Pathways to Amplification

SHAA – FEB 2019

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Disclosures

- Associate Professor – University of South Dakota
- Audiology researcher – VA medical centers
- See patients – USD and VA
- Work with all manufacturers in some capacity
- Primarily see adults – with a few kids sprinkled in
- I will be clear when things are facts/research and my opinion ☺

- The views expressed here are that of the author and not the US Government, Department of Veterans Affairs, State of South Dakota, or the South Dakota Board of Regents

What is our goal?

Communication Competence

How do patients get to us?

- Significant other/family
- Physician
- Self-advocate
- Saw an ad
- Recommendation

- Tried a "friend's" hearing aid
- Tried one from a store
- Tried one years ago – no benefit

How did we get here?

- Pre 1978 – 3 step process
- 1978 – ASHA – audiology adopts retail model
  - The start of bundling
- Today:
  - Struggle with the retail model
  - Many distribution channels
    - Audiologist
    - Dispenser
    - Big box stores
    - Internet
    - Do it yourself (MD hearing aids, Embrace, iHear, etc)

What is missing? – care??

2013 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- FDA should withdraw its draft guidance on PSAPs.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)

National Academies of Sciences Release Report on Hearing Aid Accessibility, Affordability

- 5 meetings in 2016 and 2017
- The committee recommended that the US Food and Drug Administration (FDA) remove the regulation requiring adults to have a medical evaluation or sign an evaluation waiver to purchase a hearing aid, and recommends a new category of over-the-counter, wearable hearing devices – separate from hearing aids – that could assist adults with mild to moderate hearing loss. The report does not address surgical devices, such as cochlear implants, and related services.

- So we did a "study"
  - Hearing Review publication

Hearing Review Publication

- 14% to 33% of adults 50 years and older who might benefit from hearing aids use them
- High costs, lack of insurance coverage, the stigma associated with wearing hearing aids, and limited awareness of available options are often barriers to accessing hearing healthcare – which includes services to diagnose and evaluate hearing loss, auditory rehabilitation, and hearing technologies
- Average retail price for a pair of hearing aids in 2013 was $4,700, which reflected the cost of both the hearing aids and associated professional services
- Recommendations….

Continued…

- Lower cost technologies
- Audiologists 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 examine pathways for enhancing access
- Transparency of hearing aid programming, including the development and implementation of standards for hearing aid programming that allows any hearing health care professional to program device settings
  - Aka no private labels
- Requirement for point-of-sale information about hearing aids' programming features and portability to be provided to consumers to enable them to make better informed purchasing decisions.
- More improved compatibility and interoperability of hearing technologies with communications systems are also needed, because people with hearing loss frequently use hearing aids and hearing assistive technologies that couple with cell phones and a range of other communications systems.

2016 FDA meeting

- Hearing to discuss PCAST report
- Findings
  - Hearing is vital to communication, health, functions, and quality of live. Individuals need to be alerted to their hearing health
  - Hearing loss ranges from mild to profound, It increases with age, onset is typically gradual, each person is unique
  - Hearing healthcare involves wide range of services and technologies
  - Hearing loss is a public health and societal concern
  - Action is needed across all involved people (stakeholder, people with HL, family, professionals, NPO, industry, govt, physicians, etc)

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)

NASEM (IOM) – Regulation issues

- Changes were proposed with a goal of making hearing aids more accessible and affordable
- PCAST and NASEM reports cited conditions for sale as a barrier to availability and accessibility of hearing aids
- FDA need authority from Congress to implement these recommendations due to state laws related to hearing aids
- FDA could have allowed hearing aids to be sold OTC, but preempting state laws would have been difficult

OTC Act of 2016

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

OTC 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
- Differences from 2016
  - Removed language asking for the removal of FDA draft guidelines. Now calls for finalizing draft guidance
  - Removed CMS and reimbursement discussion

What does the law do?

- The bill expressly preempts all state and local governments regulations specifically to hearing aids
  - Requirements such as mandatory return periods and consultations with Health Care Providers, will not be in effect for OTC hearing aids
  - Anyone will be able to sell OTC hearing aids
  - No provision to enforce "red flag" conditions
  - The bill only preempts state laws specific to hearing aids
  - No effect on more general state laws such as those prohibiting false claims

ASHA Position Statement
(Feb 14, 2017)

- 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.

