

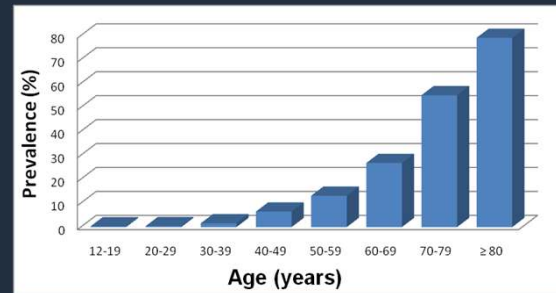
Efficacy and Effectiveness of Over-the-Counter Hearing Care

Nicholas S. Reed, AuD
(Frank R. Lin, MD, PhD)

Instructor of Otolaryngology
Johns Hopkins University
Baltimore, Maryland



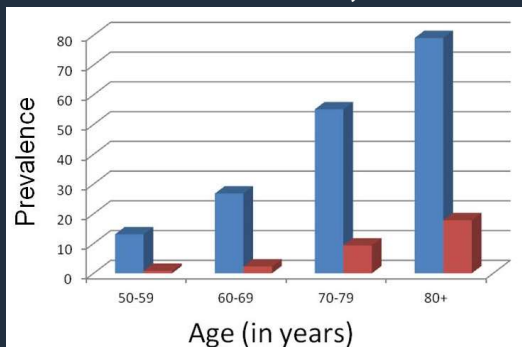
Prevalence of Hearing Loss in the United States, 2001-2008



Hearing loss defined as a better-ear PTA of 0.5-4kHz tones > 25 dB

Lin et al., Arch Int Med. 2011

Hearing Loss & Hearing Aid Use Prevalence in the U.S. , 1999-2006

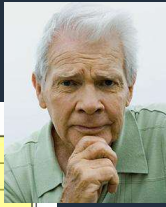
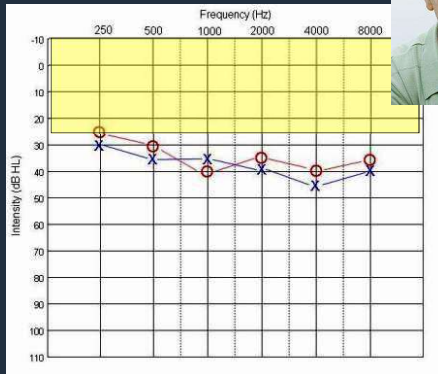


Chien W et al, Arch Int Med, 2012

Age-Related Hearing Loss (ARHL) *Basic Questions*

- What are the consequences of ARHL for older adults?
- What is the impact of treating ARHL on older adults?
- How can ARHL be effectively addressed in the community?

John Smith, 72 y.o.



Age-Related Hearing Loss (ARHL)

Basic Questions

- What are the consequences of ARHL for older adults?
- What is the impact of treating ARHL on older adults?
- How can ARHL be effectively addressed in the community?

