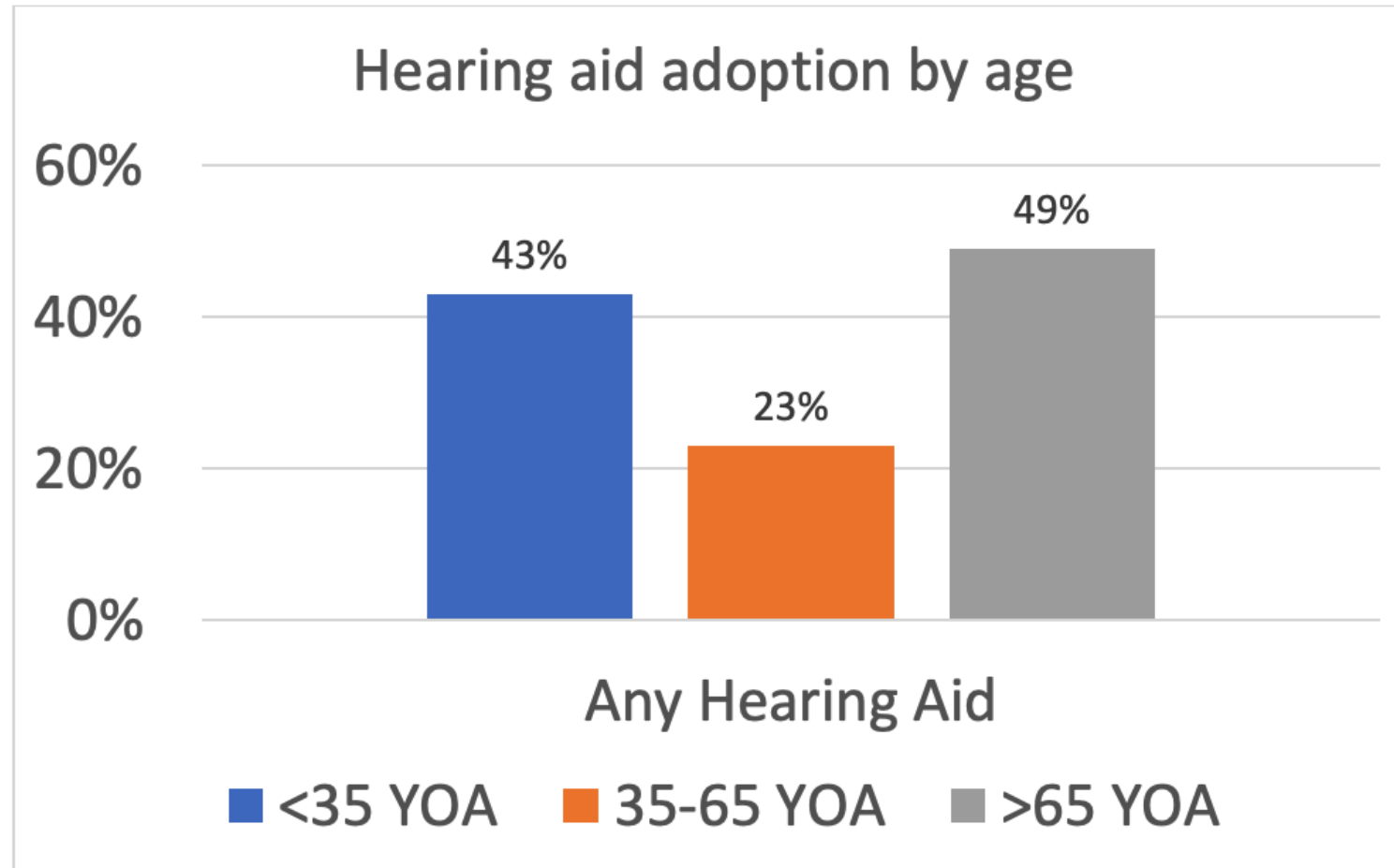
Responses	% Likely or very likely
Have an annual physical	72%
Have a cholesterol check by a doctor	70%
Have my eyes checked by optometrist	66%
Take my pet to the vet	59%
Go to a crowded space like a restaurant or party	57%
Have a mammogram or prostate exam	45%
Take a hike in nature	44%
Take a loved one to the doctor	37%
Go on a diet or start an exercise regimen	28%
Have hearing checked by an audiologist	27%
Attend a concert	20%
Listen to a podcast	15%

## “People are twice as likely to take a pet to the vet than get a hearing test”

Responses	% Likely or very likely
Have an annual physical	72%
Have a cholesterol check by a doctor	70%
Have my eyes checked by optometrist	66%
Take my pet to the vet	59%
Go to a crowded space like a restaurant or party	57%
Have a mammogram or prostate exam	45%
Take a hike in nature	44%
Take a loved one to the doctor	37%
Go on a diet or start an exercise regimen	28%
Have hearing checked by an audiologist	27%
Attend a concert	20%
Listen to a podcast	15%



# Middle-aged apathy and indifference

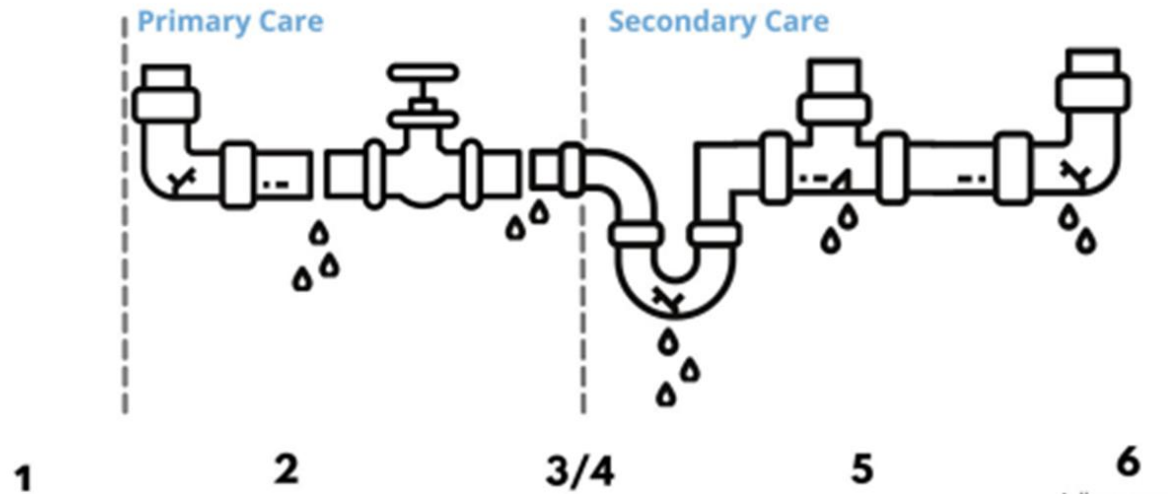


Remember those 100 adults?