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

ADA supports the bill

- 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).~~

AAA position statement (Jan 26, 2017)

- 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, noting that those under 18 should see audiologist
  - Mild loss
  - Cautions long-term use
  - If they don't notice improvement to see audiologist
  - Labeled to make comparisons between products
  - Output warning could cause more hearing loss or initial HL in those with NH
  - Output control
  - Red flag warning signs
  - Not to replace professional
  - Labeled as medical device not consumer electronics
  - Language of how to get better outcomes (with professional)
  - Not for tinnitus, dizziness, pain
  - **Negative consequences of under fitting (and over fitting)**

http://www.audiology.org/publications/accessibility-and-affordability-hearing-care-adult-consumers

http://www.audiology.org/publications/over-counter-otc-hearing-devices

AAO-HNS position statement

- 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 hearing health professional or appropriate online/technological source) - NOPE
  - Requirements related to standardized packaging - YES
    - Medical evaluation
    - Red Flags
  - Structured mechanism for at least five years of data collection – probably not

2017 Act signed – Aug 18, 2017

- President Trump signed the OTC Act
- 3 years to come up with regulations/laws

OTC defined

- Uses same scientific technology as air conduction hearing aids or wireless air conduction hearing aids
- Is intended for those 18+ to compensate for mild to moderate HL
- Through tools, test or software; allows user to control aids to customize to their needs
- May
  - Use wireless technology
  - Include tests for self assessment of hearing loss
  - Is available OTC without supervision, prescription or other involvement, intervention of a licensed person, to consumers through in-person transactions, by mail, or online

It is all about wording

- A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing.
  - A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually required to program and optimize the performance of hearing aids with these more complex features.
- 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.
  - Regulated by Radiation Control for Health and Safety Act of 1968
    - Not regulated for safety because they are NOT medical devices

OTC vs PSAP

- PSAP is not a "hearing aid"
- Okay … but what IS the difference???

Otofonix Apex Hearing Amplifier

Otofonix Apex Hearing Amplifier

Features

- Open fit design eliminates common plugged-and-stuffy sensation
- Pre-programmed digital circuit
- 4 channels & 12 bands
- Low battery Indicator
- Adaptive Layered Noise Reduction
- Acoustic Feedback Cancellation
- Button switch, 8 volume levels
- 3 Programs
  - **Default setting** – everyday use with low noise reduction
  - **Noisy setting** – reduces background noise (restaurant, wind noise etc.)
  - **Treble setting** – reduces annoying high pitched sounds (feedback, whistling, squealing)
- Amazingly low battery current consumption
  Average Battery Life: 7-10 days (wokking hours)

FDA Letter to Manufacturers July 24, 2018

That statutorily mandated process provides for FDA to publish proposed regulations by **August 18, 2020**, to consider public comments, and then to publish final regulations within 180 days of the close of the comment period.

The protections include output limits, appropriate labeling, advisements about when to consult with a licensed health care practitioner, and guidance on when premarket review by FDA would be required.

Section 709 is not self-implementing, meaning that the OTC hearing aid category, as defined by FDARA section 709, **does not exist** until the effective date of a published final regulation. Until that time, no products that are claimed to address hearing loss are, or can claim to be, OTC hearing aids within the meaning of FDARA section 709.

Association Consensus Statement Aug 14 AAA, ADA, ASHA, HIS https://www.hearabouthearing.org/

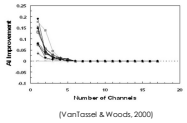
- 1) the product requirements appropriate for OTC hearing devices targeting mild-to-moderate hearing impairment;
- 2) outside-of-the-box labeling appropriate for medical devices sold over-the-counter;
- 3) comprehensive inside-the-box labeling;
- 4) naming the products Self-Fit Over-the-Counter Hearing Devices, adopting risk classifications consistent with air conduction hearing aids, and limiting 510(k) exemptions;
- 5) establishing strong consumer protection laws

Pushing the boundaries

- What is <u>currently</u> legal?
  - PSAP
    - No mention of hearing aid
  - Direct to consumer devices
    - Home based or professional "test"
    - First fit devices mailed to them (mild to moderate hearing loss)
    - Support as needed
  - Traditional hearing aid
    - Prescribed at fit by a licensed professional

Sidebar - cost!?!