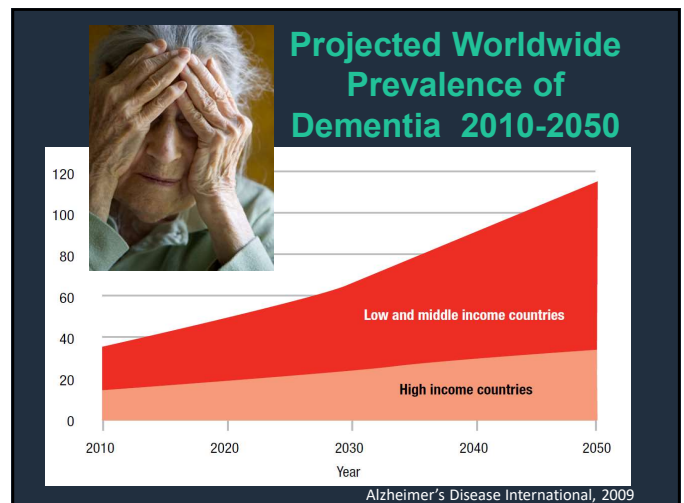
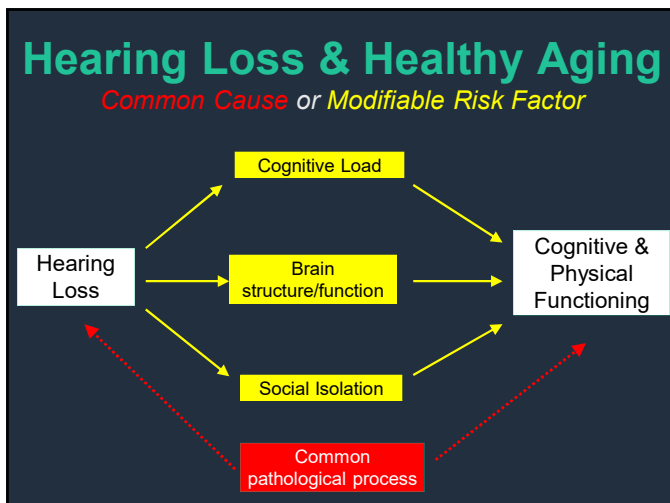
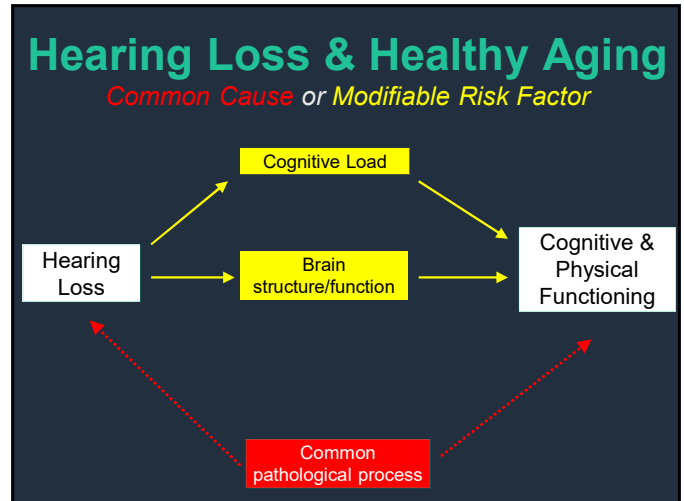
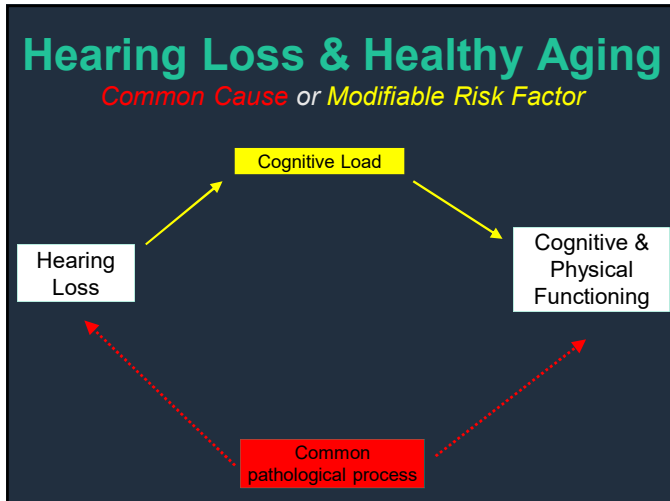
Healthy Aging

