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Over-the-Counter Hearing Aids – Opportunity or Disaster?

Presented by Catherine Palmer, Ph.D.

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Hearing Systems
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Course Objectives

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1. After this course, participants will be able to describe the current regulations related to hearing aids and how these will impact potential over-the-counter versions of devices.
2. After this course, participants will be able to pros and cons of an OTC model of hearing aid access.
3. After this course, participants will be able to describe the data that supports what an audiologist contributes to the hearing aid fitting process.

Hearing Systems
SIEMENS

OVER-THE-COUNTER HEARING AIDS – OPPORTUNITY OR DISASTER?

Catherine Palmer, University of Pittsburgh

Disclosures

- Director of the AuD program at the University of Pittsburgh
- Director of Audiology for the UPMC Integrated Health System
- See patients every week
- Work with all of the manufacturers in some capacity
- Reviewer of the NASEM document
- I will try to be clear when I am providing facts versus when I am providing you with my opinion

The first question you might ask

- Opportunity or Disaster for whom?
  - The Audiologist
  - The Person with Hearing Loss

Background

2009: NIDCD Working Group on Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss

- **August 25-27, 2009; Bethesda, Maryland**
- Purpose: To develop a research agenda to increase the **accessibility and affordability of hearing health care for adults with mild to moderate hearing loss,** including accessible and low cost hearing aids. The research recommendations should be aimed at technologies or delivery strategies that are effective, accessible, and affordable to those who want and need them; take advantage of current and evolving technologies and health care delivery models; consider innovative and creative solutions with potential for implementation; and reflect current demographics and varying socioeconomic capacities of the U.S. population. The focus is not on research related to the development of increasingly sophisticated or technologically complex custom-fit hearing aids. Research should complement and supplement, not replace, current paradigms and services.

Guidance for Industry and FDA Staff
Regulatory Requirements for Hearing Aid Devices and **Personal Sound Amplification Products**
February 25, 2009

- Write-up for Consumers as well
- www.fda.gov/consumer

Nonbinding Recommendation

- A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing.
- A personal sound amplifying product (PSAP) is a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as recreational activities.
- All dependent on labelling.

2013 FDA draft guidance

- New guidelines for PSAP advertising
- Differentiating medical devices from electronic product
- PSAPs
  - Accentuate sounds in specific listening environments
  - Rather than everyday in multiple listening situations
  - Not intended to address listening situations that are typically associated with and indicative of hearing loss
    - Difficulty hearing a person nearby
    - Difficulty hearing in a crowded room
    - Difficulty understanding movie dialogue in a theater
    - Difficulty hearing on the phone
    - Difficulty hearing in noise
    - Cannot be considered an over-the-counter substitute for a hearing aid

2015 PCAST

President's Council of Advisors on Science and Technology

- FDA should approve a distinct class of hearing aids for OTC sale, without current requirements for consultation with a professional
- FDA should withdraw its draft guidance on PSAPs. Forbids PSAP manufacturers from making truthful claims
- FTC should require professionals to provide the customer with a copy of their results at no additional cost and in a format that can be used by other dispensers/vendors
- FTC should define a process to authorize hearing aid vendors to obtain a copy of a customer's hearing test results and programmable audio profile from any audiologist who performs such a test, with no additional cost to the customer (prescription)

2016 - FDA Meeting

April 21, 2016

- Hearing to discuss the PCAST report
- Predictable presentations

2016 NASEM (IOM)

National Academies of Sciences, Engineering, and Medicine (Institute of Medicine), June 2016

- Develop and strengthen research
- Promote best practices and core competencies across the continuum of health care; mechanisms to insure adherence
- Metrics to evaluate hearing health care services
- Remove requirement that an adult needs medical clearance to obtain a hearing aid
- Right to access information
- Increase hearing health care workforce (rural areas)
- Physicians discuss potential hearing problems and overall impact
- New FDA category for OTC hearing aids , mild and moderate hearing loss
- Ensure compatibility with consumer electronics
- Transparency in fee structure, itemize, separate devices from services
- CMS, examine reimbursement, lead the way
- Evaluate the health impact of direct access to audiology (other mechanisms)

Over the Counter Hearing Aid Act of 2016

- Introduced December 1, 2016
- Goal: put PCAST and NASEM recommendations into action
- Congressional session ended before any action was taken

Change in Medical Clearance Rules

December 7, 2016

- FDA does not intend to enforce the requirement that individuals 18 and up receive a medical evaluation or sign a waiver prior to purchasing most hearing aids. This guidance is effective immediately
- Today, the FDA is also announcing its commitment to consider creating a category of over-the-counter (OTC) hearing aids that could deliver new, innovative and lower-cost products to millions of consumers.

(have to check with state regs in each state)

- http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm

Senators Elizabeth Warren (D-MA), Chuck Grassley (R-IA), Isakson (R-GA), Hassen (D-NH); US Representatives Blackburn (R-TN-7), Kennedy (D-MA-4)
December 1, 2016 and then re-introduced HR1652 and S670 March 21, 2017

- JAMA Intern Med. March 3, 2017
- Over-the-Counter hearing aids: the path forward
- Goal: put PCAST and NASEM recommendations in action
- Over the Counter Hearing Aid Act of 2016 in the 114th Congress, introduced to the 115th congress on March 21, 2017.
  - Members of Congress Introduce Bipartisan Legislation to Make Hearing Aids Available Over the Counter

Over-The-Counter Hearing Aid Act of 2017

FDA is required to generate regulations that:

- Include reasonable assurance of safety and efficacy
- Establish or adopt appropriate output limits
- Include requirements for appropriate labeling of OTC hearing aids
- Describe requirements under which sale is permitted without involvement of a licensed person by in-person transactions, mail, or online

The new (2017) bill has differences from the 2016 bill

- Removed language asking for the removal of FDA draft guidelines. Now calls for finalizing draft guidance
- Removed CMS and reimbursement discussion

On April 18, 2017, the Federal Trade Commission hosted a workshop to examine competition, innovation, and consumer protection issues raised by hearing health and technology, especially hearing aids.
FTC Announces Workshop on Hearing Health and Technology

Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care

APR 18, 2017
8:30AM–5:30PM
CONSTITUTION CENTER
400 7th St SW, Washington, DC 20024 | Directions & Nearby

ASHA Position Statement on Policy Related to Over-the-Counter Hearing Aids

February 14, 2017

http://www.asha.org/News/2017/ASHA-Position-Statement-on-Policy-Related-to-Over-the-Counter-Hearing-Aids/

- Require the FDA to:
  - establish limited gain and output thresholds for these hearing aids;
  - ensure that OTC hearing aids are only available for adults;
  - establish a means for collecting information on consumer safety and other potential complaints;
  - require labeling that strongly recommends seeking audiologic diagnostic and rehabilitative services; and
  - require labels that provide consumers with warning signs for conditions that require medical treatment.
- Ensure that current insurance coverage of hearing aids is not undermined. Currently, some states mandate that insurers, including Medicaid, provide coverage for hearing aids for adults; the U.S. Department of Veterans Affairs and the Federal Employees Health Benefits Program also provide coverage for hearing aids. Any new OTC model should not be seen as a substitute for hearing aid benefits under third-party plans.
- Further discussed issues related to coverage of audiology services.

ADA SUPPORTS S.670/H.R. 1652, THE OVER-THE-COUNTER HEARING AID ACT OF 2017

- The Academy of Doctors of Audiology (ADA) supports S. 670/H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017, and commends Senators Warren and Grassley, and Representatives Blackburn and Kennedy for their foresight in introducing this legislation, which if enacted, will remove unnecessary and burdensome barriers to hearing care for millions of Americans.

  The Over-the-Counter Hearing Aid Act of 2017 would allow hearing aids, intended to be used by adults to compensate for mild to moderate hearing impairment, to be sold over the counter (OTC), and would eliminate the requirement that adult consumers obtain a medical evaluation or sign a waiver in order to acquire these hearing aids. This landmark legislation also directs the FDA to issue regulations containing safety and labeling requirements for this new category of OTC hearing aids and to update FDA draft guidance on Personal Sound Amplification Products (PSAPs).

Accessibility and Affordability of Hearing Care for Adult Consumers
Issue Statement from the American Academy of Audiology
January 26, 2017
http://www.audiology.org/publications/accessibility-and-affordability-hearing-care-adult-consumers
Over-the-Counter (OTC) Hearing Devices
Issue Statement from the American Academy of Audiology
January 26, 2017
http://www.audiology.org/publications/over-counter-otc-hearing-devices

Items identified as important to include in any move toward OTC

- Acoustic labeling requirements
- Describe in a manner to differentiate from hearing aids
- Over 18
- Mild loss
- Cautions associated with long-term use
- Labeled to make comparisons between products
- Output control
- Red flag warning signs
- Not to replace professional
- Language of how to get better outcomes (with professional)
- Not for tinnitus, dizziness, pain
- Negative consequences of under fitting

AAO-HNS

http://www.entnet.org/sites/default/files/aao-hns_letter_otc_hearing_aids_s.670.pdf

- Supports the concept of OTC hearing aids for adults with mild-to-moderate hearing loss with these comments:
  - Medical evaluation followed by a standardized hearing test
    - (via hear… professional or appropriate online/te… source)
  - Requirements related to standardized packaging
    - Medical e…luation
    - Red Fla…
  - Structured mechanism for at least five years of data collection MAYBE 2 YEARS

Where is the bill now?

- Attached to the "must-pass" Medical Device User Fee and Modernization Act (MDUFA), FDA Reauthorization Act of 2017
- June 7, 2017 – House Energy and Commerce Committee held a mark up of the FDA Reauthorization Act, changes in the OTC hearing aid provision included the addition of language that strengthens labeling requirements (only for adults over 18) and directs Health and Human Services to analyze and report adverse events related to OTC hearing aid devices to Congress within two years after regulations are finalized.
- Rep. David McKinley submitted an amendment with language that would have OTC device include access to a test performed by a licensed hearing care professional. The amendment was withdrawn.
- Most likely there will be language to insure that states cannot make regulations that further restrict distribution of OTC hearing aids beyond FDA regulations for OTC hearing aids.

Keep in mind, as of this talk (July 11, 2017)

- OTC hearing aids cannot yet be marketed legally:
  - Federal: not clear whether hearing-aid 510(k) exemption applies to OTC
  - State: various state laws forbid or restrict OTC sale and/or mail/internet sale

But that does not stop the popular press headlines

Or comments on social media from Audiology Professionals (re: the OTC HA Debate)

Depression and anxiety hit me when I read articles like this. This just sucks.

*** my education and license, am I right?

Audiologists need to accept the harsh reality that otc heating aids are inevitable...manufacturers are not on our side folks no matter what some of them may say

I think audiologists need to stop fighting the wave so much and change their position to find different ways to preserve the occupation. Costco, OTC HAs, corporate retail models, dispensers, at-home programming - This is the way of the future, like it or not.

Sad. Who's going to be responsible when an acoustic neuroma goes undiagnosed or some other medical issue.

I think audiologists will need to re-think everything they've learned as far as hearing aid dealing is concerned and start thinking about health care.

What I meant was that audiologists can own and dictate some of the OTC delivery, by recommending OTC options or by offering them themselves.

Ludicrous. ...all about money, nothing to do with hearing HEALTHCARE.

Just out of curiosity, how many of you are unbundling or have thought about it? This may be a compelling reason to start

It's never going to work. Never. If somebody walks into your office with them, either charge them a huge fee or turn them away. The days of doing stuff for free are done

So much rage. Seriously.

Interesting to note that as of right now, with 100 participants in this survey, 91/100 OPPOSE OTC hearing aids. I guess that (informally but significantly) lays to rest where our profession sides on this issue.

This is the future. Unbundling and embracing these new trends are our only choices.

I do think a lot of them will get frustrated and end up in our offices.

So, then, why are we even doing this? Let's just all quit and that's the end of audiology. Is that what we should do?

"The Hill" newsletter Op-Eds

- Consumer opinion
- Geriatric professional association
- Otolaryngologists (pro and con)
- Gun Lobby

WHAT DO THE DATA SAY?

