Are Direct-to-Consumer Devices a Threat to Traditional Hearing Aids?

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Disclosure

Relevant Financial Relationships:

- Employee of University of Arkansas for Medical Sciences
- Former employee of University of North Texas
- Support provided by
  - EarVenture (Hearing Aids)

Relevant Nonfinancial Relationships:

- None

Etymotic Bean

SWS CS50+

Ear Technology Tweak

IHEARMAX

Perfect Choice

LifeEar

MD Hearing Aid

Banglijian Hearing

LSN Wisely

RCA Symphonic

Simplicity

Neutronic Ear

http://hearinghealthmatters.org/waynesworld/2017/otc-hearing-aids-psaps/

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Current Legislation

Examples: hr5, sres9, "health care"

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H.R.2430 - FDA Reauthorization Act of 2017

115th Congress (2017-2018) | Get alerts

LAW Hide Overview

Sponsor: Rep. Walden, Greg [R-OR-2] (Introduced 05/16/2017)

Committees: House - Energy and Commerce

Committee Reports: H. Rept. 115-201

Latest Action: 08/18/2017 Became Public Law No: 115-52. (All Actions)

Roll Call Votes: There have been 2 roll call votes

Tracker:

Introduced | Passed House | Passed Senate | To President | **Became Law**

More on This Bill

Constitutional Authority Statement

CBO Cost Estimates [1]

Subject — Policy Area:

Health

View subjects »

President Trump Signs OTC Hearing Aid Legislation into Law

Published on August 19, 2017

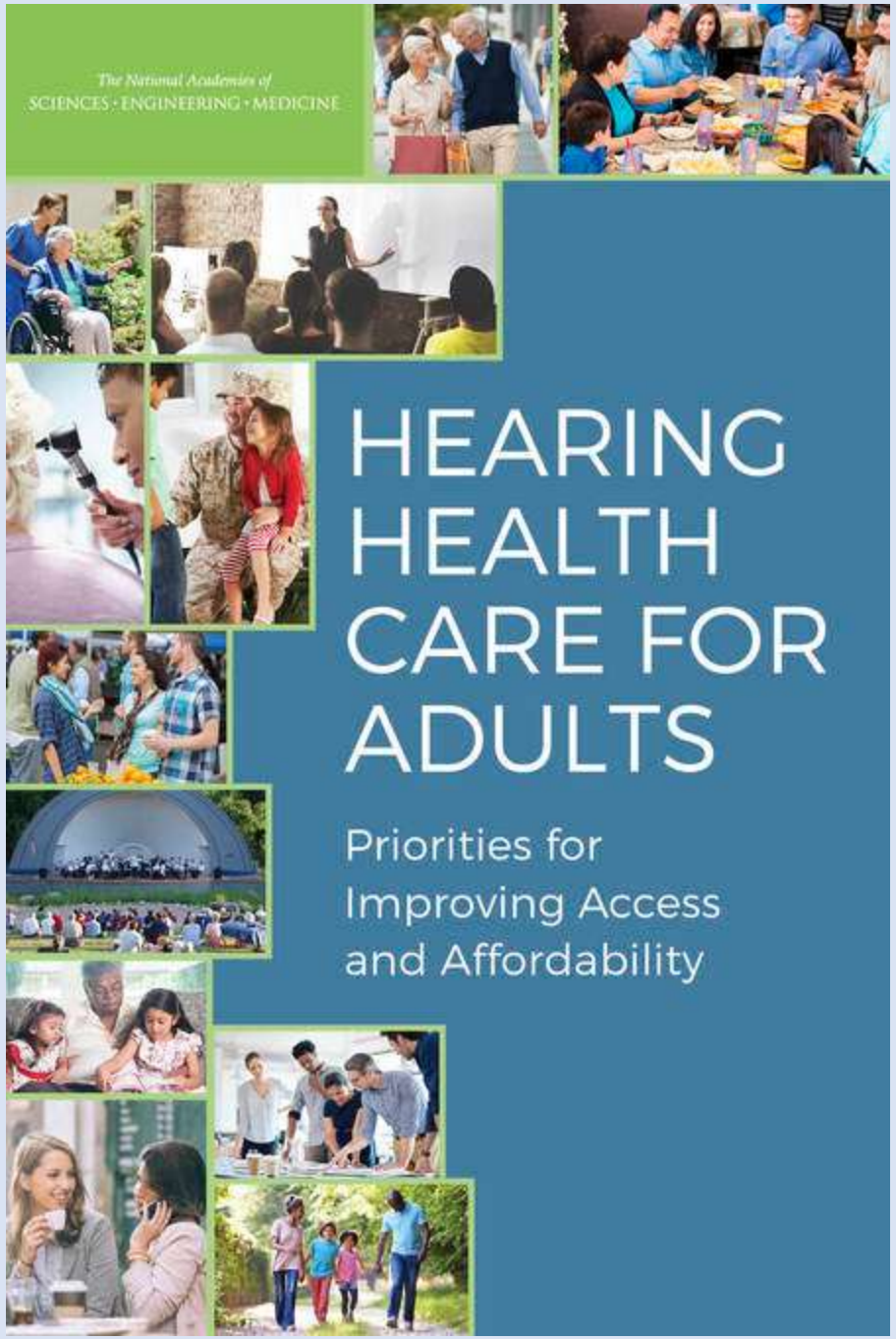
On Friday, President Donald Trump signed into law the Food and Drug Administration Reauthorization Act of 2017, legislation that includes the *Over the Counter Hearing Aid Act* designed to provide greater public accessibility and affordability with over-the-counter (OTC) hearing aids.

President's Council of Advisors on Science and Technology

Aging America & Hearing Loss: Imperative of Improved Hearing Technologies

- **Recommendation 1.** FDA should designate as a distinct category “basic” hearing aids—non-surgical, air-conduction hearing aids intended to address normal, bilateral, gradual onset, mild-to-moderate age-related hearing loss—and adopt distinct rules for such devices. The FDA should approve this class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser, and should also approve for OTC sale (retail and online) tests appropriate to the self-fitting and adjustment of OTC devices by the end user. Such hearing treatments and tests meet the FDA requirements for OTC products, which are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition.
- **Recommendation 2.** The FDA should withdraw its draft guidance document regarding Personal Sound Amplification Devices (PSAPs) and reference this new category as “devices for discretionary consumer use.” PSAP manufacturers should continue to be able to make truthful claims about their use in normal settings, and FDA should not require language in PSAP labeling or advertising that excludes their use by individuals with age-related hearing loss no worse than mild-to-moderate.

- **Recommendation 3.** Analogously to its “Eyeglass Rule,” FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and/or hearing aid vendors. Additionally, the availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test.
- **Recommendation 4.** The FTC should define a process analogous to contact lenses (ie, “Contact Lens Rule”) by which patients may authorize hearing aid vendors (in-state or out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any dispensing professional who performs such a test, and it should require that the testers furnish such results at no additional cost.


The National Academies of
SCIENCES • ENGINEERING • MEDICINE
HEARING HEALTH CARE FOR ADULTS
Priorities for Improving Access and Affordability

Improve Population-Based Information on Hearing Loss and Hearing Health Care

RECOMMENDATION 1

The National Institutes of Health, the Centers for Disease Control and Prevention, the Patient-Centered Outcomes Research Institute, the Department of Defense, the Department of Veterans Affairs, state public health agencies, and other relevant government agencies, as well as nonprofit organizations, hearing health care professional associations, academic institutions, and researchers, should strengthen efforts to collect, analyze, and disseminate prospective population-based data on hearing loss in adults and the effects of hearing loss and its treatment on patient outcomes. Specifically,

- Support and conduct studies to develop, evaluate, strengthen, and align metrics for hearing loss and communication abilities;
- Support and conduct studies, including longitudinal studies, in diverse populations to better understand:
  - the risk and natural history of hearing loss;
  - risk factors and co-morbidities of hearing loss;
  - hearing health care needs; and
  - the impact of hearing loss and its treatment on health, function, economic productivity, and quality of life; and
- Develop and strengthen research training programs to address hearing loss as a public health concern with attention to cross-disciplinary training on sensory disorders, epidemiological methods, advanced biostatistics, and health services and health economics research methods.

Develop and Promote Measures to Assess and Improve Quality of Hearing Health Care Services

RECOMMENDATION 2

The Centers for Medicare & Medicaid Services, the National Institutes of Health, the Department of Defense, the Department of Veterans Affairs, other relevant federal agencies, hearing health care professional associations and providers, advocacy organizations, health care quality improvement organizations, health insurance companies, and health systems should collaborate to:

- Align and promote best practices and core cor
across the continuum of hearing health care, a
mechanisms to ensure widespread adherence;
- Research, develop, and implement a set of qua
measures to evaluate hearing health care servi
end goal of improving hearing- and communi
patient outcomes.

Remove the Food and Drug Administration's Regulation for Medical Evaluation or Waiver

RECOMMENDATION 3

The Food and Drug Administration should remove the regulation that an adult seeking hearing aids be required to first have a medical evaluation or sign a waiver of that evaluation and should ensure consumers receive information about the medical conditions that could cause hearing loss through inclusion of that information in hearing aid user brochures.

Empower Consumers and Patients in Their Use of Hearing Health Care

RECOMMENDATION 4

Hearing health care professionals, professional associations, advocacy organizations, and relevant governmental agencies such as the Office for Civil Rights at the U.S. Department of Health and Human Services should ensure patients are aware of, and understand how to exercise, their rights of acces
about themselves under the Health Insurance Po
Accountability Act Privacy Rule (45 C.F.R. Section 164.524), including their audiograms and hearing aid programming history.

NOTE: All recommendations are of equal importance and are not prioritized.

Eric Mann, MD, PhD, announced this morning that, effective immediately, the US Food and Drug Administration (FDA) will be eliminating the so-called "physician waiver" system which requires consumers first to seek a physician for a medical evaluation or sign a waiver prior to obtaining a hearing aid. Dr Mann is the Clinical Deputy Director (ENT devices branch) at FDA, and made the announcement at today's "Dissemination Meeting: Hearing Health Care for Adults: Priorities for Improving Access and Affordability" held by the National Academies of Sciences, Engineering, Medicine (NAS). The elimination of the waiver system was Recommendation #3 in the NAS's recent 12 recommendations. He also stated that the FDA is pursuing the NAS recommendation for creating a new category for over-the-counter (OTC) hearing devices (Recommendation #7).

Dr Mann was careful to clarify two points with respect to the new physician waiver guidance:

1. It does not apply to children (they will continue to have the medical evaluation requirement without the option of a waiver);
2. The guidance indicates that dispensers are still required at this point to make available, and provide consumers the opportunity to review, the User Instruction Brochure that contains information about possible Red Flags prior to the sale of a hearing aid.

Improve Access to Hearing Health Care for Underserved and Vulnerable Populations

RECOMMENDATION 5

The Health Resources & Services Administration, state health departments, advocacy organizations, and hearing health care professional schools and associations should:

- Collaborate and partner with health care providers to ensure hearing health care accessibility throughout rural and underserved areas using mechanisms such as telehealth, outreach clinics (including federally qualified community health centers), and community health workers;
- Support and promote programs, including incentives such as tuition assistance, to increase diversity in all sectors of the hearing health care workforce; and
- Promote the training of cultural competency in the hearing health care workforce and incentivize practice in underserved communities.

Promote Hearing Health Care in Wellness and Medical Visits

RECOMMENDATION 6

Public health agencies (including the Centers for Disease Control and Prevention and state health departments), health care systems (including those of the Department of Defense and the Department of Veterans Affairs), health care professional schools and associations, advocacy organizations, health care providers, and individuals and their families should promote hearing health in regular medical and wellness visits (including the Medicare Annual Wellness Visit). Specifically,

- Use patient visits to assess and discuss potential hearing difficulties that could affect doctor–patient communication and overall patient well-being, to encourage individuals and their family members and caregivers to discuss hearing concerns, to raise awareness among older adults about age-related hearing loss, and to encourage referral when appropriate; and
- Develop and disseminate core competencies, curricula, and continuing education opportunities focused on hearing health care, particularly for primary care providers.

Implement a New Food and Drug Administration Device Category for Over-The-Counter Wearable Hearing Devices

RECOMMENDATION 7

The Food and Drug Administration (FDA) should establish a new category of over-the-counter (OTC) wearable hearing devices. This device classification would be separate from "hearing aids." OTC wearable hearing devices would be defined as wearable, over-the-counter devices that can assist adults with mild to moderate hearing loss. These devices would:

- Explicitly be defined by the FDA as intended for over-the-counter sale;
- Be able to be marketed as devices that may assist with hearing loss and be sold over the counter, by mail, or online; and would include mobile apps and associated wearable technologies intended to function as an OTC wearable hearing device for mild to moderate hearing loss;
- Be subject to regulatory requirements that would explicitly preempt current state laws and regulations for hearing aids and dispensing and preempt potential future state laws and regulations seeking to limit over-the-counter access;
- Be exempt from 510(k) premarket review to the extent that the technology is not fundamentally different from air conduction hearing aids;
- Include thorough consumer labeling, including information on:
  - frequency gain characteristics
  - adequate directions for use
  - communication challenges for which it may be helpful to seek professional consultation
  - medical situations, symptoms, or signs for which to consult with a physician
- Meet minimum safety requirements and standards, including but not limited to:
  - safe maximal sound output (e.g., upper limit for dB SPL [decibel of sound pressure level] peak output) at levels to be determined in conjunction with national experts in hearing conservation
  - criteria for eartips (e.g., maximum depth for insertion into the ear canal)
  - amplification via air conduction only. Wireless technology for programming and connectivity should be permitted
  - American National Standards Institute or other voluntary standards for audio characteristics and performance as determined by FDA, as appropriate for this category
- Be subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category; and
- Have the option to include accessory tests for self-assessment of mild to moderate hearing loss for purposes of selecting and fitting an OTC hearing device.

To further clarify the types of hearing technologies and their oversight and regulation:

- FDA should retain a guidance document on personal sound amplification products (PSAPs) that describes PSAPs as products that are not to be offered or promoted to address hearing loss and are subject to the electronic product provisions of the Federal Food, Drug, and Cosmetic Act through its 2009 PSAP guidance document or a revision of its 2013 PSAP draft guidance document. The PSAP guidance document would establish the distinction between PSAPs for normal hearing and the OTC wearable hearing device category for hearing loss.
- The Consumer Product Safety Commission and the Federal Trade Commission should exercise their respective authorities in the regulation of consumer products marketed as PSAPs.

Improve the Compatibility and Interoperability of Hearing Technologies with Communications Systems and the Transparency of Hearing Aid Programming

RECOMMENDATION 8

The Federal Communications Commission, Federal Trade Commission, Food and Drug Administration, National Institutes of Health, and other relevant federal agencies; the American National Standards Institute and other standards-setting organizations; manufacturers; and industry, professional, and consumer advocacy organizations should:

- Develop standards that ensure that hearing aids and OTC wearable hearing devices are compatible and interoperable with other technologies and communications systems;
- Increase public awareness and consumer-friendly information on the availability, connectivity, and use of hearing aids and hearing assistive technologies; and
- Develop and implement standards for an open platform approach for hearing aid programming that allows any hearing health care professional (or, as evolving technology allows, the device owner) to program the device settings, and require point-of-sale information about the programming features and programming portability of hearing aids in order to enable more informed purchasing decisions.

Improve Affordability of Hearing Health Care

RECOMMENDATION 9

The Centers for Medicare & Medicaid Services (CMS), other relevant federal agencies, state Medicaid agencies, health insurance companies, employers, hearing health care providers, and vocational rehabilitation service agencies should improve hearing health care affordability for consumers by taking the following actions:

- Hearing health care professionals should improve transparency in their fee structure by clearly itemizing the prices of technologies and related professional services to enable consumers to make more informed decisions;
- CMS should evaluate options, including possible statutory or regulatory changes, in order to provide coverage so that treating hearing loss (e.g., assessment, services, and technologies, including hearing aids) is affordable for Medicare beneficiaries;
- CMS should examine pathways for enhancing access to assessment for and delivery of auditory rehabilitation services for Medicare beneficiaries, including reimbursement to audiologists for these services;
- State Medicaid agencies should evaluate options for providing coverage for treating hearing loss (e.g., assessment, services, and hearing aids and hearing assistive technologies as needed) for adult beneficiaries;
- Vocational rehabilitation agencies should raise public awareness about their services that enable adults to participate in the workforce, and they should collaborate with other programs in their respective state to raise this awareness;
- Hearing health care professionals and professional associations should increase their awareness and understanding of vocational rehabilitation programs and refer as appropriate; and
- Employers, private health insurance plans, and Medicare Advantage plans should evaluate options for providing their beneficiaries with affordable hearing health care insurance coverage.

Evaluate and Implement Innovative Models of Hearing Health Care to Improve Access, Quality, and Affordability

RECOMMENDATION 10

The Centers for Medicare & Medicaid Services, the Patient-Centered Outcomes Research Institute, the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources & Services Administration, the Department of Defense, the Department of Veterans Affairs, researchers, and health care systems should prioritize and fund demonstration projects and studies, including randomized controlled trials, to improve the evidence base for current and innovative payment and delivery models for treating hearing loss. Specifically,

- Innovative models to be evaluated should include, but not be limited to, community health workers, telehealth, mobile health, retail clinics, and self-administered hearing health care. These projects and studies should include outcomes that are patient-centered and assess value, comparative effectiveness, and cost effectiveness.
- Demonstration projects should evaluate the health impact of beneficiary direct access to audiologist-based hearing-related diagnostic services, specifically to clarify impact on hearing health care accessibility, safety, and the effectiveness of the medical home. This excludes direct access to audiologic testing for assessment of vestibular and balance disorders and dizziness, which require physician referral. Successful outcomes would provide evidence of effective communication and coordination of care with primary care providers within a model of integrated health care, and evidence of appropriate identification and referral for evaluation of medical conditions related to hearing loss and otologic disease.
- Models that are found to be most effective should be widely implemented.

