

Understanding the 2025 Hearing Health Landscape

Bridget Dobyan, JD

Thomas Powers, PhD



Speakers



Bridget Sobek Dobyan is the Executive Director of the Hearing Industries Association (HIA). Previously, Bridget served as HIA's Director of Public Policy and Advocacy from January 2020 to December 2023, where she was responsible for the organization's state and federal legislative and regulatory policy strategy. Bridget brings nonprofit, federal, and state government experience, having previously worked on Capitol Hill as Legislative Director for U.S. Representative Dave Trott of Michigan, as policy advisor to the Michigan Senate, and as government affairs manager for a D.C.-based energy efficiency advocacy organization.



Thomas A. Powers, PhD, serves as an expert audiology consultant (strategic advisor) for the Hearing Industries Association. Dr. Powers received his B.S. from the State University of New York at Geneseo, and his M.A. and Ph.D. in Audiology from Ohio University. He began his career as a partner in an Audiology private practice and has over 35 years of experience in the hearing health care industry.



Our Mission

Trusted voice on hearing health care for product innovation, public policy, patient safety and education.

Our Vision

Improving the hearing healthcare of Americans through medical device innovation.



MarkeTrak (MT)

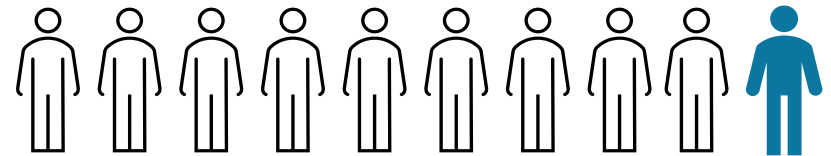
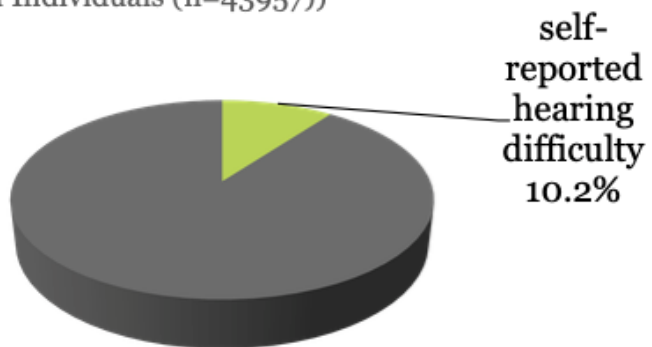
- This study has been conducted for 40+ years:
 - The first eight waves were conducted using a mail survey through the NFO panel
 - The more recent waves have been conducted online using a multi-source sample



MT22: HD Rate

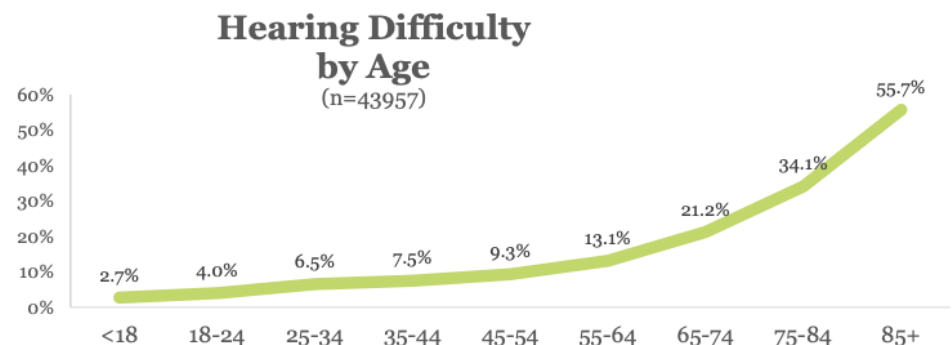
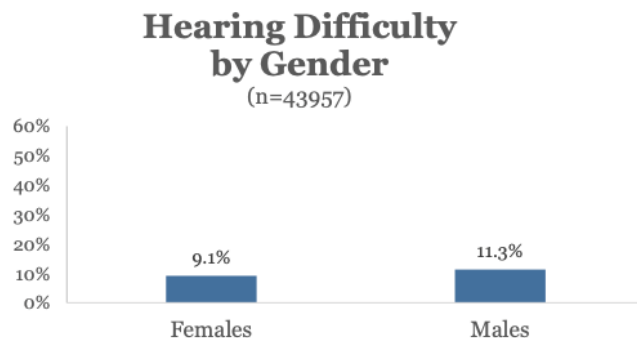
Hearing Difficulty Rate

(All Individuals (n=43957))



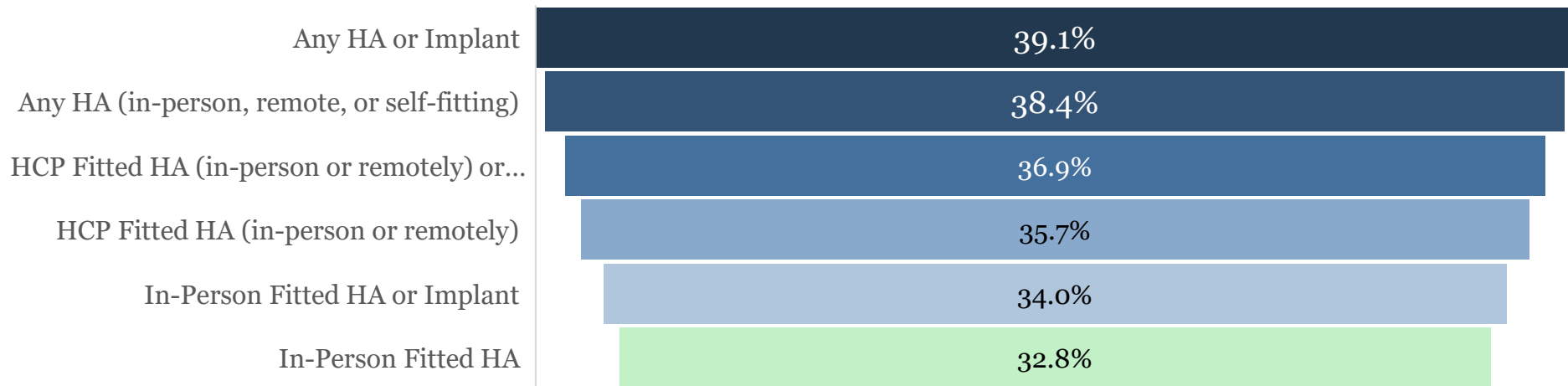
MT22: Demographics

- Across the age groups, the hearing difficulty rates changed in a few of the age groups:
 - The segments with a full percentage point or more increase compared to MT2019 include those 25-34, 35-44, 75-84, and 85+.
 - Most of these differences are fairly subtle, but something to watch going forward.