Hoping they schedule an appointment with you for a test is not a strategy

# The leaky pipeline of hearing care

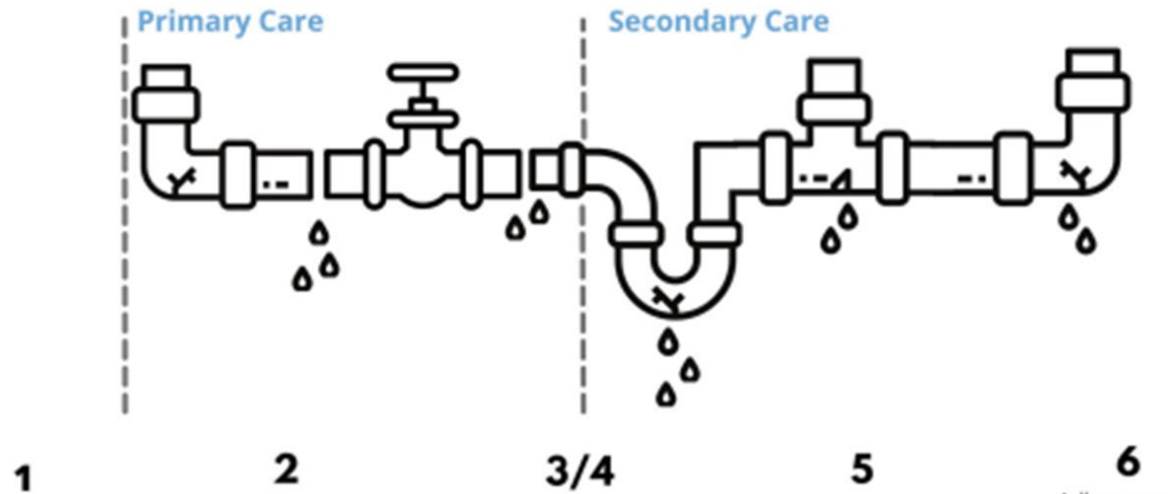


1. 34% do not acknowledge hearing loss

66/100 acknowledge



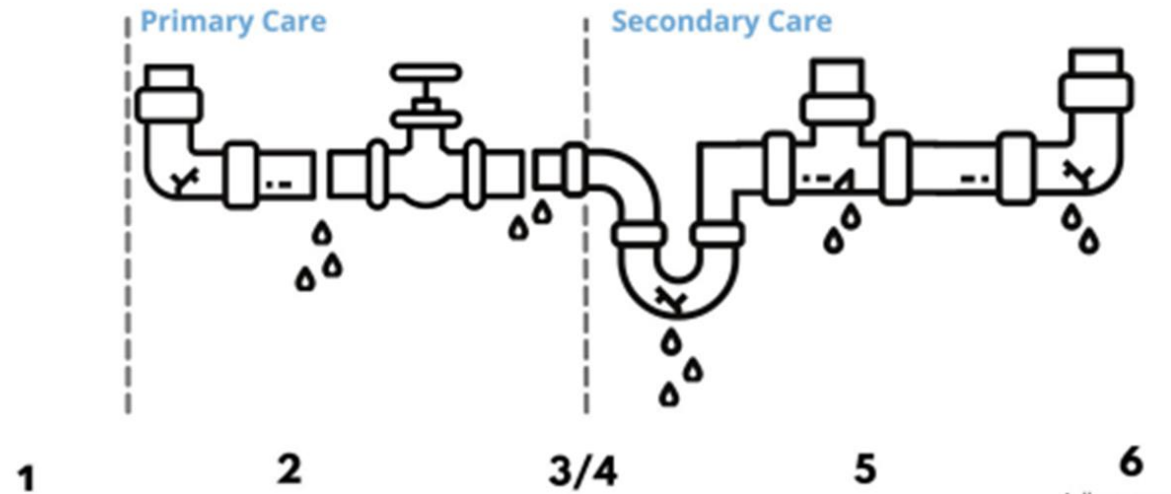
# The leaky pipeline of hearing loss



2. 35% do not disclose to their primary care physician

41/100

# The leaky pipeline of hearing loss



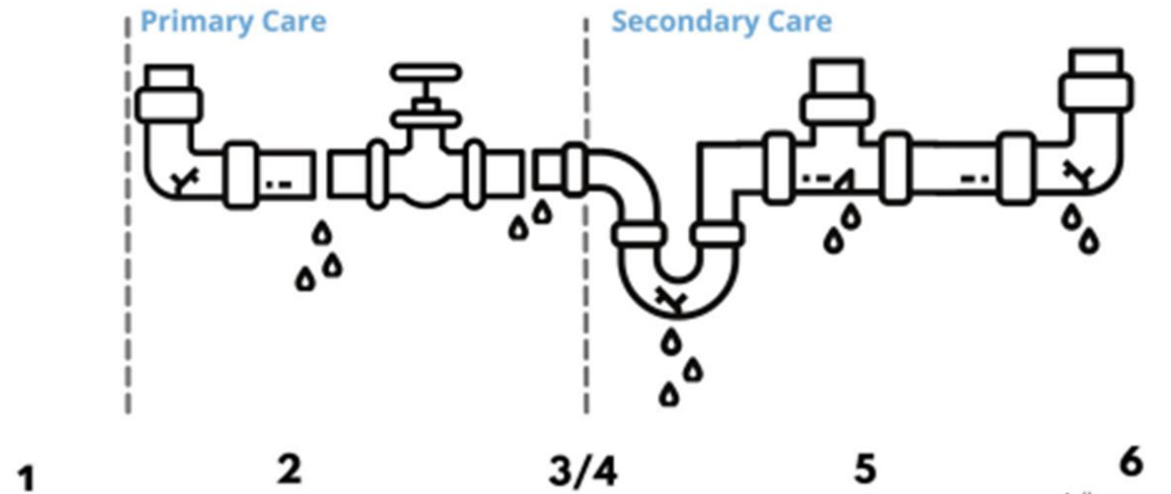
3. 18% do not accept referral to ENT/Audiology