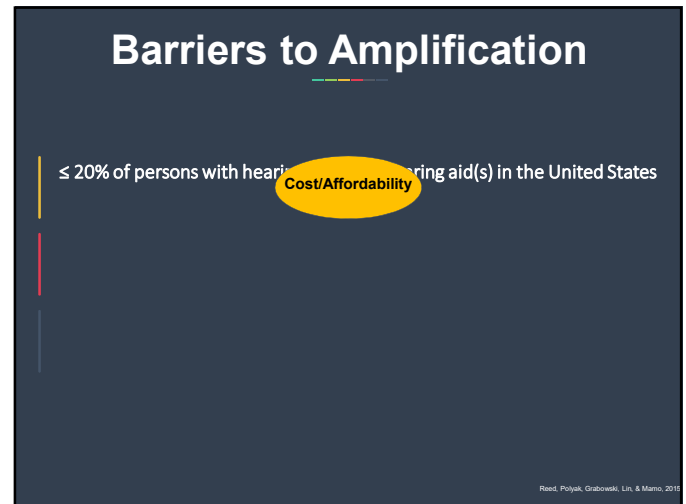
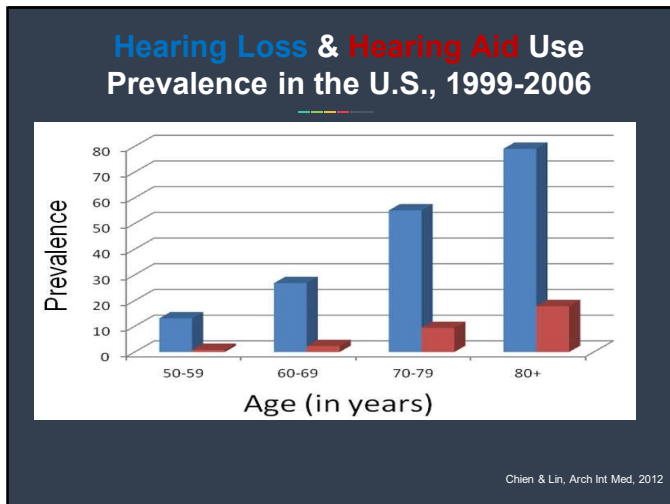
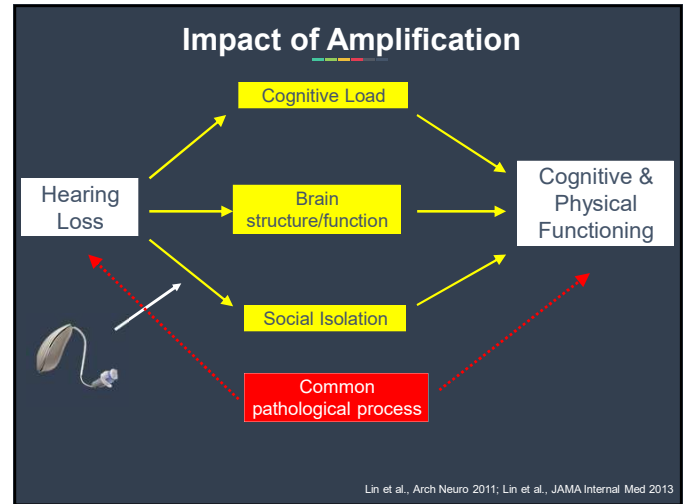
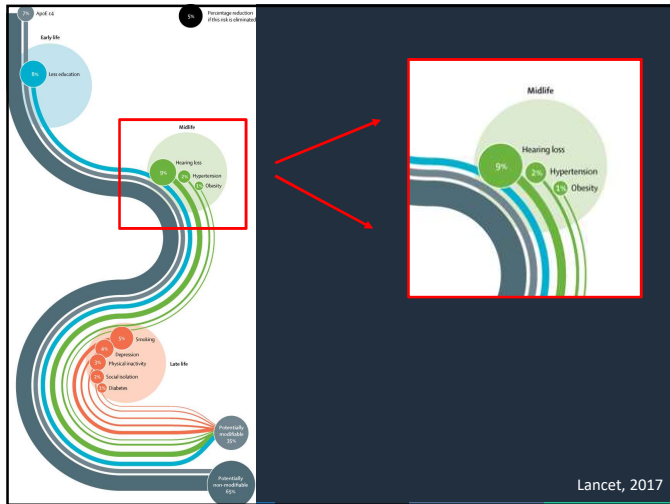


Hearing Loss & Healthy Aging

Common Cause or Modifiable Risk Factor







Barriers to Amplification

United States (Arch Int Med, 2012)

26.7M adults ≥ 50 years with hearing loss

3.8M use hearing aids

Overall rate of HA use: 14.2%

England and Wales (NICE Report, 2000)