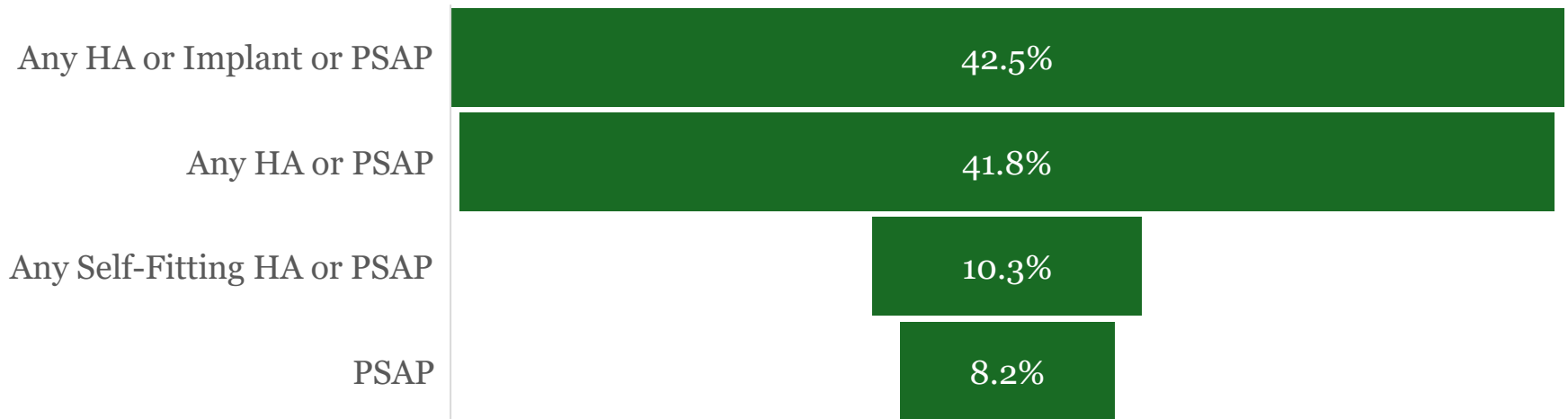
MT22: Adoption

HA Adoption Rates by Device Set Among Those with Hearing Difficulty

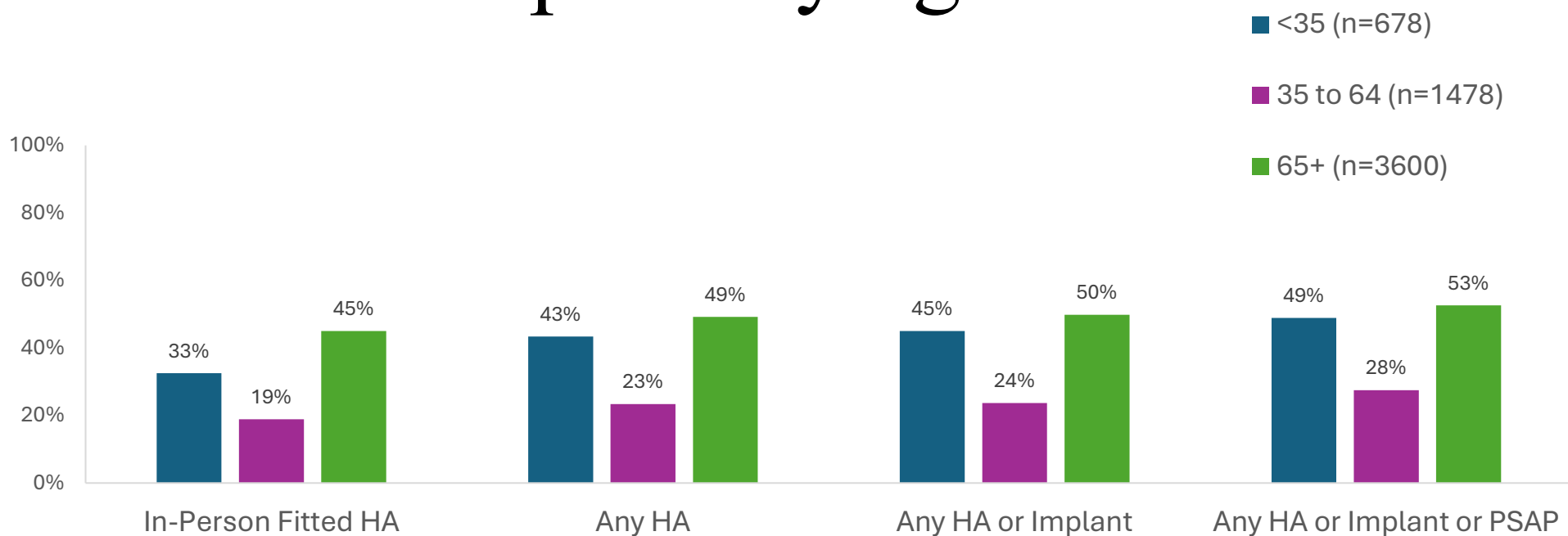


MT22: Adoption

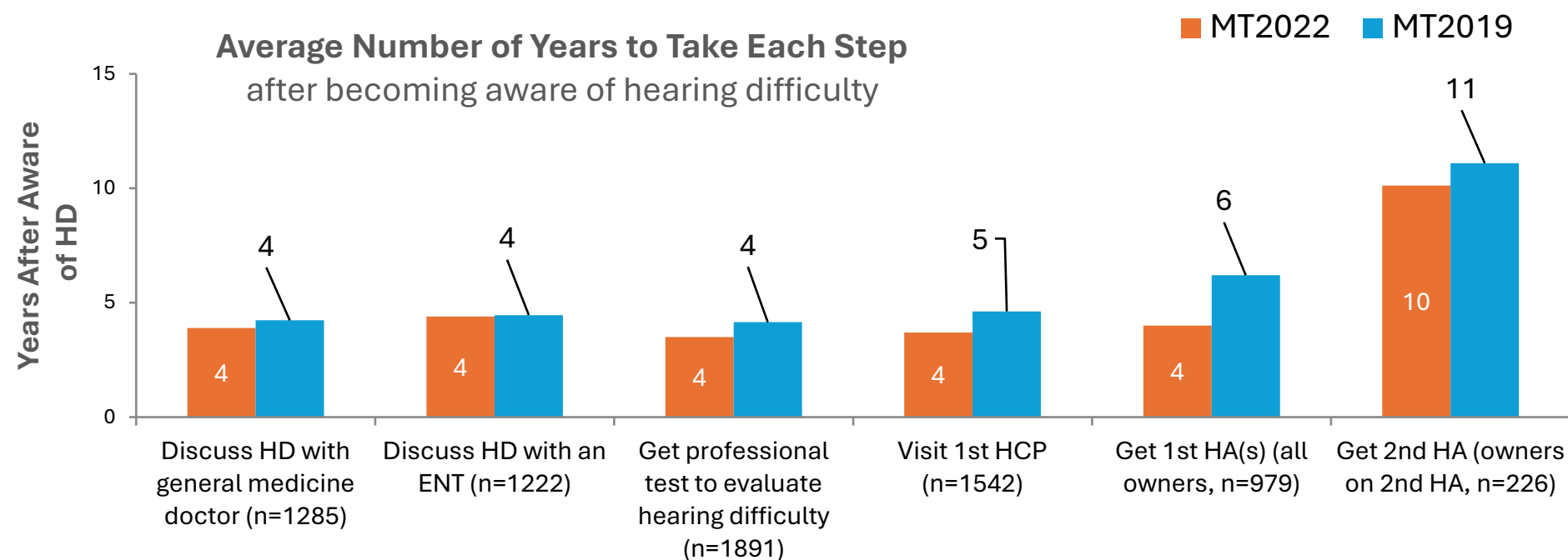
Adoption Rates by Device Type/Set Among Those with Hearing Difficulty



MT22: Adoption by Age



MT22: Years to Take Each Step



MT22: Sources of Information

Info sources/searched:	Total (n= 3218)	HA Owners (n=1139)	HA Non-Owners (n=2079)	PSAP Owners (n=208)	PSAP Non-Owners (n=3010)
Conversations with people who have had a hearing aid	25%	31%	22%	44%	24%
Online searching for general information (on loss, products, etc.)	22%	28%	18%	42%	20%
TV advertisement	21%	18%	22%	40%	19%
Online website for hearing aid manufacturer	19%	25%	16%	40%	18%
Online website for hearing care professional/practice	16%	23%	11%	39%	14%
Print advertisement	13%	19%	10%	35%	12%
Articles in magazines or newspapers	12%	15%	11%	25%	11%
Medical Doctor/Hospital	3%	4%	2%	2%	3%
Other type of advertisement	1%	2%	1%	1%	1%
HCP Office (audiologist, hearing center, etc.)	1%	2%	1%	0%	1%
VA	1%	2%	0%	0%	1%
Insurance/Medicare	1%	1%	0%	0%	1%
Friend/Family	1%	1%	0%	0%	1%
Other	1%	1%	0%	0%	1%
Did not search for/get information on hearing aids beforehand	39%	26%	48%	12%	42%
NET online search: (only counted once if searched multiple sites)	36%	45%	29%	67%	33%

MT22: Social Media

HA Owners:

- Facebook
- Instagram

Non-owners:

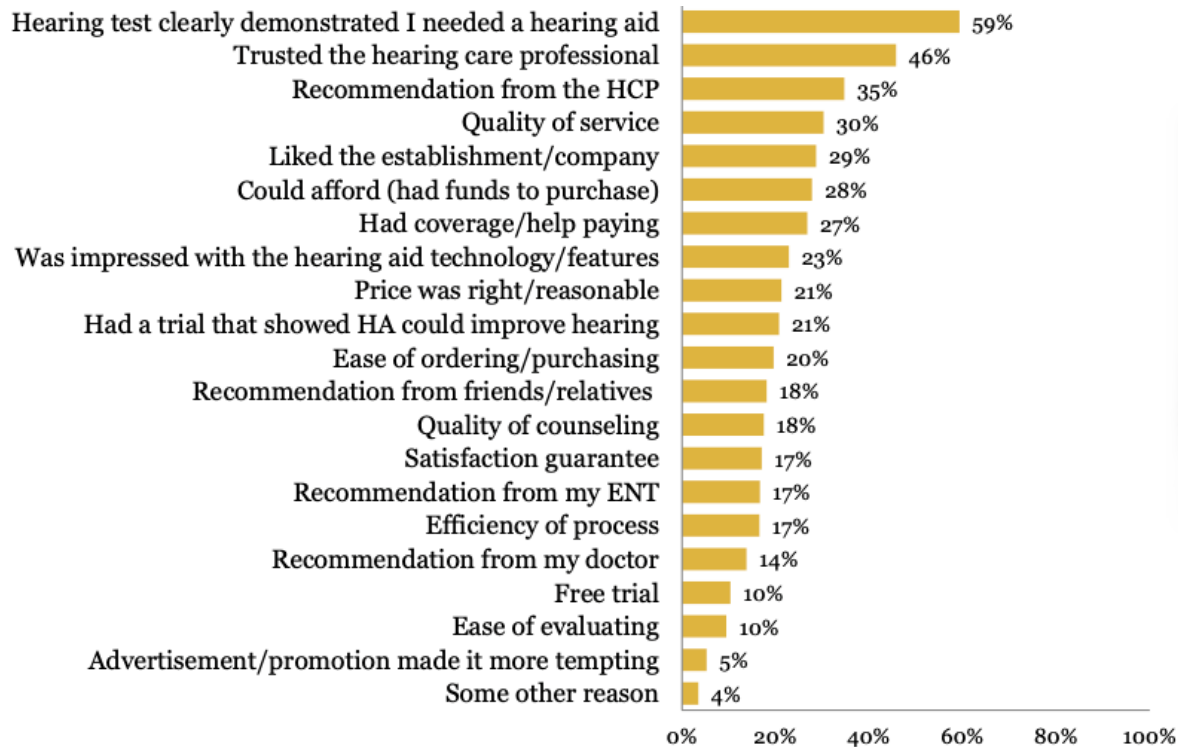
- TikTok
- Facebook

PSAP

- Instagram
- All social media sites



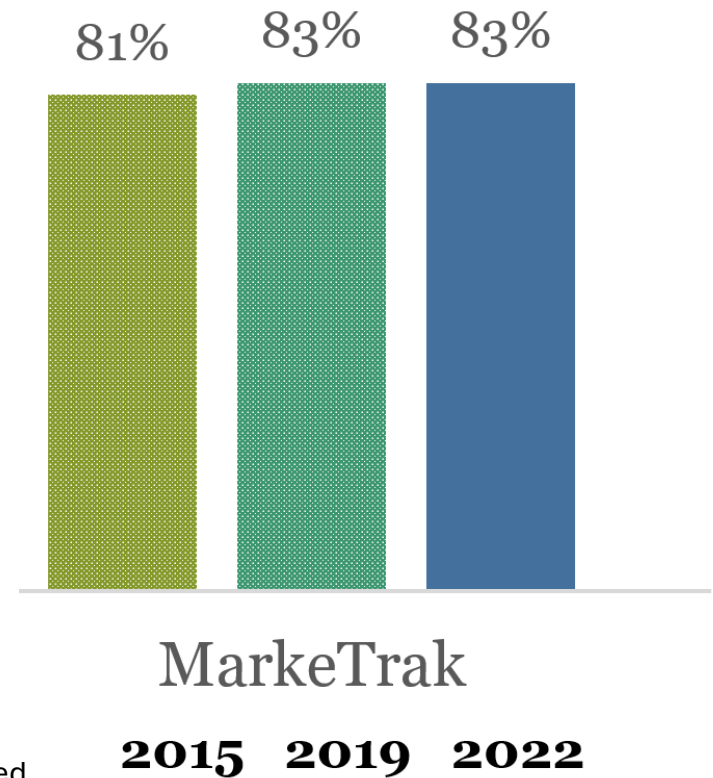
MT22: Motivations



MT22: HCP Satisfaction



MT22: Device Satisfaction



What Has Changed Since MT22?