We really have very little data…

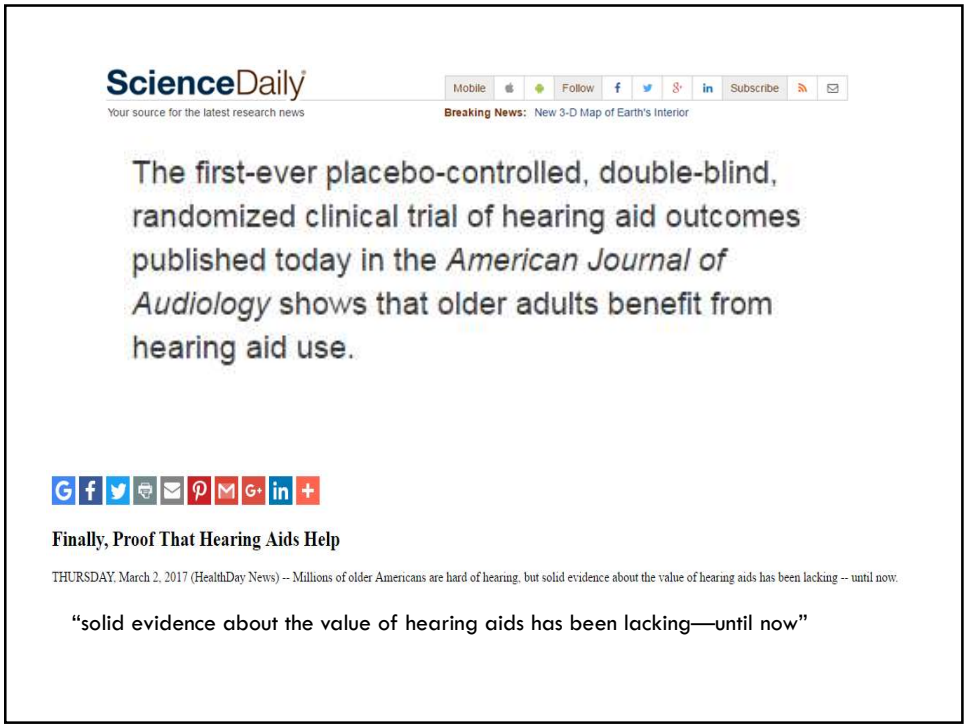
- Direct to consumer studies:
  - McLaughlan (1995)
  - Walden et al (2002)
  - Parving et al (2004)
  - Callaway et al (2008)
  - Walden et al (2009)
  - Hawkins and Stamper (2010)
  - Sacco et al (2016)
  - Reed et al (2017)
- Range of findings
- Some devices work well
- Some devices have mid-frequency gain only
- Least expensive have worse sound quality
- Wore less hours
- Complaints of physical discomfort

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

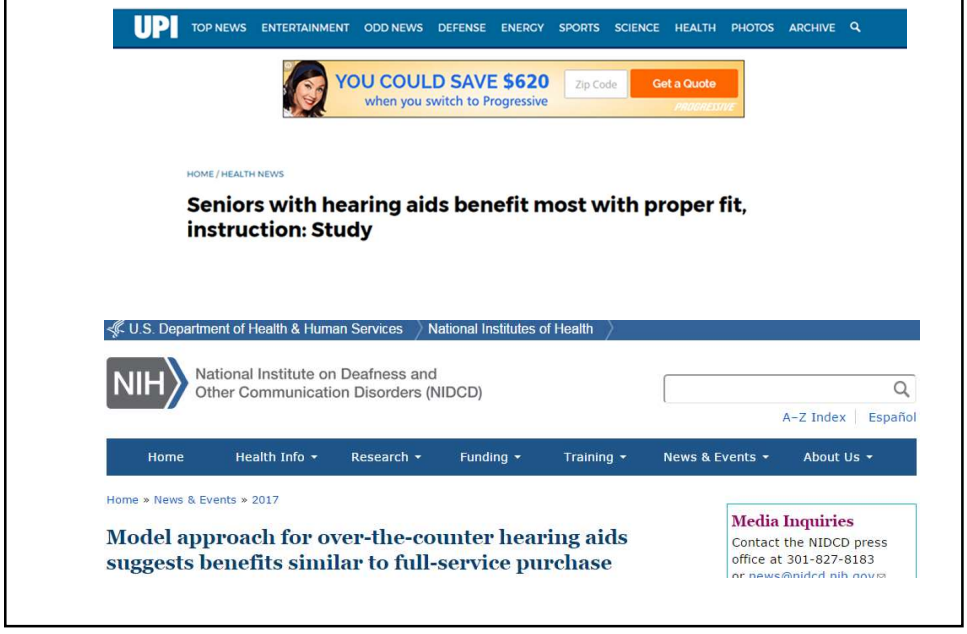
Larry E. Humes, Sara E. Rogers, Tera M. Quigley, Anna K. Main, Dana L. Kinney, and Christine Herring

Tags: hearing aids, placebos, delivery of health care, measures of outcome

American Journal of Audiology, March 2017, Vol. 26, 53-79. doi:10.1044/2017_AJA-16-0111



"solid evidence about the value of hearing aids has been lacking—until now"



The effects of service-delivery model and purchase price on hearing-aid outcomes in older adults: a randomized double-blind placebo-controlled clinical trial

Humes, L., Rogers, S., Quigley, T.,
Main, A., Kinney, D., Herring, C.