Improve Publicly Available Information on Hearing Health

RECOMMENDATION 11

The National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Veterans Affairs, the Administration for Community Living, state public health agencies, other relevant government agencies, advocacy organizations, hearing health care professional associations, hearing technology manufacturers, hearing health care professionals, and media organizations should improve public information on hearing health and hearing-related technologies and services and promote public awareness about hearing and hearing health care. Specifically,

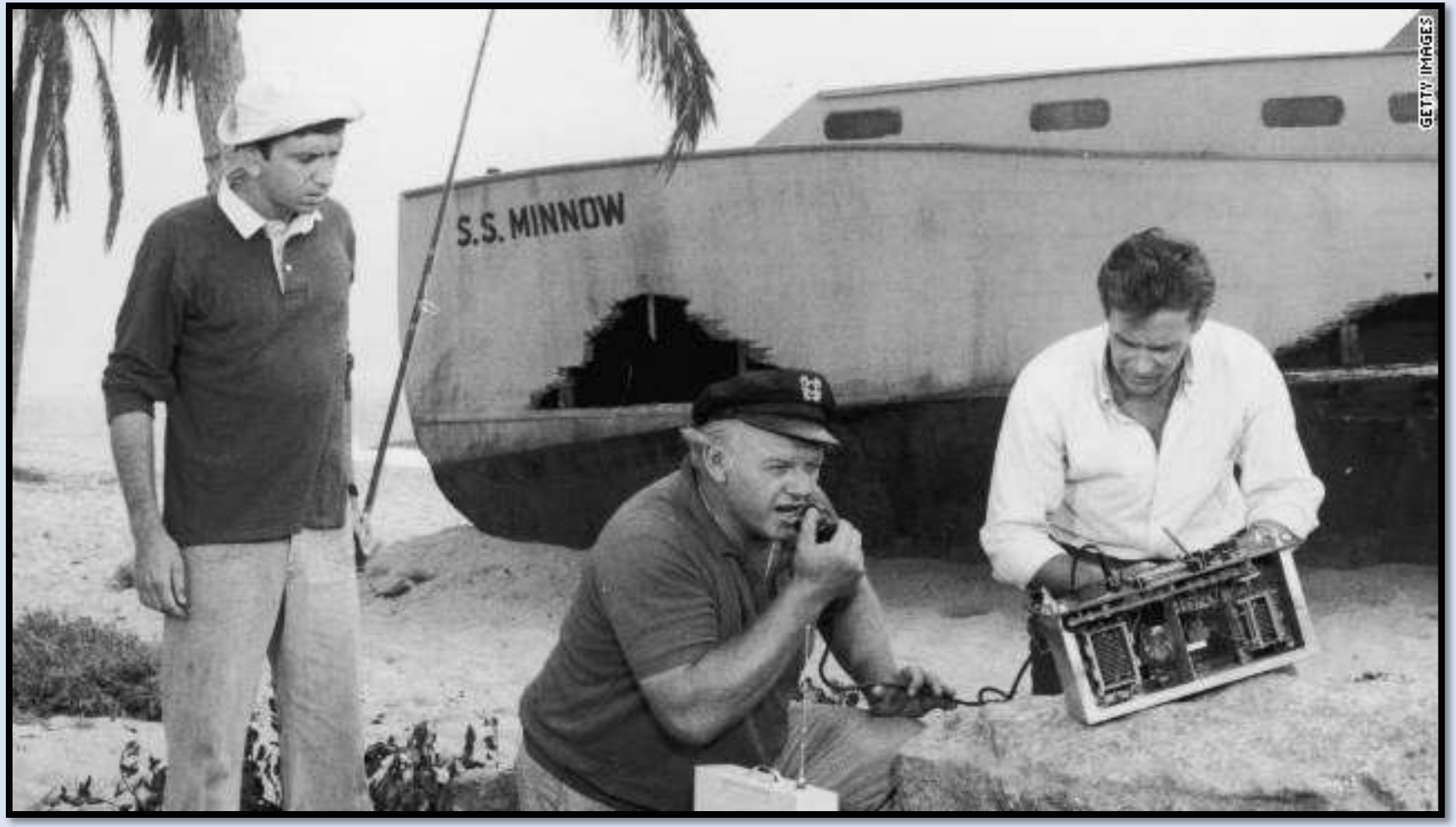
- Strengthen publicly available, evidence-based information on hearing through multiple avenues (e.g., centralized websites, community-based services, local councils on aging) that explain hearing and related health concerns for adults of all health literacy levels, and address the breadth of services and technologies, including their comparative effectiveness and costs;
- Work through media, social marketing, and public education campaigns to disseminate and evaluate key evidence-based messages about hearing and hearing health and to promote accuracy in media portrayals;
- Implement and support a consumer-based metric to enable individuals to understand and track their communication abilities and hearing needs and a consumer-oriented format for audiogram and other hearing test results;
- Adopt standardized terminology across manufacturers about the features and capabilities of hearing aids and hearing assistive technologies so that consumers and hearing health care professionals can make easy, clear, unambiguous comparisons; and
- Develop and disseminate criteria that individuals and families can use to evaluate and compare hearing-related products and services.

Promote Individual, Employer, Private Sector, and Community-Based Actions to Support and Manage Hearing Health and Effective Communication

RECOMMENDATION 12

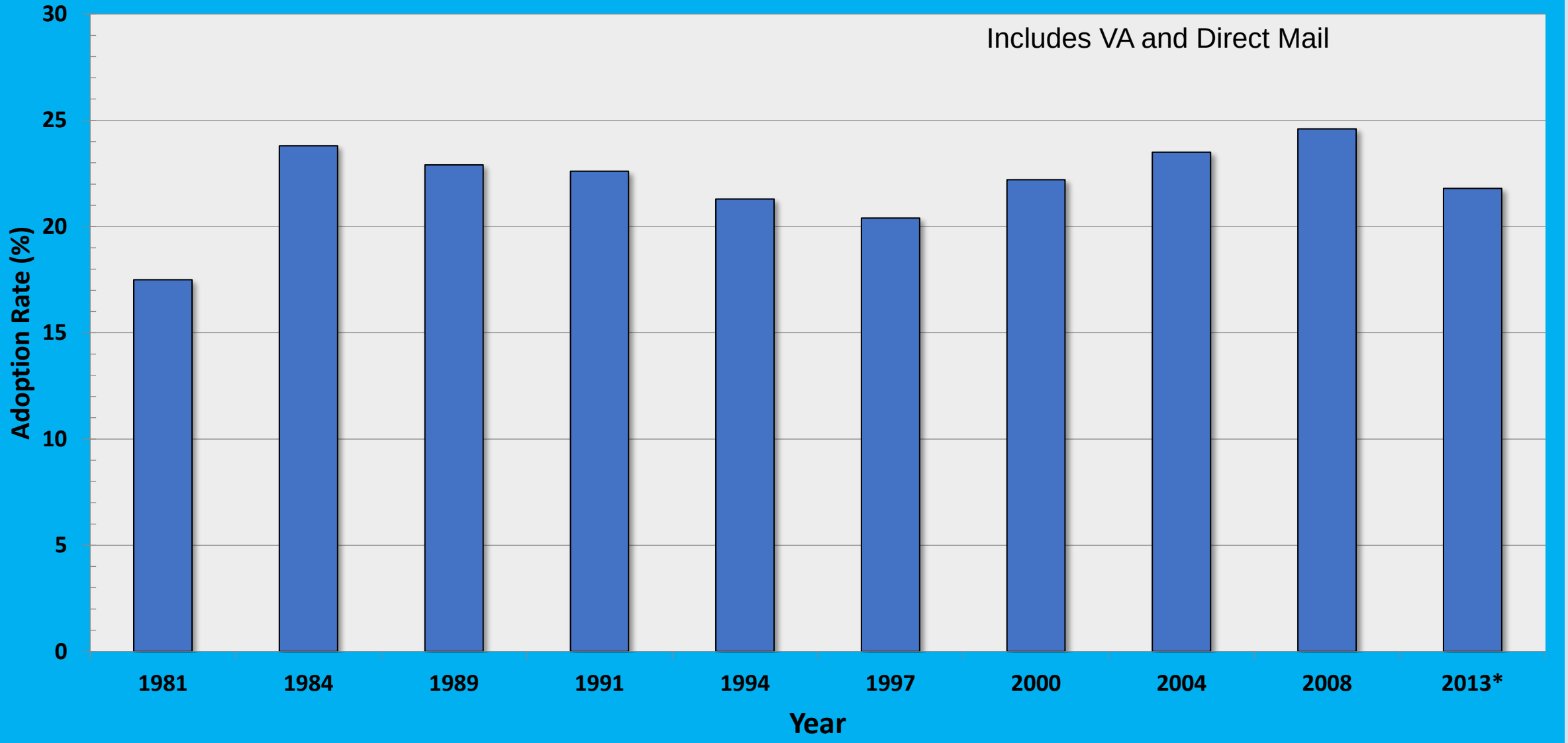
Individuals, families, community-based organizations, advocacy organizations, employers, private-sector businesses, and government agencies (local, state, federal) should take actions to support and manage hearing health and foster environments that maximize hearing and communication for all individuals.

- Individuals and their family members can
  - Reduce exposure to noise that is at high volume levels for extended periods of time and use hearing protection as appropriate,
  - Be aware of and recognize difficulties in hearing and communication and seek information and care through the range of available services and technologies when appropriate, and
  - Seek out peer-support groups and other opportunities for those living with hearing loss, when appropriate.
- Community-based organizations, advocacy organizations, employers, private sector businesses, and government agencies (local, state, federal) should promote work and community environments that are conducive to effective communication and that support individuals with hearing loss. Specifically, they should:
  - Ensure compliance with the Americans with Disabilities Act and other related laws supporting people with disabilities and strive to exceed their minimum requirements;
  - Research and incorporate features into buildings and public spaces that improve hearing and communication (e.g., universal design, hearing assistive technologies).

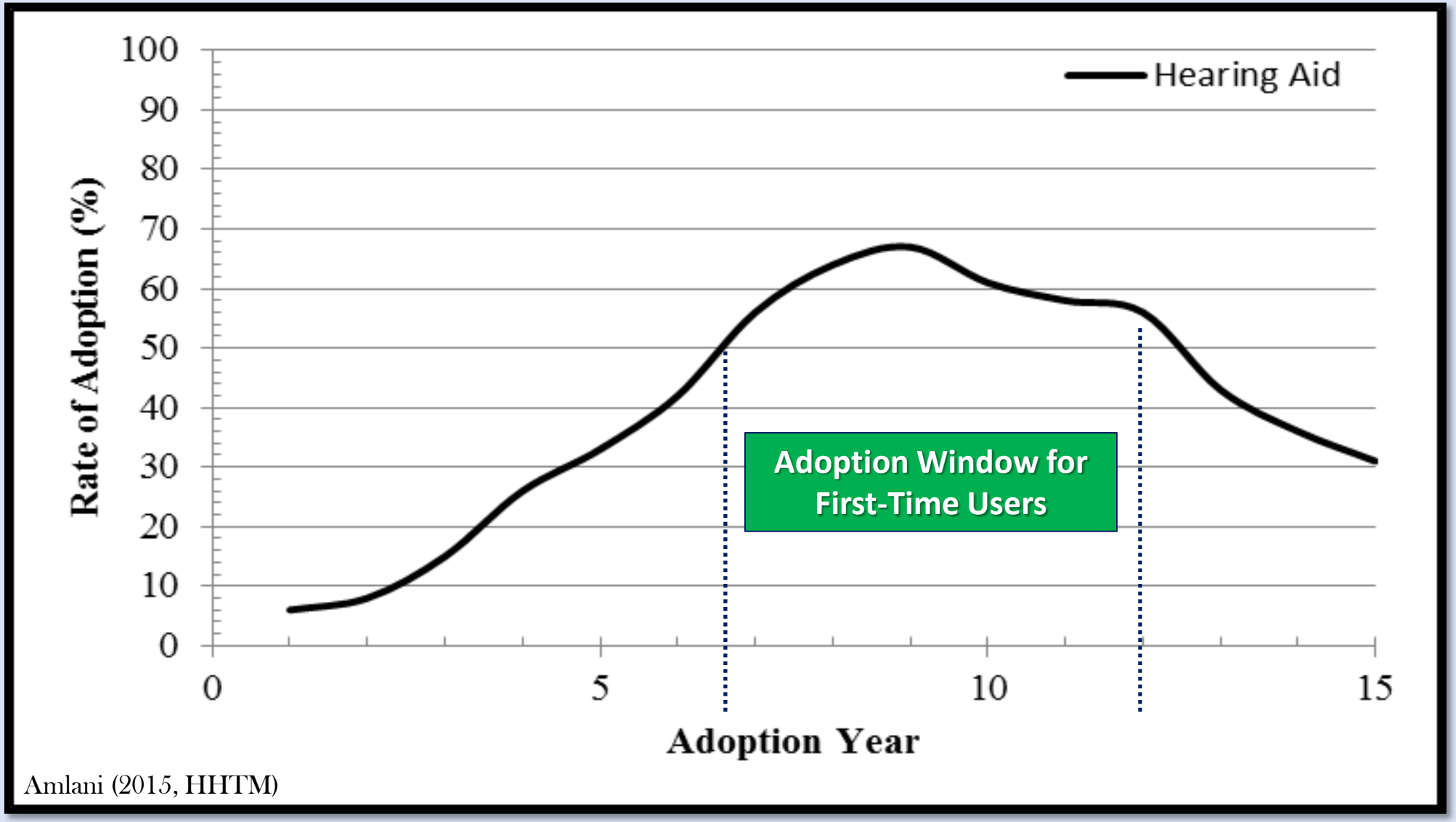


How did we get to this point?

US Adoption Rates - Historic



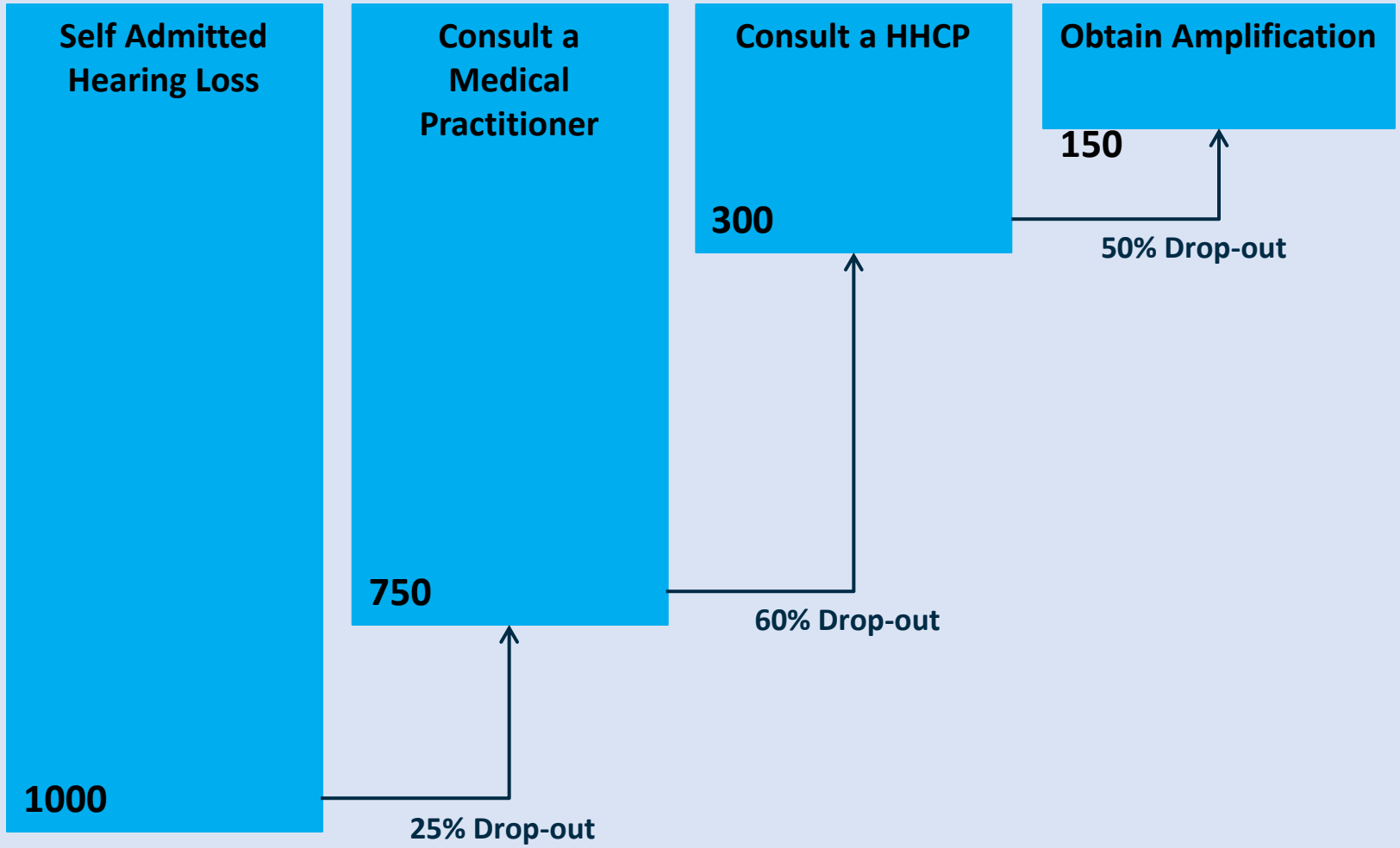
Kochkin (2009); * William Dement Holdings (June, 2013)

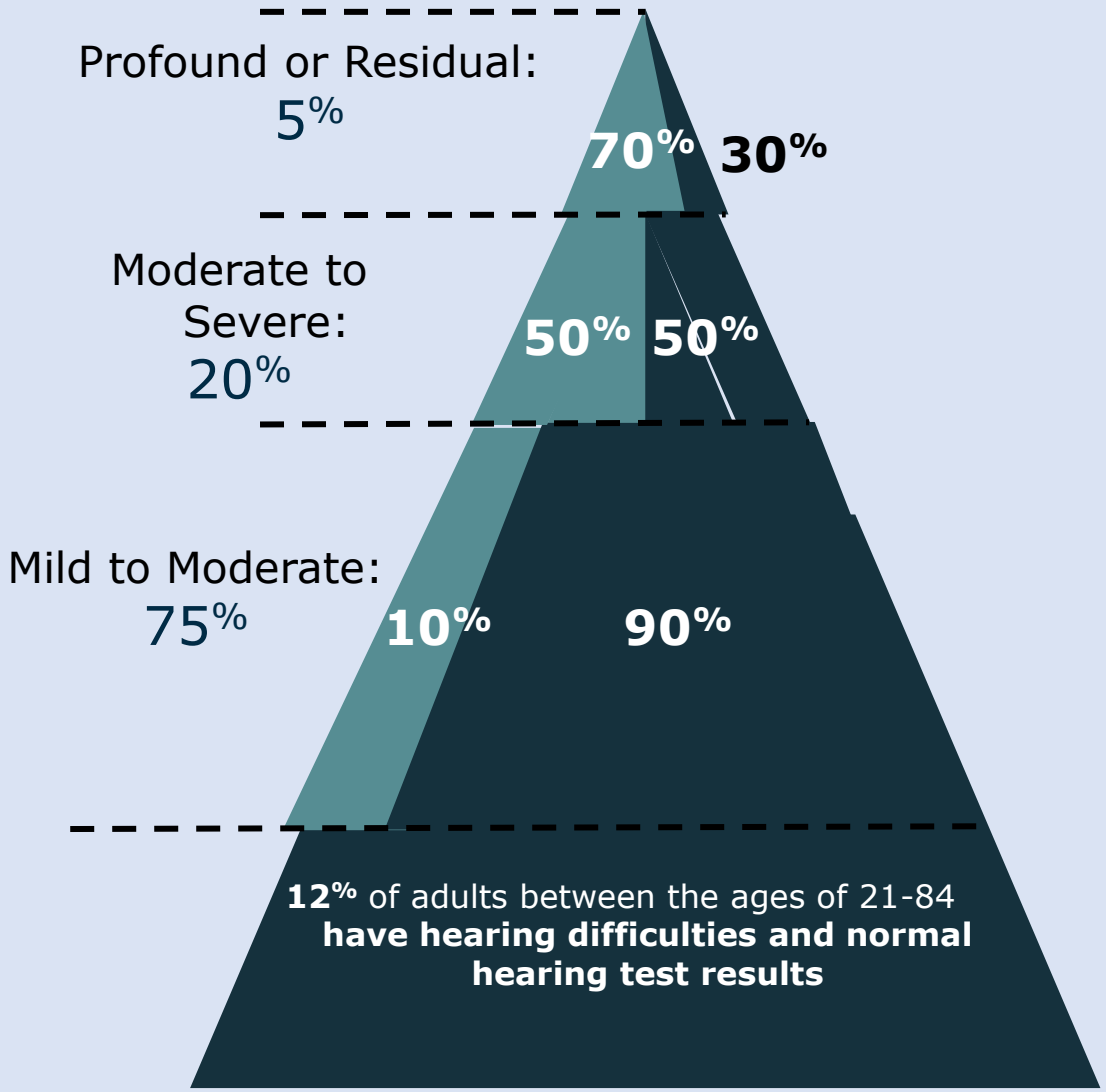


Amlani (2015, HHTM)