8.1M with hearing loss

1.4M use hearing aids

Overall rate of HA use: 17.3%

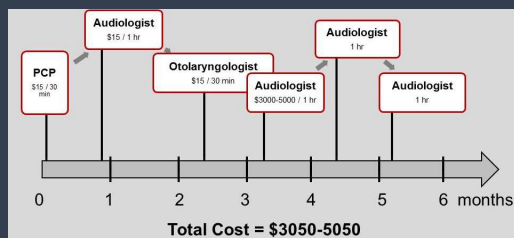
Barriers to Amplification

Cost/Affordability

Access to Services
& Technology

Reed, Poljak, Grabowski, Lin, & Mamo, 2015

Barriers to Amplification



Barriers to Amplification

Cost/Affordability

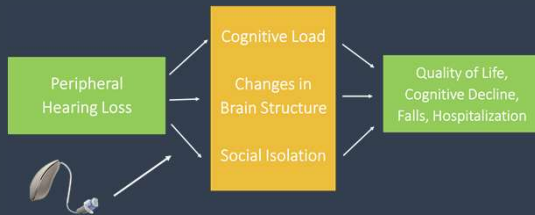
Awareness & Understanding

Access to Services
& Technology

Reed, Poljak, Grabowski, Lin, & Mamo, 2015

Barriers to Amplification

Awareness of impact/public health importance



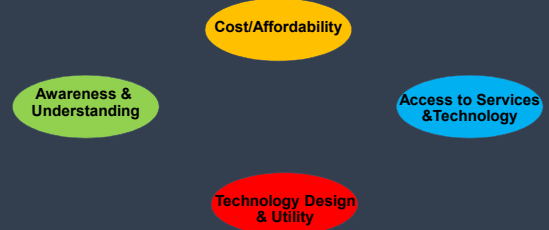
Understanding of treatment options:

Hearing Loss Intervention – Hearing aids? Sound amplifiers? Audiologists? ENTs? Hearing aid dispensers? Mail order hearing aids? Costco?



Reed, Poljak, Grabowski, Lin, & Mammo, 2011

Barriers to Amplification



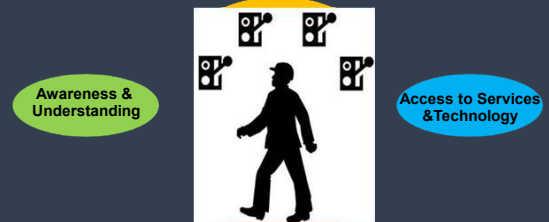
Reed, Poljak, Grabowski, Lin, & Mammo, 2011

Barriers to Amplification

Hearing when it really matters...



Barriers to Amplification



Regulation & Legislation

Presidents Council of Advisors on Science & Technology (Report Oct 2015)
 National Academies of Sciences, Engineering, & Medicine (Report June 2016)
 Food and Drug Administration
 Federal Trade Commission

#1 - Congress has established a regulatory framework for hearing aids, but the FDA has not yet issued a regulation. The FDA has a hearing aid (HAI) advisory committee (AC) that meets regularly to discuss HAI regulation. The AC is composed of experts in the field of hearing aids, including audiologists, engineers, and consumer advocates. The AC has issued several recommendations to the FDA, including the need for a regulatory framework for HAI. The FDA has a hearing aid (HAI) advisory committee (AC) that meets regularly to discuss HAI regulation. The AC is composed of experts in the field of hearing aids, including audiologists, engineers, and consumer advocates. The AC has issued several recommendations to the FDA, including the need for a regulatory framework for HAI.

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Regulation & Legislation

Over the Counter Hearing Aid Act 2017*
 *FDA Reauthorization Act



Amplification



Amplification

Hearing Aids:

Regulated by the FDA
 \$800 to \$3000 per device
 Minimal insurance benefit (no Medicare benefit)
 Accepted gold standard of care

Personal Sound Amplification Products:

Unregulated by the FDA
 Cost \$30-300 per device
 E-commerce
 Tremendous recent advances



Reed et al., JAMA, 2017; Reed et al., Otolology & Neurotology, 2017

Amplification

Legislation is moving faster than the science

What evidence do we currently have?

PSAPs/OTC devices

Literature Review

Low cost devices tend to produce high EIN, THD, and limit amplification to low frequencies (Chan & Mcpherson, 2000, 2015)

Some devices in the mid-price range performed similar to hearing aids (Callaway & Punch, 2008)

Comparison of PSAPs and Hearing aids shows high end devices provided appropriate levels of amplification and directional benefit for mild to moderate hearing loss (Smith et al., 2016)

Callaway & Punch, 2008 AJA; Chan & Mcpherson, 2015 BioMed Res Int; Smith et al., 2016, Hearing Review

PSAPs/OTC devices

Literature Review

No preference for environmental and music sounds between PSAP and hearing aid – though hearing aid was preferred for speech (Breitbart et al, 2014)