- How the heck do they get the so cheap!?!
- Buy in bulk
- Direct to consumer = less overhead
- Potentially – classes of amplifier and microphones
  - Electret vs silicone
- Number of channels/bands
  - How many is enough?



(VanTasseI & Woods, 2000)

What studies do we have?

- Pubmed, CINAHL, etc search
- Terms: Google, Google scholar, PSAP, OTC, adult
- Note: several really good overview articles (Manchaiah et al 2017, SIH May 2018 – Jill et al)
- 3 themes
  - Consumer based studies
  - Electroacoustic based studies
  - Outcomes based studies

What data do we have?

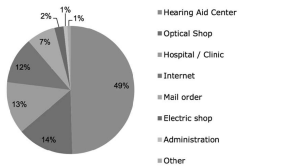
- Range of findings
- Some devices work well
- Some devices have mid-frequency gain only
- Least expensive have worse sound quality
- Wore less hours
- Complaints of physical discomfort

Studies

- Consumers:
  - Kochkin 2010 & 2014
  - Consumer Electronics 2014
  - JapanTrack 2012&2015
- Electroacoustic studies:
  - Cheng & McPherson 2000
  - Calloway & Punch 2008
  - Chan & McPhearson 2015
  - Smith etal 2015
  - Reed et al 2017
- Outcomes
  - Parving & Christensen 2004
  - McPhearson & Wong 2005
  - SaccTedeschi & Kihm 2016
  - Niemal 2017
  - Humes et al 2017
  - Brody et al 2017
- Plus many opinion publications

Manchaiah et al 2017
Jilla et al 2018

Consumer opinion studies
(not peer reviewed)



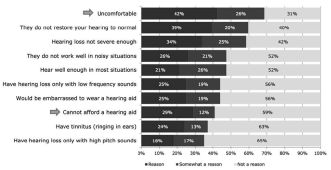
JapanTrak (2015)

How are people purchasing?

What percent are purchasing (remember self-reported HL)?

	France	Germany	UK	Japan	US	Veterans
Adoption Rate	30.4	34	41.1	13.5	30.2	~40
Satisfaction Rate	84	70	77	39	81	

MarkTrak (2014), EuroTrak (2015), JapanTrak (2015), Dennis (2015)



JapanTrak (2015)

Some reasons why they don't like them

Overall

- 5-19% of people with hearing loss purchase aids through direct-mail or online
- ¾ of direct-mail and PSAP owners could have purchased hearing aids
- Direct-mail and PSAP were associated with **LOWER** satisfaction compared with hearing aids purchased through HHC
  - Expectations????

Electroacoustic Studies

Measurements (Frye and KEMAR)

Table 5: Summary of the results of OTC hearing aids' 2-cc coupler measurements.

OTC	OSPL 90				THD (%)			
	Peak frequency (Hz)	Peak SPL (dB SPL)	HFA FOG (dB)	Frequency range (Hz)	EIN (dB)	500 Hz	800 Hz	1.6 kHz	Battery life (hours)
A tone N	1600	127.6	44.0	375–4000	28.4	1.9	N/A	0.4	DNT
A tone L	1600	128.5	39.7	667–4667	28.2	N/A	N/A	0.7	DNT
B	700	129.0	29.0	354–>8000	35.2	0.3	0.1	0.7	DNT
C tone N	1400	128.6	52.8	<200–3667	26.4	2.3	N/A	0.1	DNT
C tone H	1400	126.3	52.5	<200–3667	25.3	2.4	N/A	0.3	DNT
C tone L	1400	126.1	41.8	196–3667	29.7	3.3	3.1	0.1	DNT
D	1400	129.3	37.2	<200–3667	30.8	2.1	1.2	0.5	142
E	1700	118.8	19.1	<200–4667	38.1	4.2	N/A	0.1	182
F	1400	125.9	32.6	<200–3333	24.9	1.4	N/A	0.3	233
G	1600	126.8	39.6	<200–5333	33.2	2.7	N/A	0.2	233
H	800	124.4	14.2	<200–4333	45.6	6.6	1.2	10.1	307
I	2000	113.1	20.9	<200–5000	31.4	23.3	46.5	10.8	114
J	700	118.4	7.6	<200–4667	52.9	4.8	0.8	4.6	212

