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Efficacy and Effectiveness of Direct to Consumer Devices and Interventions

Nicholas S. Reed, AuD, Instructor, Johns Hopkins University School of Medicine
Jonathan J. Suen, AuD, Research Fellow, Johns Hopkins University School of Medicine

Moderated by:
Fawn Carson, MS, OTR/L, ATP

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Learning Objectives

• Introduce background information on direct to consumer hearing care

• Present efficacy studies of direct to consumer technology

• Apply efficacy knowledge to real-world decision making

Learning Objectives

• Apply established knowledge of health disparities and barriers to hearing care for older adults

• Integrate established public health research approaches to the evolving field of community-delivered hearing care

• Discuss a first-in-kind, community-delivered hearing care intervention tailored for older adults
Efficacy of Direct to Consumer Devices

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

Impact of Hearing Loss

Peripheral Hearing Loss

Cognitive Load
- Changes in Brain Structure
- Social Isolation

Quality of Life, Cognitive Decline, Falls, Hospitalization

Hearing Care

Lin et al., Arch Neuro 2011; Lin et al., JAMA Internal Med 2013

Hearing Loss & Hearing Aid Use


Estimated 23 million older Americans with hearing loss do not use hearing aids

Chien & Lin (2012)
Amplification

• ≤ 20% of persons with hearing loss own hearing aid(s) in the United States

• Barriers: financial cost, time commitment, access to a licensed audiologist/HA dispenser, and stigma

• Possible changes on the horizon:
  Presidents Council of Advisors on Science & Technology
  National Academies of Sciences, Engineering, & Medicine
  Over-the-counter Hearing Aid Legislation

Source: Adapted from Amanda Allen (2015)
NASEM, 2016; Reed et al., JAMA, 2017; Reed et al., Otology & Neurotology, 2017

Amplification

<table>
<thead>
<tr>
<th>Hearing Aids:</th>
<th>Personal Sound Amplification Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulated by the FDA</td>
<td>Unregulated by the FDA</td>
</tr>
<tr>
<td>$800 to $3000 per device</td>
<td>Cost $30-300 per device</td>
</tr>
<tr>
<td>Minimal insurance benefit (no Medicare benefit)</td>
<td>E-commerce</td>
</tr>
<tr>
<td>Accepted gold standard of care</td>
<td>Tremendous recent advances</td>
</tr>
<tr>
<td>Minimal Internet Sales</td>
<td></td>
</tr>
</tbody>
</table>

NASEM, 2016; Reed et al., JAMA, 2017; Reed et al., Otology & Neurotology, 2017
PSAPs/OTC: 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)

PSAPs/OTC: 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)
Electroacoustic Analysis

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., Otology & Neurotology, 2017

Study 1 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 0.5-4k 21-55 dB in the better ear)
- Adult onset 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)

---

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

---

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

Results: Demographics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Participants</td>
<td>N=42 (14 Male, 28 Female)</td>
</tr>
<tr>
<td>Mean Age</td>
<td>71.6 years (SD 6.0)</td>
</tr>
<tr>
<td></td>
<td>(61-83 years)</td>
</tr>
<tr>
<td>Mean Perceived Duration of Hearing Loss</td>
<td>4.9 years (0-55 years)</td>
</tr>
<tr>
<td>Mean MMSE</td>
<td>28.8 (25-30)</td>
</tr>
<tr>
<td>Mean PTA (.5-4k) Right</td>
<td>34.7 dB (21.25-52.5 dB)</td>
</tr>
<tr>
<td>Mean PTA (.5-4k) Left</td>
<td>36.1 dB (22.25-51.25 dB)</td>
</tr>
<tr>
<td>Percent Reported Noise Exposure Hx.</td>
<td>33.3% (14/42)</td>
</tr>
<tr>
<td>Percent Reported Perceived Tinnitus</td>
<td>52.4% (22/42)</td>
</tr>
<tr>
<td>Percent Reported Perceived Hearing Loss</td>
<td>88.0% (37/42)</td>
</tr>
</tbody>
</table>
Results: **Primary Outcome**