Evidence that cost does not necessarily drive outcomes (Cox et al. 2014)

Efficacious consumer selection OTC approach (Humes et al., 2017)

~1.5 million w/ hearing loss own PSAP or OTC device and of them, ~18% would have purchased traditional hearing aid without PSAP option and ~75% used PSAP for hearing loss (Kochkin, 2010)

Breitbart et al., 2014 Poster; Cox et al., 2014 Gerontology; Humes et al., 2017 AJA; Kochkin 2010, Hearing Journal

Electroacoustic Analysis of PSAPs

Initial Investigation

Electroacoustic exploration of PSAPs and OTC HAs

10 Devices: 9 in \$150-400 range, 1 was \$30

6 Devices: appropriate frequency range (200-6000+ Hz), Relatively Low EIN (<24), Low THD (<1%)

6 Devices: able to approx. NAL targets within 10 dB at 6+ targets

3 Devices: able to approx. NAL targets within 5 dB at 6+ targets

Reed et al., JAMA, 2017; Reed et al., Otolaryngology & Neurology, 2017

Electroacoustic Analysis of PSAPs

Initial Investigation



4 devices were able to approximate the electroacoustic output standards for a hearing aid

Reed et al., JAMA, 2017; Reed et al., Otolaryngology & Neurology, 2017

Study Objective

Comparative analysis of PSAPs and a hearing aid on speech-in-noise performance among adults with mild-to-moderate hearing loss

Reed et al., JAMA, 2017

Methods

Study Population

Inclusion:

Mild-to-moderate sensorineural hearing loss (PTA .5-4k 21-55 dB in the better ear)

Adult on set hearing loss

60-85 years of age

No cognitive impairment (MMSE ≥ 24)

Exclusion:

Unilateral/asymmetric hearing loss

Conductive hearing loss

Hearing loss secondary to medical conditions

Prior hearing aid usage

Powered to N=42 for non-inferiority trial with type I error rate of 0.05 and 80% power (Williams Design)

Reed et al., JAMA, 2017

Methods

Device Selection

One mid-level technology hearing aid (\$1910 wholesale cost)

Four electroacoustically acceptable PSAPs from in-house analysis: SoundHawk, SoundWorld Solutions CS-50+, Etymotic Bean, Tweak Amplifier

One electroacoustically unacceptable PSAP from in-house analysis: MSA-30x

Reed et al., JAMA, 2017

Methods

Study Design

Single-blind crossover; within-subject

Screening

- Consent & Otoscopy
- Audiologic evaluation
- MMSE (≥ 24)
- Questionnaire

Speech-in-Noise Testing

- Complete Az Bio in 7 conditions: unaided, 5 PSAPs, & HA
- Order of devices and AZ bio sentences randomized
- Participants blinded
- 1-5 likert scale for quality after each run

Device Fitting

- Audiologist/Grad Student fit devices (unilateral – best ear) based on participant's hearing loss (Real Ear Measures-NAL with 65 dB input). Fit to limits of the devices.

Analysis

- 42 participants data

Reed et al., JAMA, 2017

Methods

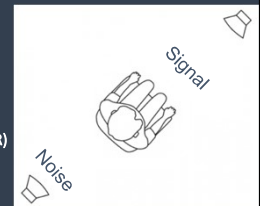
Speech-in-Noise Testing

Calibrated sound booth, speakers, and audiometer

Four-Talker Babble

0° azimuth (Signal), 180° azimuth (Noise)

Presentation Level: Signal at 35 dB, Noise 30 dB (+ 5 SNR)



Reed et al., JAMA, 2017

Outcomes

Primary:

Change in % correct from baseline unaided speech-in-noise scores to that in aided conditions

Secondary:

Ability to approximate NAL prescriptive targets

Subjective perception of devices

Reed et al., JAMA, 2017

Results

Demographics	
Number of Participants	N=42 (14 Male, 28 Female)
Mean Age	71.6 years (SD 6.0) (61-83 years)
Mean Perceived Duration of Hearing Loss	4.9 years (0-55 years)
Mean MMSE	28.8 (25-30)
Mean PTA (.5-4k) Right	34.7 dB (21.25-52.5 dB)
Mean PTA (.5-4k) Left	36.1 dB (22.25-51.25 dB)
Percent Reported Noise Exposure Hx.	33.3% (14/42)
Percent Reported Perceived Tinnitus	52.4% (22/42)
Percent Reported Perceived Hearing Loss	88.0% (37/42)