Regulatory Changes

OTC Hearing Aid rule effective in October 2022

Accessibility



Affordability



Innovation



Policy/Political Changes

- Medicare Advantage provision of hearing health benefits, including professional services and hearing aids
- State-level minimum coverage requirements
- Changing Administrations and political control that drives policy, including coverage, research, and early detection and identification



Amplified Awareness

- Increased media coverage of the importance of hearing health and available treatment options following publication of the OTC hearing aid rule
- Education and awareness campaigns promoting hearing health, sponsored by professional associations, consumer groups, and industry/manufacturers
- New market entrants and innovations



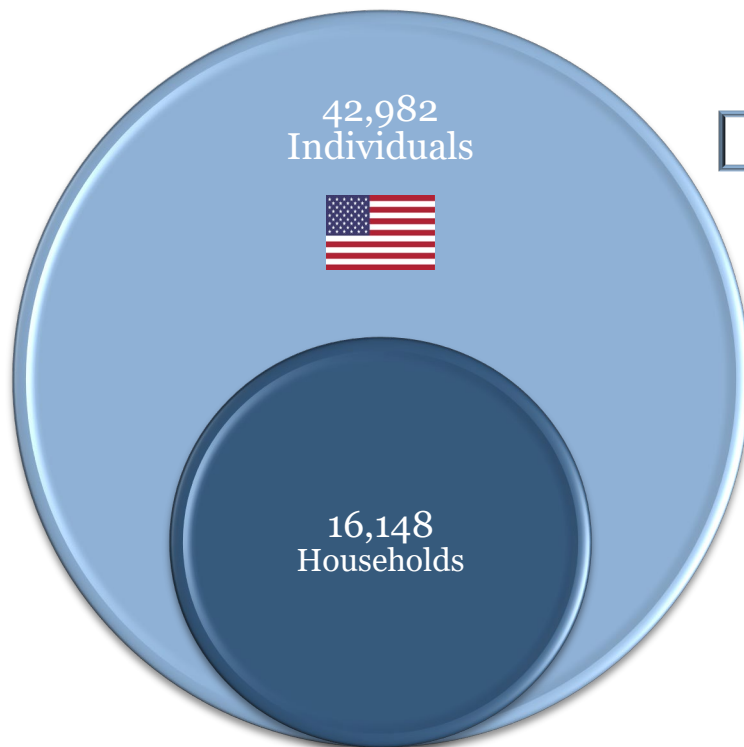


MARKETRAK 2025 (MT25)

MT25

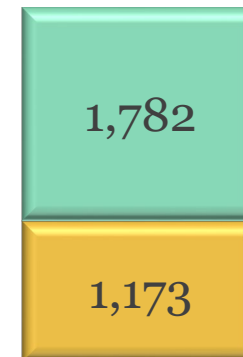
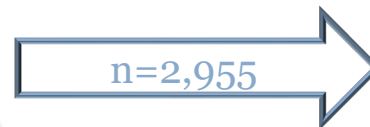
Part-1:

National sample (aligned with Census)



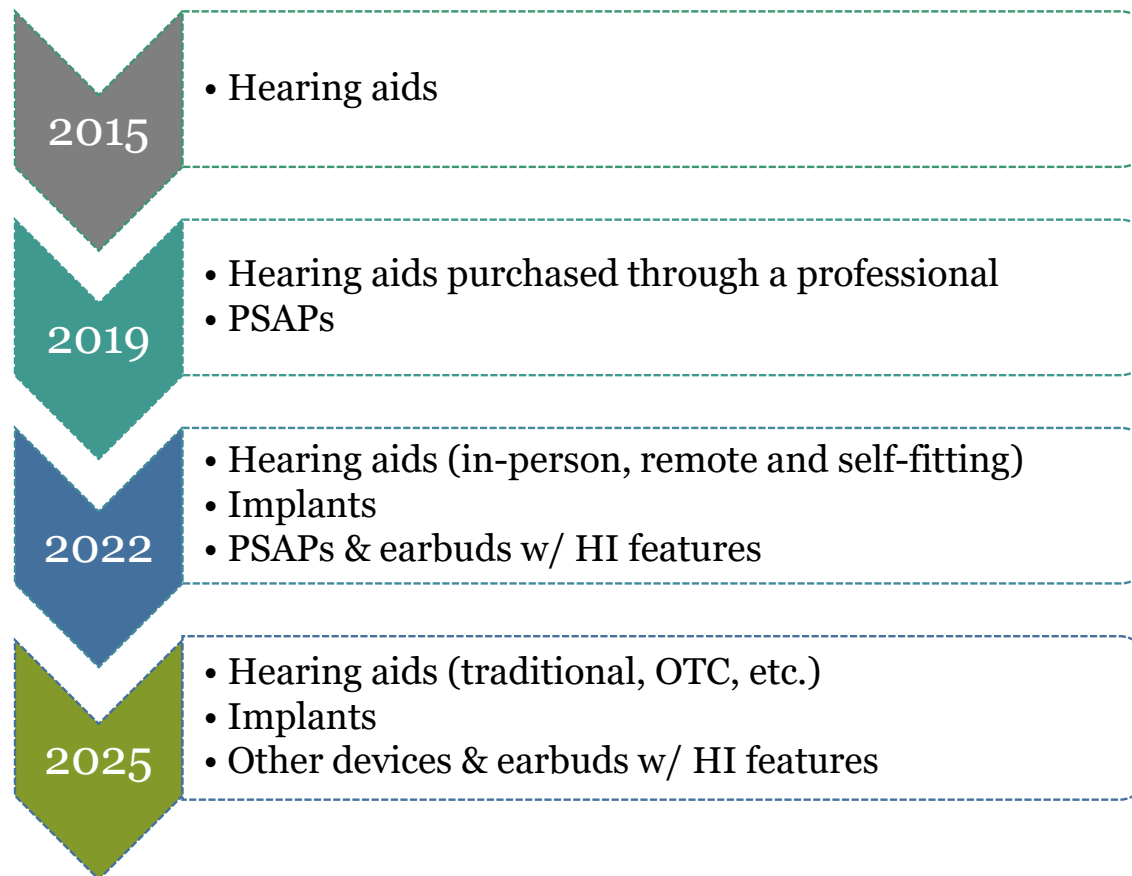
Part-2:

Sample of those with self-reported hearing difficulty provide insight about the journey



■ Non-Owner

MT25: What's Changed



MT25: Hearing Difficulty Rate

Self-Reported Hearing Difficulty Over Time



MT2015

MT2019

MT2022

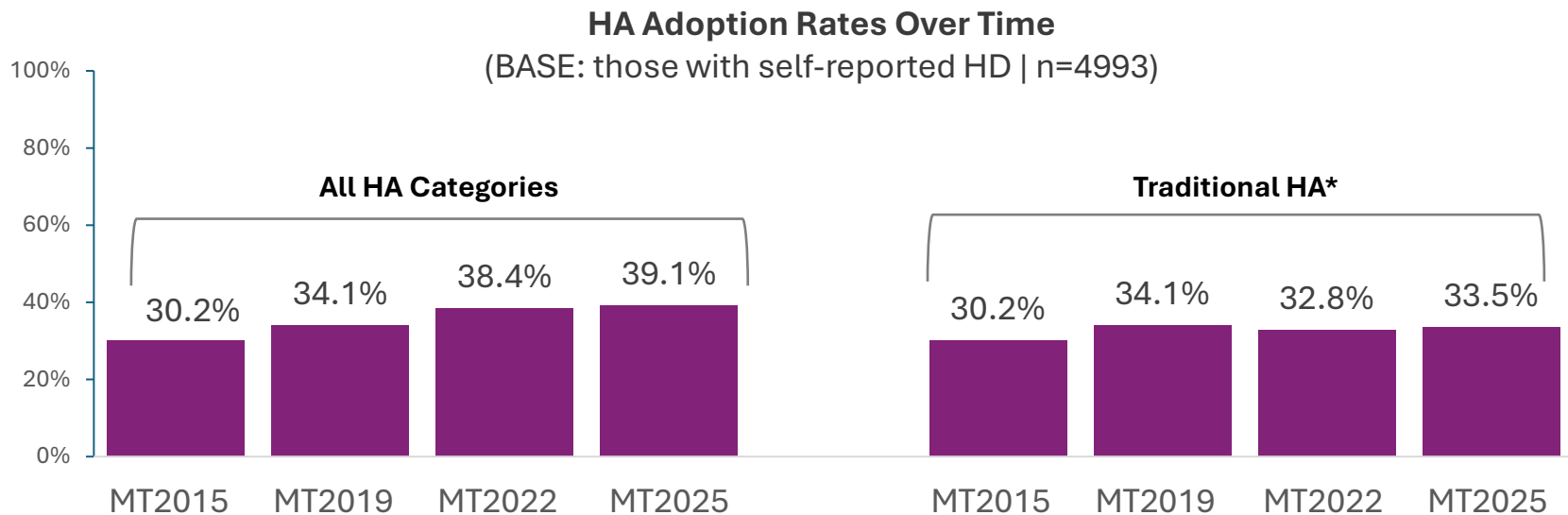
MT2025

MT25: Adoption

HA Adoption Rates by Device Set
(BASE: those with self-reported HD | n=4993)