American Journal of Audiology,
26 (1): 53-79

What they asked…
Two Service-Delivery Models

- What is the efficacy of hearing aids in older adults using
  - Audiology best practices model
  - Alternative over-the-counter (OTC) model

What they did…
Study Overview

- Placebo-controlled double-blind randomized clinical trial with three parallel branches
  - AB: audiology best practices model
  - CD: consumer decides
  - P: Placebo model
- Outcome measures obtained before and after 6 week trial and after following 4-week AB-based trial for CD & P

What they did…
Participants

- Adults, 53 – 83 years old
- Mild-to-moderate, bilaterally symmetrical sensorineural hearing loss
- No prior hearing aid experience
- 154 participants completed the study

What they did…
Hearing Aids

- High-end digital mini-BTE open-fit
- Features include
  - Directional microphone
  - Dynamic feedback suppression
  - Noise reduction
  - Four push-button memory used as VC

What they did…
Three Groups

AB: Audiology best practice (n=53)

- Aids programmed to NAL-NL2 based on audiogram
- Push-button volume range 12 or 24 dB based on high frequency hearing loss
- Real-ear verification, LDL adjustment
- 45-60 min hearing aid orientation session

What they did…
Three Groups

P: Placebo (n=50)

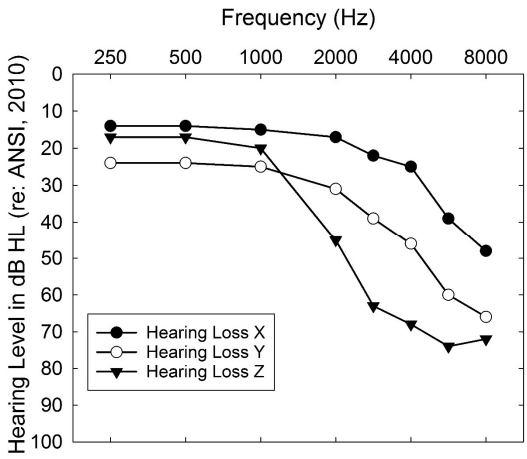
- Identical to AB group except
  - Hearing aid set to 0 dB Insertion Gain
  - Push-button volume range of 3 dB
  - No LDL adjustment
  - Some aids directional and some omnidirectional

What they did…
Three Groups

CD: Consumer Decides (n=51)

- Three different hearing aids: X, Y, Z
- Programmed (NAL-NL2) to match the 3 most common patterns of loss in older adults
- Push-button volume range 12 or 24 dB based on high frequency hearing loss
- Same basic features as AB aids

What they did…
X, Y, Z Audiograms



What they did…
Unaided Baseline Measures and outcome measures

- HHIE: Hearing Handicap Inventory - Elderly
- CST: Connected Speech Test
- PHAPglobal: Profile of Hearing Aid Performance (5 communication subscales)
- PHAPavds: Profile of Hearing Aid Performance (2 distorted/aversiveness subscales)

What they concluded…
AB vs. CD

- Hearing aids are efficacious for older adults (with mild-to-moderate loss) for both AB and CD service-delivery model
- CD model service delivery yielded only slightly poorer outcomes than the AB model

Things to keep in mind (in my opinion)

- Consumer Decides did not mimic any typical version of OTC (42% of participants recruited were rejected)
- AB did not mimic best practices since best practices are all about customizing both acoustically (not just at a 65 dB SPL and max output) and physically
- Placebo group – no gain?
- Group of people who could all afford $3600.00

Most interesting data in my opinion…

- 90% of CD group tried 2-4 HAs
- 20% of the CD group needed help and/or a visit for troubleshooting
- CD and Placebo group moved to customized fit and majority kept aids
- Great data to support need for ongoing maintenance appointments

Perhaps most importantly in my opinion…

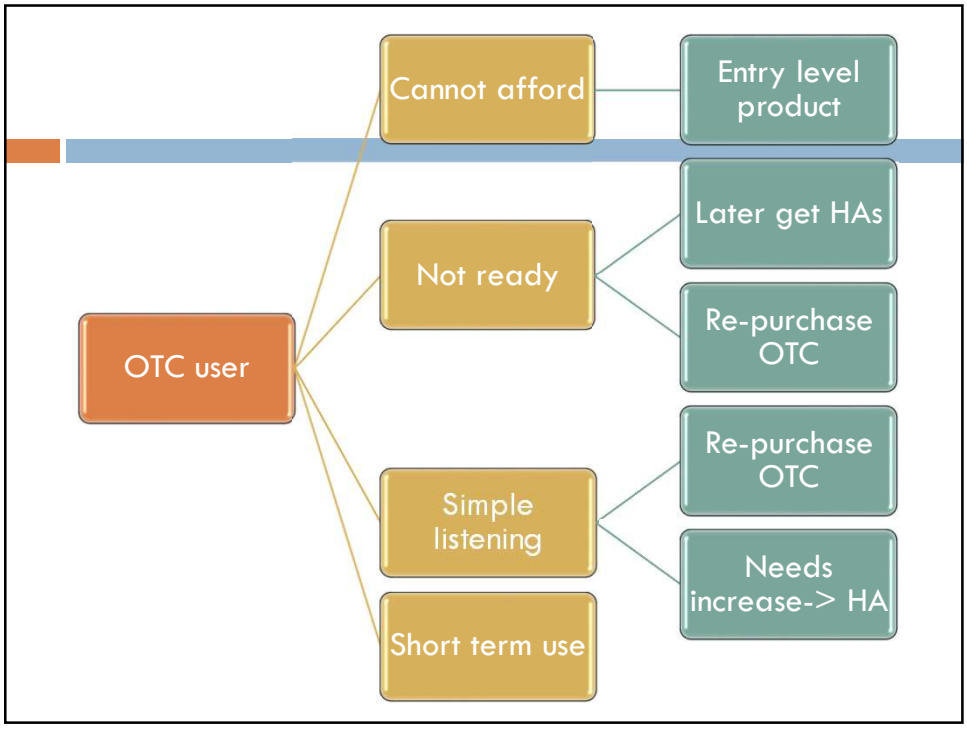
- 55% CD (N=28), after best practices 14 more wanted to keep the aids
  - Clinics need a way to move CD patients into clinic or start them in clinic and move them into more advanced services (not more advance technology)
- 36% of placebo wanted to keep their aids
  - Individuals are not judging adequate amplification accurately