Note. Peak SPL: peak sound pressure level; N/A: not applicable. According to the 12 dB rule, THD does not need to be measured at that frequency when its second harmonic was amplified 12 dB more than the first harmonic in the frequency response curve (Frye, 2018) [15].
DNT: did not test. Measurement of battery current drain was not conducted since no battery substitution pills for AA and AAA battery size were available.

Summary

Table 2: Estimated hearing thresholds of elderly people based on Steinkler and Lazá's data [28].

	Frequency (Hz)					
	250	500	1000	2000	3000	4000
Estimated hearing threshold (dB HL)	23.4	23.6	27.1	38.1	51.8	55.8

Note. These values show mean hearing thresholds of elderly people aged 60 or above, including both male and female and left and right ears.

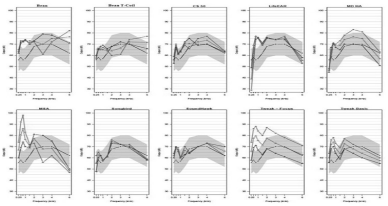
Table 6: Judgment of matching prescriptive targets for presbycusis with stricter criterion.

OTC	Matching the prescriptive targets for presbycusis?					Match the targets at four or more frequencies?
	0.25 Hz	0.5 Hz	1 kHz	2 kHz	3 kHz	4 kHz	
A tone N	✗	✗	✗	✗	✗	√	✗
A tone L	✗	√	√	✗	√	√	√
B	✗	✗	√	√	✗	√	✗
C tone N	✗	✗	✗	✗	√	✗	✗
C tone H	✗	✗	✗	✗	√	√	✗
C tone L	✗	✗	✗	√	√	✗	✗
D	✗	✗	✗	✗	√	✗	✗
E	√	✗	✗	✗	✗	✗	✗
F	✗	√	√	√	√	✗	√
G	√	√	√	√	√	✗	√
H	✗	√	√	✗	✗	✗	✗
I	✗	✗	✗	√	✗	✗	✗
J	√	√	✗	✗	✗	✗	✗

Note. √: OTC hearing aid matched prescriptive target.

S-REM

Article did not specify the target
Assume = 65 dB
Actual = Pink



Reed et al 2017

Conclusions

- Many are VERY loud
- ANSI recommendations of OSPL90, Distortion, and EIN are not met
- Many do not provide HF gain (or much gain)
- Note:
  - If you are first-fitting aids, are you doing much better?
  - If you choose to carry OTC in office, choose carefully

Effectiveness

- Low-cost OTC for mild to moderate MHL/SNHL
- Objective changes in hearing & self-report performance and benefit
- Conclusions:
  - Yes it provided benefit (84%)
    - But they went from nothing to something
    - Same as FF?
  - Wore aids 1-8 hours per day
  - It was "worth it"
  - Outcomes (IOI-HA and COSI) showed benefit
  - Negatives = feedback or background noise

McPherson & Wong (2005)

Outcomes Studies

- Humes et al (2017)
- https://aja.pubs.asha.org/article.aspx?articleid=2608398

AJA

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]