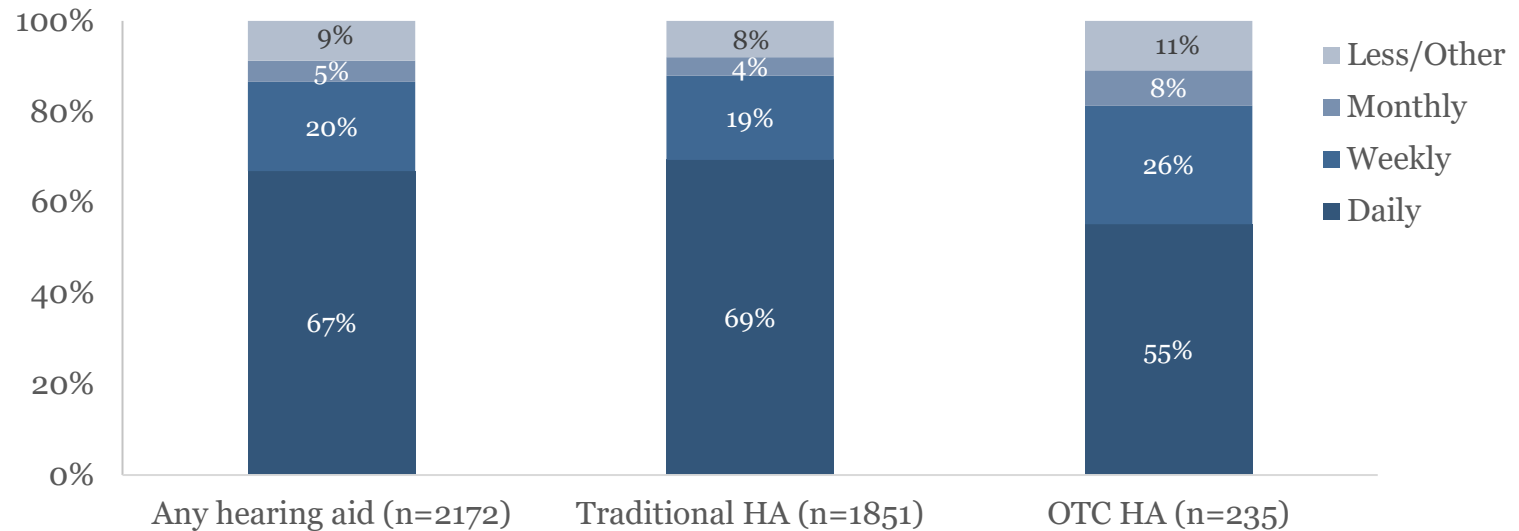


MT25: Adoption Over Time



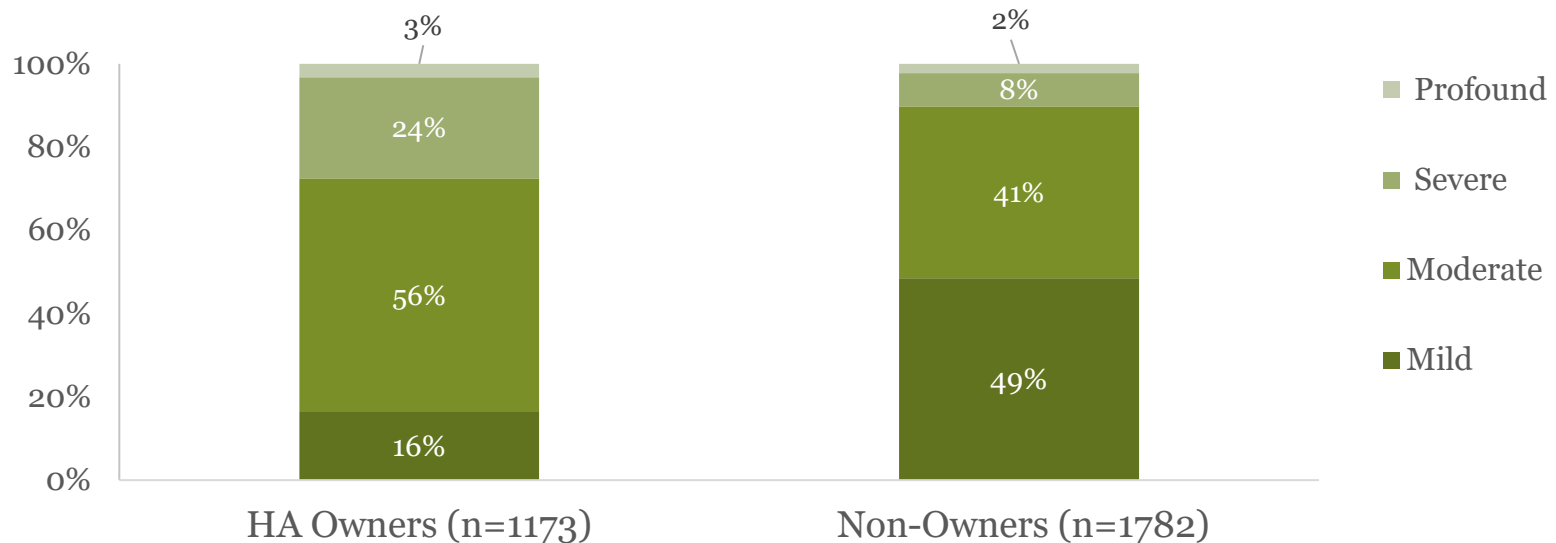
MT25: Wear Metrics

How Often Wear HA (Current Owners)



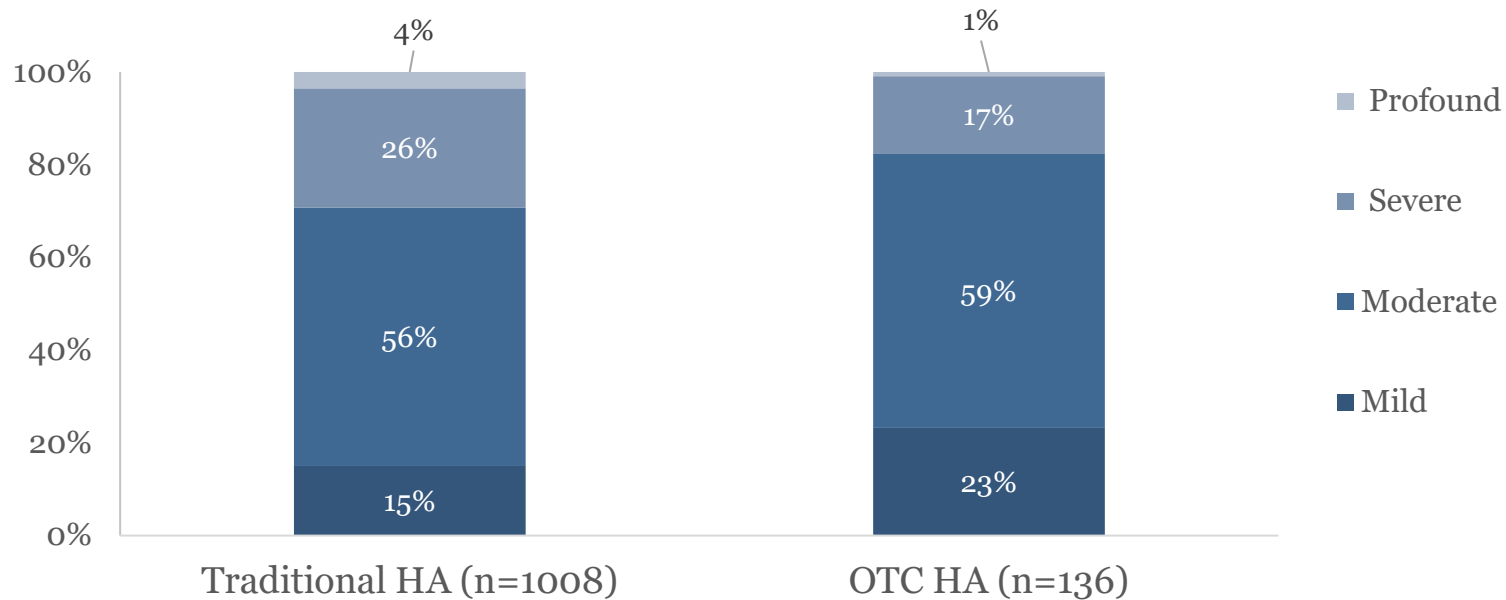
MT25: Degree of Hearing Loss

Degree of Hearing Loss by HA Ownership



MT25: Degree of Hearing Loss cont'd

Degree of Hearing Loss by HA Category



MT25: Motivations

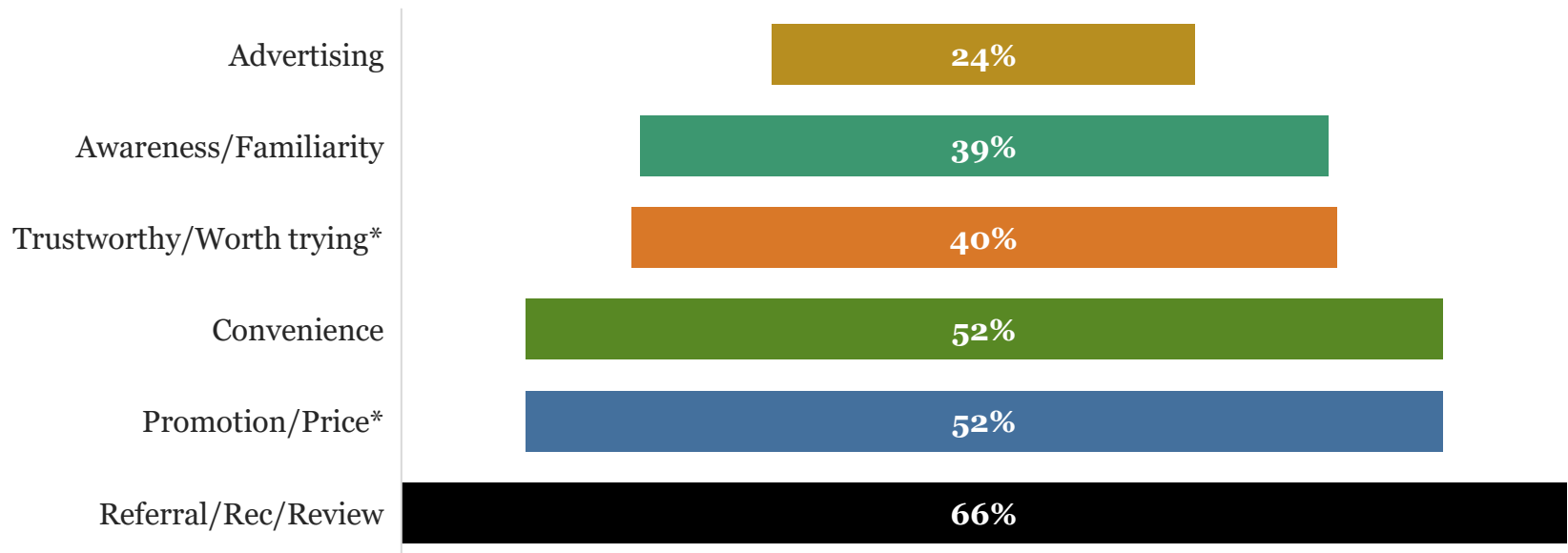
Key BHI Hearing Check Items Top-2 Agreement - 5-point scale (when not using HA or other device)	Traditional HA (n=1008)	OTC HA (n=136)
I have trouble hearing conversations in a noisy background such as a restaurant	90%	89%
Family members and friends have told me they think I may have hearing loss	79%	84%
I have trouble following the conversation when 2+ people are talking	80%	78%
I have trouble understanding audio content on TV, social media and so on	77%	72%
I have trouble understanding the speaker in a large room such as a meeting	73%	65%
I get confused about where sounds come from	46%	51%

MT25: Sources of Information

Info sources/searched:	Traditional HA (n=1008)	OTC HA (n=136)
Discussion with or info from a medical/hearing care professional	59%*	33%
Online search / website / online message	22%	53%*
Input from family, friends, coworkers, hearing aid owners, etc.)	28%	33%
Insurance provider/Medicare/Medicaid	21%	26%
Info/article about hearing loss/hearing aids, etc.	17%	30%*
Advertisement (radio, TV, paper, etc.)	9%	24%*
Store provided / sent info	16%	23%
Social media	5%	15%*
Info event about hearing loss and/or hearing aids/devices	5%	14%*
Did not search for/get information on hearing aids beforehand	14%*	4%