<table>
<thead>
<tr>
<th>Device</th>
<th>Cost, US $^a</th>
<th>Mean Accuracy, % (95% CI)</th>
<th>Change From Unaided Hearing, Percentage Points (95% CI)</th>
<th>Difference Between PSAP and Hearing Aid Change, Percentage Points (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaided hearing</td>
<td></td>
<td>76.5 (72.7 to 80.3)</td>
<td>11.9 (9.8 to 14.0)</td>
<td>NA</td>
</tr>
<tr>
<td>Oticon Nera 2 hearing aid$^c$</td>
<td>1910.00</td>
<td>88.4 (84.5 to 92.4)</td>
<td>11.0 (8.8 to 13.1)</td>
<td>-1.0 (-2.7 to 0.8)</td>
</tr>
<tr>
<td>PSAP</td>
<td>349.99</td>
<td>87.4 (83.5 to 91.4)</td>
<td>10.2 (8.0 to 12.3)</td>
<td>-1.8 (-3.5 to 0)</td>
</tr>
<tr>
<td>Sound World Solutions CS50+</td>
<td>349.99</td>
<td>88.7 (82.7 to 90.6)</td>
<td>7.7 (5.5 to 9.8)</td>
<td>-4.3 (-6.1 to -2.5)</td>
</tr>
<tr>
<td>Soundhawk</td>
<td>299.99</td>
<td>84.1 (80.2 to 88.1)</td>
<td>4.9 (2.8 to 7.0)</td>
<td>-7.0 (-8.8 to -5.3)</td>
</tr>
<tr>
<td>Etymotic BEAN</td>
<td>299.99</td>
<td>81.4 (77.4 to 85.3)</td>
<td>-11.2 (-15.7 to -7.3)</td>
<td>-23.1 (-26.9 to -19.4)</td>
</tr>
<tr>
<td>Twsak Focus</td>
<td>299.99</td>
<td>65.3 (60.1 to 70.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

* 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.

$^a$ 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, Twsak 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.
Study 2: *User Fittings?*

Objective is to examine the impact of user fittings

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

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<tr>
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<td>87</td>
<td>77</td>
<td>62</td>
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<td>54</td>
<td>75</td>
<td>84</td>
<td>54</td>
<td>61</td>
<td>59</td>
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<tr>
<td>003</td>
<td>62</td>
<td>80</td>
<td>81</td>
<td>84</td>
<td>74</td>
<td>86</td>
<td>82</td>
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<tr>
<td>009</td>
<td>52</td>
<td>90</td>
<td>87</td>
<td>81</td>
<td>66</td>
<td>77</td>
<td>77</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td><strong>57.16</strong></td>
<td><strong>69.80</strong></td>
<td><strong>71.60</strong></td>
<td><strong>75.09</strong></td>
<td><strong>60.61</strong></td>
<td><strong>69.38</strong></td>
<td><strong>71.97</strong></td>
</tr>
<tr>
<td><strong>SD</strong></td>
<td><strong>12.58</strong></td>
<td><strong>11.12</strong></td>
<td><strong>13.51</strong></td>
<td><strong>7.66</strong></td>
<td><strong>10.42</strong></td>
<td><strong>10.73</strong></td>
<td><strong>10.83</strong></td>
</tr>
</tbody>
</table>

Greene-Oliver, 2017, Towson U.

![Graph showing mean difference scores and SD for Soundhound and CS 50](Image)
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.

Early data suggests user fitting is slightly less impactful than audiologist fitting.

OTC hearing care devices may represent a transitory step in hearing healthcare that addresses situation specific needs, reduce amplification gap, reduce time to hearing aid adoption, and increase technologic innovation.

Reed et al., JAMA, 2017

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Discussion

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.

We don’t know the impact of real-world factors.

Other methods of assessment are important! Quality of Life improvement, subjective perception, etc.

More research needed – efficacy and effectiveness trials!