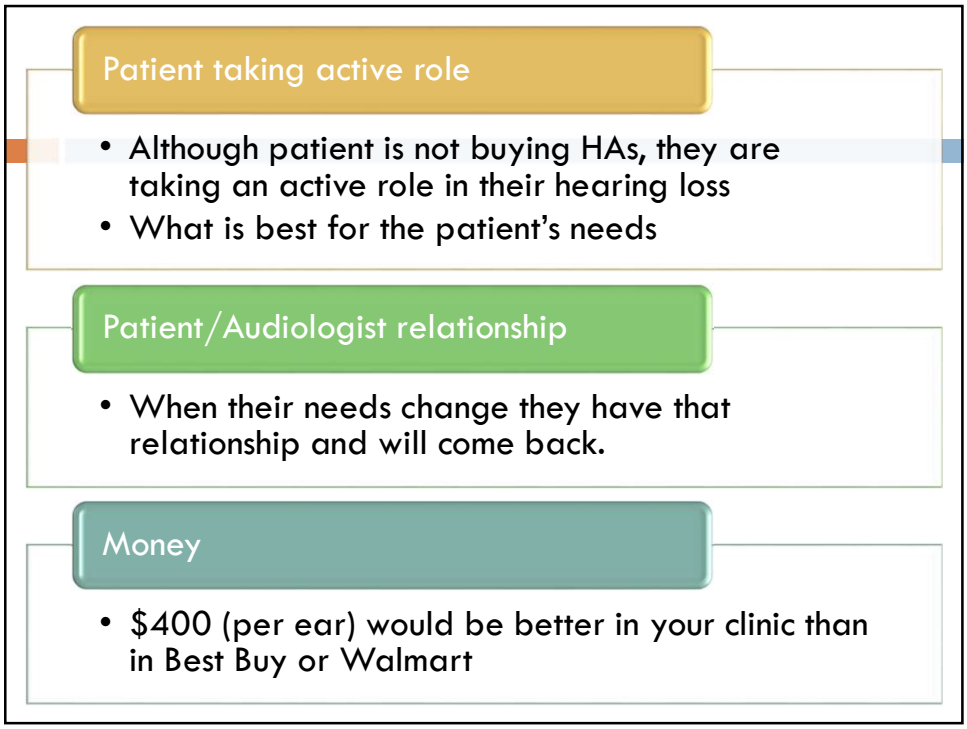
A few other things to consider

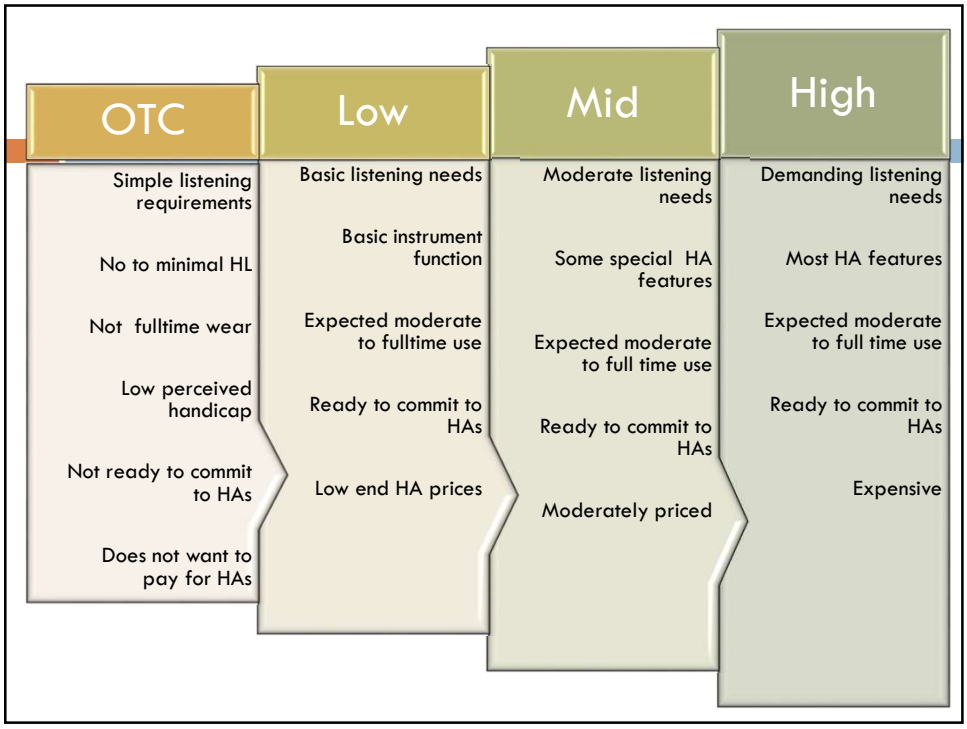
- Is 65 dB SPL the most meaningful presentation level for the clinic speech testing?
  - The difference would be for quieter inputs
- How good were the CD group at picking the best hearing aid for them?
  - 73% picked the wrong aid based on their audio and the three NAL-NL2 choices
- How did the CD group self-fitting compare to the "typical" fitting by audiologists in the U.S.?
  - SII in Humes study was better than the SII achieved for manufacturer first fit (Sanders et al, 2015)

OTCs Embraced

- If we assume that these products (and more importantly, this pathway) will exist, then what are we resisting?
  - They are not fitted by an audiologist
  - They could be harmful
  - They are not purchasing hearing aids
  - OTCs are not traditionally programmed for their hearing loss
- Instead of wishing them to go away, what if they were embraced for what they are.
- What if we emphasized what we bring to the table.


OTC user
Cannot afford
Entry level product
Not ready
Later get HAs
Re-purchase OTC
Simple listening
Re-purchase OTC
Needs increase-> HA
Short term use


Patient taking active role
• Although patient is not buying HAs, they are taking an active role in their hearing loss
• What is best for the patient's needs
Patient/Audiologist relationship
• When their needs change they have that relationship and will come back.
Money
• $400 (per ear) would be better in your clinic than in Best Buy or Walmart



On a scale from 1 to 10, 1 being the worst and 10 being the best, how would you rate your overall hearing ability?