Reed et al., JAMA, 2017

Results

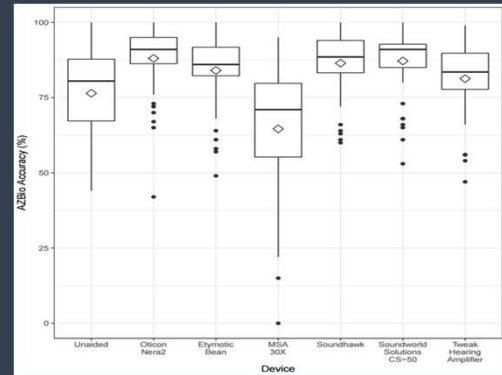
Table. Accuracy in Speech Understanding in Noise From Unaided to Aided With PSAPs and a Hearing Aid Among 42 Older Adults With Mild to Moderate Hearing Loss*

	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 product.
^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).
^c Oticon Nera 2 is a US Food and Drug Administration-regulated hearing aid, whereas all other devices are PSAPs.

JAMA July 4, 2017 Volume 318, Number 1
 Reed et al., JAMA, 2017

Outcomes



Results

Device ability to approximate NAL target within 5 dB 500-4000 Hz

Device	500 Hz	1000 Hz	2000 Hz	4000 Hz	Total Targets Met
Hearing Aid	12/12	12/12	12/12	9/12	45/48 (93.75%)
CS50	12/13	8/13	8/13	5/13	33/52 (63.46%)
Soundhawk	13/13	7/13	4/13	11/13	35/52 (67.31%)
Bean	10/13	8/13	7/13	3/13	28/52 (53.85%)
Tweak	13/13	10/13	10/13	3/13	36/52 (69.23%)
MSA 30X	1/13	4/13	4/13	0/13	09/52 (17.3%)

Results

Subjective Quality of Devices (1-5 likert scale):

	HA	CS-50+	SoundHawk	Bean	Tweak	MSA-30X
Mean	2.03	2.27	2.12	3.39	3.03	4.75
Contrast to HA (p-value)	N/A	0.28	0.69	<.001	<.01	<.001

Discussion

Analysis suggests in ideal conditions two higher-end PSAPs are not significantly different from a hearing aid in speech-in-noise sentence testing while less advanced products may actually degrade speech-in-noise results

Study limitations include : One-time snapshot, Unilateral fitting, Ideal conditions (clinical setting, clear signal, audiologist fit device), Advantage to directionally capable devices, may not be representative population, analysis of other factors not included

Reed et al., JAMA, 2017; Reed et al., Otology & Neurology, 2017

Pilot Study 2 Objective

Comparative analysis of different fitting conditions of PSAPs on speech-in-noise performance among adults with mild-to-moderate hearing loss

Study 2: Methods

Same criteria and same speech-in-noise outcome

Out-of-Box Fit
No device manipulation

Advanced Fit
User free to manipulate with instructions and full access to internet

Audiologist Fit
Gold-standard fitting with real-ear measures

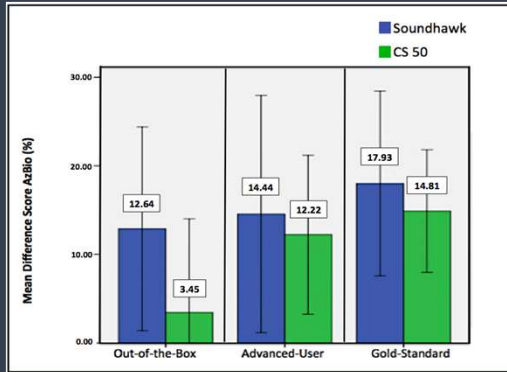
Greene-Oliver, 2017, Towson U.