34/100

4. 30% do not make an appointment for a hearing aid evaluation with HCP

20/100

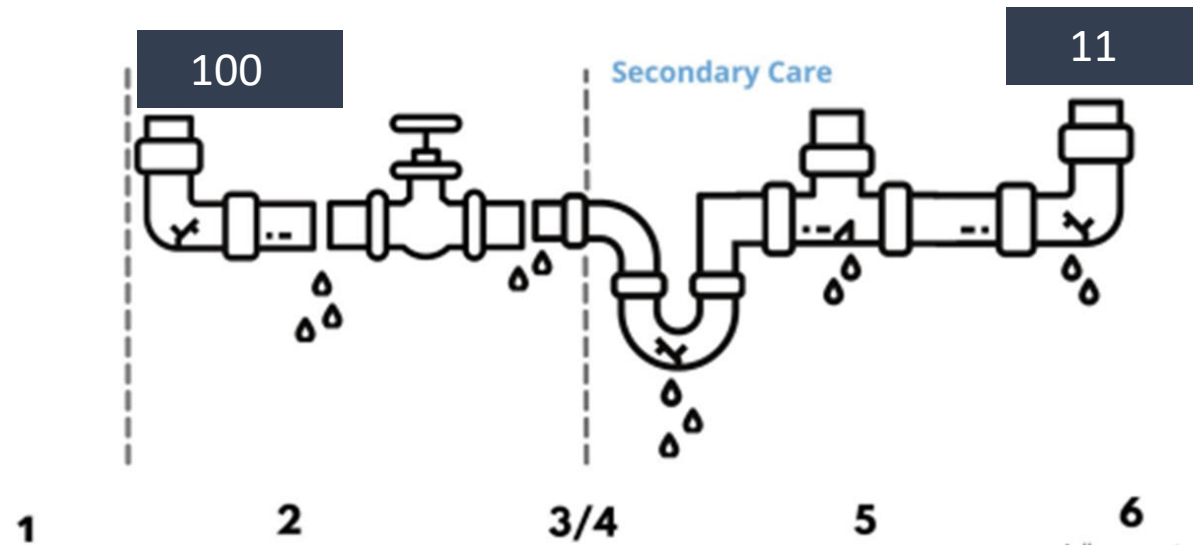
# The leaky pipeline of hearing loss



5. 27% do not accept recommendation,  
following HAE with audiologist

15/100

# The leaky pipeline of hearing loss



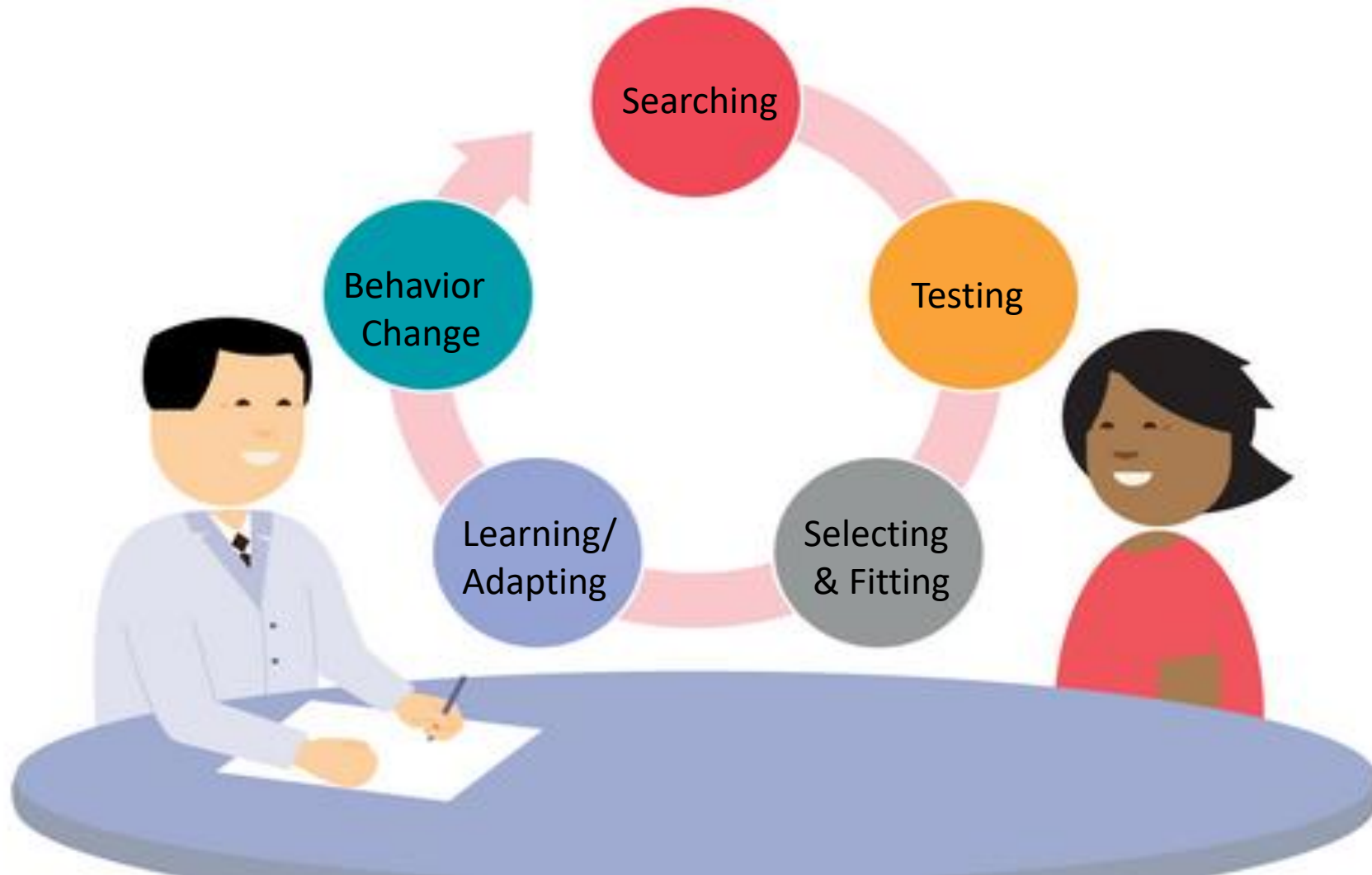
6. 27% do not adhere to treatment guidance

11/100 – potentially loyal customers

How do we shore up the leaks?