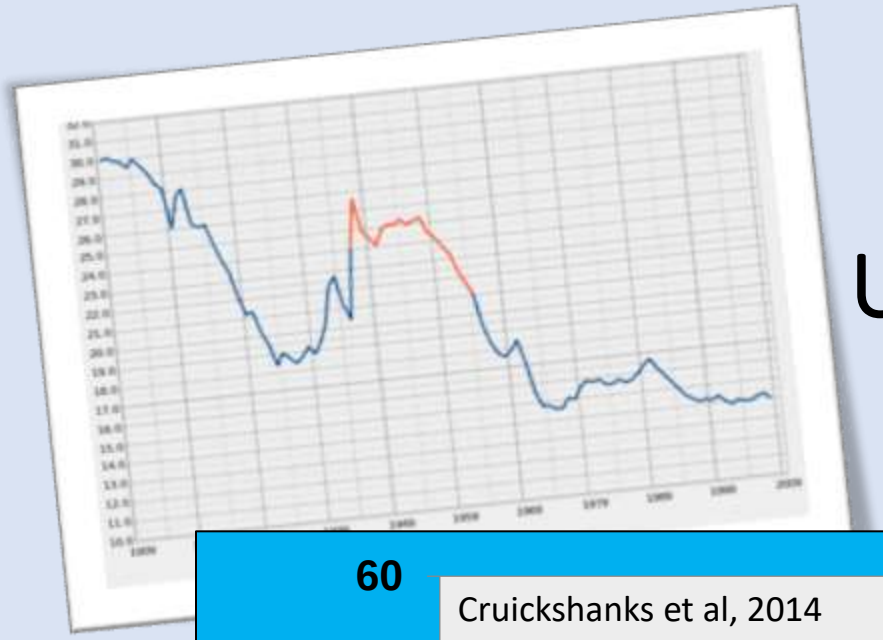
n = 851

The Consumer Journey to Obtaining Traditional Amplification

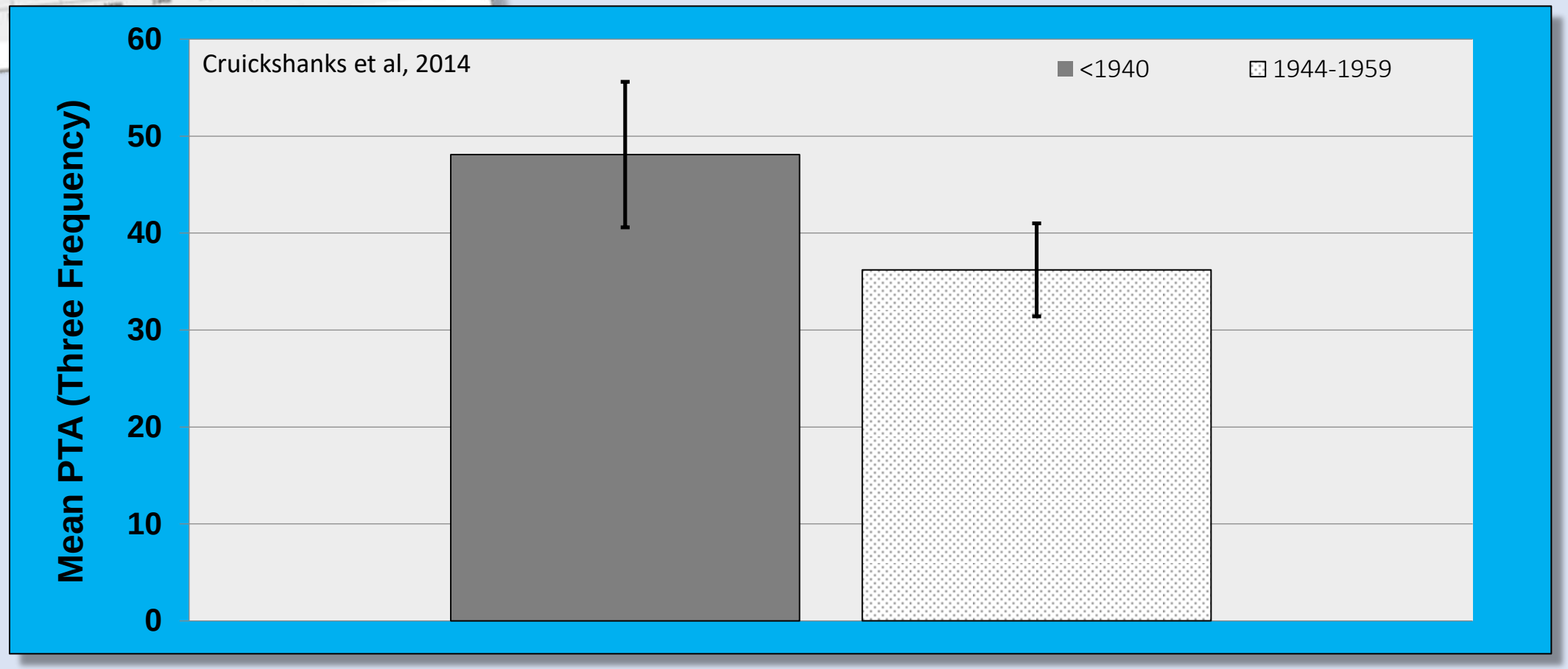




Nash et al 2013; Tremblay, et al 2015

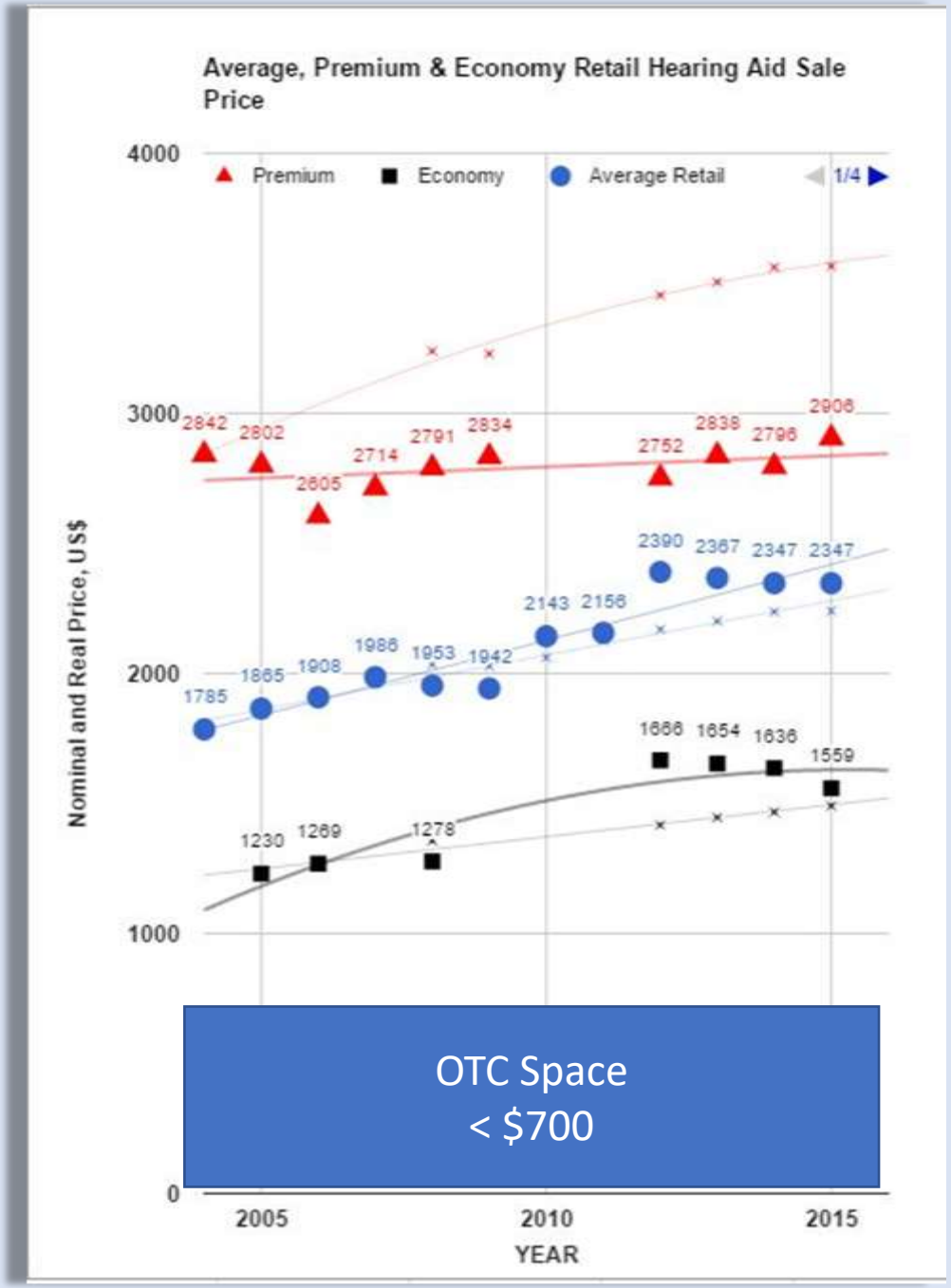


US Baby Boomer Generation



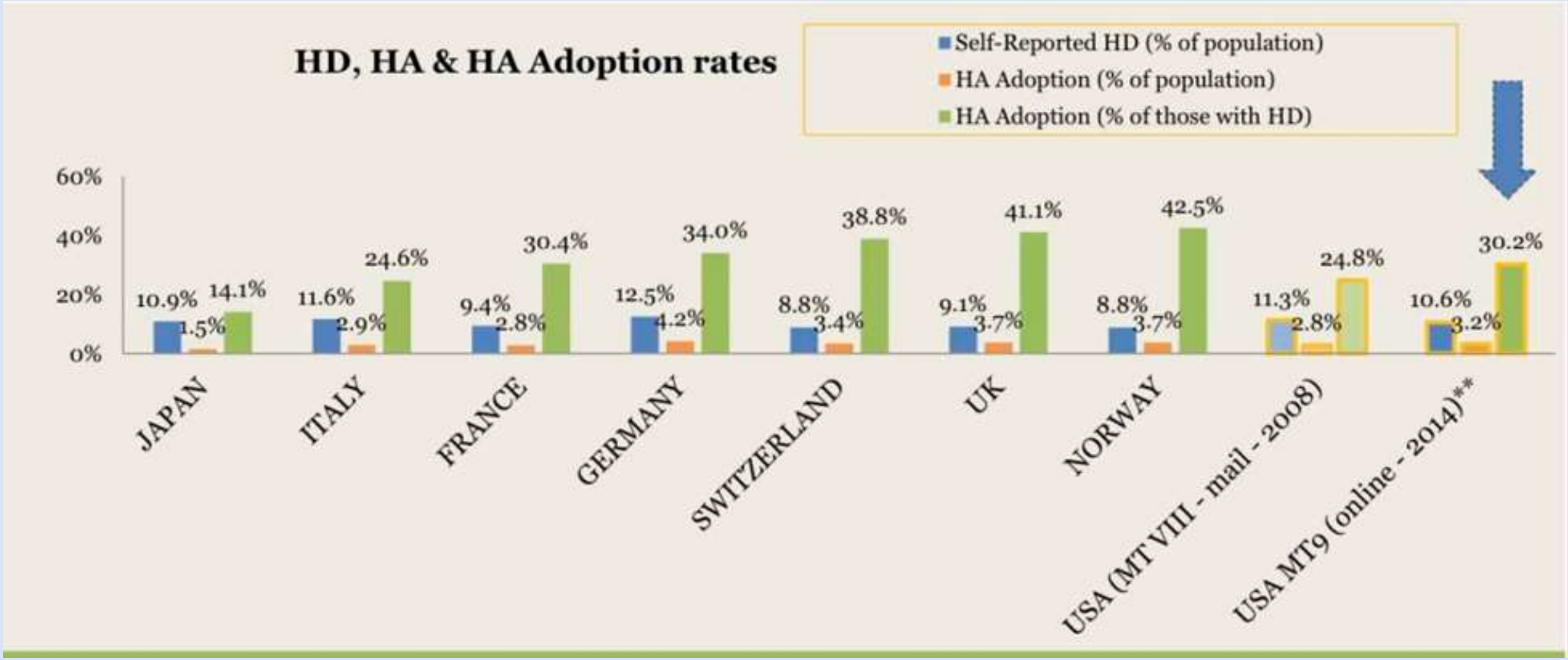
Economic Landscape: Demand-Side

HA Price



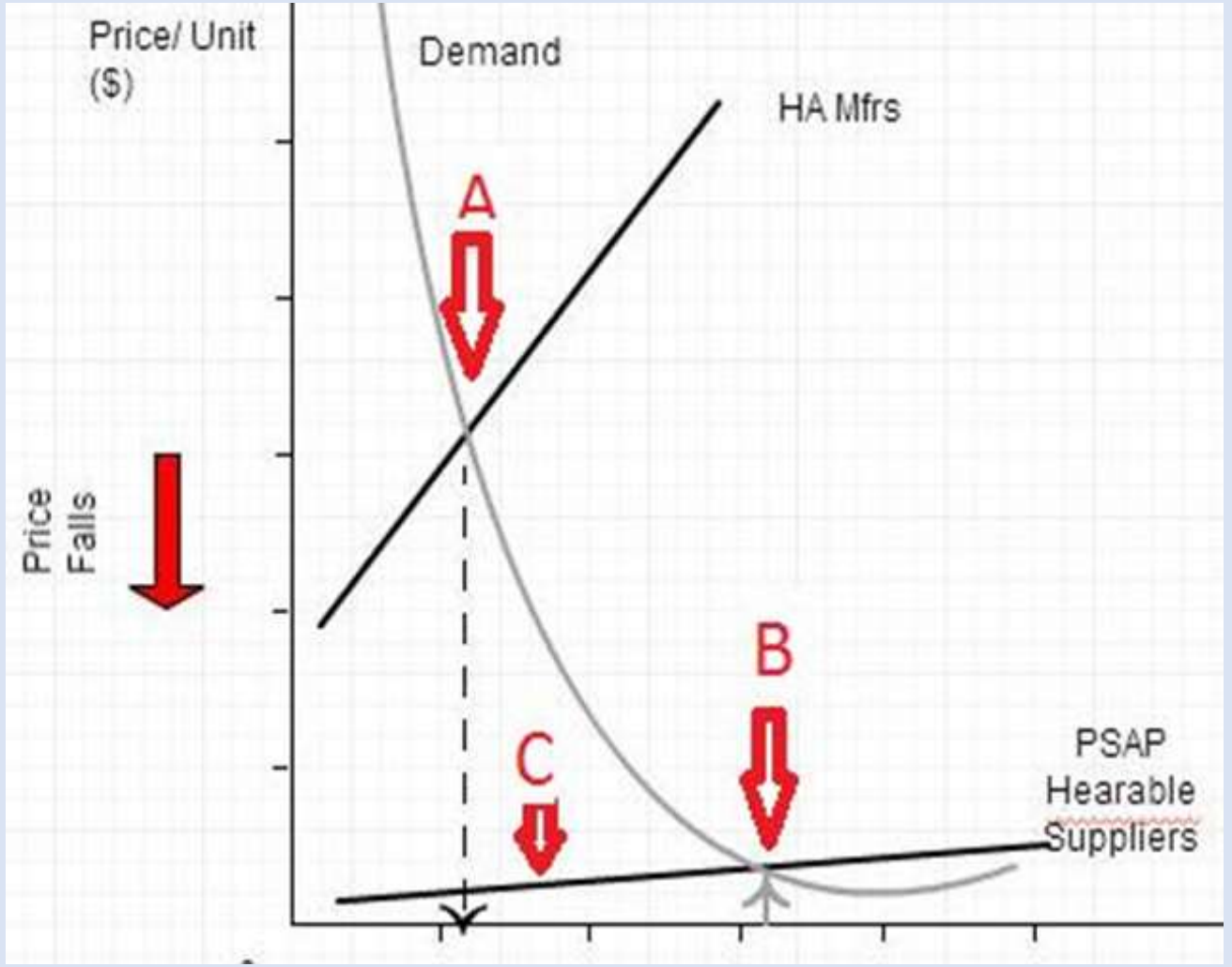
Hosford-Dunn & Amlani (2016)

Price is a Barrier to Adoption

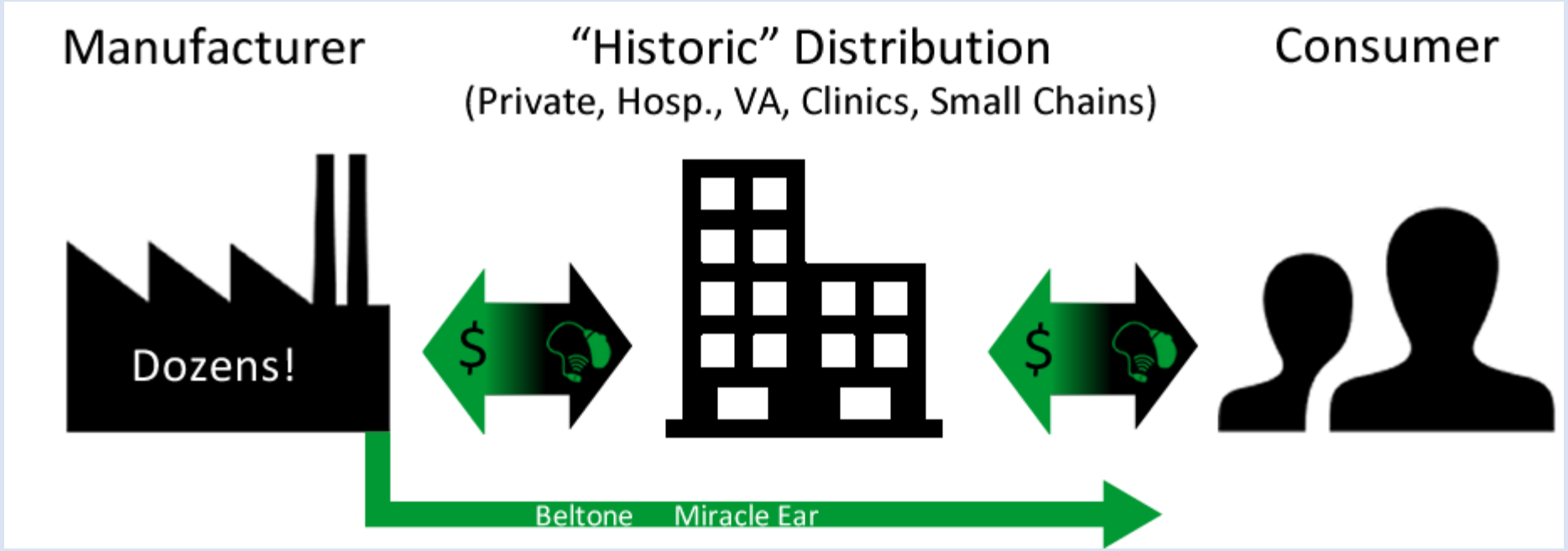


Valente & Amlani (2017)