Objectives: The objectives of this study were to determine efficacy of hearing aids in older adults using audiology best practices, to evaluate the efficacy of an alternative over-the-counter (OTC) intervention, and to examine the influence of purchase price on outcomes for both service-delivery models.
Design: The design of this study was a single-site, prospective, double-blind placebo-controlled randomized trial with three parallel branches: (a) audiology best practices (AB), (b) consumer decides OTC model (CD), and (c) placebo devices (P). Outcome measures were obtained after a typical 6-week trial period with follow-up 4-week AB-based trial for those initially assigned to CD and P groups.
Setting: Older adults from the general community were recruited via newspaper and community flyers to participate at a university research clinic.
Participants: Participants were adults, ages 55–79 years, with mild-to-moderate hearing loss. There were 188 eligible participants: 163 enrolled as a volunteer sample, and 154 completed the intervention.
Intervention(s): All participants received the same high-end digital mini-behind-the-ear hearing aids fitted bilaterally. AB and P groups received best-practice services from audiologists; differing mainly in use of appropriate (AB) or placebo (P) hearing aid settings. CD participants self-selected their own pre-programmed hearing aids via an OTC model.
Primary and Secondary Outcome Measures: Primary outcome measure was a 66-item self-report, Profile of Hearing Aid Benefit (Cox & Gilmore, 1990). Secondary outcome measure was the Connected Speech Test (Cox, Alexander, & Gilmore, 1987) benefit. Additional measures of hearing-aid benefit, satisfaction, and usage were also obtained.
Results: Per-protocol analyses were performed. AB service-delivery model was found to be efficacious for most of the outcome measures, with moderate or large effect sizes (Cohen's *d*). CD service-delivery model was efficacious, with similar effect sizes. However, CD group had a significantly ($p < .05$) lower satisfaction and percentage (CD: 55%; AB: 81%; P: 36%) likely to purchase hearing aids after the trial.
Conclusions: Hearing aids are efficacious in older adults for both AB and CD service-delivery models. CD model of OTC service delivery yielded only slightly poorer outcomes than the AB model. Efficacious OTC models may increase accessibility and affordability of hearing aids for millions of older adults. Purchase price had no effect on outcomes, but a high percentage of those who rejected hearing aids paid the typical price (85%).
Trial Registration: Clinicaltrials.gov: NCT01788432; https://clinicaltrials.gov/ct2/show/NCT01788423
Supplemental Materials: https://doi.org/10.23641/asha.5382499

This report is dedicated to the memory of Dr. Gordon Blackistone Hughes, MD, clinical trials coordinator for the

According to the 2012 National Projections made by the U.S. Census Bureau, about 50 million

What did they do?

- Audiology Best Practices device
- Over the counter type device
- Adults, 53 – 83 years old
- Mild-to-moderate, bilaterally symmetrical sensorineural hearing loss
- No prior hearing aid experience
- 154 participants completed the study

How did they do it?

- Placebo-controlled double-blind randomized clinical trial with three parallel branches
  - AB – audiology best practices
  - CD – consumer decision
  - P – placebo
- Measurement: outcomes before/after 6 weeks trial and after 4 weeks for CD and P

About the aids

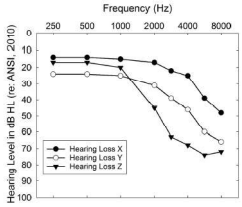
- Hearing aid:
  - High-end, open-fit
  - Directional microphone
  - Dynamic feedback suppression
  - Noise reduction
  - Memory button (4 memories – used as VC – similar to OTC)

AB group (53 participants)

- Programmed to NAL-NL2 "first fit"
- Push button VC with 12/24 dB range
- REAR within 3 dB for 65 dB input only
- LDL adjustment using MPO
- 45-60 minute HA orientation (scripted)

CD group (51 participants)

- 3 different OTC aids
- Programmed to NAL-NI2 to match 3 most common patterns of hearing loss in older adults
- Push button 12/24 dB volume control
- Same basic features as AB aids



The Audiograms

P group (50 participants)

- Hearing aid set to 0 dB IG
- Push button VC range of 3 dB
- No LDL adjustment
- Some aids in directional some in omni

Measurements

- HHIE
- CST – connected speech test
- PHAPglobal – profile of hearing aid performance (5 communication subscales)
- PHAPavds – 2 aversiveness subscales

Findings

- Everyone does better with hearing aids (well those with mild to moderate hearing loss)
- AB had only slightly better results than CD
- Things to keep in mind:
  - Their OTC model was atypical
  - AB did not do full REAR (just 65 dB)
  - P group – was it REALLY acoustically transparent?
  - Nothing about cost/time/participation in studies

Long term findings

- 90% of CD group tried 2-4 different aids
- 20% of CD needed additional help and came back to clinic
- 36% of P wanted to keep their aids
- CD and P moved to AB group and kept the aids
  - 55% of CD who went to AB kept the aids
- What does this mean for audiologist?