Study 2: Results

		PSAPs					
		SOUNDHAWK			CS 50+		
Participant	Unaided	Out-of-the-Box	Advanced User	Gold Standard	Out-of-the-Box	Advanced User	Gold Standard
001	63	75	87	77	62	82	85
002	55	54	75	84	54	61	59
003	62	80	81	84	74	86	82
004	64	72	69	80	72	69	74
005	55	70	77	68	60	71	75
006	64	67	51	64	67	63	67
007	72	62	60	70	44	66	78
008	28	58	56	68	48	51	52
009	59	60	87	84	66	77	77
Mean	57.16	69.80	71.60	75.09	60.61	69.38	71.97
SD	12.88	11.12	18.81	7.88	15.12	16.78	18.88

Greene-Oliver, 2017, Towson U.

Study 2: Results



Greene-Oliver, 2017, Towson U.

Discussion

Preliminary analysis suggests in ideal conditions audiologist adjusted PSAPs are superior in speech-in-noise sentence recognition improvement when compared to out of the box and patient fit conditions

Study limitations include : One-time snapshot, Unilateral fitting, Ideal conditions (clinical setting, clear signal, audiologist fit device), Advantage to directionally capable devices, may not be representative population, analysis of other factors not included

PSAPs/OTC hearing care may represent transitory step in hearing healthcare that addresses situation specific needs, Reduce amplification gap, Reduce time to hearing aid adoption, and increase technologic innovation

More research needed – efficacy and effectiveness trials

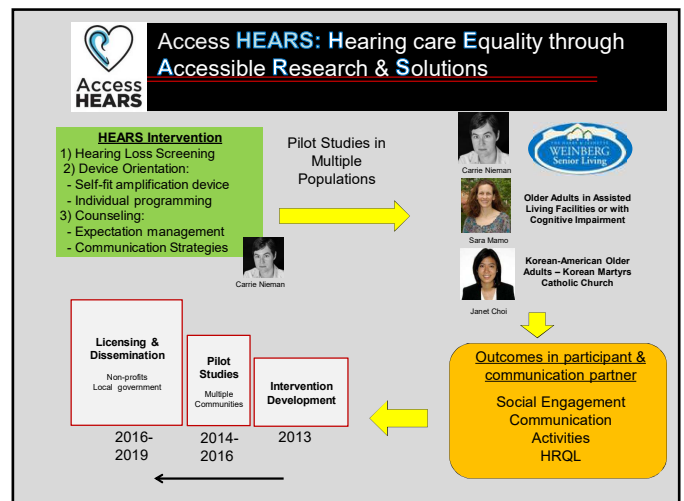
Reed et al., JAMA, 2017; Reed et al., Otolology & Neurotology, 2017

Implementation

Baltimore HEARS (ACCESS HEARS) in the community

Dementia Clinic

Counseling and fitting in the clinic



Principles of Design

- Text (font & size)
- Colors (hues & high contrast)
- Icons & graphics
- Reading level



© 2014 Johns Hopkins University

Fisk et al. (2009); Nieman et al. (2016)

Baltimore HEARS Approach



1. Set a goal



2. Demonstrate



3. Practice



4. Teach

Tablet by Matthew from The Noun Project
 Meeting by Larissa Haralick from The Noun Project
 Swimmer by Mike Shupp from The Noun Project
 Adventure by Ben Markings from The Noun Project



Tip #1: Attention First

The conversation can't start until you are in the same room and both of you are aware you want to share something.



Example

Talking across a room

Person by Wilson Jordon from The Noun Project

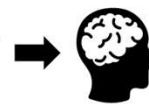


How We Hear

There are 3 main steps in how we hear.



Sound enters ear



Signal goes to brain

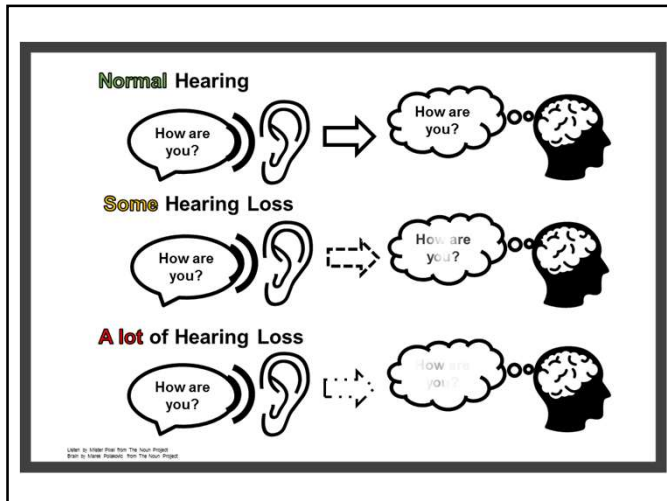


Brain interprets signal

Checklist

☐ Explain the 3 steps of hearing

Letter by Christopher from The Noun Project
 Brain by Kowal Prokopenko from The Noun Project