MT25: Reasons to Make Next Step

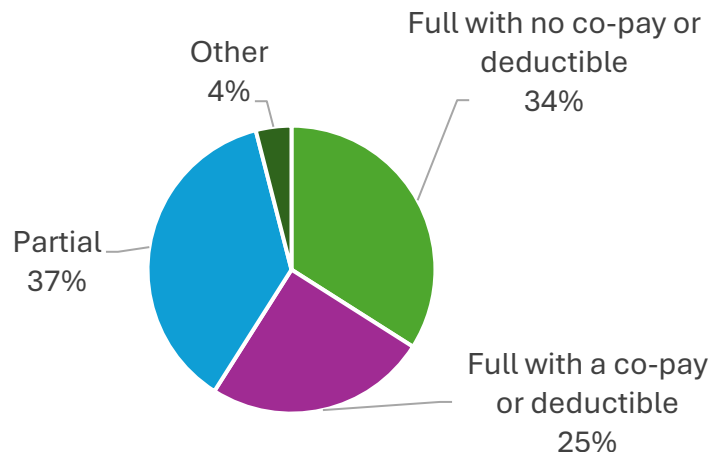
Reasons Visit/Check out Particular Establishments with HAs
(n=1808 Engaged with Establishment) | NET Categories from aggregated responses – multi-response question)



MT25: Coverage

Level of Coverage

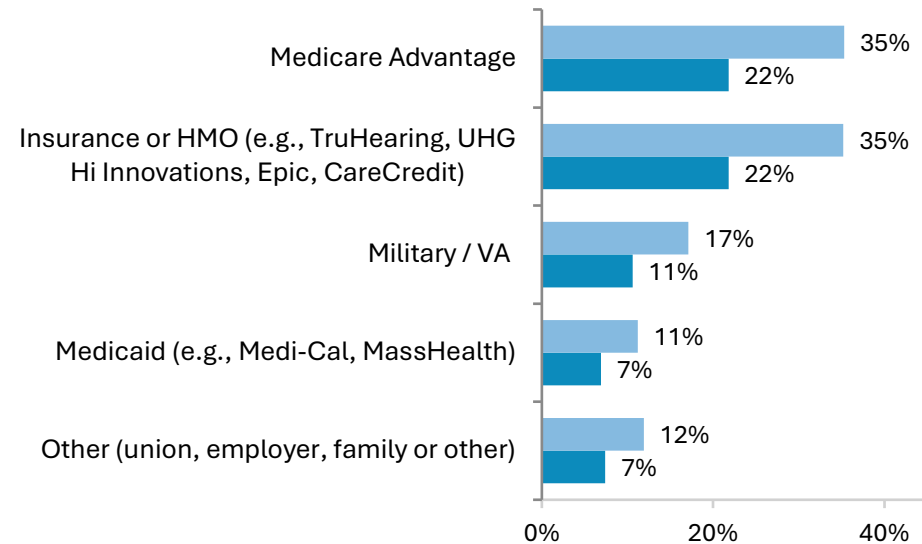
(HA Owners with Coverage (n=719))



Sources of Coverage

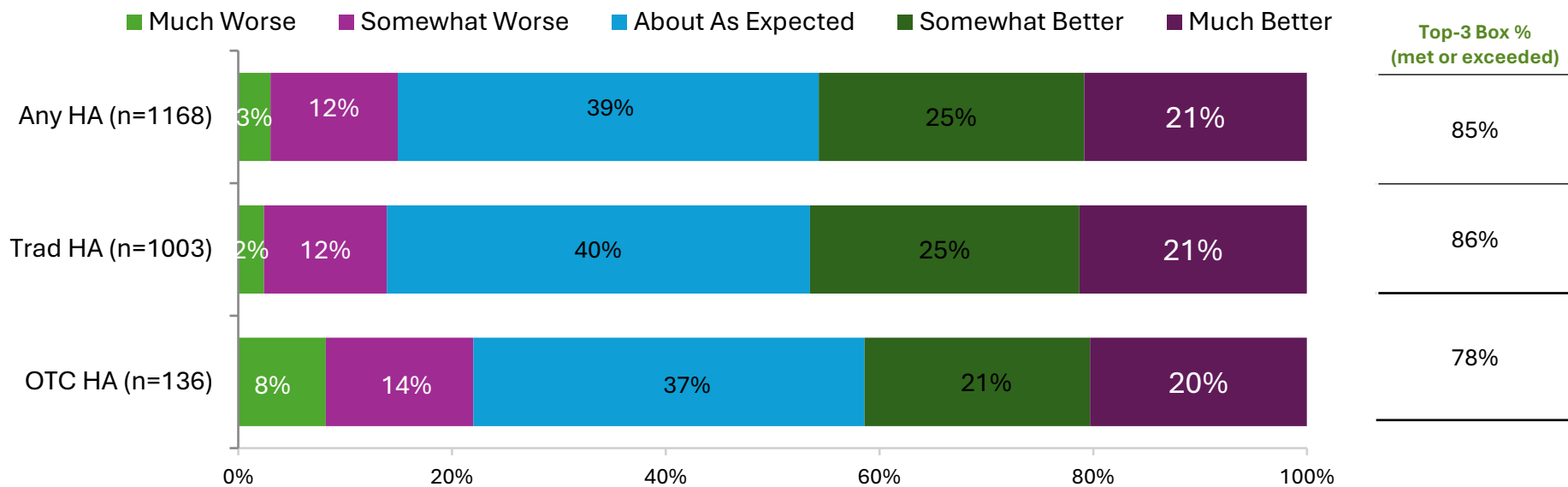
- multiple responses allowed -

■ Owners With Coverage (n=719)



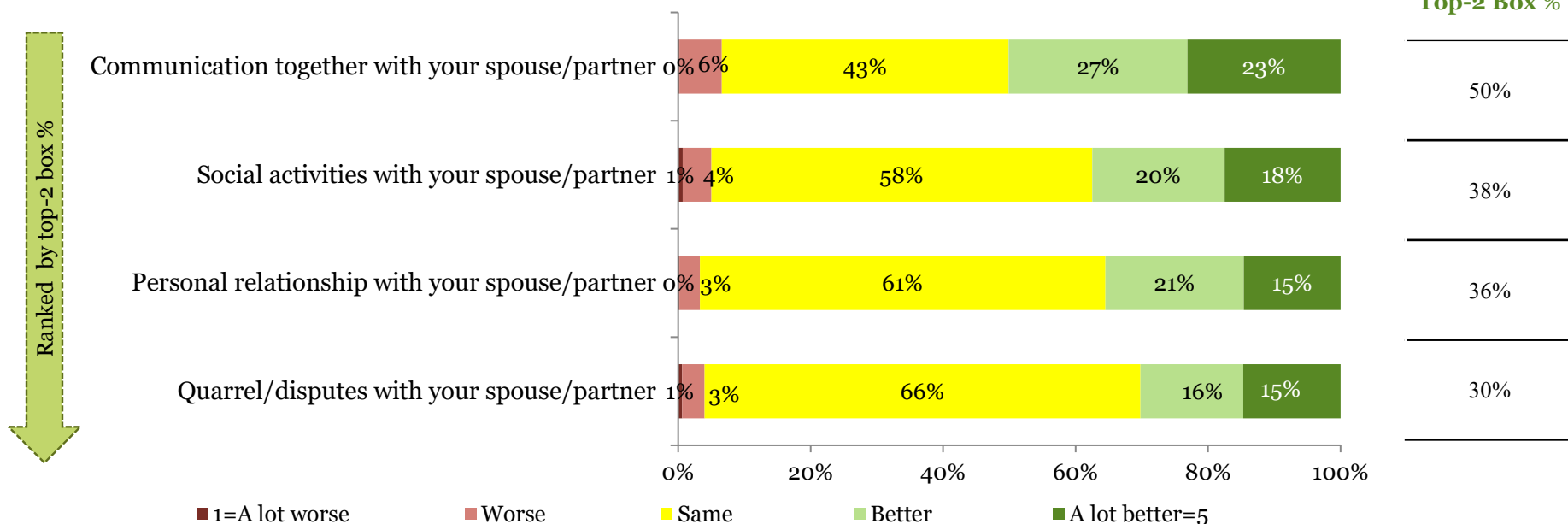
MT25: Expectations

How Hearing Aid Compares to Expectations by HA Type



MT25: Engagement

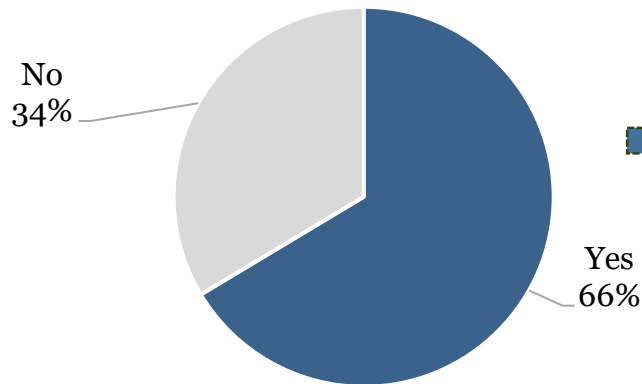
Relationship Changes Since Started Wearing HA (Household Head with HA who has Partner (n=357))



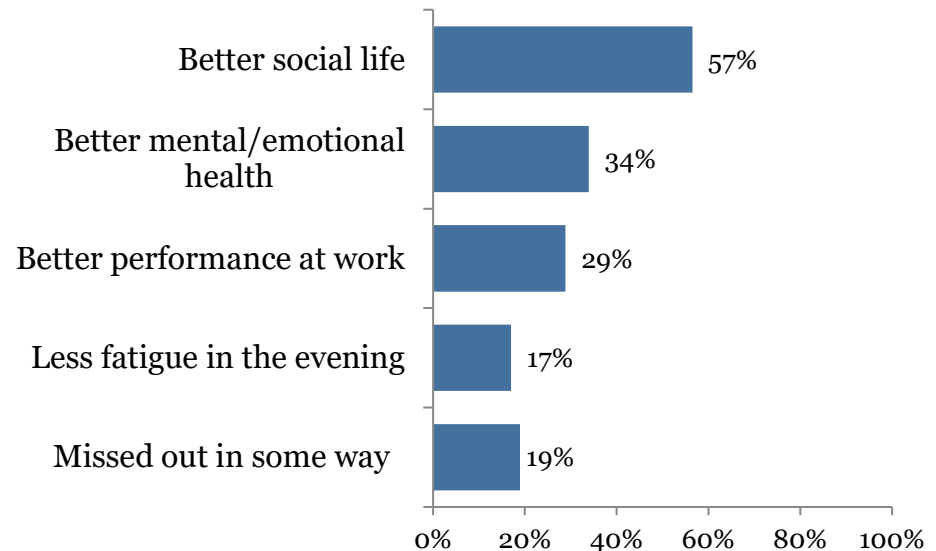
MT25: The Why

- The main reason is an improved social life, followed by better mental/emotional health and better work performance.
- The ratings are similar across both HA categories.