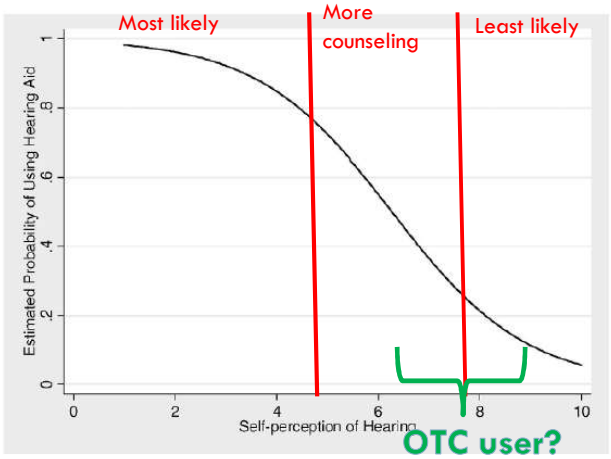
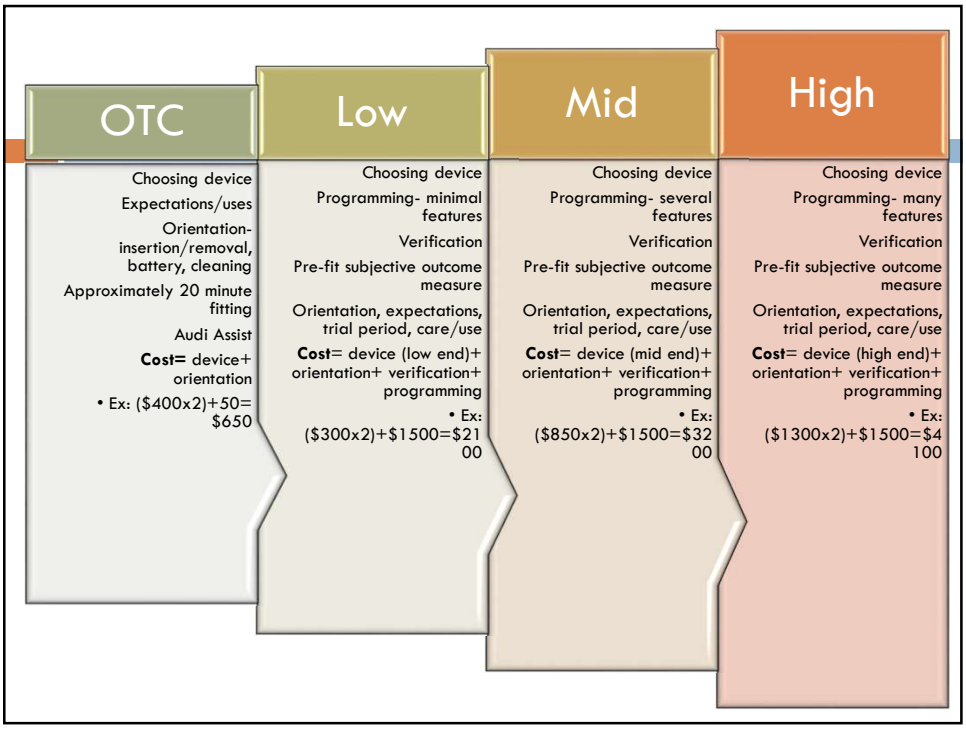


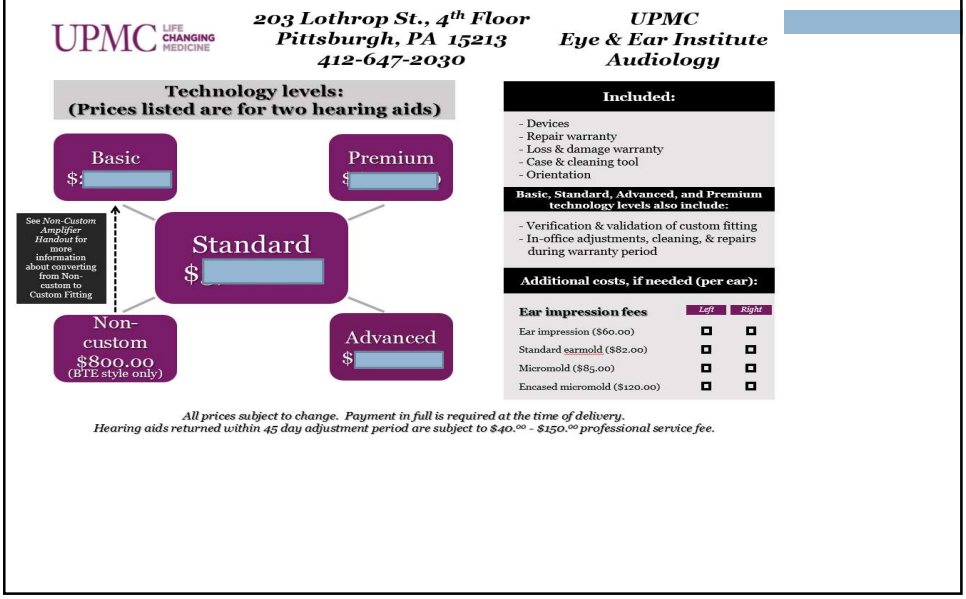
Figure 4. Probability of using a hearing aid vs. self-rating of hearing ability.

Palmer, et al (2009).

Audiology Assistants

- No FDA /licensure requirements for distributing OTC hearing aids
- Excellent use of audiology assistants
  - Audiologist does not need to fit it
  - Aud Asst can do basic: fitting of tubing/dome, instruct on batteries, cleaning, and insertion/removal





How do you differentiate yourself?

- Customization
  - Matching technology to needs
  - Physical coupling of the device to ear
  - Acoustic fit (measured in the individual ear canal)
- Unbundle pricing so the person can come to you with whatever device they have
- Ideally, makers of OTC's would make them so the audiologist could "unlock" them and customize them for the patient.