Economic Landscape: Supply-Side

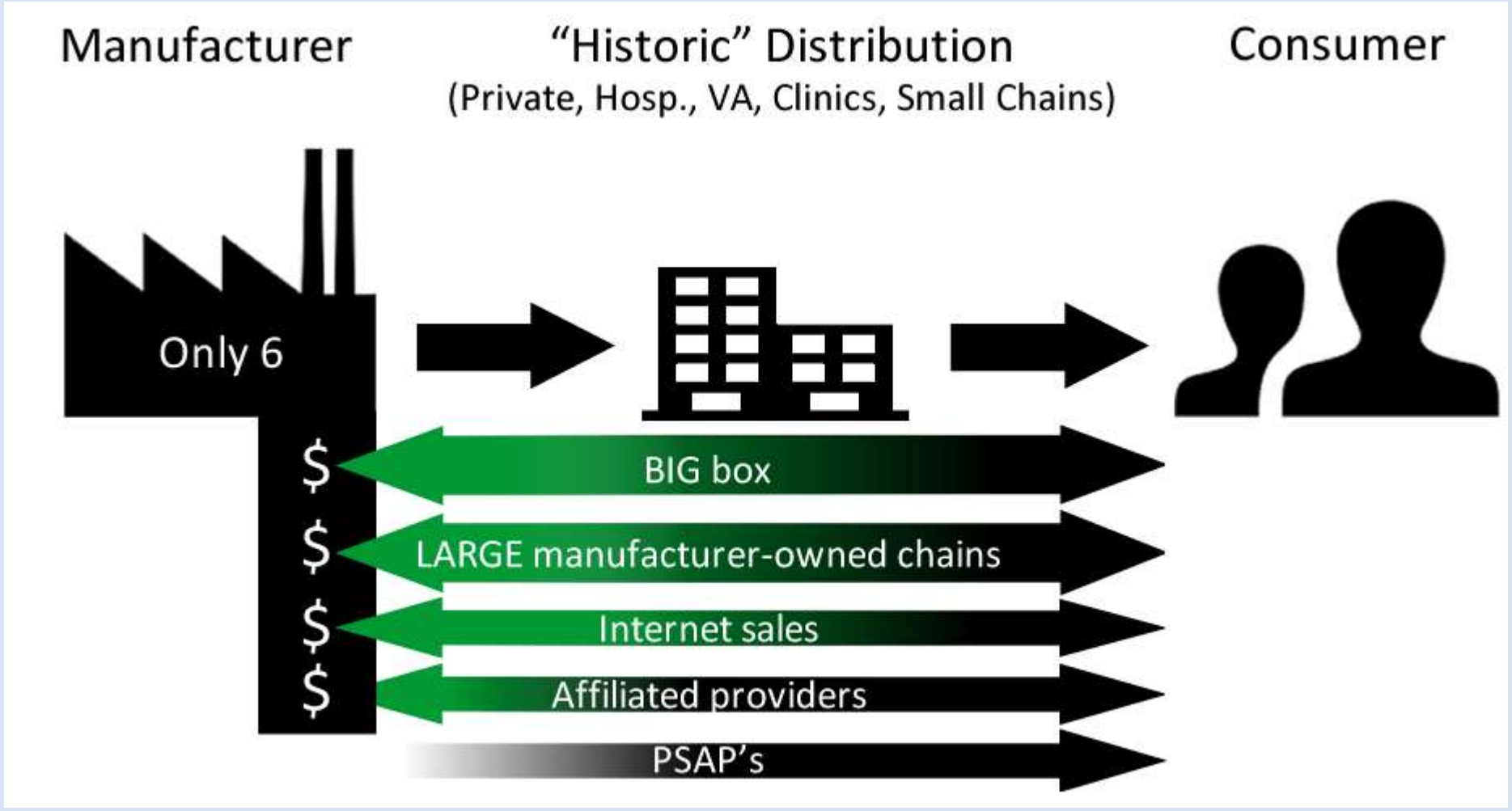


Traditional Hearing Aid Supply Chain Model



Smriga, D. "Who are we really working for?" presentation at ADA 2014

Evolving Hearing Aid Supply Chain Model

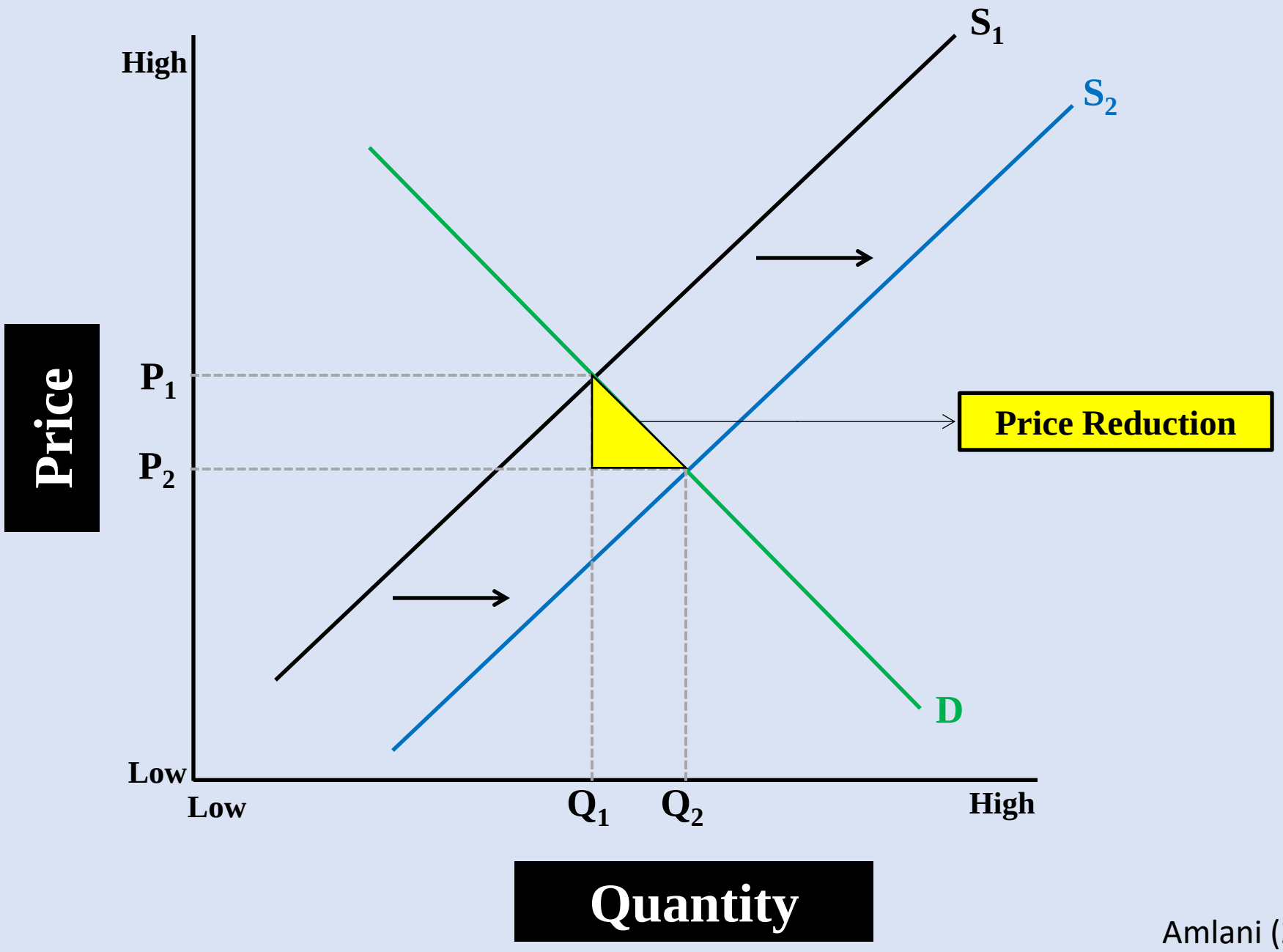


Smriga, D. "Who are we really working for?" presentation at ADA 2014

Evolving Product and Service Delivery

- Expected to…
  - Provide improved access to hearing aids
  - Offer lower cost alternatives than historically available (next slide)
  - Shift focus towards the product as the solution

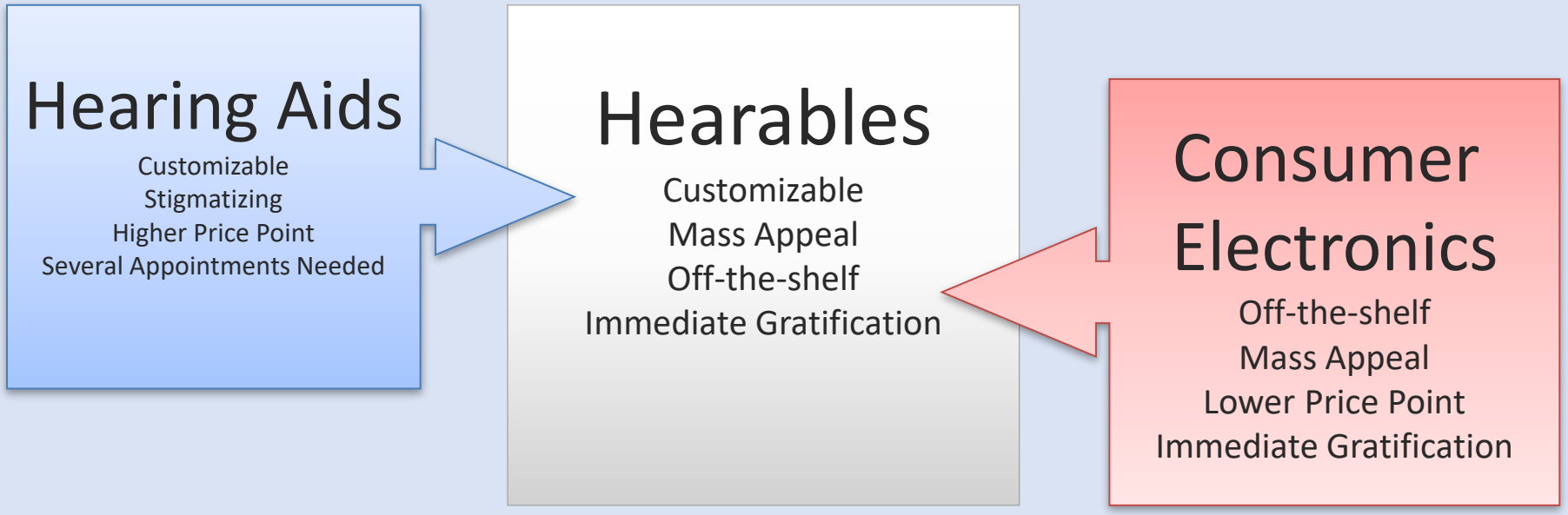
More Manufacturers/Providers Increase Supply of Hearing Aids

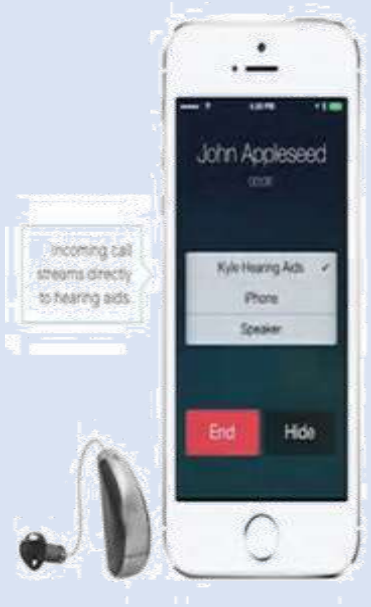


Amlani (2014)

Hearables


OR,
WHAT
IS IT?
OR,
WHAT
IS IT?
Is it an Animal? Is it Human? Is it an Extraordinary FREAK of NATURE? or, is it a Legitimate Member of Nature's Works? Or is it the long sought for LINK between Man and the OURANG-OUTANG, which Naturalists have for years decided does exist, but which has hitherto been undiscovered?
The Exhibitors of this Indescribable Person or Animal, do not pretend to assert what it is; they have named it THE WILD MAN OF THE PRAIRIES; or, "WHAT IS IT," because this is the universal exclamation of all who have seen it. Its Features, Hands, and the upper portion of its Body, are to all appearances Human: the lower part of its Body, the hind Legs, and Haunches, are decidedly Animal! It is entirely covered, except the Face and Hands, with long flowing Hair of various shades. IT IS LARGER THAN AN ORDINARY SIZED MAN, but not quite so tall. "WHAT IS IT" is decidedly the most extraordinary Being that ever astonished the World. It has the intelligence appertaining to Humanity, and can do anything it sees done, or anything which Man or Animal can do, except speak, Read, or Write. It Leaps, Climbs, Runs, &c., with the Agility of a Monkey; it lays the Cloth and sets a Table with the sang froid of a London Waiter; Bows, lifts its Hat, &c., with the grace of a Master of Ceremonies; distinguishes Colors; remembers what is said to it; goes through the Military Exercises; and Plays various Games with an Instinct and Skill that would reflect honor on HOYLE himself. "WHAT IS IT" was caught in the WILDS of CALIFORNIA; its Food is chiefly Nuts and Fruit, though it occasionally indulges in a Meal of RAW MEAT; it Drinks Milk, Water, and Tea, and is partial to Wine, Ale, and Porter. For the last Ten Months it has been with a Tribe of Indians, who were however uncivilised, and nearly as Wild as "WHAT IS IT" itself. Though sometimes shy and savage when approached too near by Strangers, is kind, docile, and obedient to the slightest commands of its Keeper. It is neat in all its Habits, fond of Ornament, and its Exhibition cannot offend the most delicate taste.
HOURS OF EXHIBITION,


Hearing Aids
Customizable
Stigmatizing
Higher Price Point
Several Appointments Needed
Hearables
Customizable
Mass Appeal
Off-the-shelf
Immediate Gratification
Consumer Electronics
Off-the-shelf
Mass Appeal
Lower Price Point
Immediate Gratification



Made for iPhone

Personal Sound Amplification Products (PSAPs)

Augmented Reality

Smartphone Apps

Directed Audio

Hearables:

Different Service Delivery, ***Not*** inferior

Ear level consumer electronics device

Commonalities

- Wireless
- Bluetooth
- Monaural/binaural
- Battery-challenged
- Smartphone

Differentiation

- Looks
- Functionality
- Price
- Distribution channels
- Target market
- Development
- Fulfillment

Table 1 Recommended Direct-to-consumer Hearing Devices and Key Technological and User Features

	Bean T-Coil	CS-50+	Tweak Focus	Soundhawk	Songbird
					
Frequency Output	● Too much low frequency gain	✓ 1. Within prescribed targets 2. Smartphone programming matches gain to hearing loss	✓ Within prescribed targets	✓ 1. Within prescribed targets 2. Customize gain preferences with Smartphone	✓ Within prescribed targets
Signal-to-Noise Ratio	● T-Coil feature	✓ 1. Directionality setting 2. Speech enhancement software	● Directionality	✓ Remote microphone	✗
Listening Comfort	✗	✓ Noise reduction processing	● Low internal noise	● Low internal noise	● Low internal noise
User Features	● User manual only	✓ 1. User videos on Sound Word Solution's Web site 2. Large rechargeable battery	✓ DVD with: 1. User demonstrations 2. Expectation guidance	✓ 1. User videos on Sound Word Solutions' Web site 2. Rechargeable (USB)	● User manual only
Web site	www.etymotic.com/consumer/personal-sound-amplifiers/bean-qsa.html	www.soundworldsolutions.com/store/personal-sound-amplifiers-psa/cs50	www.tweakhearing.com/shop/tweak-focus-personal-sound-amplification-product/	www.soundhawk.com/product	www.songbirdhearing.com/products/songbird-ultra-20.770091
Price	$349/each; $599/pair	$349	$224.99	$349.99	$395/each; $745/pair

✓ Fully available

● Partially available

✗ No special feature

The Frequency Output was tested using simulated real-ear measures consistent with best practice hearing aid verification procedures. The Signal-to-Noise Ratio (SNR) ratings were based on expected improvement in SNR given the processing approach. For Listening Comfort, a true noise reduction algorithm is best; however, "Low internal noise" as measured via electroacoustic analyses indicates no unpleasant circuit noise and so was included as a comfort feature.

Mamo et al (2016)

Literature Review – EAC

RESEARCH

PSAPs vs Hearing Aids: An Electroacoustic Analysis of Performance and Fitting Capabilities

Published on June 14, 2016

Research | July 2016 *Hearing Review*

A study of 11 low-end and high-end hearing aids and PSAPs

By Chase Smith, Laura Ann Wilber, PhD, and Kim Cavitt, AuD

This study evaluating 11 low-end and high-end hearing aids and PSAPs showed that all high-end hearing aids were able to fit most audiometric configurations, and two high-end PSAPs and one app were able to fit up to a moderate loss configuration. Most low-end hearing aids and PSAPs had inappropriately high amounts of low-frequency gain. High-end PSAPs provided appropriate levels of

Current estimates place the number of Americans age 50 or older with a measureable hearing loss at 26.7 million.[1] Most forms of sensorineural hearing loss are not medically treatable, and without intervention can have a severe negative impact on an individual's quality of life.[2] Hearing loss has been positively correlated with increased likelihood of dementia,[3] cognitive impairment,[4] and social isolation.[5] Hearing

Related Articles


The Changing Landscape of Hearing Aid Batteries


Hearing Aid Dispensing Practices: Take Our Current Market Trends Survey

Hear what people are saying about Oticon Opn™


NASEM Committee Looks at Regulations for OTC Hearing Devices


NEW Webinar: Hearing Loss and Associated Comorbidities: What Do We Know?