Reed et al., JAMA, 2017
Effectiveness of Community-Delivered Care: The HEARS Intervention

Behavioral Model & Access to Medical Care

Enabling Resources = Actual Ability to Obtain Care

Facilities, personnel, means, know-how, income, insurance, travel, wait time, availability of provider, spatial distribution

Andersen (1995)
Hearing Care Journey

Our Older Adults

- Independent, subsidized housing community
- Primary residents:
  - Age 62+
  - Age < 62, with disability
- 16-24% live below poverty
- 50% live alone
- About 20% completed education before receiving high school diploma, or equivalent

Centers for Disease Control and Prevention (2008-2012)
City of Baltimore Department of Finance (2015)
Weinberg Senior Living Communities (2017)
Traditional Care Model

Source: Adapted from Amanda Allen (2015)
Lack of Minority Older Adult Representation in Population Studies of Hearing Loss = Limitation

<table>
<thead>
<tr>
<th>Total Household Income</th>
<th>60–69 years (n = 291)</th>
<th>70–79 years (n = 571)</th>
<th>80 and older (n = 523)</th>
<th>Total Population Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$20,000</td>
<td>0.84 (0.74,0.95)</td>
<td>2,132,000</td>
<td>0.83 (0.78,0.88)</td>
<td>1,904,000</td>
</tr>
<tr>
<td>$20,000–44,999</td>
<td>0.91 (0.83,1.00)</td>
<td>2,853,000</td>
<td>0.77 (0.69,0.85)</td>
<td>2,686,000</td>
</tr>
<tr>
<td>&gt;$45,000</td>
<td>0.75 (0.61,0.88)</td>
<td>2,413,000</td>
<td>0.70 (0.64,0.77)</td>
<td>1,959,000</td>
</tr>
<tr>
<td>TOTAL UNTREATED</td>
<td>7,397,000</td>
<td>6,549,000</td>
<td>5,473,000</td>
<td>19,419,000</td>
</tr>
</tbody>
</table>

Poverty-Income Ratio

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>0–1.30</td>
<td>0.88 (0.79,0.96)</td>
<td>1,651,000</td>
<td>0.84 (0.79,0.93)</td>
<td>1,504,000</td>
<td>0.70 (0.61,0.78)</td>
<td>1,312,000</td>
<td>4,557,000</td>
<td></td>
</tr>
<tr>
<td>1.50–3.50</td>
<td>0.88 (0.80,0.96)</td>
<td>2,509,000</td>
<td>0.75 (0.68,0.83)</td>
<td>3,413,000</td>
<td>0.70 (0.65,0.76)</td>
<td>2,539,000</td>
<td>7,451,000</td>
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</tr>
<tr>
<td>&gt;3.50</td>
<td>0.73 (0.61,0.85)</td>
<td>2,755,000</td>
<td>0.72 (0.65,0.79)</td>
<td>1,988,000</td>
<td>0.66 (0.57,0.75)</td>
<td>1,822,000</td>
<td>6,564,000</td>
<td></td>
</tr>
<tr>
<td>TOTAL UNTREATED</td>
<td>7,315,000</td>
<td>6,994,000</td>
<td>5,973,000</td>
<td>20,283,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Hearing loss defined as speech-frequency pure tone average (PTA) $>25$ dB HL in the better hearing ear $= 500, 1000, 2000, 4000$ Hz used to calculate PTA.

Sample size shows the number of people in the sample with hearing loss.

Numbers do not sum to total because of rounding.

*Numbers differ due to some missing data in the total household income variable.*

*FIPR $<1.3$ corresponds to poverty level where government agencies provide services (e.g., supplemental nutrition assistance & Medicaid).

Mamo et al. (2016)
Hearing Screening & Hearing Aid Use
Prevalence in the U.S., by Race/ethnicity

- White Older Americans
- Black Older Americans
- Older Mexican Americans

Recent Hearing Screening
- 20.5%

Regular Hearing Aid Use
- 9.5%
- 10.2%

*p value 0.002
*p value 0.41

Nieman et al. (2015)

Culturally-adapted & -sensitive health promotion programs aimed at engaging ethnic minorities are effective.

Resnicow et al. (1999); Barrera et al. (2013)
Baltimore HEARS
HEAR. LIVE. LOVE.

A Community-Delivered, Affordable, Accessible Hearing Care Intervention for Older Adults

1. Hearing Screening
2. Device Fitting & Orientation
3. Education & Counseling

Nieman et al. (2016)

Baltimore HEARS
HEAR. LIVE. LOVE.