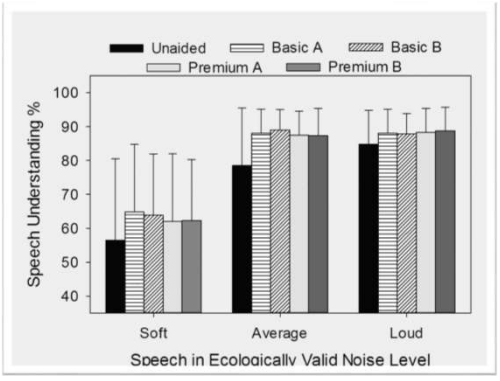
Verification

- Measuring the output of a hearing aid in the individual's ear and matching the output to an evidence-based target

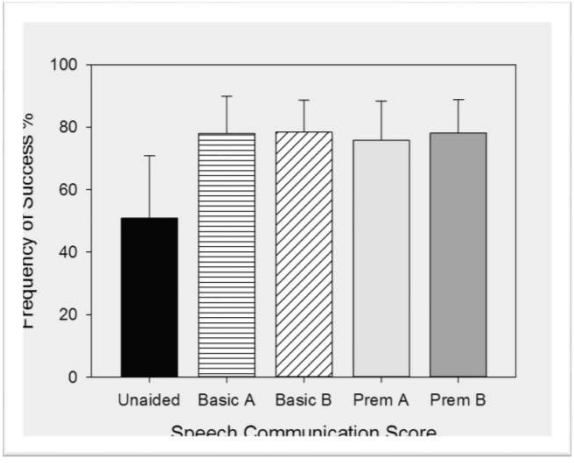
Impact of Advanced Hearing Aid Technology on Speech Understanding for Older Listeners with Mild to Moderate, Adult-Onset, Sensorineural Hearing Loss

Robyn M. Cox, Jani A. Johnson, Jingjing Xu

Gerontology, 60(6), 557-568



APHAB, speech communication



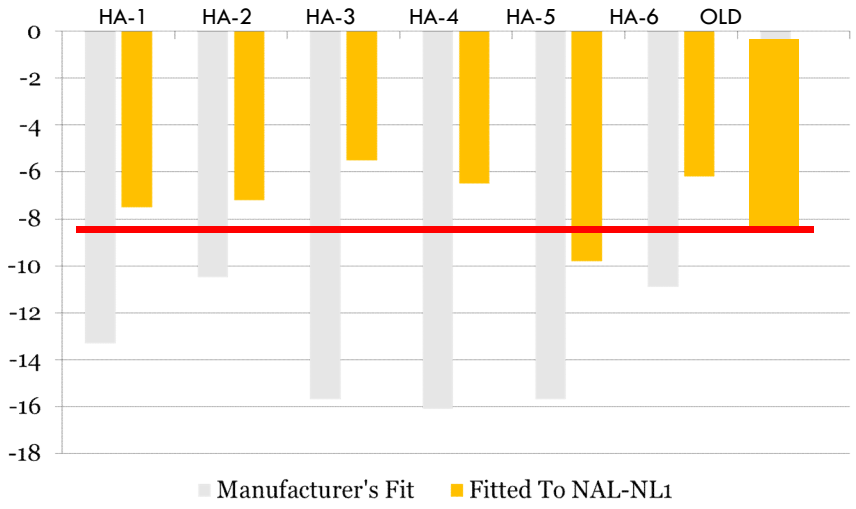
- Speech understanding and quality of life are improved with hearing aids
- Regardless of technology level, best-practice fitting protocols (matching outputs across input and frequency to evidence-based targets) optimize results for every patient

The importance of audibility in successful amplification of hearing loss

Ron Leavitt and Carol Flexer

Hearing Review, December

Performance for the aided QuickSIN presented soundfield at 57 dB SPL. Bars indicate "SNR-Loss": The average SNR *disadvantage* compared to individuals with normal hearing

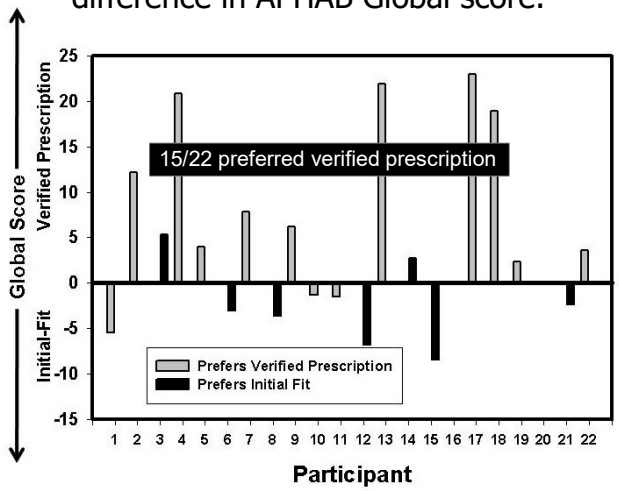


Initial-Fit Approach Versus Verified Prescription: Comparing Self-Perceived Hearing Aid Benefit

Abrams, H., Chisolm, T., McManus, M., McArdle, R.

Journal of the American Academy of Audiology, 23(10), 768-778

Preference for "initial" versus "verified prescriptive" fitting plotted as a function of difference in APHAB Global score.



A COMPARISON OF CONSUMER SATISFACTION, SUBJECTIVE BENEFIT, AND QUALITY OF LIFE CHANGES ASSOCIATED WITH TRADITIONAL AND DIRECT-MAIL AID USE

Kochkin, S

Hearing Review, 21(1)

What he asked…

Direct-mail and Best Practices

- How do direct-mail hearing aids compare to traditionally fit hearing aids?
- How do Best Practices impact on performance of traditionally fit hearings and their comparison to direct-mail hearing aids?

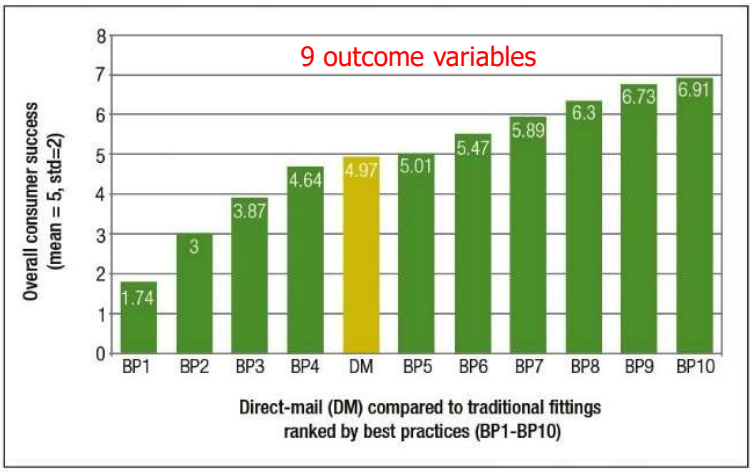
What he did…

MarkeTrak surveys

- MarkeTrak survey in 2009 of traditionally fit hearing aids ≤ 3 years old (n = 1721).
- Survey in 2013 of customers of a very large US direct-mail hearing aid firm (n= 2332)
- Compared traditionally fit aids (94% digital) to direct-mail aids (95% analog) on a variety of measures.