Conclusions

- Improvement with use of OTC (as compared with nothing)
- PSAPs work as well in noise and music, but not for speech
- HHC support = higher satisfaction

Overall conclusions based on all the studies

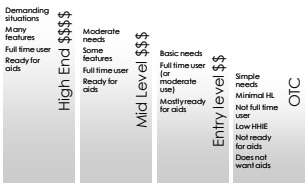
- OTC compared with nothing
- Convenience sampling
- No blinding (other than Humes)

Meaningful OTCs?

- What are OTCs?
  - Can be harmful?
  - Not buying 'hearing aids'
  - Not buying your service
  - OTCs are not programmed for their hearing loss
  - Not fitted by audiologist

How do you currently sell aids?

- 3 levels of technology
  - Entry
  - Mid
  - High
- Differences?
  - How do you explain the differences?
  - How could an OTC add to this?



How to incorporate…

- Part of your sales
- Audiology assistant

- What is your restocking fee? Do you apply this?
- How much energy do you put into the "fitting"?

Who are you going to see/who do we already see?

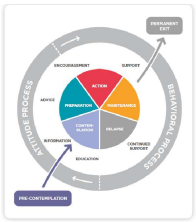
- Informed patients
  - Know hearing loss
  - Know about aids
- Question the difference between audiologist and self-fit
- Already tried OTC and/or PSAP
- Expect you can fix/repair/reprogram/modify aids that you don't fit in your office

What do we know?

	Hearing Aid	OTC	PSAP	Apps
FDA?	Yes	Yes	No	No
Need license?	Yes	No	No	no
Est price	$1,000-$5000 (each)	$250-8000	$20-50	$0-20
Intended User	HL	HL	NH	NH
Actual user	HL/NH	NH/HL	NH/HL	NH/HL

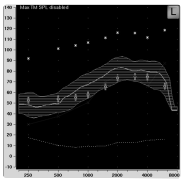
Final thoughts on OTC

- Selection and candidacy
  - Are they ready??
  - Define your group of candidates
  - Define your context of use
- Expectations
  - Does lower cost = lower expectations
  - Demonstrate differences between OTC and your products
- EAA
  - Test box measurements
  - Choose products wisely



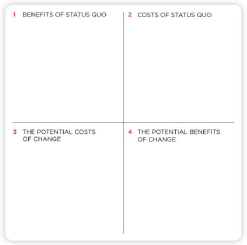
Final thoughts on OTC

- Verification & Validation
  - REAR
    - Think it through
- User experience
  - Fitting
  - Vanity
  - Decision process of consumers
    - Disconfirmation theory
  - Use and maintenance



Final thoughts on OTCs

- Factors that may influence outcomes
  - SES
  - Cost of the device
  - Health literacy
  - Guidance from HHC
  - AR
- Economic considerations
  - Cost-benefit analysis
  - Cost-effectiveness analysis
  - Cost-utility analysis



- Do OTC hearing aids equate to HAs?
  - In all ways
  - In no ways
  - In some ways
  - What? We talked about OTCs? - lime

- For whom is an OTC appropriate?
  - Previous HA user
  - Potential user reporting 2 on the Palmer et al 2009 scale
  - Potential user reporting a 7 on the Palmer et al 2009 scale
  - Anyone - lime

- Which of the following is a "fault" of OTC aids?
  - Potential for electrical shock
  - Potential for hurting the patient
  - Potential for a patient to love it
  - No negatives - lime

- How could you incorporate OTCs into your practice?
  - Offer as an option below your entry product with assistance
  - Offer as an option below your entry product with assistance
  - Not offer it at all
  - Fix the ones that come in and roll your eyes - lime

Thank you

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