ACCESS to HEALTHY AGING through HEARING.
The Need

Many hearing aid user guides were rated “not suitable” for older adults in areas of:

- Scope
- Vocabulary & reading grade level
- Layout & typography
- Learning stimulation & motivation

Nieman et al. (2016)

Caposecco et al. (2014)
Principles of Design

• Text (font & size)

• Colors (hues & high contrast)

• Icons & graphics

• Reading level

Czaja & Sharit (2013); Fisk et al. (2009)

Principles of Instruction

• Engage in solving meaningful problems

• Activate relevant previous experience

• Demonstration

• Use new skill to solve problems

• Integrate new skill into daily life

Czaja & Sharit (2013); Fisk et al. (2009)
Principles of Design

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

Baltimore HEARS

- Learn to Use a Listening Device
- Understanding Hearing
- Communication Tips and Tricks

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

Baltimore HEARS Approach

1. Set a goal
2. Demonstrate
3. Practice
4. Teach

Czaja & Sharit (2013)
Fisk et al. (2009)
Nieman et al. (2016)
**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

---

**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
How are you?

Normal Hearing

Some Hearing Loss

A lot of Hearing Loss

Turn ON the Pocket Talker

Microphone

ON

Checklist

- Turn ON Pocket Talker
- Note red ON light
Traditional Care Model

Community-Delivered Model

Source: Adapted from Amanda Allen (2015)
Study Goals & Methodology

Is a community-delivered, affordable, accessible hearing care intervention....

feasible?

acceptable?

demonstrate preliminary effectiveness?

Design:

Prospective, randomized control pilot with 3-month delayed treatment group as a waitlist control

Nieman et al. (2016)

Our Participant Demographic (N=15)

- 70.1 years old (median)
- 60% minority
- 80% live alone
- 53.4% HS education or less
- $1,100 monthly household income (median)
- 93.3% mild to moderate hearing loss

Nieman et al. (2016)
### Outcome Measures

<table>
<thead>
<tr>
<th>Domain</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Communication Function</strong></td>
<td>Hearing Handicap Inventory for the Elderly – Screening (HHIE-S)</td>
</tr>
<tr>
<td></td>
<td>Revised Quantified Denver Scale of Communication (RQDS)</td>
</tr>
<tr>
<td><strong>Social-Emotional Function</strong></td>
<td>UCLA Loneliness Index – Revised</td>
</tr>
<tr>
<td></td>
<td>Patient Health Questionnaire (PHQ-9)</td>
</tr>
<tr>
<td><strong>Health-related Quality of Life</strong></td>
<td>Short Form – 36 (SF36)</td>
</tr>
<tr>
<td><strong>Acceptability &amp; Satisfaction</strong></td>
<td>International Outcome Inventory – Alternative Interventions (IOI-AI)</td>
</tr>
<tr>
<td></td>
<td><strong>Focus group</strong></td>
</tr>
</tbody>
</table>

---

Nieman et al. (2016)
Change in Hearing Handicap

Mean change = -9.5
Effect Size = -0.96

Hearing aid interventions = -8 to -16

Nieman et al. (2016)

Change in Depression

Mean change = -1.93
Effect Size = -0.43

Nieman et al. (2016)
Our participants reported:

- 87% Would **not** be able to use his/her device as well **without** the program
- 93% Benefited from the program
- 80% Felt more connected with others
- 100% Would recommend the program
- 67% Interested in helping train others
- $87.50 Median amount willing to pay for program
**Clinician & Community Health Worker Team Model**

Source: Adapted from Amanda Allen (2015)

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**Community Health Worker (CHW)**

“A frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery.

A CHW also builds individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy.”

Source: Community Health Workers (2017) Retrieved from APHA.org
Current Status

- Pilot study of intervention effectiveness with audiologist-community health worker (CHW) team currently ongoing:
  - Two (2) trained CHW interventionists currently operating under audiology supervision
  - Ten (10) residents received audiologist-CHW team delivered intervention as of August 2017

- Plans to expand to broader randomized controlled trial across multiple community residences throughout Baltimore City

References

References