OTC Hearing Aid Act Bundled with MDUFA; Expected to Pass through Committee

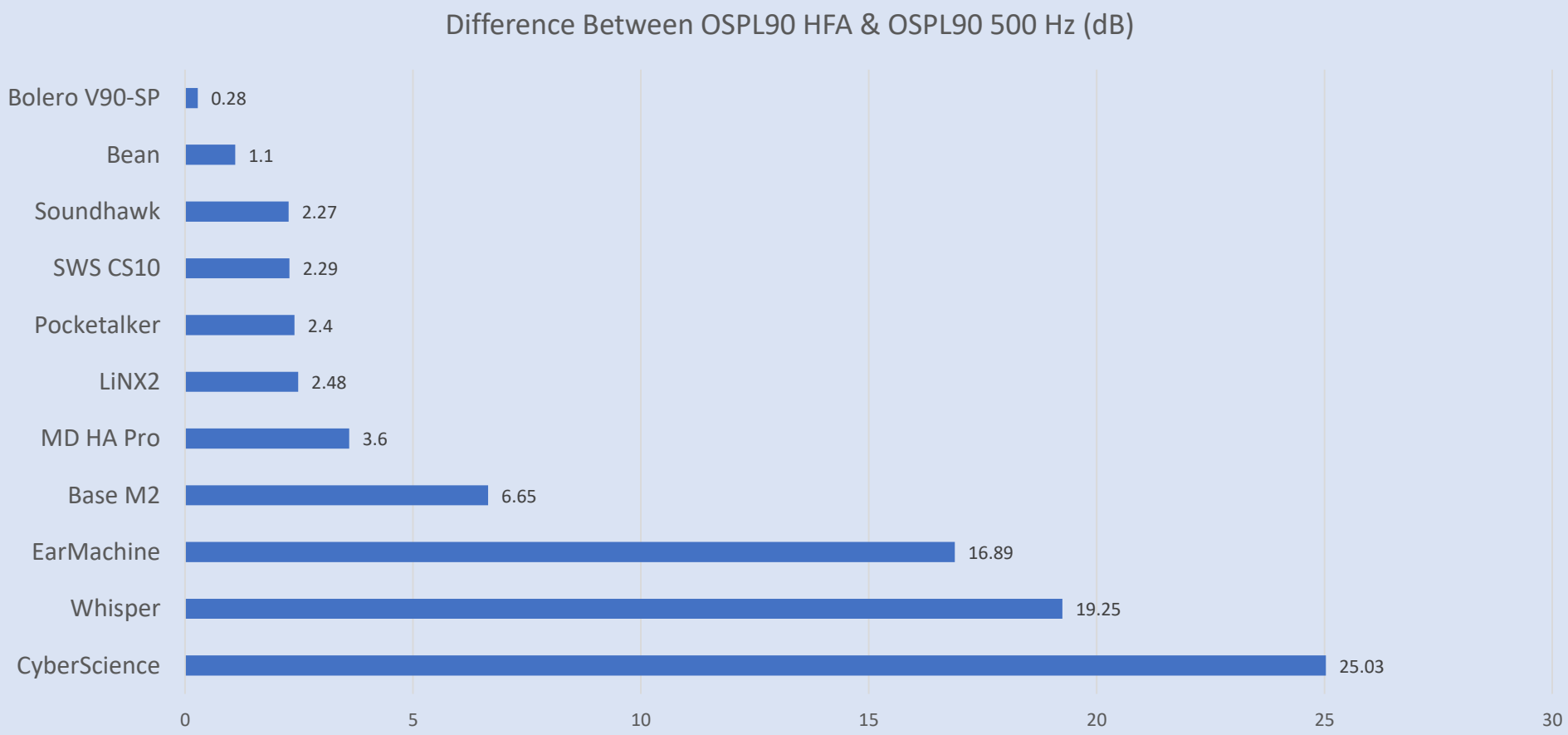
Videos & Podcasts

PSAPs			Hearing Aids		
Low-End	**Price**	**Retailer**	**Low-End**	**Price**	**Retailer**
EarMachine	$1	Apple App Store	MD Hearing Aid Pro	$199	Mdhearingaid.com
Woodland Whisper	$8	CVS	Etymotic Bean	$299	Etymotic.com
Cyberscience Amplifier	$49	Amazon.com	Hansaton Base m2	$399	Lloydhearingaid.com
High-End	**Price**	**Retailer**	**High-End**	**Price**	**Retailer**
Williams Sound Pocketalker Ultra	$117	Amazon.com	ReSound LiNX^2 9	$3200	Available only from authorized dispensing professionals
Soundworld Solutions CS10	$149	Soundworldsolutions.com	Phonak Bolero V90-SP	$3200	Available only from authorized dispensing professionals
Soundhawk	$349	Store.soundhawk.com			

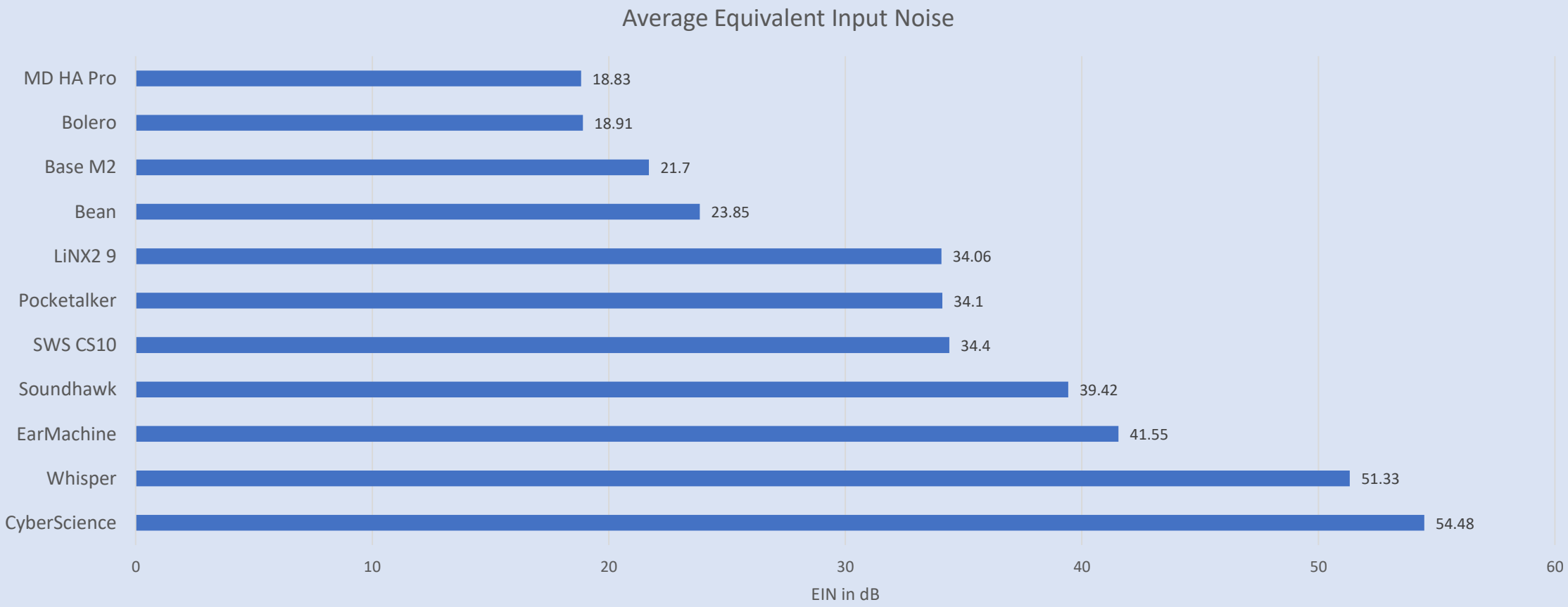
Part 1: EAA

- Each device placed in Aurical HIT test box with 2 cc coupler
  - Multiple measurements performed on each device
- Examining:
  - OSPL90 High Frequency Average vs. 500 Hz
  - Equivalent Input Noise Level
  - Total Harmonic Distortion
  - Directionality

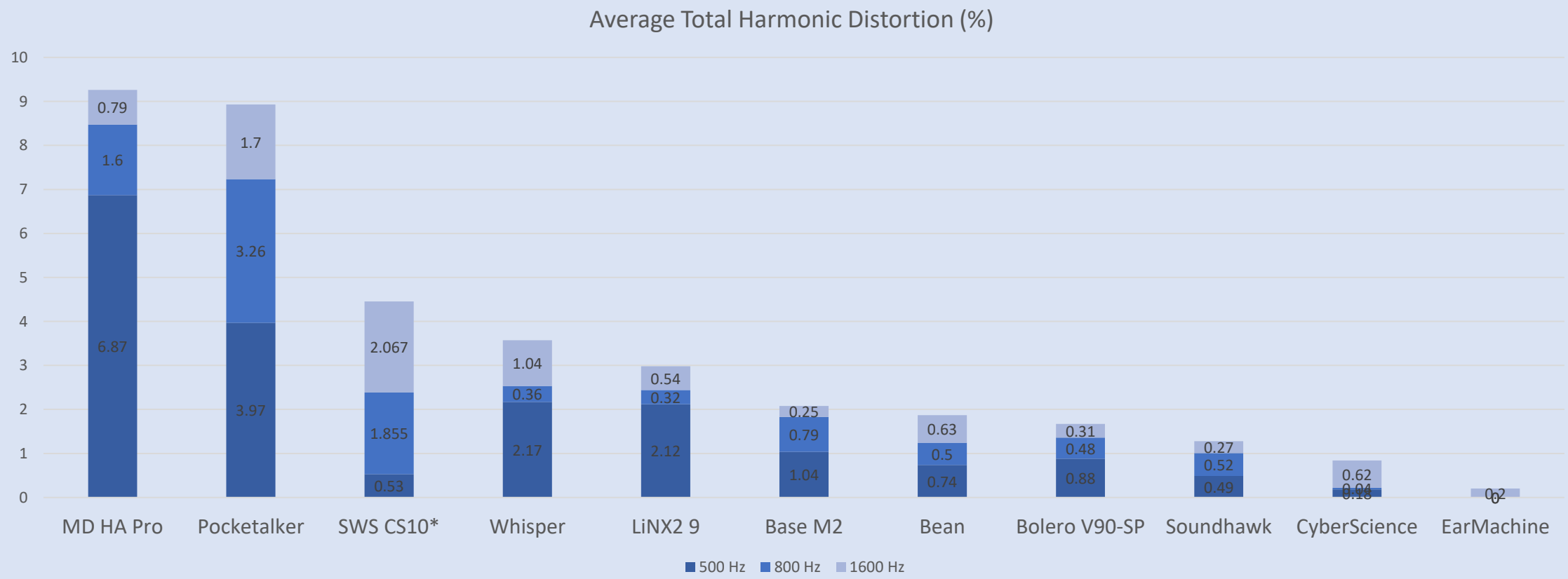
OSPL90 HFA vs. 500 Hz



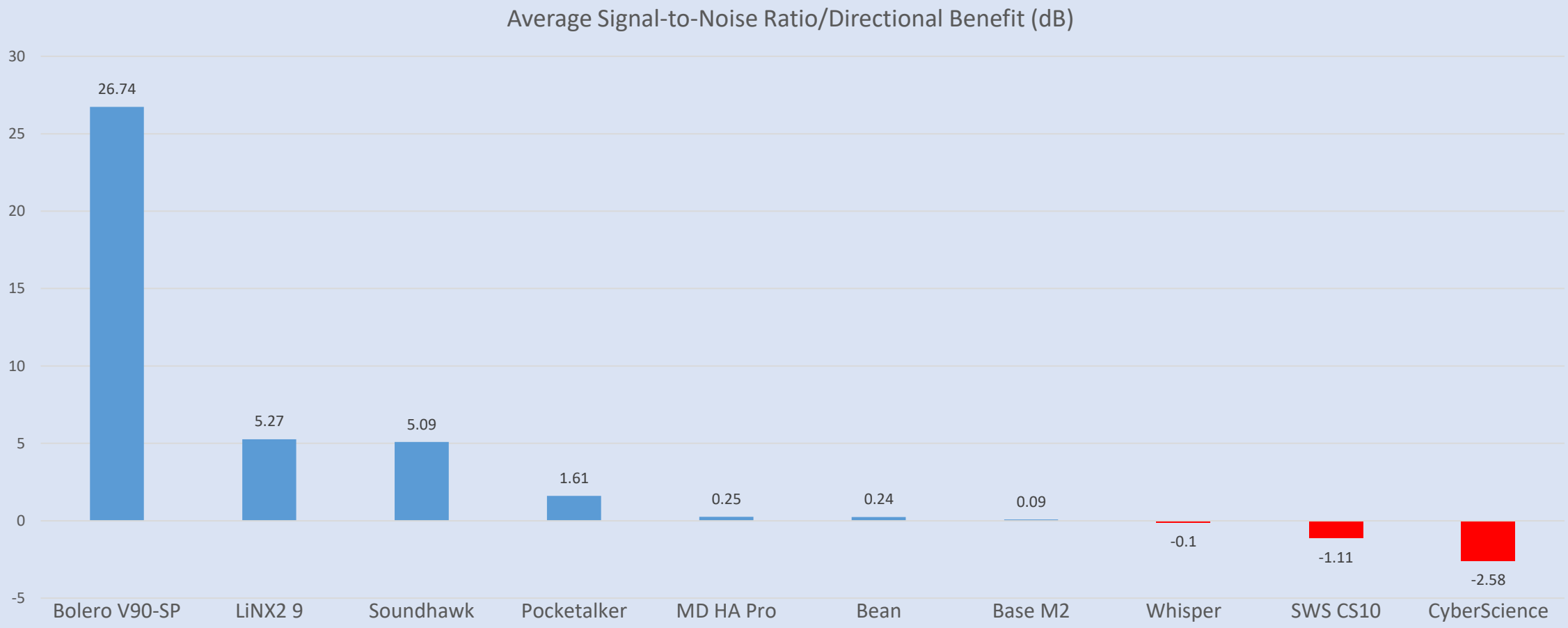
Equivalent Input Noise



Total Harmonic Distortion



Directionality



Part 2: Real-Ear Measurements

Flat & Moderately Sloping									
Configuration	250	500	750	1000	1500	2000	3000	4000	6000
Very Mild	10	10	10	10	10	15	20	30	40
Mild	20	20	22.5	25	30	35	40	45	50
Moderate	35	35	35	40	45	50	55	60	65
Moderate/Severe	55	55	55	55	60	65	70	75	80
Severe I	65	70	72.5	75	80	80	80	80	80
Severe II	75	80	82.5	85	90	90	95	100	100
Profound	90	95	100	105	105	105	105	105	105
Precipitously Sloping									
Configuration	250	500	750	1000	1500	2000	3000	4000	6000
Very Mild	10	10	10	10	10	15	30	55	70
Mild	20	20	22.5	25	35	55	75	95	95
Moderate/Severe	30	35	47.5	60	70	75	80	80	85

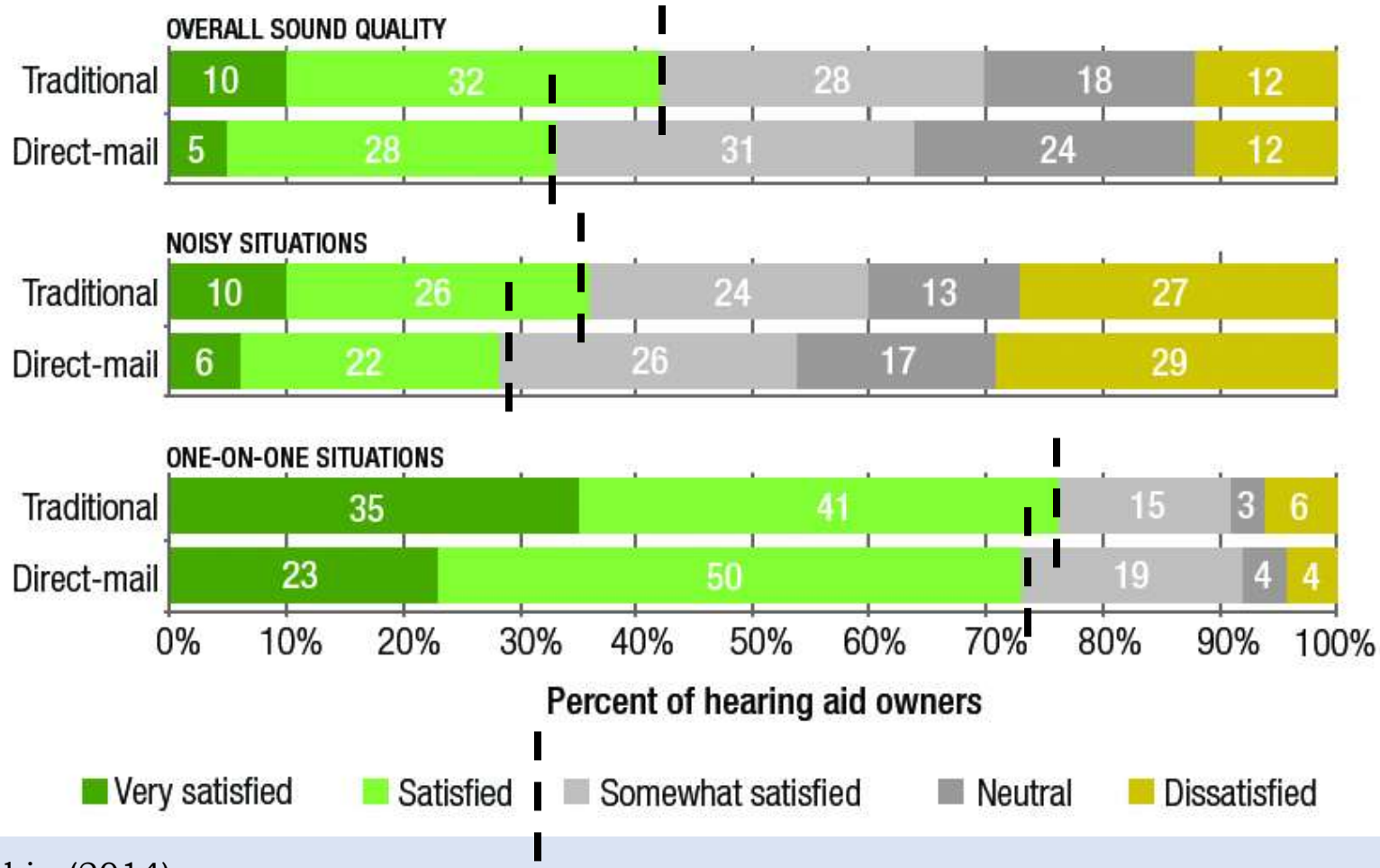
		Flat & Gently-Sloping						
Device	Category	Very Mild	Mild	Moderate	Moderate-Severe	Severe I	Severe II	Profound
LiNX2 9	HE HA	99%	100%	100%	100%	97%	90%	66%
Bolero V90	HE HA	98%	100%	99%	97%	79%	61%	36%
Base m2	LE HA	93%	98%	95%	92%	40%	8%	1%
Soundhawk	HE PSAP	99%	98%	96%	65%	13%	0%	0%
EarMachine	LE PSAP	93%	97%	88%	57%	27%	12%	0%
SWS CS10	HE PSAP	98%	96%	91%	84%	23%	0%	0%
Bean	LE HA	99%	94%	69%	14%	0%	0%	0%
Pocketalker	HE PSAP	90%	88%	75%	72%	47%	21%	3%
MD HA Pro	LE HA	80%	78%	71%	65%	36%	14%	0%
Cyberscience	LE PSAP	52%	46%	37%	35%	39%	21%	2%
Whisper	LE PSAP	38%	37%	31%	30%	21%	14%	0%

		Steeply-Sloping		
Device	Category	Very Mild	Mild	Moderate-Severe
LiNX2 9	HE HA	98%	98%	99%
Bolero V90	HE HA	97%	96%	91%
Base m2	LE HA	90%	93%	72%
Soundhawk	HE PSAP	99%	98%	68%
EarMachine	LE PSAP	91%	88%	48%
SWS CS10	HE PSAP	96%	86%	69%
Bean	LE HA	94%	67%	23%
Pocketalker	HE PSAP	87%	82%	63%
MD HA Pro	LE HA	77%	82%	60%
Cyberscience	LE PSAP	47%	36%	31%
Whisper	LE PSAP	44%	38%	31%

± 10 dB of target
88% cutoff

Literature Review – Behavioral

Figure 3. Consumer satisfaction on overall sound quality, performance in noise and one-on-one situations comparing traditional and direct-mail hearing aids.