What he found…

Overall success vs. Best Practice



WHAT IS YOUR CUSTOMER LOYALTY QUOTIENT (CLQ)

Kochkin S, Dennison L, Jackson L

Hearing Review, 21(9)

What they asked…

Satisfaction & Loyalty

- Consumer satisfaction with HHP (Hearing Healthcare Provider)
- Consumer loyalty ratings with HHP
- Impact of consumer satisfaction on loyalty
- Relationship between consumer loyalty and best practice

What they did…

National survey (2009) of hearing aid owners (n=3174)

- They rated HHP on 7 factors
  - Professionalism
  - Knowledge level
  - Explained care of hearing aid
  - Explained hearing aid expectations
  - Quality of service during fitting
  - Quality of service post-fitting
  - Level of empathy

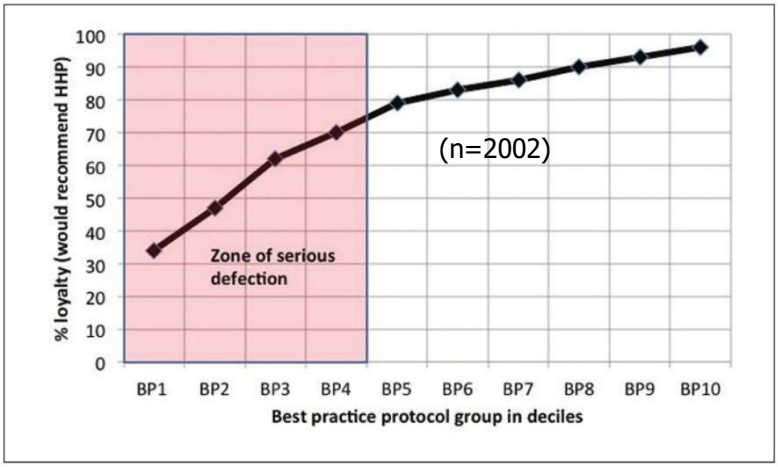
What they did…

National survey of hearing aid owners (exclude direct-mail)

- They used a 7 point Likert scale
  - Very dissatisfied
  - Dissatisfied
  - Somewhat dissatisfied
  - Neutral
  - Somewhat satisfied
  - Satisfied
  - Very satisfied

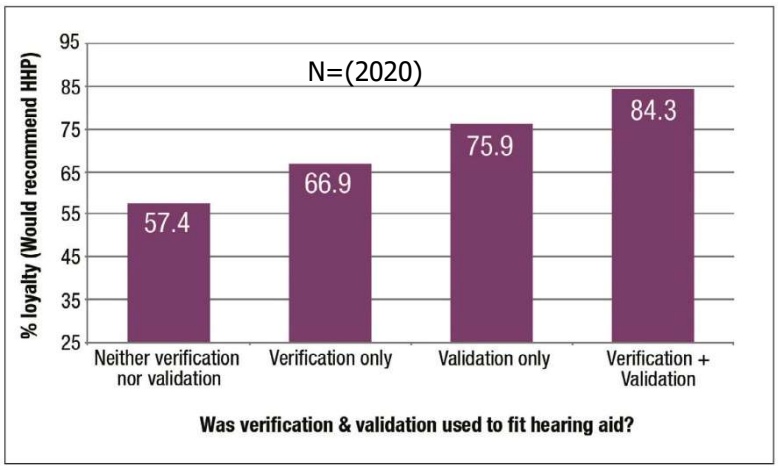
What they found…

Relationship between consumer loyalty and best practice



What they found…

Relationship between consumer loyalty and verification / validation



- Make sure the OTC pathway runs through your clinic (physically, over the internet, over the phone)
- Make sure you are offering something more than a device when you sell a hearing aid.
- The fact that you are offering something beyond a device will be most evident if the device and services are not bundled.
- Find a way to tell your story in a sentence or two – what do you bring to the table.
- Get ready to offer services to people who already have devices.

2017 Signia Expert Series

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July 11, 2017 at 12 PM ET

Over-the-counter hearing aids - opportunity or disaster?

Presented by Catherine Palmer, Ph.D.

How to position your practice and your thinking to embrace over-the-counter hearing aid sales will be discussed. Strategies to engage patients at all points of entry into hearing health care will be explored based on the current evidence base.

August 3, 2017 at 12 PM ET

Hearing aid speech mapping verification: Some explanations for puzzling outcomes.

Presented by H. Gustav Mueller, Ph.D.

Speech mapping has become a routine method to verify prescriptive fittings. Sometimes, however, things just don't look right, and we wonder... is it the equipment, the hearing aid, the patient, or me? In this course, we'll take a look at some of these unusual findings, and see if we can determine who the culprit really is.

August 16, 2017 at 4 PM ET

Tinnitus Activities Treatment.

Presented by Richard Tyler, Ph.D.

This protocol is focused on collaborative counseling in the four areas affected by tinnitus: thoughts and emotions, hearing, sleep, and concentration. Principles of cognitive behavior therapy, acceptance and mindfulness, are included. TAT is picture-based to facilitate ease and interaction with client. Low-levels of partial masking are included.

August 25, 2017 at 12 PM ET

Nonlinear Frequency Compression for the Busy Clinician.

Presented by Joshua Alexander, Ph.D.

The purpose of this talk is to empower the busy clinician by reviewing the hearing aid fitting process as it relates to nonlinear frequency compression. Goals for using frequency lowering for different hearing losses will be reviewed, factors that may influence its effectiveness will be briefly described, and general guidelines for verification using probe microphone measurements will be discussed.

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Thank you!!!