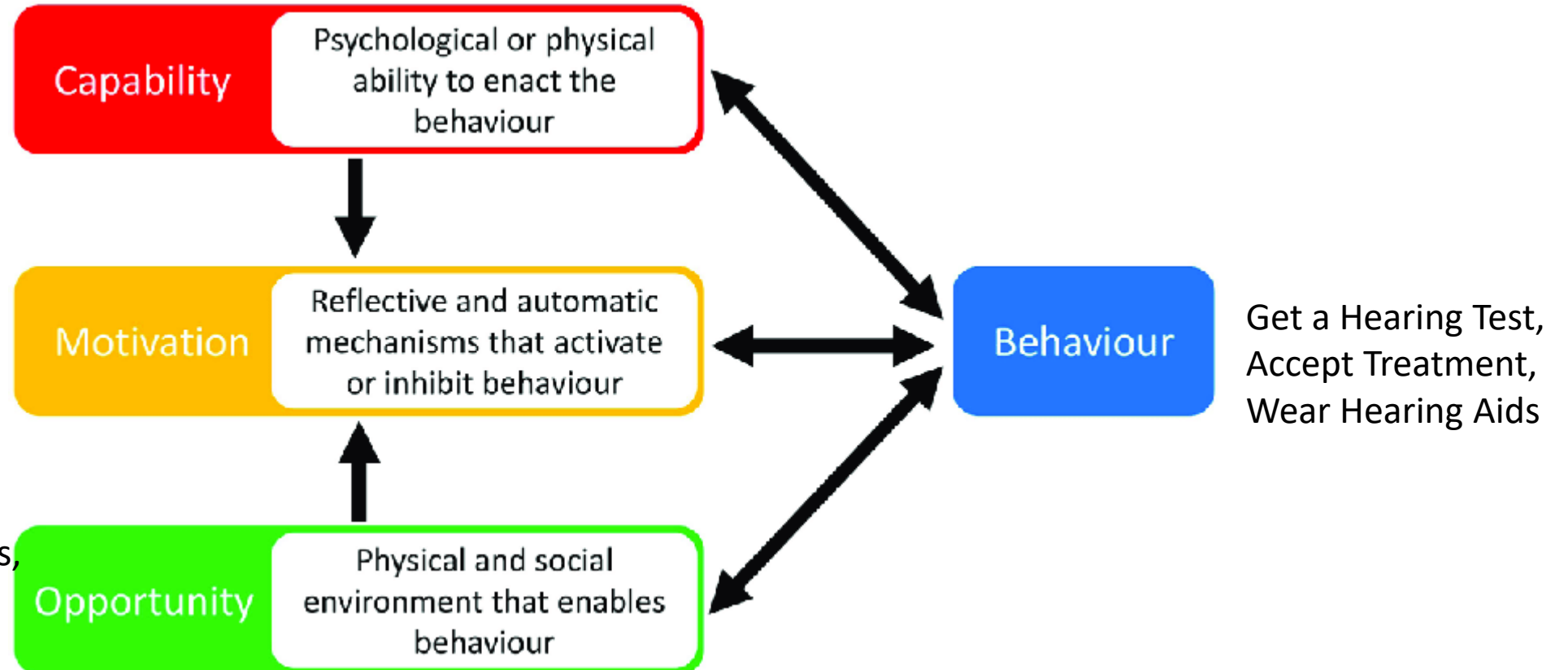


# The Patient Journey



# COM-B Model of Behavior Change

- Ability to self-fit with smartphone app,
- Digital literacy



- Seeing OTCs in stores,
- Trying OTCs from comforts of home,
- Seeing friends have success with OTCs

# OTCs: Social Opportunity



Because you see them in places like this.....





# Patient segmentation based on the medical model



- Brent Edwards, NAL
- Seminars in Hearing, Feb 2020

# Two Broad Overlapping Categories

## A. Self-reported Hearing Difficulty

Medical & Science

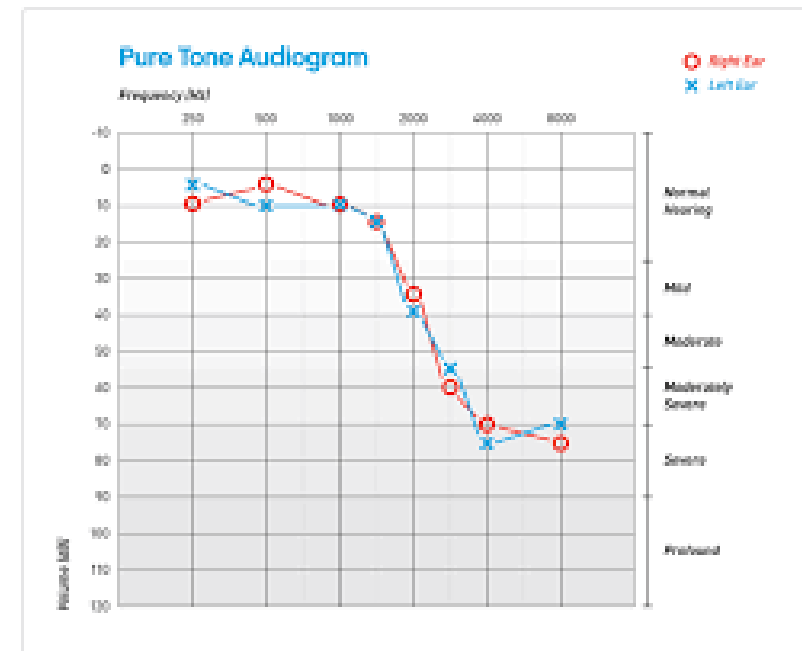
**HHIE-S**

means

Hearing Handicap Inventory for the Elderly--Screening Version

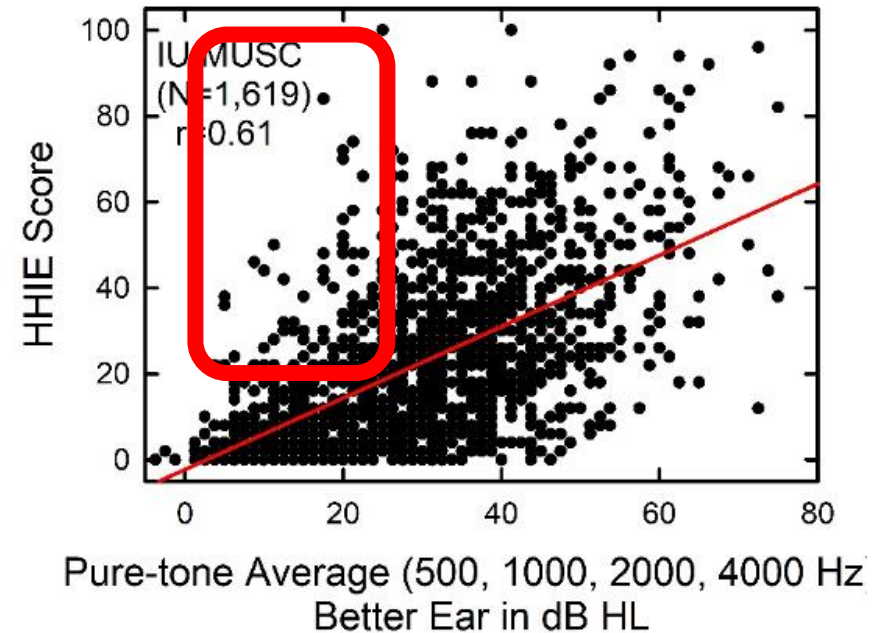
by [acronymsandslang.com](https://www.acronymsandslang.com)

## B. Measured Hearing Loss



# Self-reported Hearing Difficulty: Auditory Wellness

	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?	_____	_____	_____
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?	_____	_____	_____
<b>TOTAL SCORE = _____</b> (sum of the points assigned to each of the items)				