Kochkin (2014)

Speech Understanding in Noise

Reed et al (2011)

Table. Accuracy in Speech Understanding in Noise From Unaided to Aided With PSAPs and a Hearing Aid Among 42 Older Adults With Mild to Moderate Hearing Loss[a]

	Cost, US $[b]	Mean Accuracy, % (95% CI)	Change From Unaided Hearing, Percentage Points (95% CI)	Difference Between PSAP and Hearing Aid Change, Percentage Points (95% CI)
Unaided hearing		76.5 (72.7 to 80.3)		NA
Oticon Nera 2 hearing aid[c]	1910.00	88.4 (84.5 to 92.4)	11.9 (9.8 to 14.0)	
PSAP				
Sound World Solutions CS50+	349.99	87.4 (83.5 to 91.4)	11.0 (8.8 to 13.1)	−1.0 (−2.7 to 0.8)
Soundhawk	349.99	86.7 (82.7 to 90.6)	10.2 (8.0 to 12.3)	−1.8 (−3.5 to 0)
Etymotic BEAN	299.99	84.1 (80.2 to 88.1)	7.7 (5.5 to 9.8)	−4.3 (−6.1 to −2.5)
Tweak Focus	269.99	81.4 (77.4 to 85.3)	4.9 (2.8 to 7.0)	−7.0 (−8.8 to −5.3)
MSA 30X Sound Amplifier	29.99	65.3 (60.1 to 70.4)	−11.2 (−15.2 to −7.3)	−23.1 (−26.9 to −19.4)

Abbreviations: NA, not applicable; PSAP, personal sound amplification products.

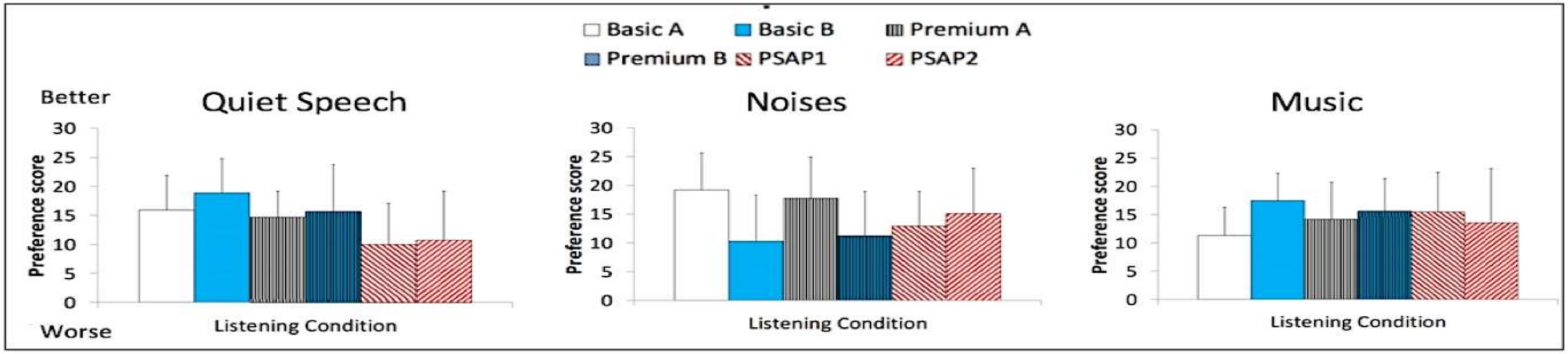
[a] The pure-tone average was 500-4000 Hz; the mean dB HL was 34.7 in the right ear and 36.1 in the left ear.

[b] The cost of the hearing aid was the wholesale price paid by the Johns Hopkins University Audiology Clinic. PSAPs were purchased online (Sound World Solutions CS50+, Soundhawk, Etymotic BEAN, Tweak Focus) and storefront retail (MSA 30X Sound Amplifier). All devices were purchased between January 2016 and April 2016.

[c] Oticon Nera 2 is a US Food and Drug Administration–regulated hearing aid, whereas all other devices are PSAPs.

Sound Quality Preference

Xu, Johnson, Cox, & Breitbart (2015)…*American Auditory Society*



9 Exp HA user

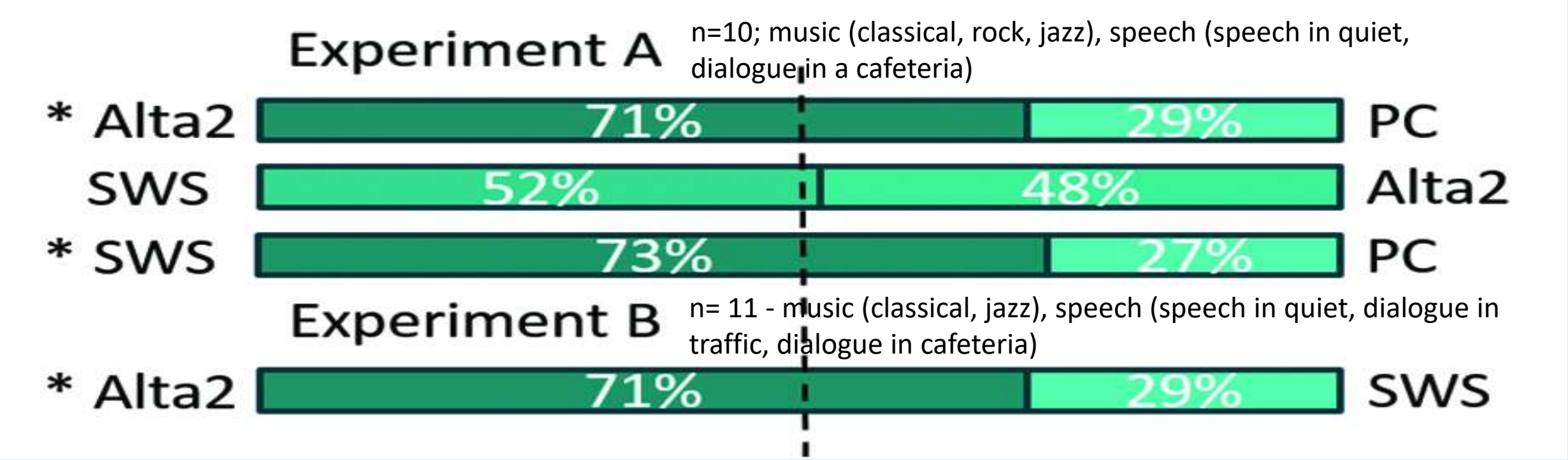
All devices adjusted to NAL-NL2

Stimuli presented as WAV files, monaurally

Preferences based on round-robin paired comparisons

Sound Quality

Ronne & Rossing (2016)…*Hearing Review*



PC = Perfect Choice
SWS = Sound World Solutions CS50+
Alta2 = Oticon

Study Rationale

OTC products, presumably, have poorer sound quality, as measured electroacoustically (Chan & McPherson, 2015; European Association of Hearing Aid Professionals/European Federation of Hard of Hearing People (2015)).

It is conjectured, then, that OTCs—which have lower retail prices—will demonstrate poorer sound quality, and reduced perceived value, compared to premium hearing aids

Relationship between OTC Electroacoustic Performance and Price

Relationship between OTC Price and Behavioral Performance: A Guiding Light

By Holly Hosford-Dunn On August 22, 2017 · Add Comment

by Amyn Amlani, PhD

Amyn Amlani, PhD

The reality of over-the-counter (OTC) products becoming federally regulated took one step closer to certainty last week. The FDA Reauthorization Act of 2017 (HR 2430), which includes provisions for OTC hearing aids for adults with perceived mild-to-moderate hearing loss, passed successfully through the US House of Representatives in July 2017 and through the US Senate in August 2017, and was signed into law by President Trump late last week.

While this bill will improve consumer access to a low-cost alternative to traditional hearing aids, the literature on OTC performance and patient outcome is still in its infancy. In fact, the preconceived notion—from the provider side—is that OTC devices are inferior in performance to traditional hearing aids, and thus performance and patient outcomes will be compromised compared to a traditional hearing aid.

In this post, we take a closer look at the existing literature on OTC electroacoustic performance, and how these electroacoustic data influence behavioral performance *for devices fit by an experienced practitioner*. The findings from the literature are then cast to provide insight into what the future holds for the hearing aid market.

Electroacoustic Performance

There is a growing body of research on OTCs and hearing aids that indicates, "*You get what you pay for.*"[1-5]

In general, OTC devices and traditional hearing aids that retail for *less* than $150 and $500 per unit, respectively, tend to yield unacceptable levels of equivalent input noise (EIN) and total harmonic distortion based on ANSI standards for traditional hearing aids. These same, economically-priced devices provide insufficient high-frequency amplification and too much low-frequency amplification for moderate degrees of hearing losses relative to a prescriptive target.

For OTC devices and hearing aids retailing for *more* than $150 and $500 per unit, respectively, the literature indicates that most devices provide acceptable electroacoustic tolerance levels relative to the ANSI standards for traditional hearing aids. These same, premium-priced devices tend to yield appropriate levels of amplification for moderate degrees of hearing losses relative to a prescriptive target.

Amlani (2017)

Table 1. Overview of hearing device characteristics for all over-the-counter devices included in the study, listed by unit cost.

Device	Unit cost	Manufacturer	Style	Processing type	Input/output type
Low-range devices					
SSI Mini Hearing E&P	$10	SSI LLC	BTE: receiver ITC	ANP	Linear
Woodland Whisper ITE AC	$15	Nature Vision	ITC	ANP	Linear
MagniEar+	$17	Well Brain International	ITC	ANP	Linear
SSI Gamestalker	$18	SSI LLC	ITC	ANP	Linear
Woodland Whisper 2	$18	Nature Vision	BTE: receiver ITC	ANP	Linear
Mini Ear Amplifier	$27	GBL	ITC	ANP	Linear
Original AmpliEar	$35	Well Brain International	ITC	ANP	Linear
EarMaster	$73	Baron Trading	BTE: receiver ITC	ANP	Linear
Midrange devices					
NaturEar	$349	Noexpress NaturEar	ITC	D, 1 ch	AGC-O
MaxiSound Digital	$399	Sonic Technology	ITE with eartips	D, 1 ch	AGC-O
HearPod II	$495	HearPod Hearing Aids	ITC	D, 1 ch	AGC-O

Note. BTE = behind-the-ear; ITC = in-the-canal; ITE = in-the-ear; ANP = analog nonprogrammable; D = digital; AGC-O = automatic gain control-output.

Table 2. Comparison of high-frequency average (HFA) and special-purpose average (SPA) full-on gain (FOG) with a 60-dB SPL input, listed by HFA FOG value.

Device	HFA FOG	SPA FOG	Difference in dB
Low-range devices			
SSI Gamestalker	2.4	16.9	14.5
Woodland Whisper ITE	11.7	30.9	19.2
Woodland Whisper 2	17.3	33.4	16.1
MagniEar+	18.7	33.9	15.2
Mini Ear Amplifier	21.2	40.9	19.7
AmpliEar	22.7	34.8	12.1
SSI Mini Hearing E&P	34.8	35.4	0.6
EarMaster	35.4	38.8	3.4
Midrange devices			
NaturEar	20.0	—	—
MaxiSound Digital	24.4	—	—
HearPod II	34.0	—	—

Note. Dash indicates data not available.

HFA-FOG = Data obtained at 1600 Hz, 2500 Hz, 4000 Hz
SPA-FOG = Data obtained at 1000 Hz, 1600 Hz, 2500 Hz

Calloway & Punch (2008)

Speech Understanding in Noise

Reed et al (2011)

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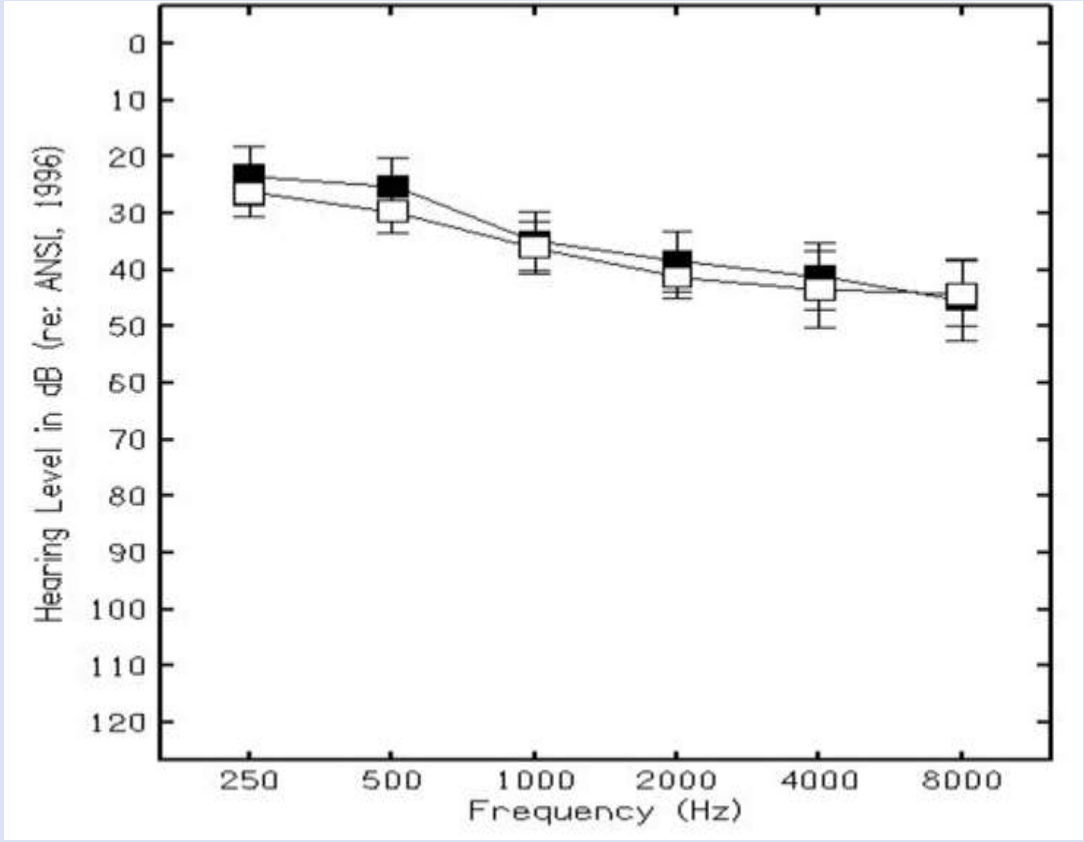
Methods

- Recruited 18 participants with bilateral, symmetrical, mild-to-moderate hearing sensitivity
  - Aged between 58 and 81 years
  - Mean = 64.8 years; SD = 4.9 years
  - 11 Females; 7 Males

  - Criteria
    - HA use bilateral for at least 10 hours/daily; >1 year experience with current device
    - No Hx of Middle- or Inner-Ear Pathology
    - Pass cognitive screening task



Methods – Traditional Devices

- Own HA (Retail price ≥ $2400 per unit)
  - Premium Level
    - ≥ 16-channel WDRC
  - Noise reduction, Fixed directionality, Adaptive feedback suppression
- EarVenture faVor (Retail price < $500 per unit)
  - 4-channel WRDC
  - 12 bands of gain adjustment
  - Noise reduction, Fixed directionality, Adaptive feedback suppression

Methods – OTC Devices

- Perfect Choice HD Ultra (Retail price < $200 per unit)
  - WDRC
  - Noise reduction, Feedback suppression
- iPod = EarMachine app (Retail price < $200 iPod; free app)
  - 9-channel wide-dynamic range compressor/limiter
  - 12-band equalizer
  - User interface allows the listener two controllers:
    - (1) frequency response
    - (2) loudness, which changes gain, compression, and limiting parameters in all 9-compression channels simultaneously
  - Hardwired with in-ear headphones having inline microphone (Klipsch Si4), fit with open domes

Smartphone Apps

FaVor

OTC – Mail Order

Traditional Hearing Aid

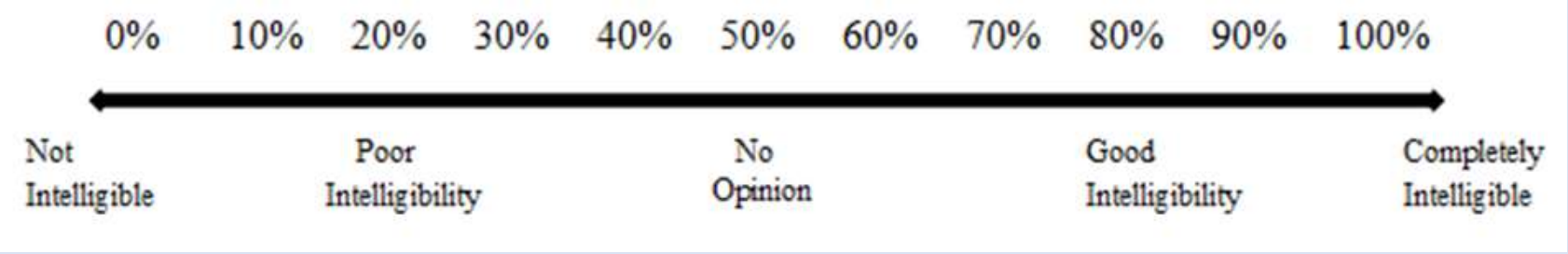
Methods

- Own hearing aid served as baseline
- All devices tested electroacoustically
- Gain for all other devices was matched to the participant's hearing aid
  - Participants hearing aids were within ± 5 dB of NAL-NL2 targets, as determined via real-ear measures (includes frequency-response changes preferred by listener)
  - Gain for all devices (save the OTC) within ± 3 dB of participant's hearing aid
    - i.e., ±8 dB of NAL-NL2 targets
  - Gain for OTC ± 8 dB of participant's hearing aid (i.e., ± 5-dB of OTCs)
    - i.e., ±13 dB of NAL-NL2 targets
    - Frequency bandwidth was narrower than other devices (F1 = 420 Hz; F2 = 4400 Hz)

- All devices professionally fit (no self-fit)
- Subjects apprised of retail price at outset of study

Methods

- Listeners were asked to wear devices in three real-world environments over a six-week period
  - Quiet (home, one-on-one conversations with no background noise)
  - Noisy (coffee shop, restaurant, group setting with multiple talkers)
  - Reverberant (house of prayer, theater)
- Devices worn for at least 15 minutes in each environment
- Device use was counterbalanced across listeners
- Two sets of sound quality ratings per environment, separated by two weeks
  - Modified version of Gabrielsson et al (1979)