Should have Gotten HA Sooner
(HA Users | n=1130)

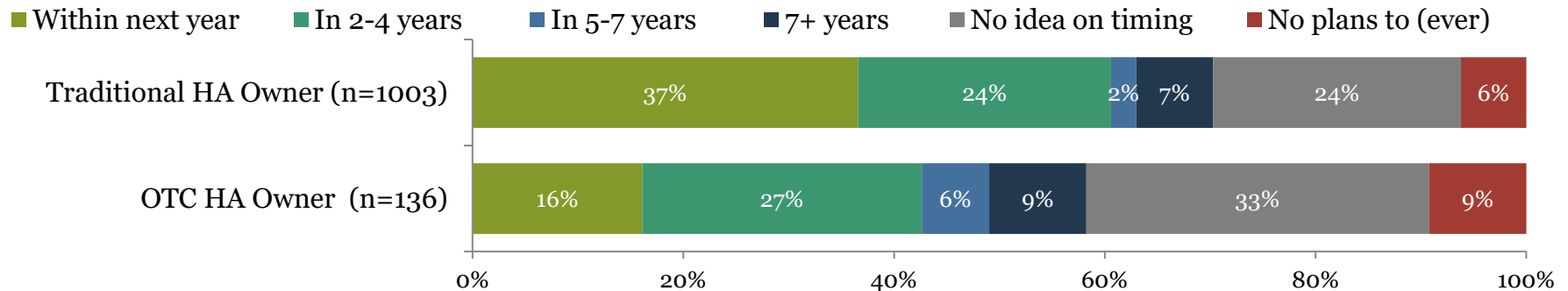


Reasons Should have Gotten HA Sooner
(Among those Wished Gotten HA Sooner | (n=751)



MT25: Next Purchase

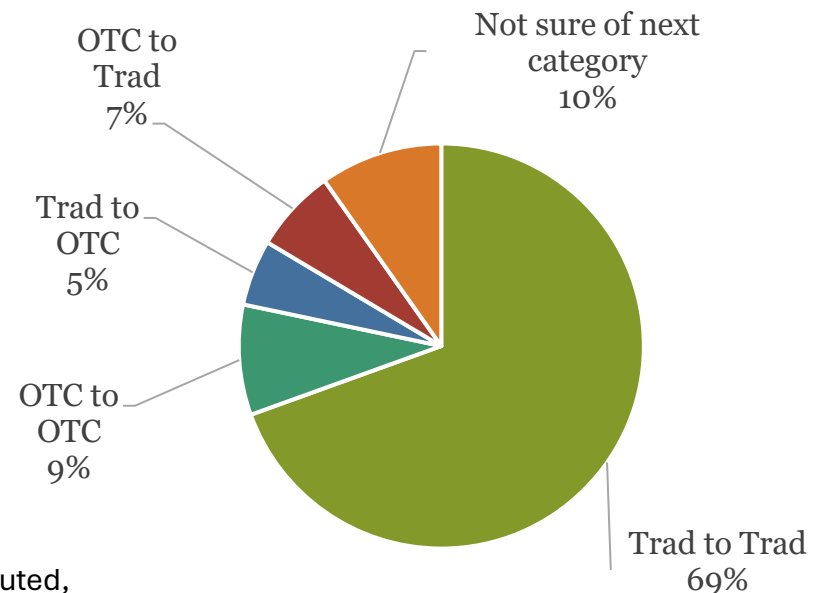
Expected Timing of Next HA Purchase by Category



MT25: Plan to Purchase

- This chart shows the distribution of HA owners based on what category they currently have in combination with what category they plan to buy:
 - The largest group, at seven in ten, are traditional HA owners who plan to purchase the traditional category.
 - The percentage of traditional HA owners who plan to purchase OTC next time is very small in comparison.
 - The next largest group, at one in ten, are OTC HA owners who plan to purchase the OTC category again.
 - Almost as many current OTC owners are leaning toward a traditional HA, however.

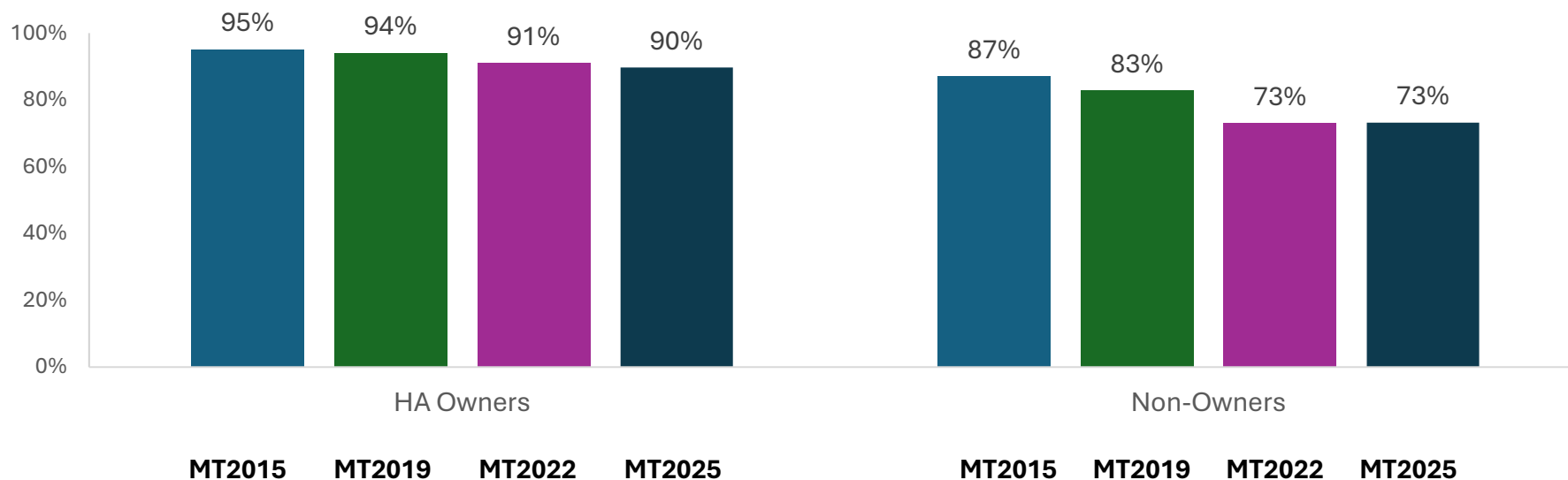
**HA Category Consistency/Switching
among HA Owners who Plan to
Purchase in Next 3 years**
(n=468)



MT25: HCP Satisfaction

Hearing Care Professional Satisfaction Rates Over Time

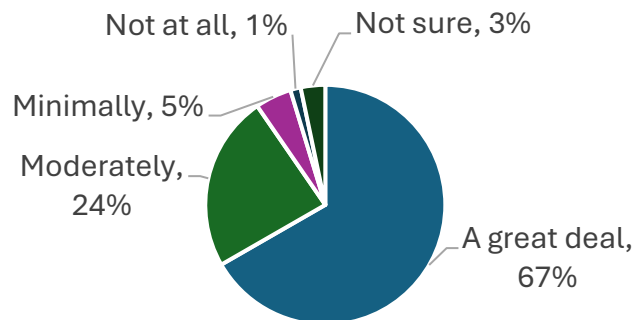
(Top-3 Box: Those Who Saw an HCP [in the Last 5 Years](#))



MT25: How HCPs Help

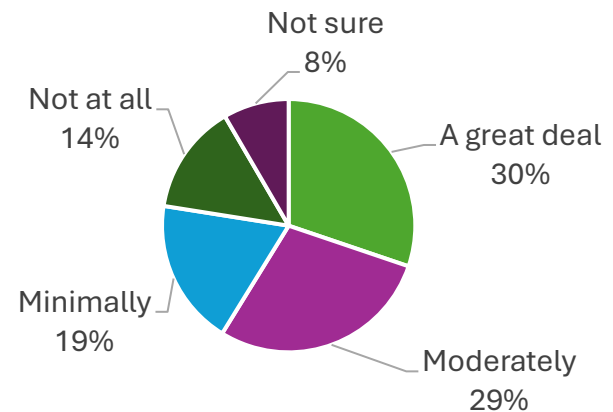
How Much Hearing Care Professional Helped

(Trad HA Owners Plus OTC w/ HCP Assistance (n=1070))



How Much Would Have Likely Benefited From Having HCP Help

(OTC/No HCP Assistance (n=42*))



MT25: Hearing Aid Features

Rechargeable hearing aid which includes an integrated rechargeable battery that is never removed

Program button or switch to change the hearing aid response for different listening environments, like 'Restaurant', 'Outdoors', 'Phone', etc.