Humes, 2021

**Auditory Wellness Scale**  
 Excellent: 0-2  
 Good: 3-7  
 Fair: 8-15  
 Poor: 16-23  
 Very Poor: <24



# Uncovering New Patient Categories

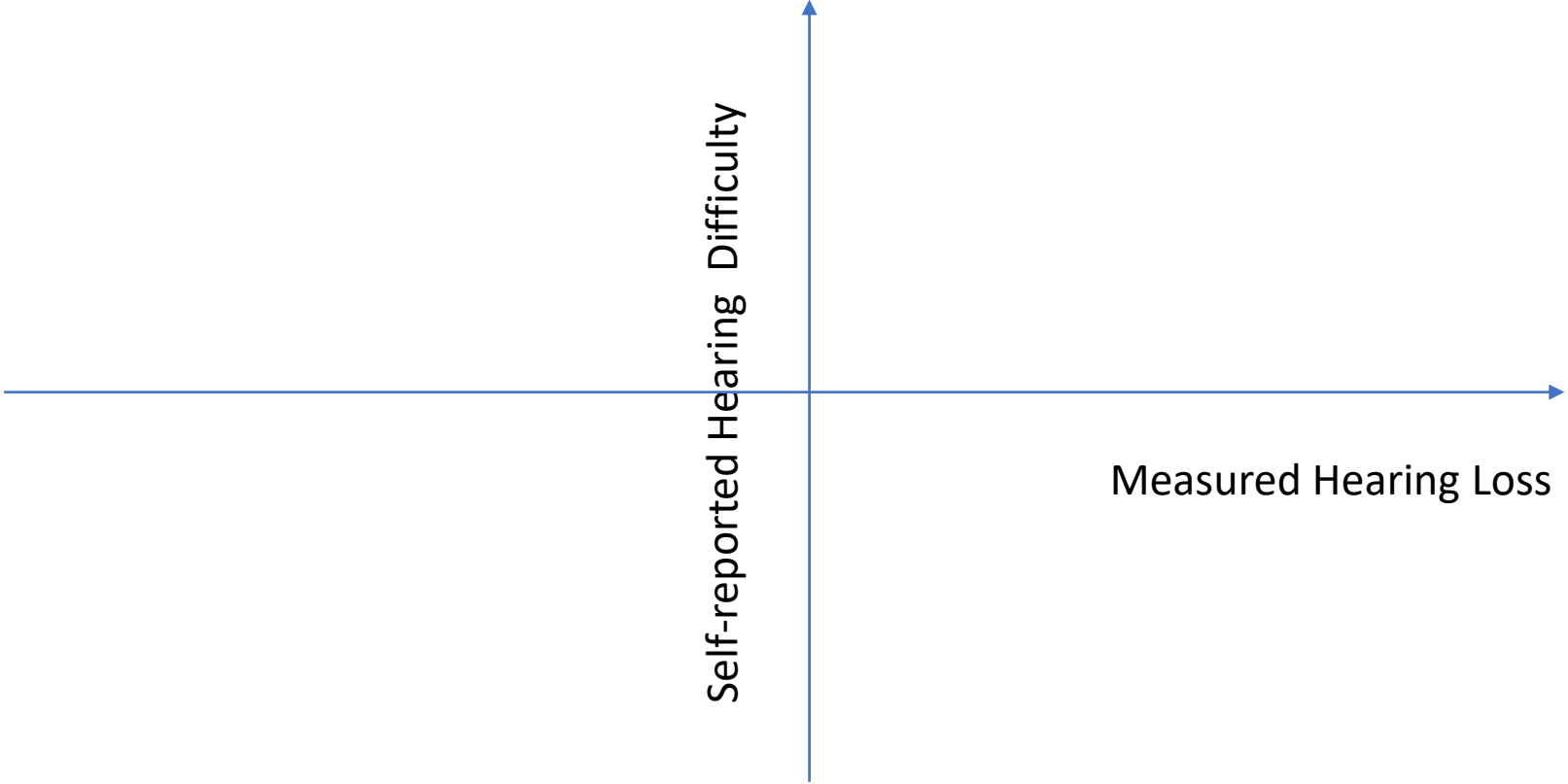


Self-reported Hearing Difficulty - “Normal Hearing”