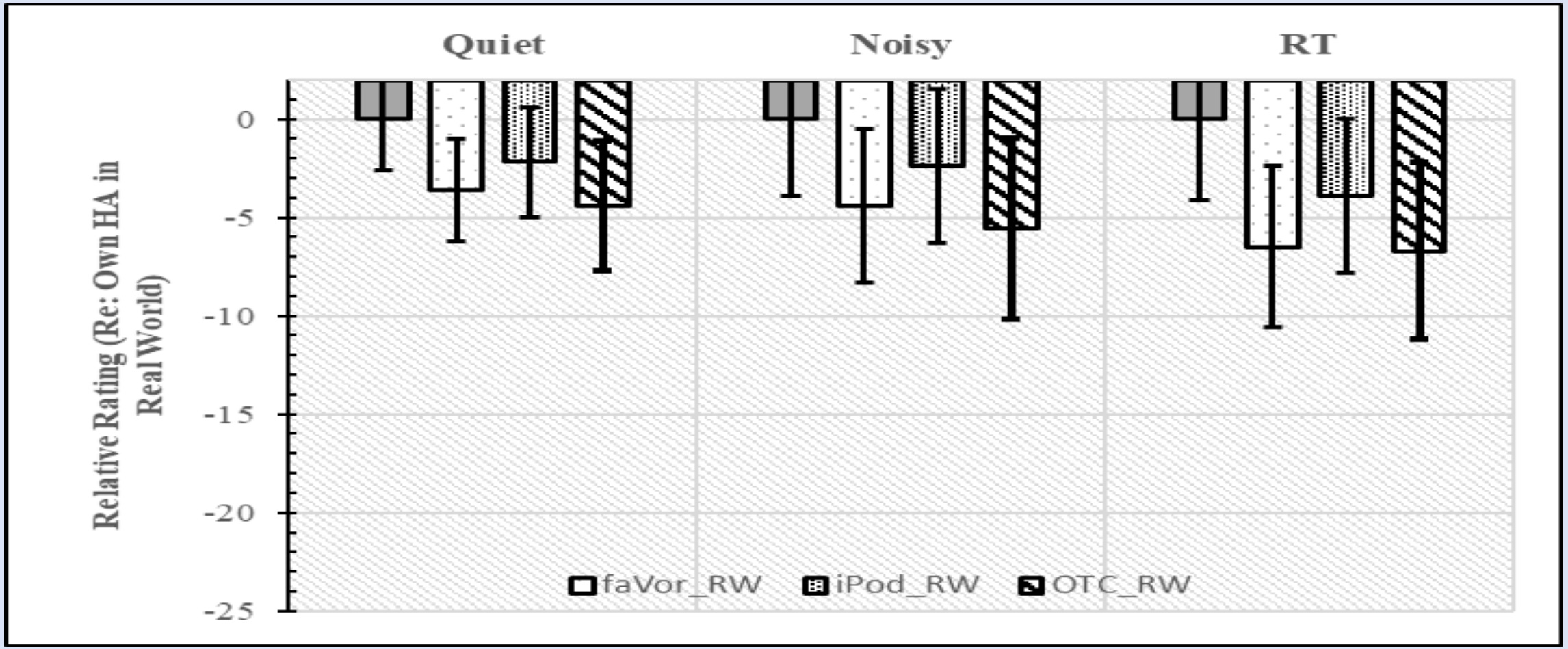


Methods

- Listeners also heard speech in a laboratory setting for these same three environments
  - Simulated using digital editor (Goldwave)
    - Target speech were the passages from the Connected Speech Test
    - Noise was multi-talker babble from CST
    - RT was applied for a medium room having RT = 1.17 sec
      - Based on sound measurement at local coffee shop
  - Scheduled 4-6 weeks after real-world trial period was completed

- Four ratings were made per simulated environment
  - Same scale used for real-world data collection
- Device use was counterbalanced across listeners

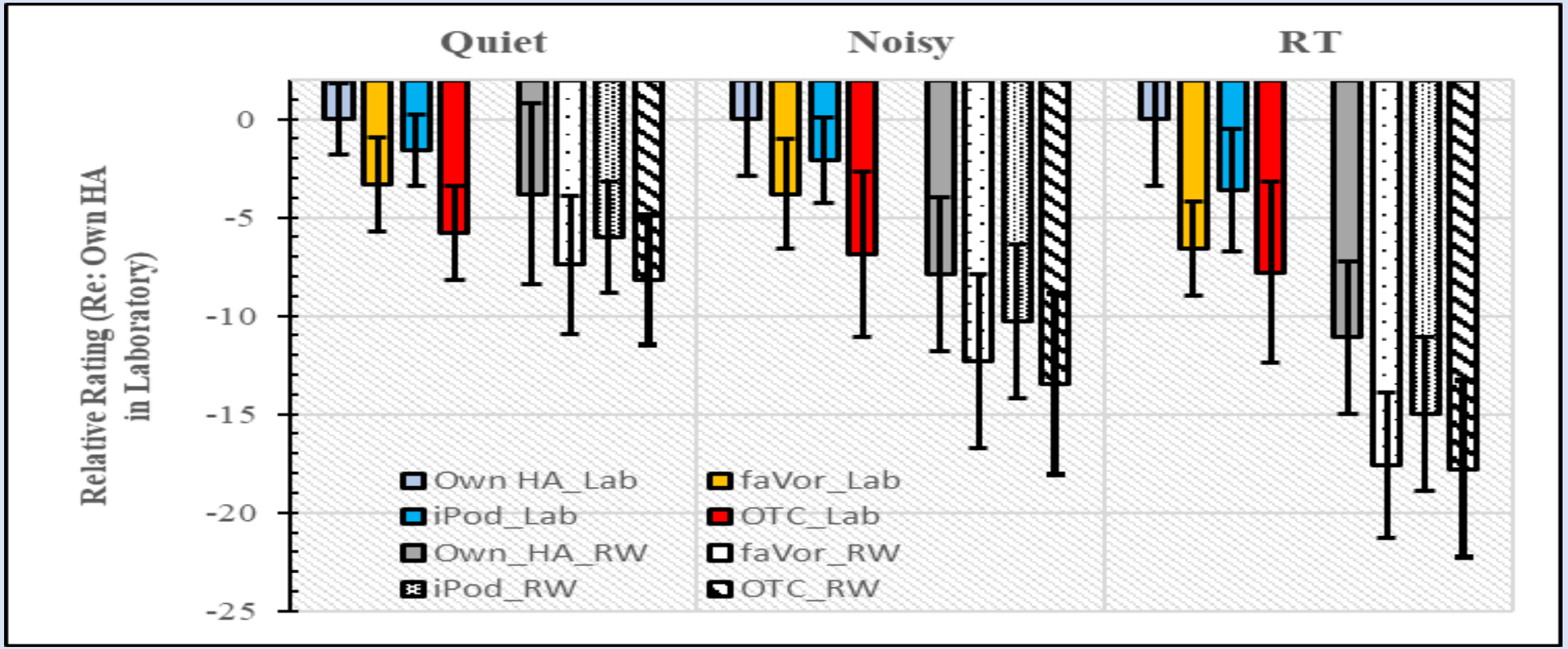
Clarity Ratings – Real World



How ***clear*** is the primary talker's speech after listening for a minimum of 15 minutes?

Own HA

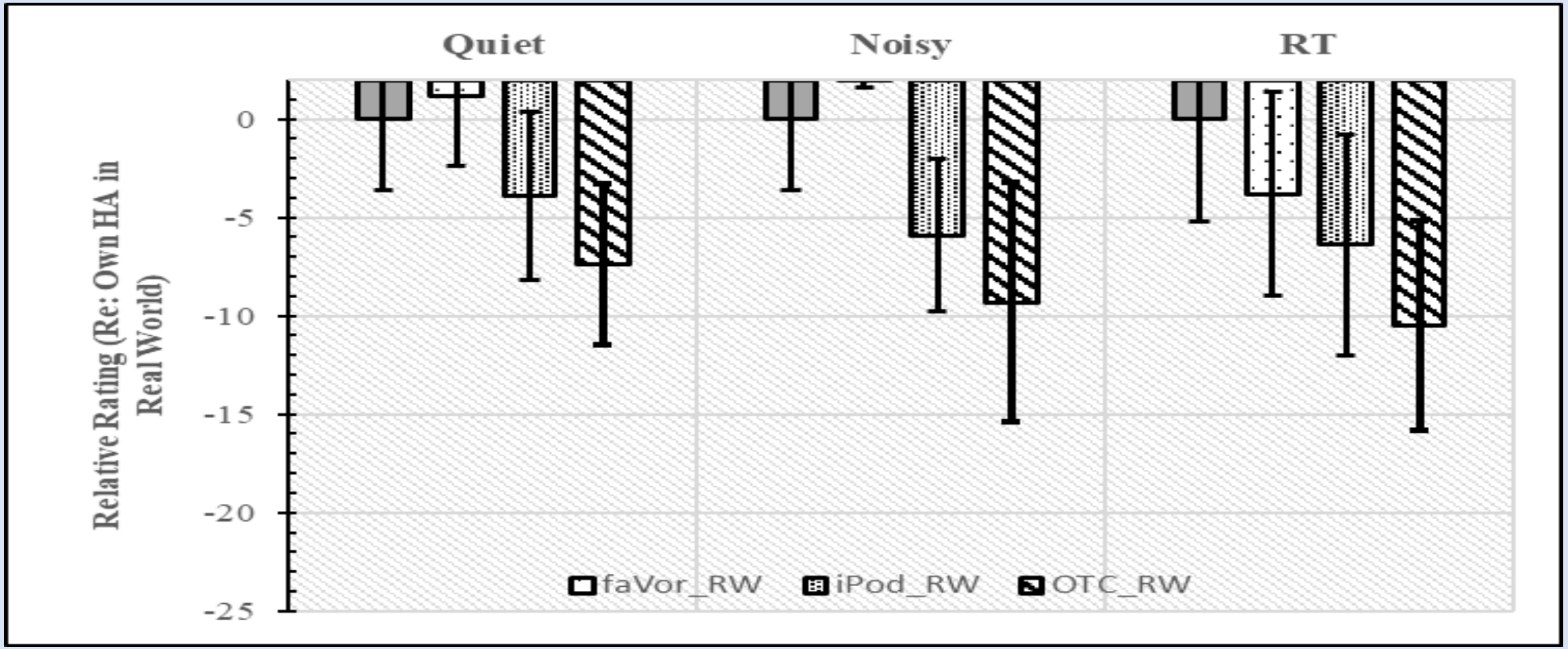
Clarity Ratings – Real World vs. Laboratory



How ***clear*** is the primary talker's speech after listening for a minimum of 15 minutes?

Own HA
Lab > RW

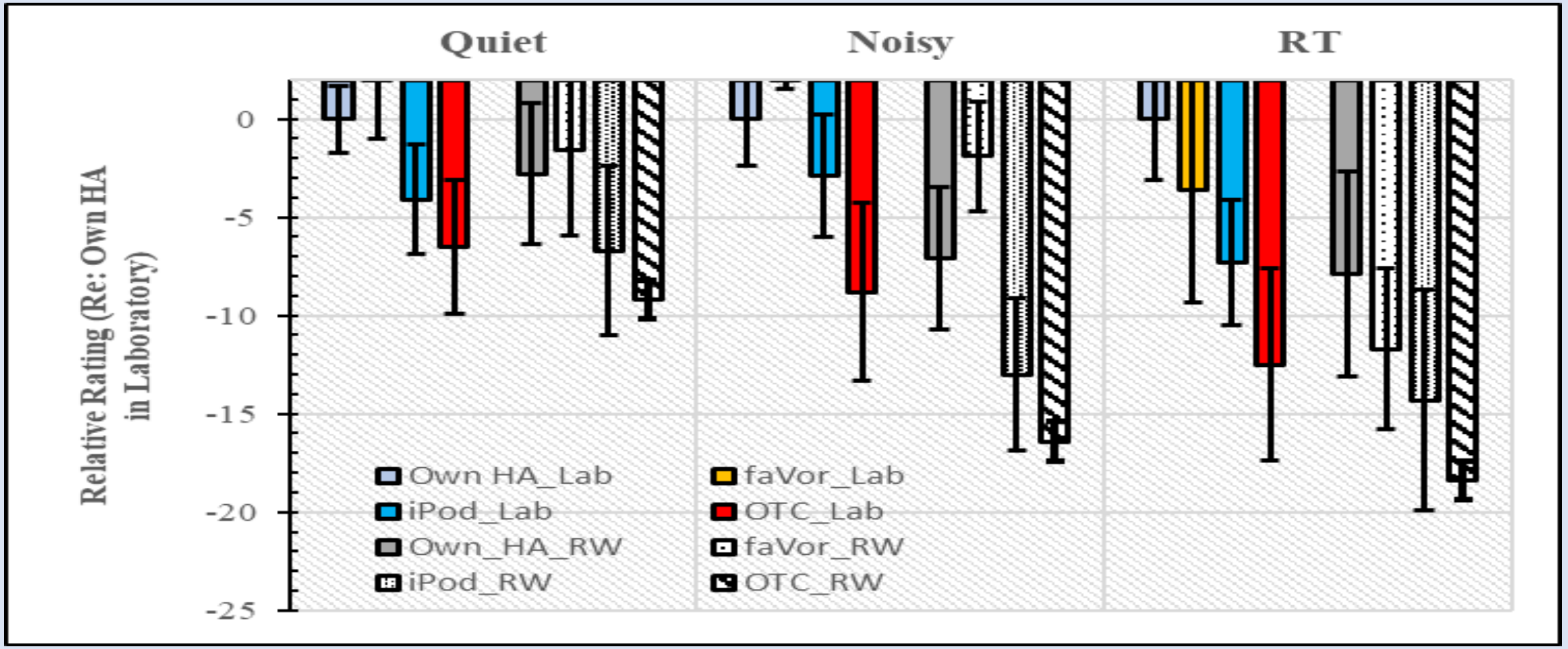
Comfort Ratings – Real World



How ***comfortable, based on loudness,*** is the primary talker's speech after listening for a minimum of 15 minutes?

iPod, save RT

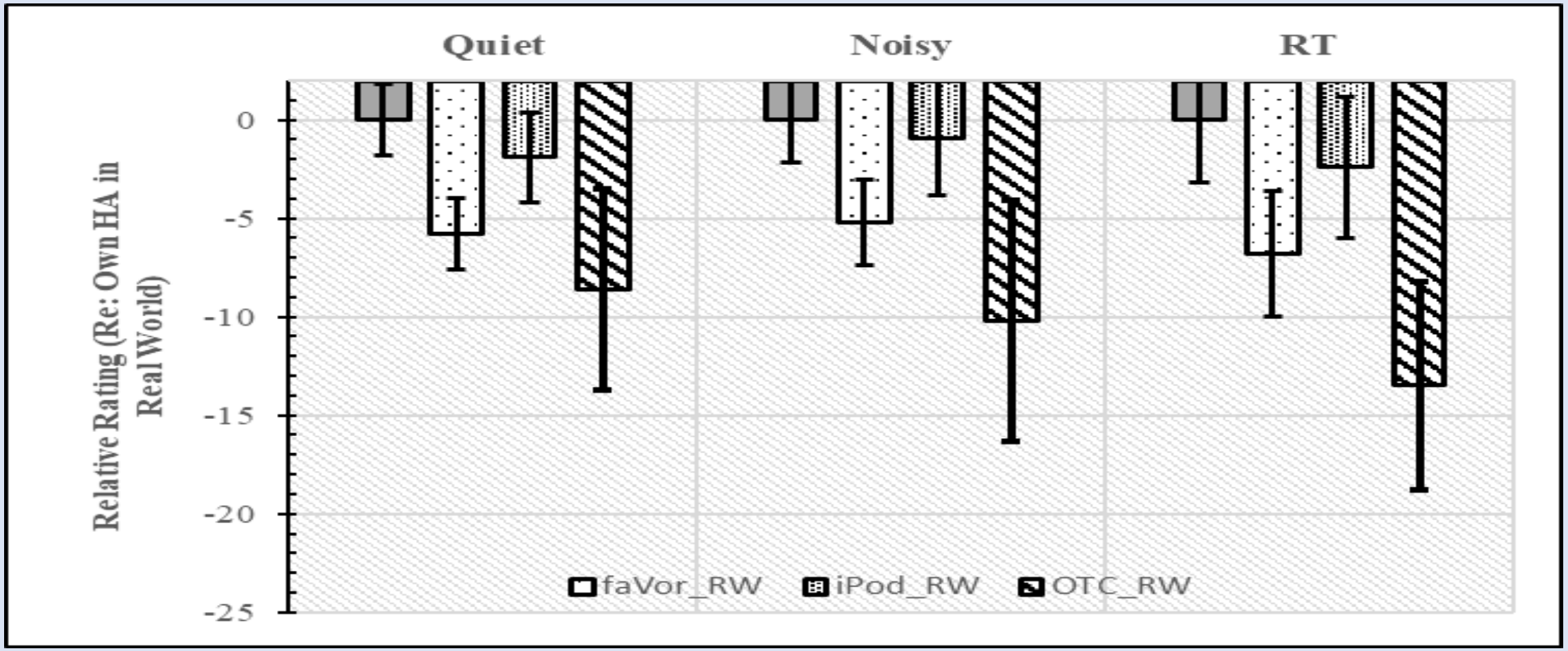
Comfort Ratings – Real World vs Laboratory



How ***comfortable, based on loudness,*** is the primary talker's speech after listening for a minimum of 15 minutes?

iPod, save RT
Lab > RW

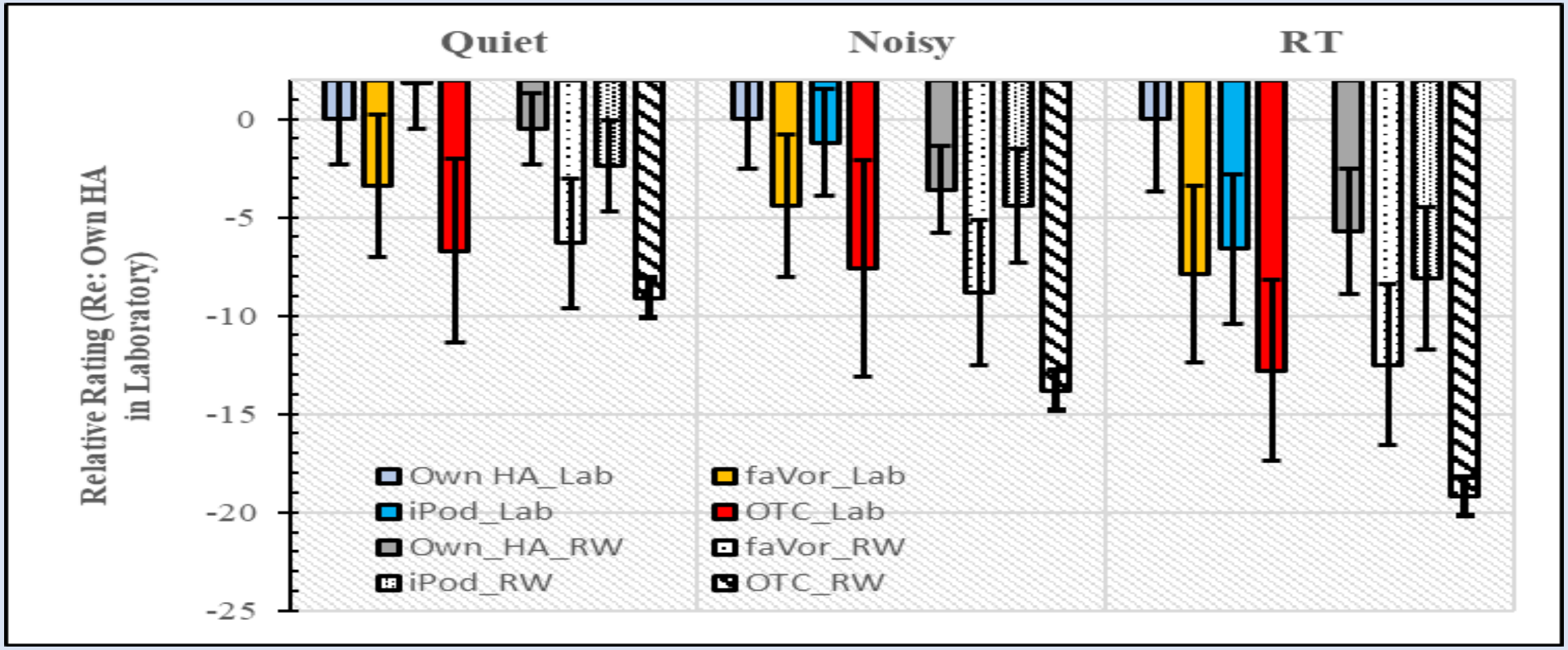
Intelligibility Ratings – Real World



How ***intelligible, or understandable,*** is the primary talker's speech after listening for a minimum of 15 minutes?