Place the Battery, Turn on CS-50

Battery **Earpiece**

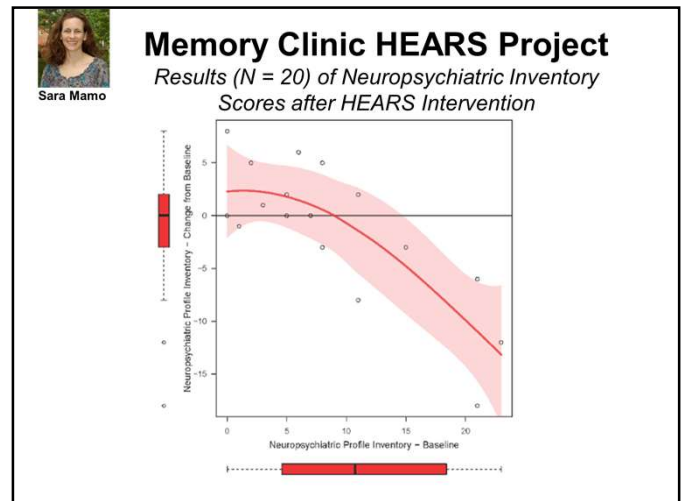
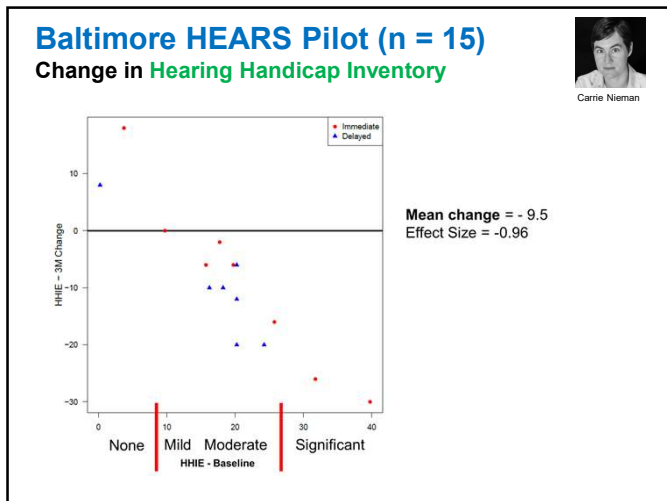
ON
Ready to use

Checklist

- ☐ Connect battery to earpiece
- ☐ Indicate when CS-50 is ON

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14





Memory Clinic HEARS Project

Feedback – Son-in-law of a 91 yo woman with MMSE of 17

Sara Mamo

Week 1	Notes, questions, concerns: This week there was trouble adjusting the volume. Different TV stations had different levels of volume. People came into her room with different ways of expressing themselves. She would rather that the device was too loud.
Week 2	Notes, questions, concerns: The "help" stopped right away. Her asking to repeat a statement has almost disappeared. The speed of comprehension has quickly picked up. She helped us to adjust the hearing device to make things more comfortable.
Week 3	Notes, questions, concerns: She began telling her historical stories more accurately. She asked me questions in smoother sentences. Her patience was extended. There were less "hurry-up"s.
Week 4	Notes, questions, concerns: She seemed to be less interested in having her way and imposing restrictions on the second party when she didn't get her way.
Week 5	Notes, questions, concerns: Her willingness to make decisions is stronger. Such decisions have sounder sense. Notes: The dementia is still there, but it seems to take more of a back seat in her life.

Additional Models of Hearing Health Care are Needed

Audiologist as the Leader of a Team

Community Health Worker
\$
1/2 day

PSAP or OTC Hearing Aid
\$
1-2 hours

Hearing Aid Dispenser
\$\$\$
1-2 months

Gold Standard Audiology Care
\$\$\$\$
3-6 months

Time/
Expense/
Expertise



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