Directional, dual, twin, or multiple microphones for enhanced hearing in noisy situations

Telecoil for use with the telephone or for listening in public places that have a special 'hearing loop' sound system designed to communicate wirelessly with some hearing aids

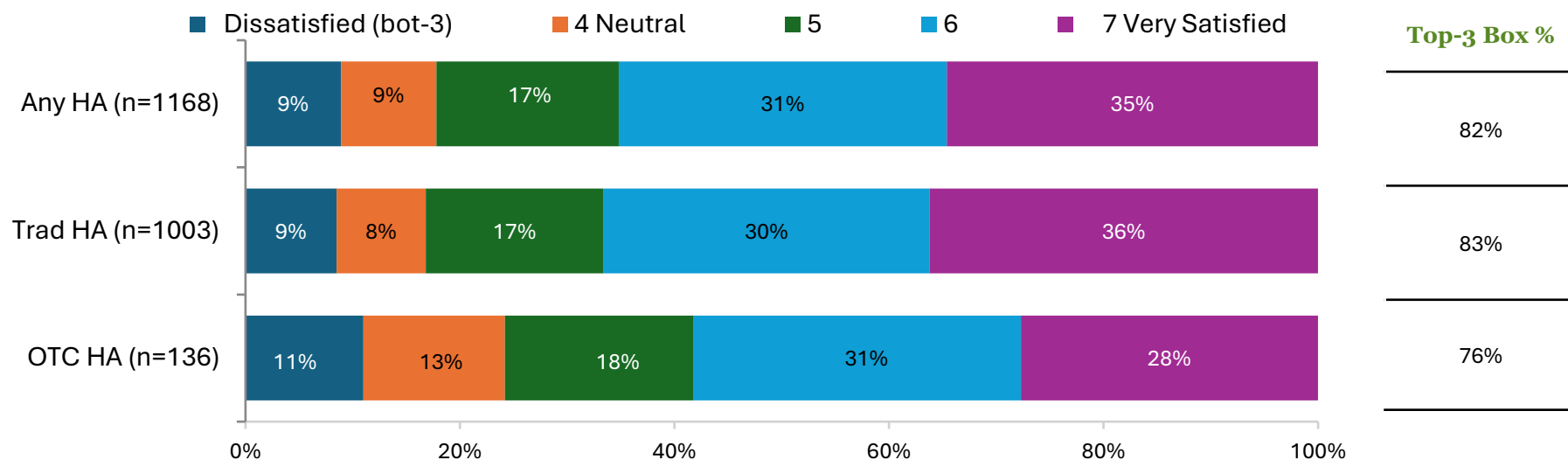
Rechargeable batteries for hearing aids

Tinnitus masker, which masks or reduces the negative effects of tinnitus

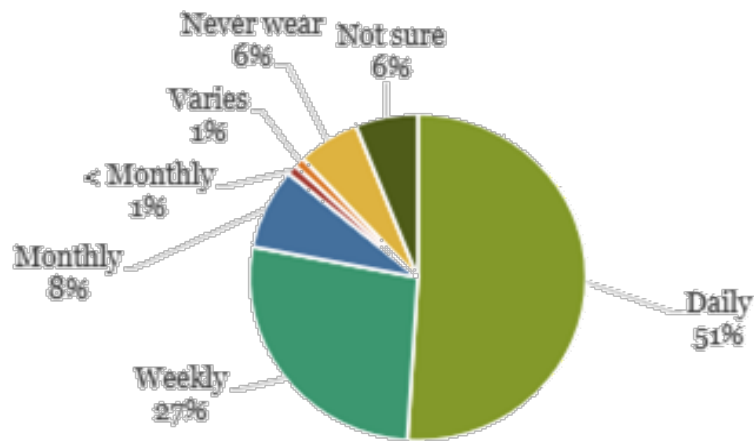


MT25: Device Satisfaction

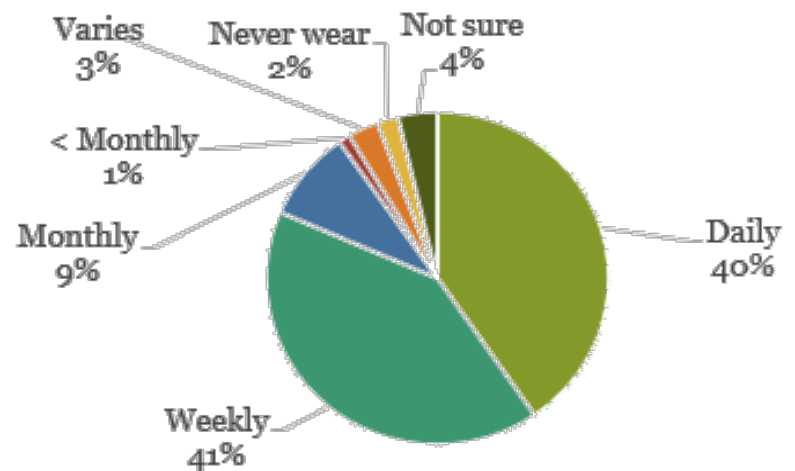
Overall Satisfaction by Category



MT25: Implant Use

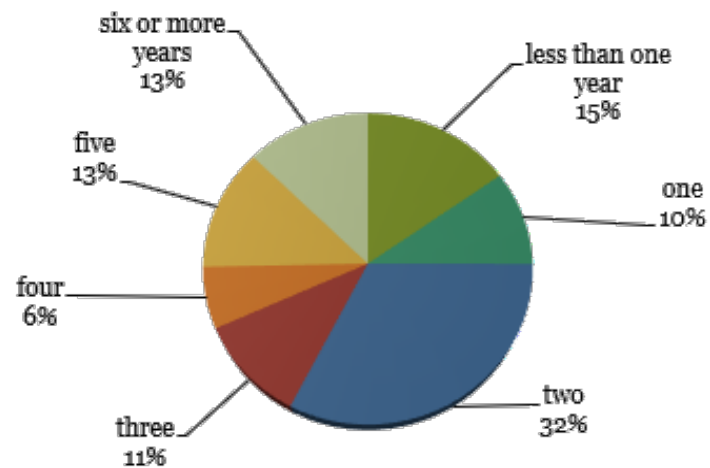


MT22

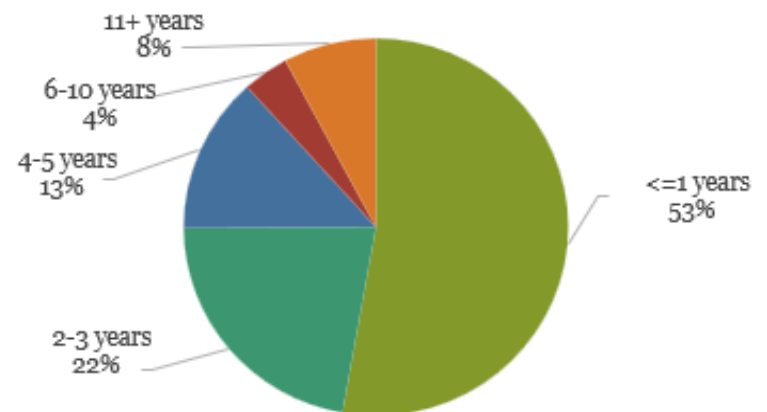


MT25

MT25: Age of Implant

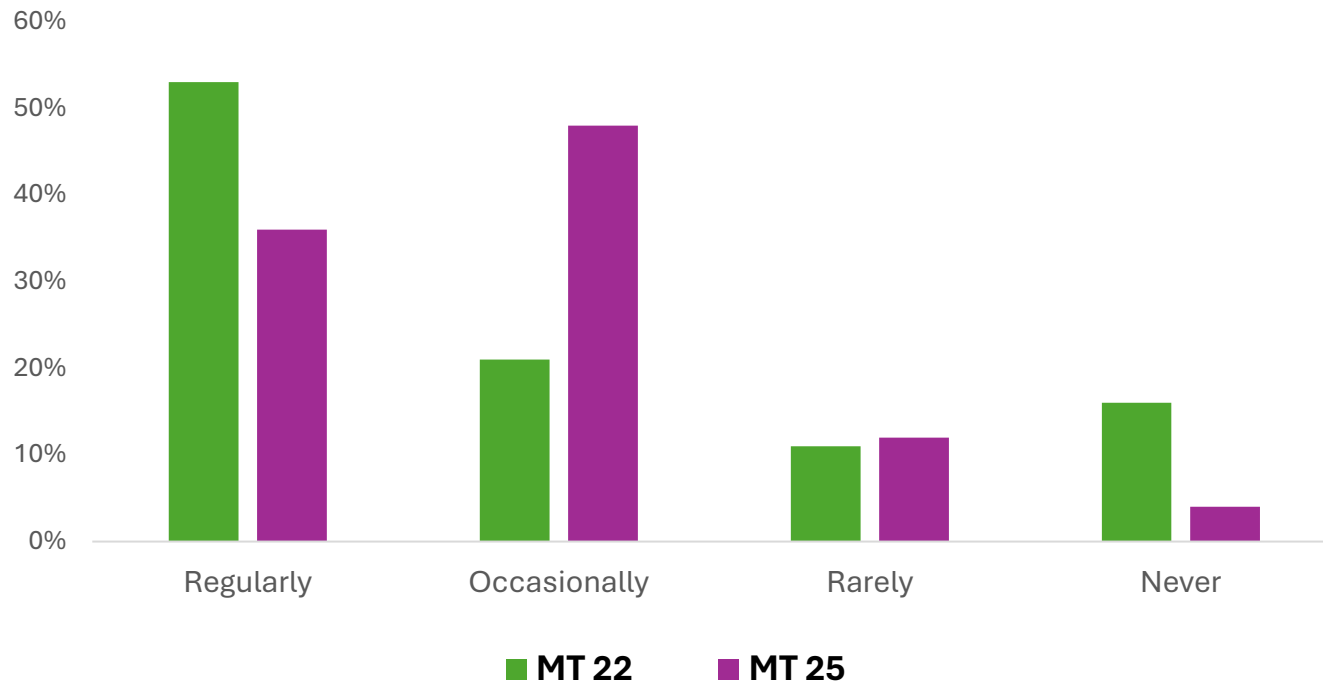


MT22



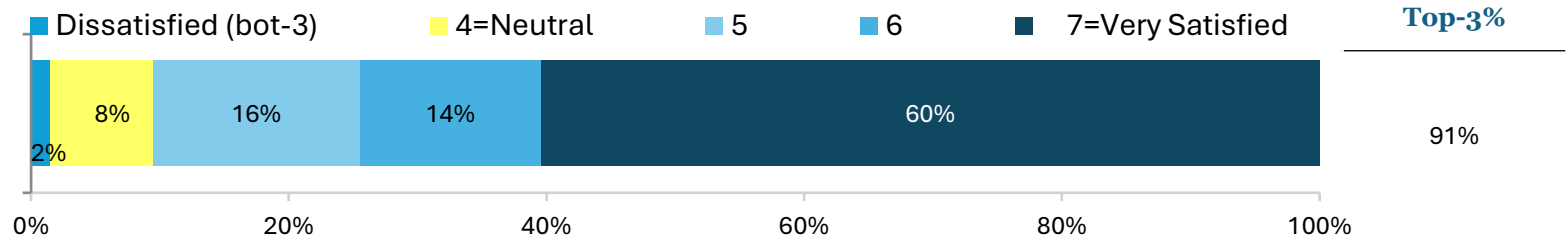
MT25

MT25: Implant & Quality of Life

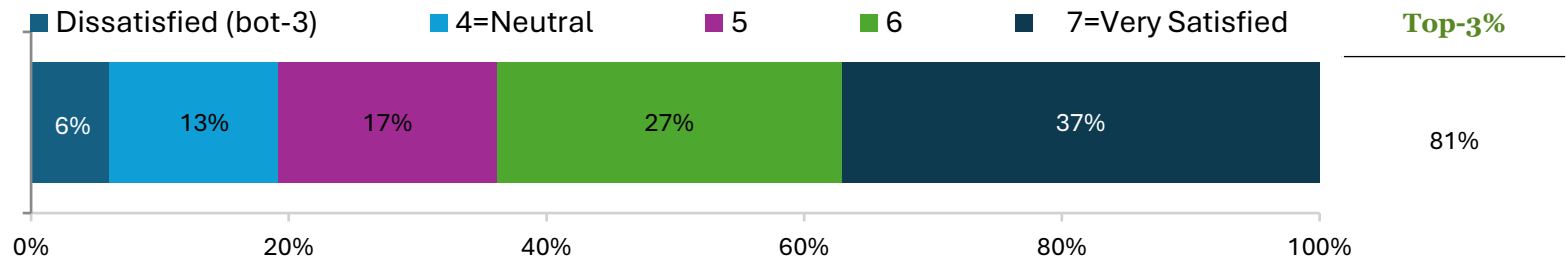


MT25: Satisfaction with Implant

MT22



MT25



Innovations



FDA Search Page



**U.S. FOOD & DRUG
ADMINISTRATION**

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SEARCH

HomeFoodDrugsMedical DevicesRadiation-Emitting ProductsVaccines, Blood & BiologicsAnimal & VeterinaryCosmeticsTobacco Products