iPod and Own HA

Intelligibility Ratings – Real World vs. Laboratory

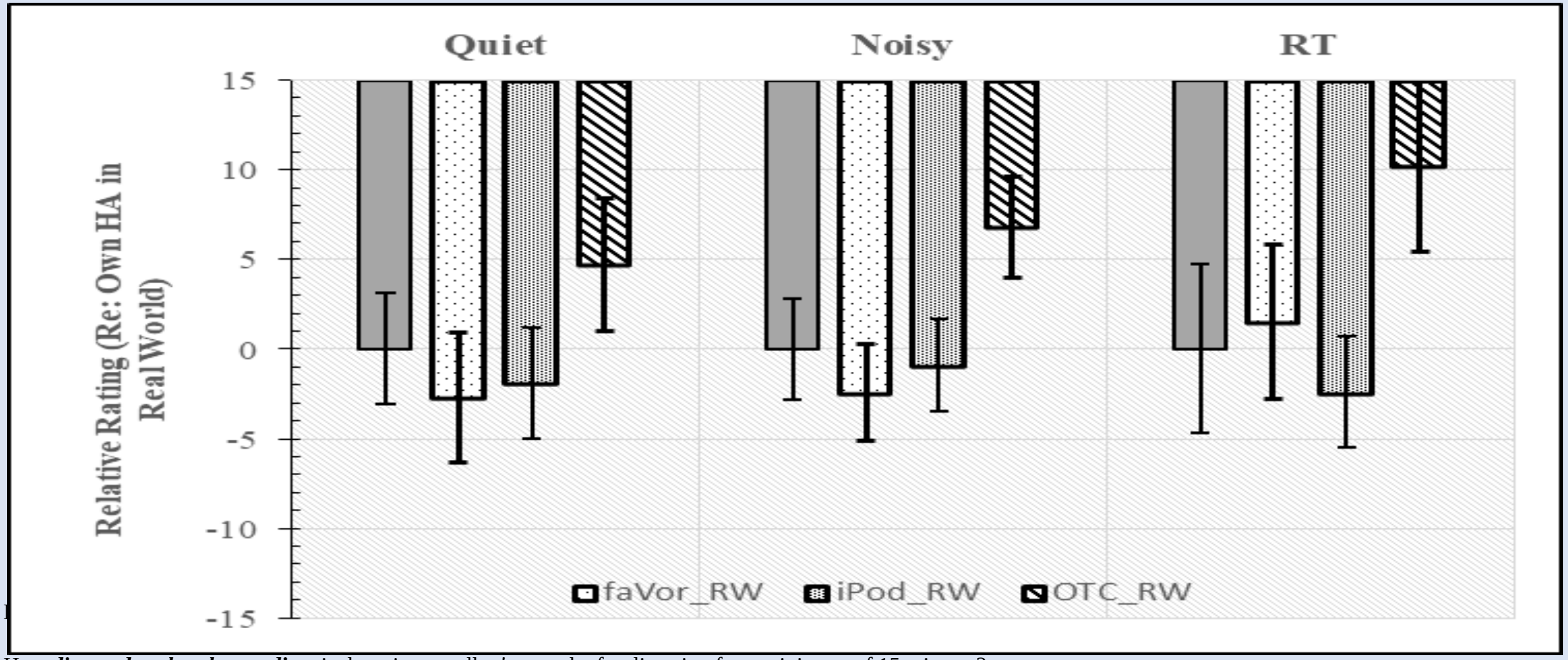


How ***intelligible, or understandable,*** is the primary talker's speech after listening for a minimum of 15 minutes?

iPod and own HA, save RT

Lab > RW

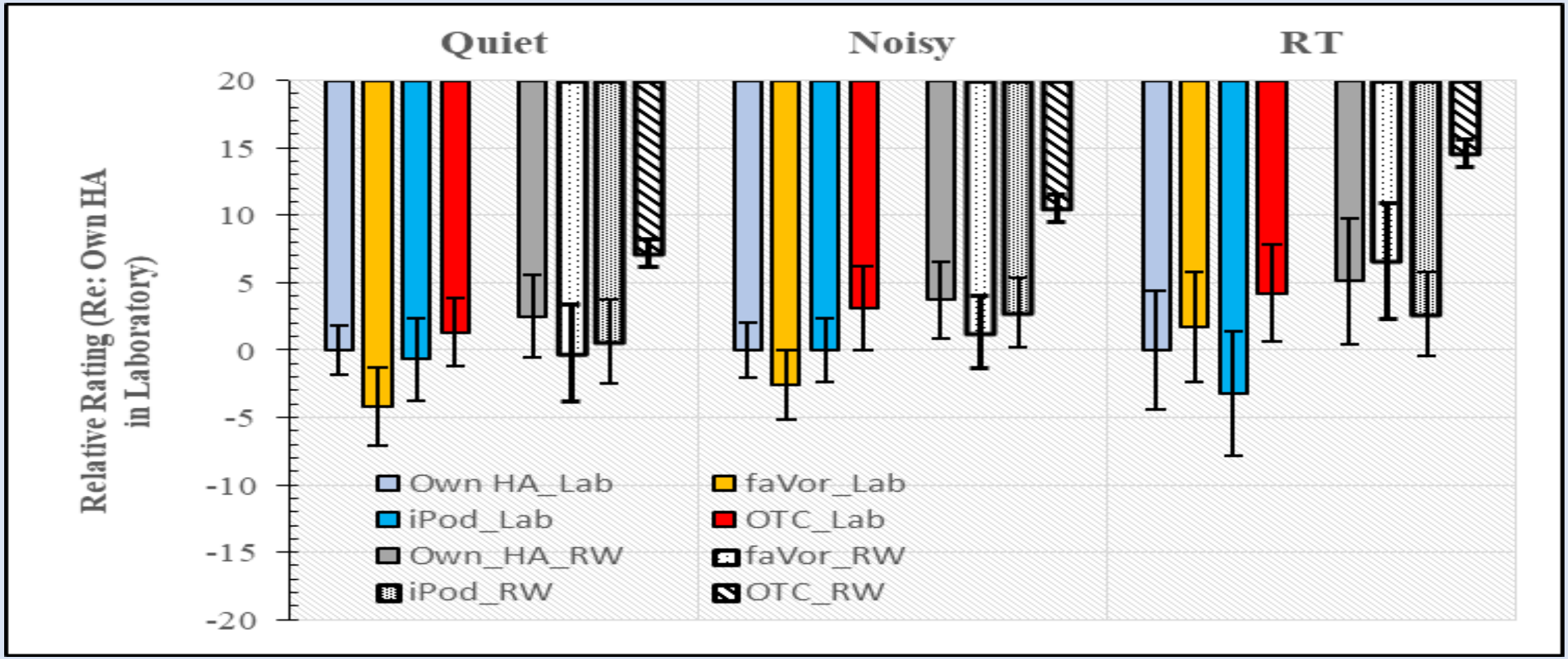
Distortion Ratings – Real World



How ***distorted, or harsh sounding,*** is the primary talker's speech after listening for a minimum of 15 minutes?
Closer to 0% is better; closer to 100% is worse

Own HA

Distortion Ratings – Real World vs Laboratory



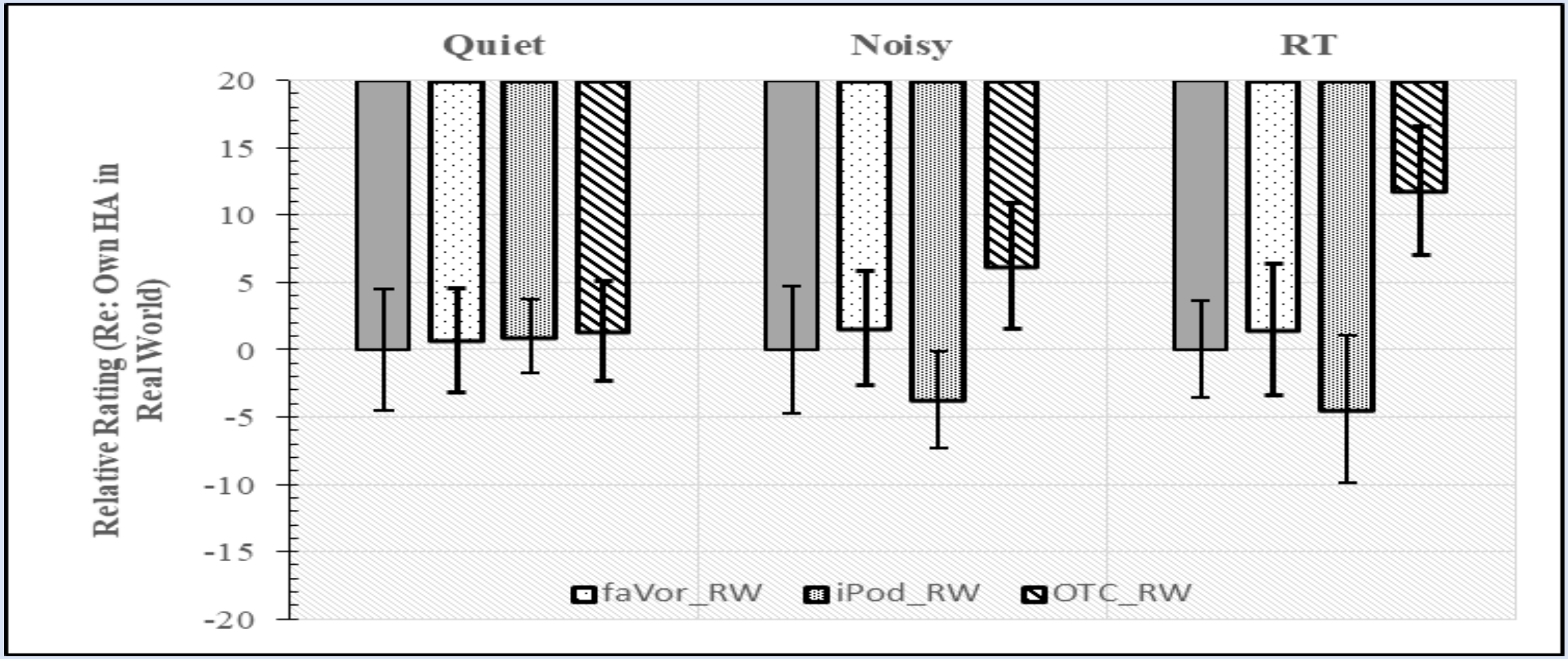
How ***distorted, or harsh sounding,*** is the primary talker's speech after listening for a minimum of 15 minutes?
Response closer to 0% is better; closer to 100% is worse

OTC is poorest

Lab > RW

Own HA

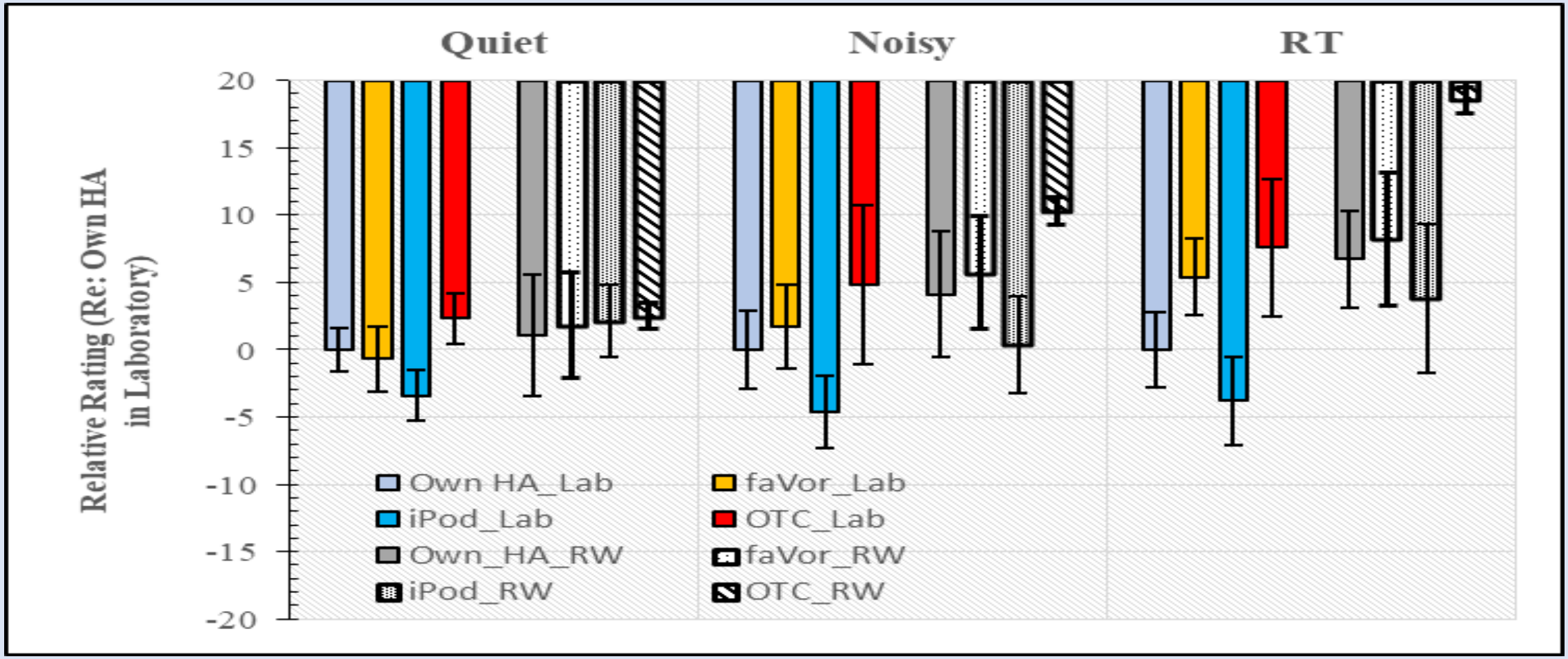
Noise Interference Ratings – Real World



How much did background noise ***interfere*** with your ability to understand the primary talker's message after listening for a minimum 15 minutes?
Response closer to 0% is better; closer to 100% is worse

Own HA

Noise Interference Ratings – Real World vs Laboratory



How much did background noise ***interfere*** with your ability to understand the primary talker's message after listening for a minimum 15 minutes?
Response closer to 0% is better; closer to 100% is worse

Own HA

Purchasing Trends – Post –Study (Lab portion)

- “If you were a first-time buyer again, and based on sound quality, which device would you select?”
  - faVor
    - 33% (6 out of 18)
  - iPod
    - 33% (6 out of 18)
  - Own HA
    - 22% (4 out of 18)
  - OTC
    - 11% (2 out of 18)

Purchasing Trends – Post –Study (RW portion)

- “If you were a first-time buyer again, and based on sound quality, which device would you select?”
  - iPod
    - 28% (5 out of 18)
  - Own HA
    - 28% (5 out of 18)
  - faVor
    - 28% (5 out of 18)
  - OTC
    - 17% (3 out of 18)

Purchasing trends based on perceived value, *NOT* price

Research Article

The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial

Larry E. Humes,[a] Sara E. Rogers,[a] Tera M. Quigley,[a] Anna K. Main,[a] Dana L. Kinney,[a] and Christine Herring[a]

Satisfaction		
Group	Uptake	Undecided (i.e., Benefit)
AB	81%	1.9%
CD	56%	17.6%
P	36%	38%

Table 6. Summary of significant main effects and interactions for general linear model (GLM) analyses of all hearing-aid outcome measures in the clinical trial.

Outcome measure	Service delivery (S)	Purchase price (PP)	S × PP
PHABglobal	AB > P, CD > P	NS	NS
PHABavds	NS	NS	NS
CST benefit	AB > P, CD > P	Typical > reduced[a]	NS
HHIE benefit	AB > P, CD > P	NS	NS
HASShaf	AB > CD, P	NS	NS
HASSdisp	AB, P > CD	NS	NS
Usage	NS	NS	NS

Note. AB = audiology best practices group; CD = consumer decides/over-the-counter group; P = placebo device group; NS = not significant ($p > .05$); PHABglobal = difference between aided and unaided scores of PHAPglobal (Profile of Hearing Aid Performance, average of the five communication-related subscales: Familiar Talkers, Ease of Communication, Reverberation, Reduced Cues, and Background Noise); PHABavds = difference between aided and unaided scores of PHAPavds (PHAPavds = Profile of Hearing Aid Performance, average of the Aversiveness of Sound and Distorted Sound subscales); CST benefit = difference between aided and unaided Connected Speech Test scores; HHIE benefit = difference between aided and unaided Hearing Handicap Inventory for the Elderly scores; HASShaf = Hearing Aid Satisfaction Survey, items concerning hearing aid features; HASSdisp = Hearing Aid Satisfaction Survey, items concerning dispenser-related processes.

[a]Typical > reduced also for unaided CST scores.

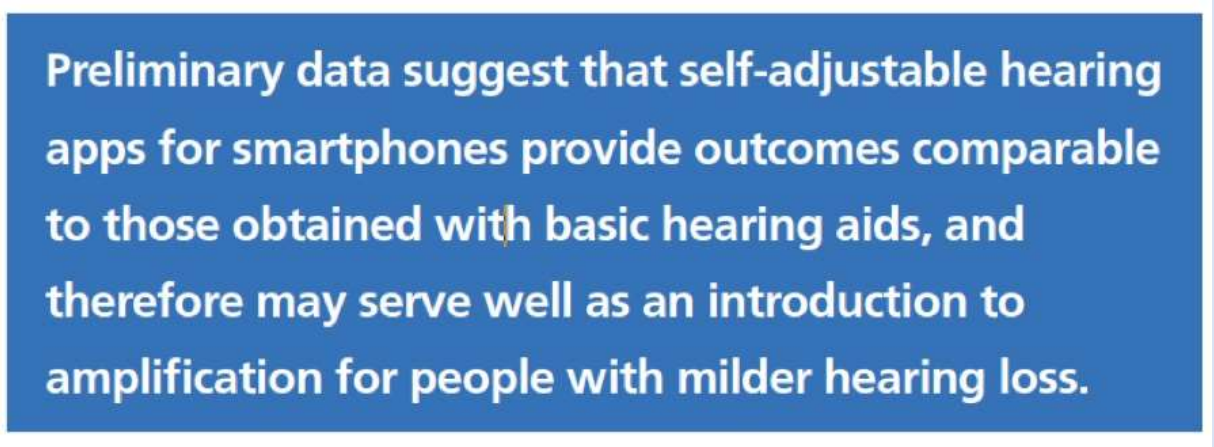
Summary

- Patients in US have options regarding amplification devices
- Sound quality ratings were higher (over-estimated) in the laboratory setting compared to the real-world setting
  - In-house patient counseling required to temper real-world expectations
- Sound quality dimensions yield differing ratings across products and environments
- Small perceptual differences in sound quality among most PSAP devices compared to traditional hearing aids
  - These differences could lend to increases /decreases perceived value

Are PSAPs a threat to traditional amplification?

- Under experimental conditions (i.e., clinician-fit), there is little difference between the electroacoustic properties among most devices
  - Most are adjustable to a prescriptive target
  - Economic standpoint = opportunity for patients and providers

- Unknown – PSAP outcomes from patient self-fitted devices



Convery et al (2016) – Self-Fitting Hearing aids

- Humes et al (2017) study – Used traditional hearing aids with 3 pre-programmed frequency responses

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