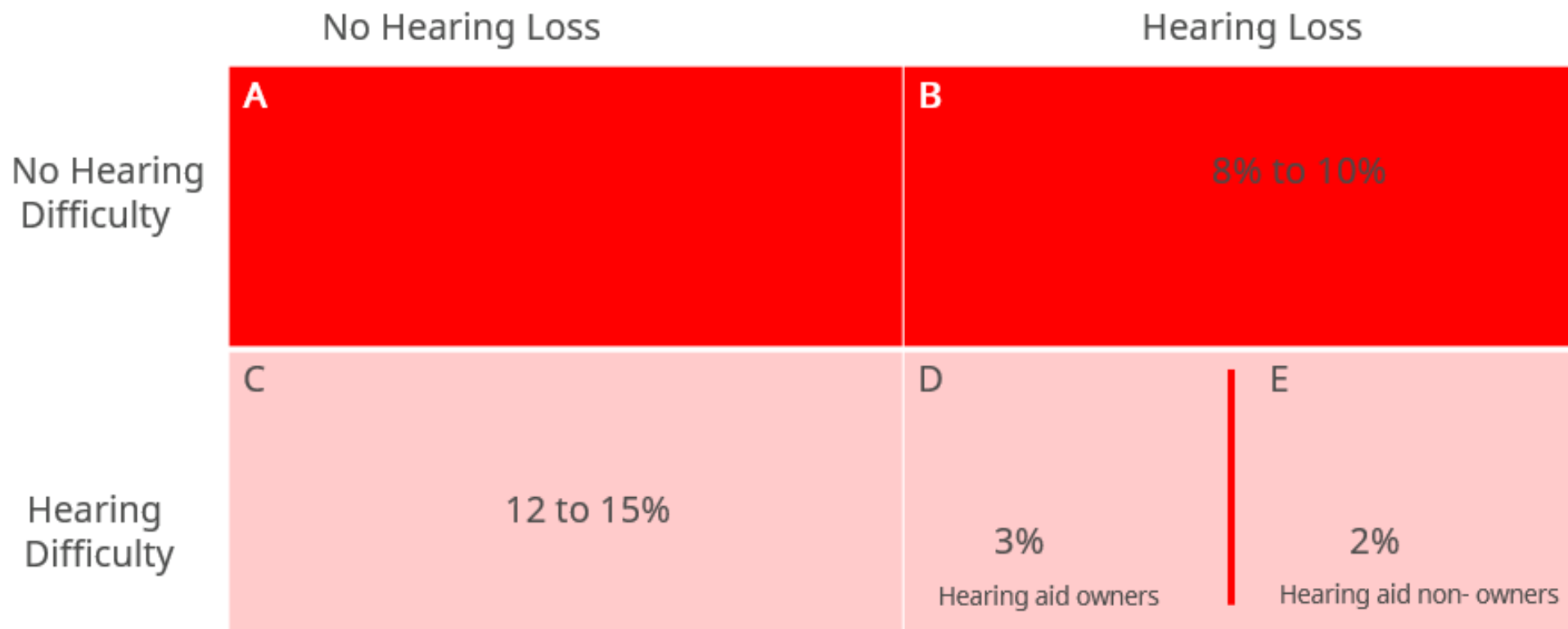


Measured Hearing Loss

# Unmet Needs of the Population

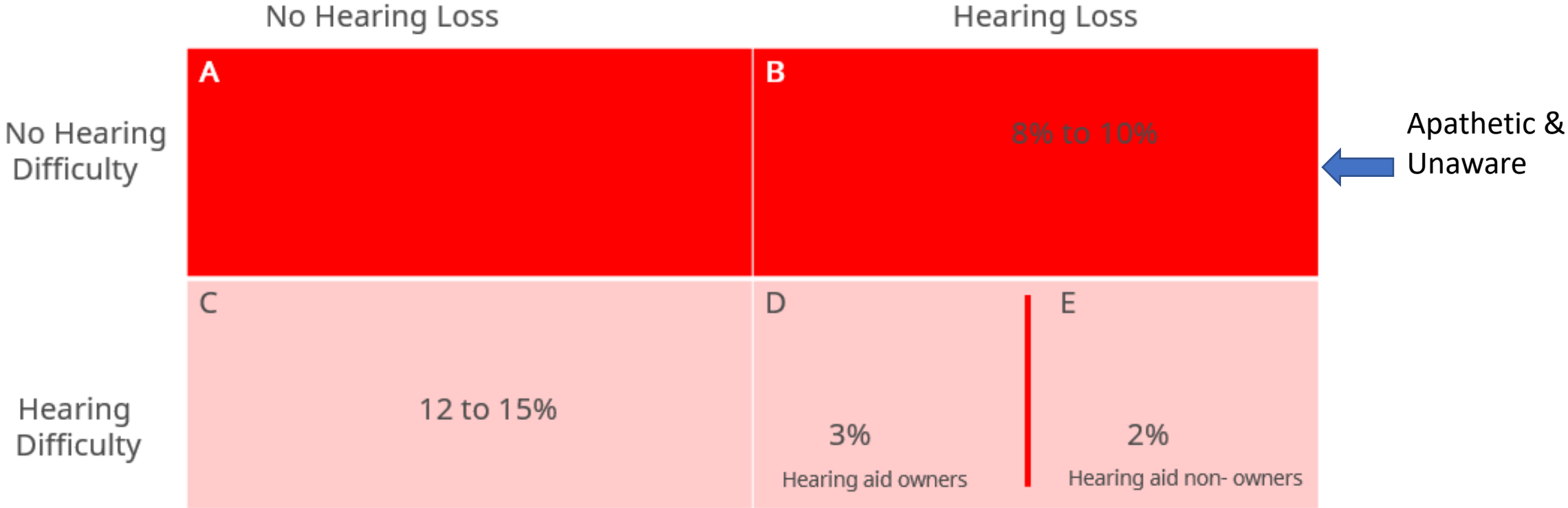


# Where is the unmet need?



% = total US population

# Where is the unmet need?



% = total US population  
Edwards, 2020

↑  
Maybe good  
hearable candidates

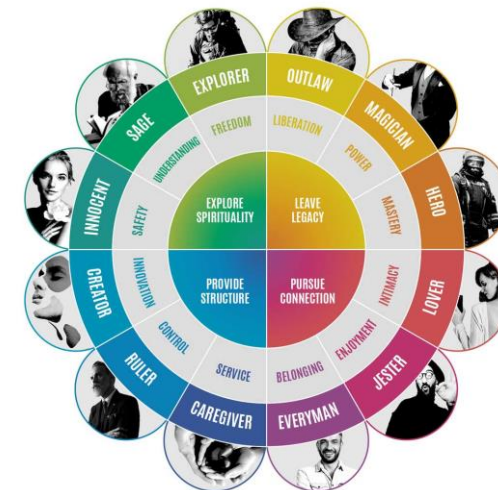
↑  
Rejects traditional,  
professional-driven care



Activate Windows

# Customer Archetypes

- Archetype: A pattern of behaviors and attitudes that describe a group of consumers
- Commonly used in marketing research
- Better understand the emotional connection to purchasing
- Singh & Dhar, 2023 surveyed 1,037 adults – all over age of 50 and hearing aid non-owners
- Published Nov 2023 at AJA





# Two Archetypes in Hearing Health Care

**Explorer**



**Entrusting**



# Two Archetypes in Hearing Health Care

## **Explorer = 453 (44%)**

- Highly independent
- Comfortable buying online
- Verify sources before buying

## **Entrusting = 584 (56%)**

- Rely heavily on influence of others
- Low comfort buying online
- Does not check multiple sources prior to buying

# Which archetype might find OTC appealing?

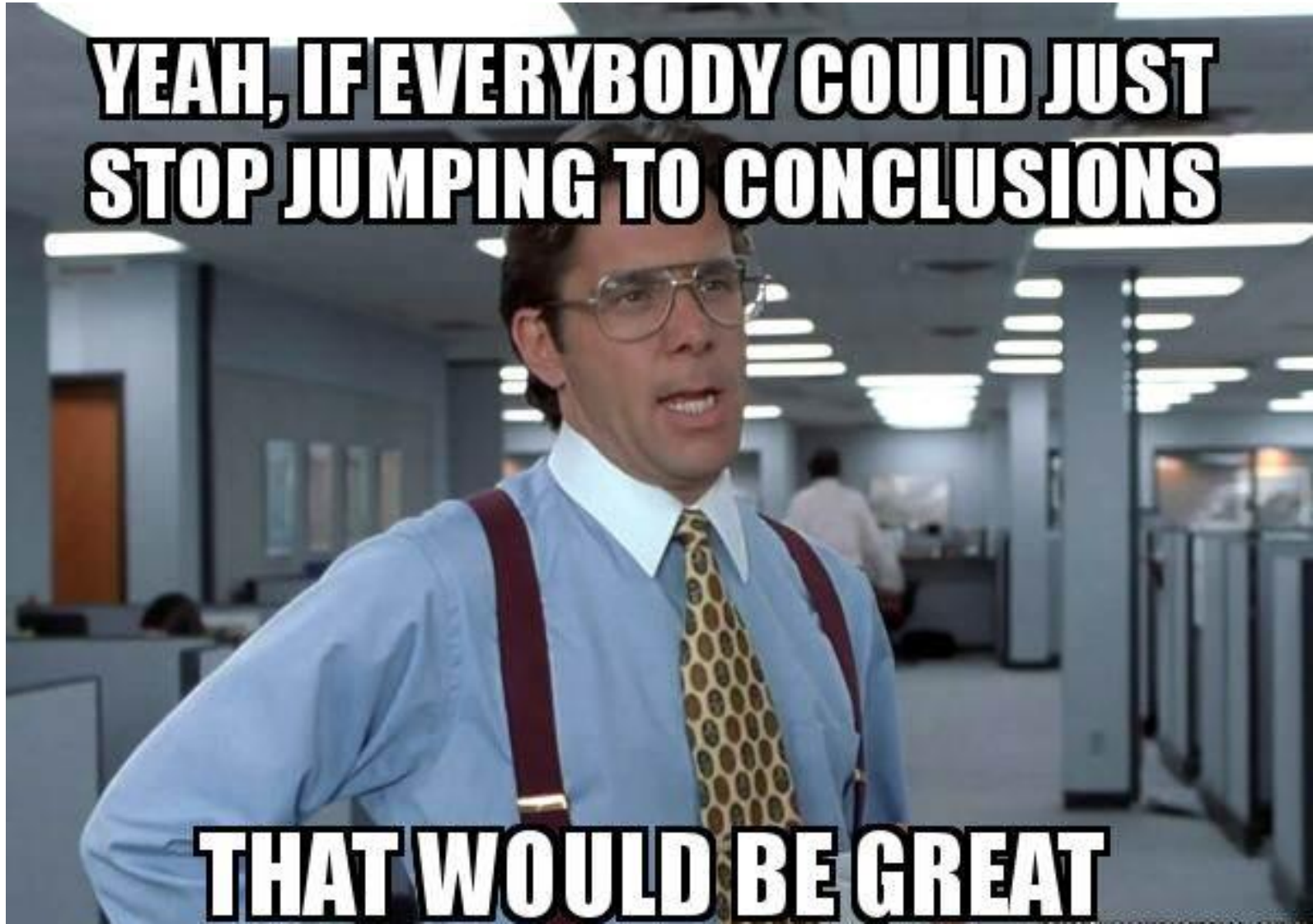
**Explorer**



**Entrusting**



**YEAH, IF EVERYBODY COULD JUST  
STOP JUMPING TO CONCLUSIONS**



**THAT WOULD BE GREAT**

# Key Finding

- Both groups have a strong preference for in-person delivery pathway
- 84% of both groups preferred in-person pathway
- Why?
- Lack of knowledge about OTC
- Lack of trust in OTC pathway

# Developing Your Own OTC Strategy

Key Point: If you can build-out an effective OTC program, maybe you can attract a new market segment or archetype -- Explorers



Not true for OTC – yet!