Establishment Registration & Device Listing

FDA HomeMedical DevicesDatabases

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

Search Database

HelpDownload Files

Establishment or Trade Name		Registration or FEI Number	
Owner/Operator Name		Owner/Operator Number	
Proprietary Name		Classification Device Name	
Product Code		Establishment Type	
Establishment State (U.S.)		Establishment Country *	

[Quick Search](#)[Clear Form](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Need to update your information? To modify, add, or delete information, log onto your FURLS account.

The changes will appear in the public registration and listing database when it is updated. Please note: There is a delay between the time that the data is uploaded and the time that the data appears in the public registration and listing database. Existing device listings may also be effected by the update and may not be fully viewable until after the update has been completed. Updates are generally completed weekly by Monday evening.

* Category includes Countries, States and Regions

FDA Product Codes for OTC and Prescription(RX) Devices

Product Code	Regulation Number	OTC	Description	Companies Registered
OSM	874.3305	No	Prescription wireless air-conduction hearing aid -- 510k exempt	82
QDD	874.3335	No	Self-fitting hearing aid that may be sold online, RX -- 510k	19
QUG	874.3335	Yes	Preset-based OTC hearing aid , air-conduction, with wireless technology -- 510k exempt	73
QUH	874.3325	Yes	Wireless self-fitting OTC hearing aid that may be sold online AND in stores, pharmacies, etc. -- 510k	30
ESD	874.3300	No	Prescription air-conduction hearing aid -- 510k exempt	100
QUF	874.3300	Yes	Preset-based OTC hearing aid , air-conduction -- 510k exempt	64

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OTC Software as a Medical Device

Software as a Medical Device (SaMD): Clinical Evaluation

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 8, 2017.

The draft of this document was issued on October 14, 2016.

For questions about this document, contact the Office of the Center Director at 301-796-6900 or the Digital Health Program at digitalhealth@fda.hhs.gov.

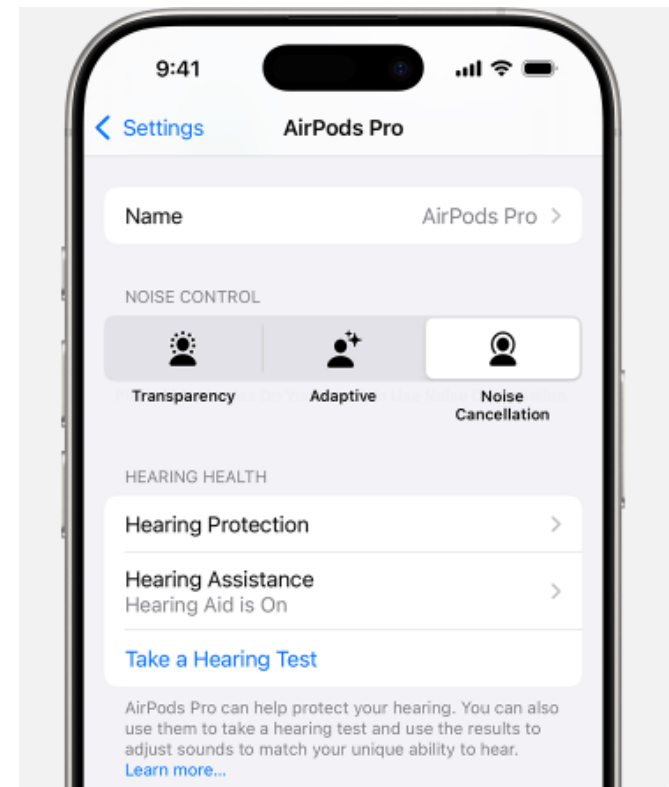
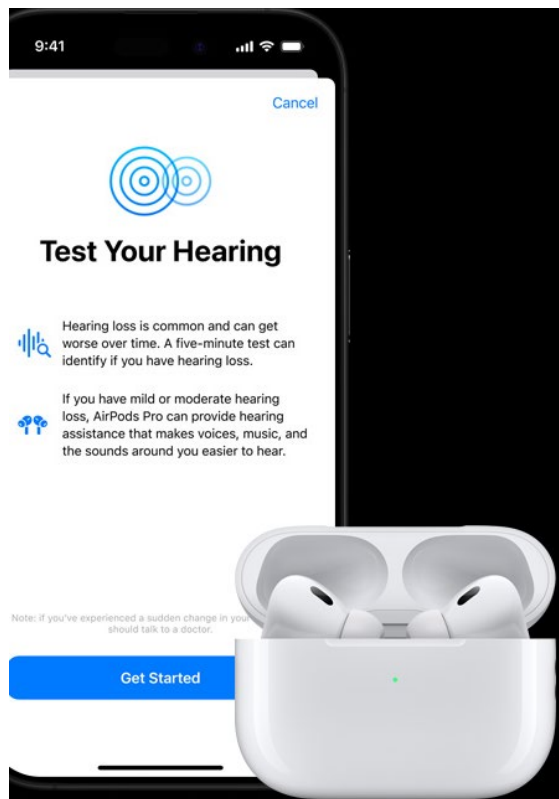
The term Software as a Medical Device is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

The FDA refers to software functions that are device functions as "device software functions." Device software functions may include "Software as a Medical Device (SaMD)" "Software in a Medical Device (SiMD)."

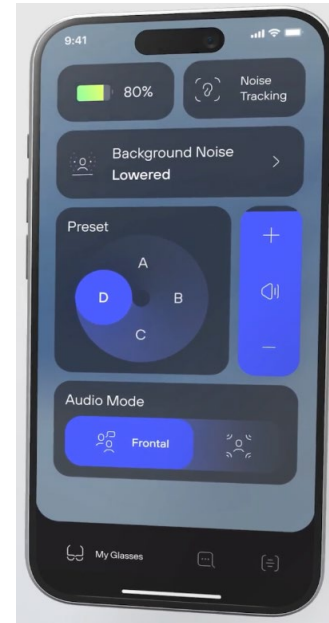
SCR – Software as a Medical Device

Device	air-conduction hearing aid software
Definition	Air-conduction hearing aid software is a device that is intended to be used with a compatible wearable hardware platform to compensate for impaired hearing. The software also allows for customization to the user's hearing needs. Devices in this classification are also subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable. This classification does not include software that is used with hardware as part of a hearing-aid device system classified in other regulations, e.g., § 874.3300, § 874.3305, or § 874.3325.
Physical State	N/A - device is software. The compatible hardware platform(s) is/are physical, but considered separate non-medical product(s).
Technical Method	Medical device software that enables a compatible wearable hardware platform to function (together) as a hearing aid. This software may consist of multiple software / firmware modules for multiple hardware platforms, such as for a headworn product (like "smart earbuds") along with a mobile device ("smartphone") product.
Target Area	Air-conduction hearing-aid software, when used with compatible hardware platform, provides amplified sound to the ear

OTC SMD: Apple AirPods Pro



OTC SMD: Es silor Luxottica



**Your hearing
is unique...**



Communications

Help Spread the Message of Hearing Health

ADVOCATES

Share the Joy of Hearing

[FIND A HEARING PROFESSIONAL](#)



The “HEARING BONE’S” Connected to the WHAT?

*Treating hearing loss can lead to healthier,
happier, and more vital daily living.*

MENTAL HEALTH

Less risk of depression in people who choose to treat hearing loss.



BALANCE & SAFETY

Hearing loss is tied to increased risk of falling and accidental injury.



DIABETES

People with diabetes are 2x more likely to develop hearing loss.



HEART HEALTH

Your hearing health may suggest your risk of cardiovascular disease.



STAYING SHARP

Hearing aids may help slow cognitive decline.



HEALTH CARE COSTS

Good hearing can lead to savings in health care costs.



LONGEVITY

Hearing aids can lower the risk of mortality for people with hearing loss.



Treating hearing loss can improve communication skills, decrease social isolation and loneliness, strengthen interpersonal relationships, enhance cognitive functioning, and lead to a longer, healthier life.

Take an online hearing check at [HEARING.ORG](https://hearing.org)

Good hearing
connects us
to each other



What pairs well with a
glass of pinot grigio?

A conversation you can
hear and understand.

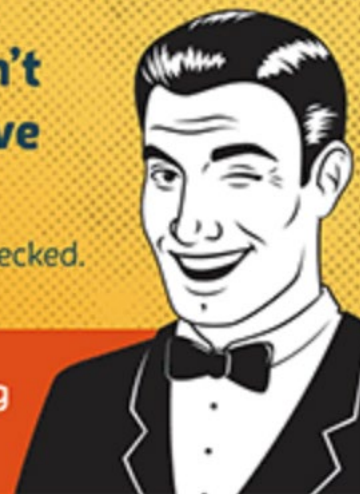
Try the Take 3 For Me
Hearing Challenge to take 3
steps toward better hearing.



“Sweet nothings” aren’t
as romantic when I have
to shout them.

Maybe it’s time to get your hearing checked.

Visit hearing.org and see a hearing
professional to hear your best.



Visit a hearing
professional
today











Questions?

thank you!

Info@hearing.org

bdobyan@hearing.org

BetterHearing.org

drtompowers@comcast.net



Please scan the QR Code to access this
workshop's survey.



Your feedback is greatly appreciated!