# Remember ....

## Explorer



## Differentiating Characteristics

- Highly independent
- Comfortable buying online
- Verify sources before buying

# Which archetype might find OTC appealing?

**Explorer**



**Entrusting**





# Two Archetypes

## **Explorer = 453 (44%)**

- Highly independent
- Comfortable buying online
- Verify sources before buying

# Boosting Opportunity and Capability

## Explorer



## Comfortable Buying Online

- Your website needs to have:
  - Vetted self-guided hearing test
  - Vetted devices
  - Thorough educational information

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# Boosting Knowledge and Confidence

## Explorer



## Verify sources before buying

- An outstanding reputation for service excellence
- Service excellence stems from being kind and caring....
- And use of best-practice standards

# Boosting Knowledge and Confidence

## Explorer



## Highly Independent

- Use of decision aids that guide Explorers through the buying process

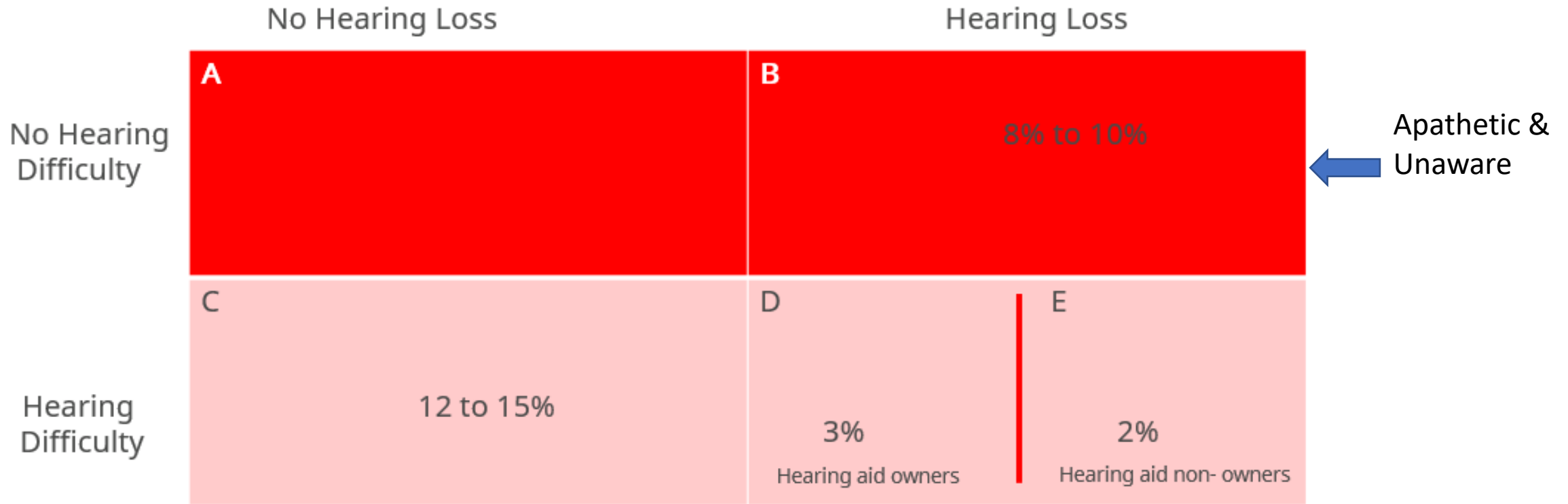
**GENERIC ENT** Hearing Healthcare Treatment Options  
Communication Ability Scale and Corresponding Treatment Options

LOW DIFFICULTY	MODERATE DIFFICULTY	HIGH DIFFICULTY	
			
<b>High Quality PSAPs*</b>	<b>Hearing Aids</b>	<b>Hearing Systems</b>	<b>Cochlear implants</b>
Benefits Include:** <ul style="list-style-type: none"><li>• Improved Audibility in Quiet</li><li>• Improved Speech Understanding in Quiet</li><li>• Limited Improvement in Noise</li></ul>	Benefits Include:** <ul style="list-style-type: none"><li>• Improved Ability in Noise</li><li>• Improved Comfort in Noise</li><li>• Improved Speech Understanding in Noise</li><li>• Localizing of Sounds</li><li>• Telephone Use</li><li>• Listening to Music</li></ul>	Benefits include:** <ul style="list-style-type: none"><li>• <b>ALL THE BENEFITS OF HEARING AIDS PLUS</b></li><li>• Streaming TV Audio</li><li>• Streaming Directly from Phone</li><li>• Remote Companion Microphone</li><li>• Remote Adjustments and Programming</li></ul>	Benefits include:** <ul style="list-style-type: none"><li>• <b>ALL THE BENEFITS OF HEARING SYSTEMS PLUS</b></li><li>• Direct Stimulation of the Inner Ear</li><li>• Optimizes Speech Understanding in Quiet and Noise</li></ul>

\*Personal Sound Amplification Products  
\*\*Benefits are achieved when devices are properly fitted by a professional.

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# Many Explorers are likely in Quadrants B and C



% = total US population  
Edwards, 2020

Maybe good hearable candidates

Rejects traditional, professional-driven care



# “We Carry OTC – and We Do It Better Than Anyone”



- Anyone in your clinic getting a hearing test is probably a better candidate for prescription hearing aids
- Offer bundled options with service included in the fee
- The power of the informed decision – let each patient know OTC devices do not have service included with their purchase price
- “85% of patients need some type of clinic service during the first year”  
- John Tecca, PhD (2018)

# Fee-for-Service OTC Opportunities in Your Practice

- OTC prospects:
  - Hearing test
  - Candidacy evaluation (prescription or OTC?)
  - OTC selection guidance (which OTC?)
- OTC owners:
  - Orientation and training
  - Quality control (2cc coupler)
  - Prescription fitting (REM)
  - Outcome assessment (use of aided testing and self-reports to document benefit and satisfaction)
  - Provide aural rehab or auditory training

# ANSI/CTA-2051 Evaluation



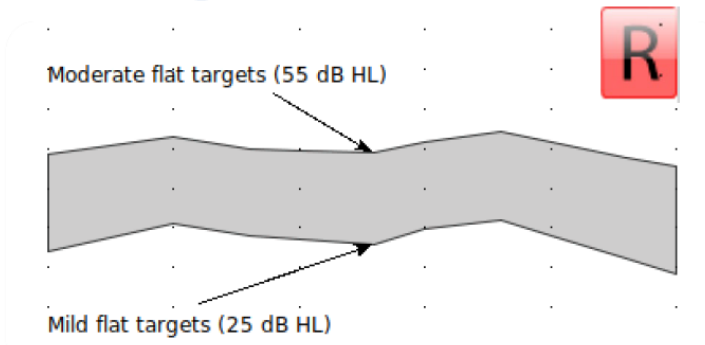
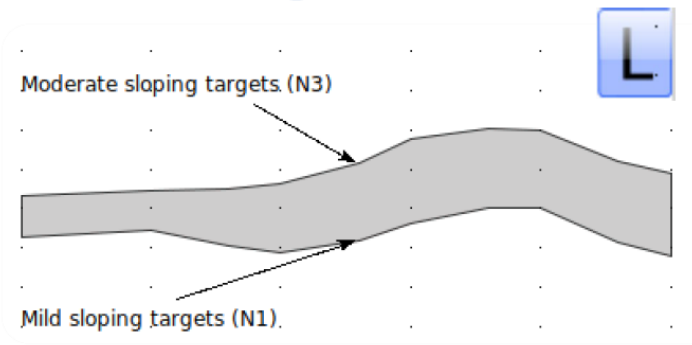
Device measured meets FDA ruling criteria per ANSI/CTA-2051 methods



Device measured does not meet FDA ruling criteria per ANSI/CTA-2051 methods



## Targets & HL Configuration



Stimulus:

Level:  ▼

Targets:

Stimulus:

Level:  ▼

Targets:

23 Audioscan E...

oscar

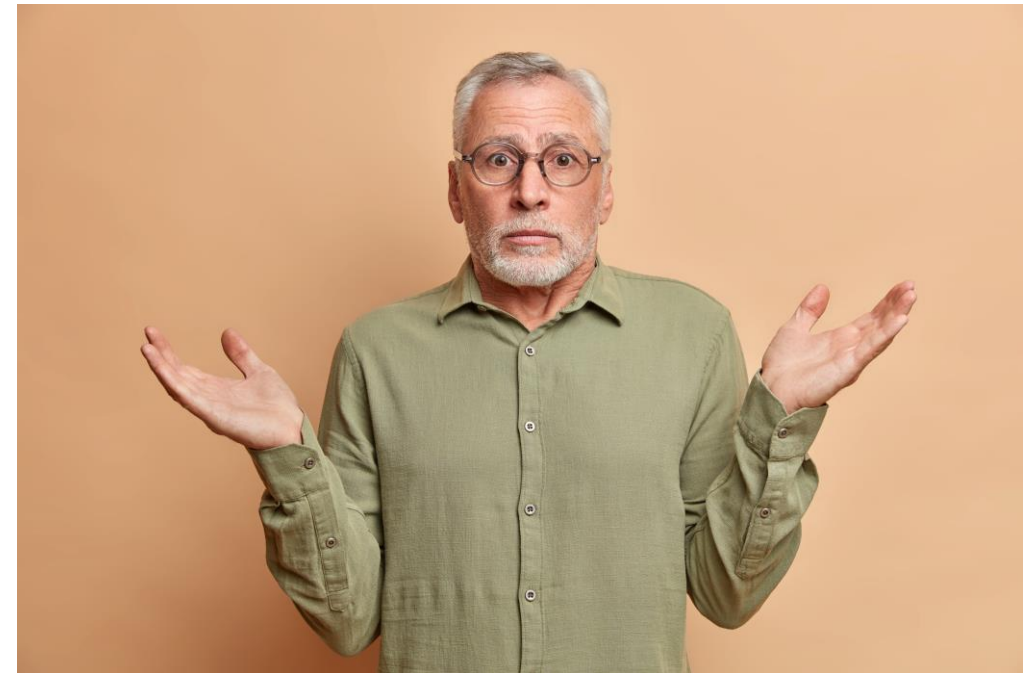


# Service Package

## 1 hour:

- Hearing evaluation
- Quick SIN
- HHIE, COSI or SSQ-12

“Help me decide”



# Service Package

“Help me make the most of these devices”



1 hour: Hearing evaluation including basic assessment plus:

- Quick SIN
- HHIE, COSI or SSQ-12
- REM
- Orientation
- Goal setting

# Service Bundle

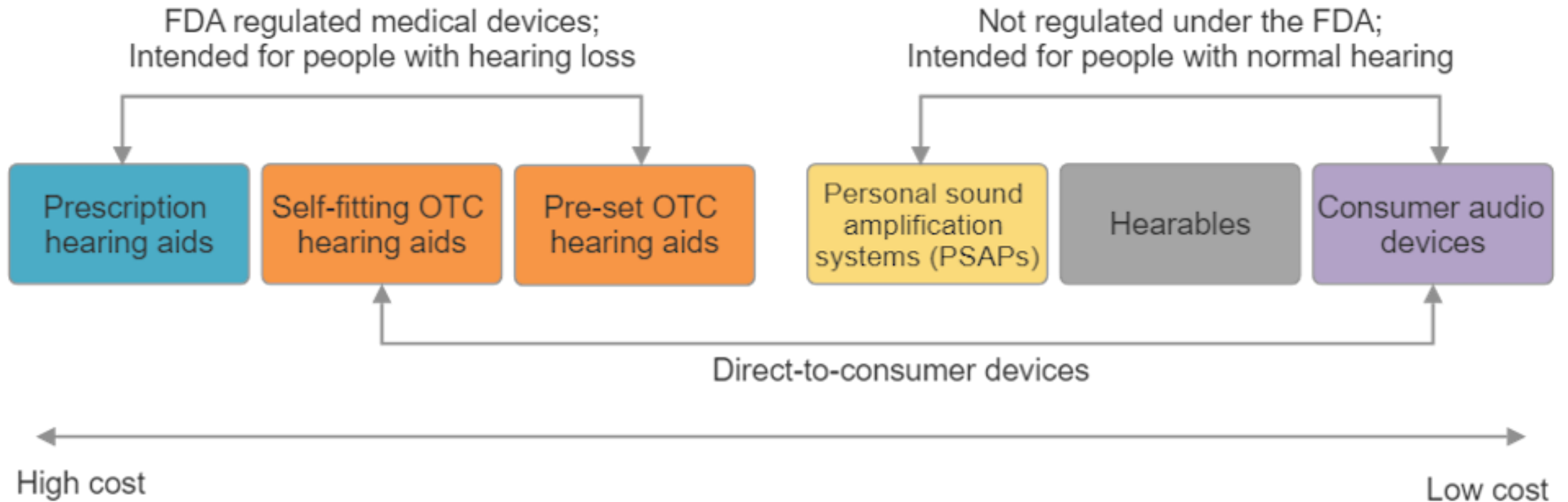
“Help me keep them in my ears over the long haul”



- Service contract
  - Aural rehab/training
  - Annual test and hearing aid check
  - Ear cleaning
  - Renew annual communication goals

# New Device Landscape: Two Pathways

In-person and Over-the-counter



# Conclusions (8 considerations)



1. OTCs are technically feasible, but not yet deemed a practical or effective treatment option by many consumers
2. Apathy is likely the largest root cause of poor hearing aid uptake
3. Use the COM-B Behavior Change Model as a guide for improving uptake rates
4. The Explorer archetype seems to be an excellent segment for OTC, the problem is they need more knowledge and confidence in OTC
5. Use of best-practice standards in your clinic is a great off-ramp for OTC buyers
6. Eagerly provide service for OTC buyers, charge accordingly
7. Dispense OTCs from your website with an effective mechanism to drive patients to your clinic **"Yes, we carry OTCs, and we do it better than anyone."**
8. OTCs speed the patient journey toward earlier treatment

# Questions

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