

# OTC FROM CLINICAL TRIAL TO CLINICAL CARE

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# DISCLOSURES

- Honorarium for today's talk
- Paid by OTC manufacturer for field trials
- Various relationships with hearing and verification manufacturers for research/clinical outcomes

# WHO AM I?

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**Professor**

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**Audiologist**

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**Researcher**

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**Department Clinic**

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**Clinic Director**

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**Wife**

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**Mom**

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**Organizer of all the things**



# WHY IS THIS EVEN A DISCUSSION?



**What goes into a cost of hearing aid?**



**History**

Easier channel to obtain hearing aids  
Gave FDA until 2020 for guidelines  
Fall 2022 guidelines  
October 2022 went into effect

CHANNELS OF  
HEARING AID  
DELIVERY

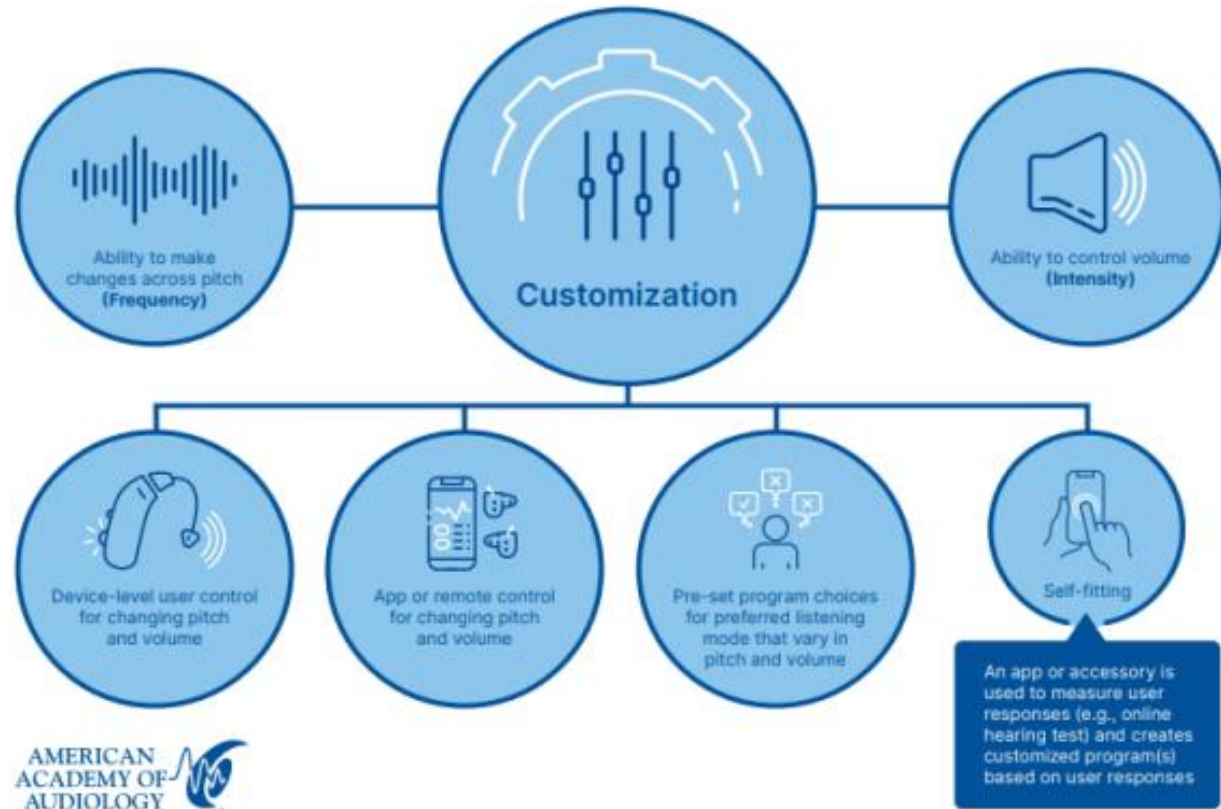
Prescription of hearing aids

DTC Self-fit

Not-self fit

Amplifier

# Over-the-Counter (OTC) Hearing Aids



## OTC VS PRESCRIPTION

- Must have a way for the user to manipulate frequency response (e.g., bass versus treble) and intensity (volume control)
- Self-fitting is one approach and is defined specifically as a process where user responses are used by an algorithm to create a listening program(s) for the user
- HAs must be user-customizable for frequency response and intensity, but self-fitting is not required.

# CLASSES OF "OTC"

## Self-fitting

- Needs FDA approval (510K)

## Non-self fitting

- Does not need FDA approval

# WHAT IS A 510-K?

Class I, II, and III device intended for human use, for which a Premarket Approval application (PMA) is not required

PMA is for class III devices

- Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury

Premarket submission made to FDA to demonstrate that the device to be marketed is a safe and effective, that is, substantially equivalent, to a legally marketed device



# SUBSTANTIALLY EQUIVALENT

has the same intended use as the predicate; and

has the same technological characteristics as the predicate;  
or

has the same intended use as the predicate; and

has different technological characteristics and does not raise different questions of safety and effectiveness; and

the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device

# SO WHAT DOES THIS MEAN FOR HEARING AIDS?

No more harmful

Introducing a device  
into commercial  
distribution (marketing)  
for the first time

Change or modification  
to a legally marketed  
device could  
significantly affect its  
safety or effectiveness

# THE STUDY..

- Why?
  - Contracted by HA manufacturer who is intending to market an OTC
- My job
  - Objectively compare what will be the self-fitting OTC to a currently available HA

# THE PRIMARY EFFECTIVENESS OBJECTIVE

- To demonstrate that the *self-fit hearing aid* strategy is non-inferior to the *currently available HA* fitting strategy in subject's perceived hearing aid benefit after using the *OTC* and *currently available* fit hearing aids in real-life conditions

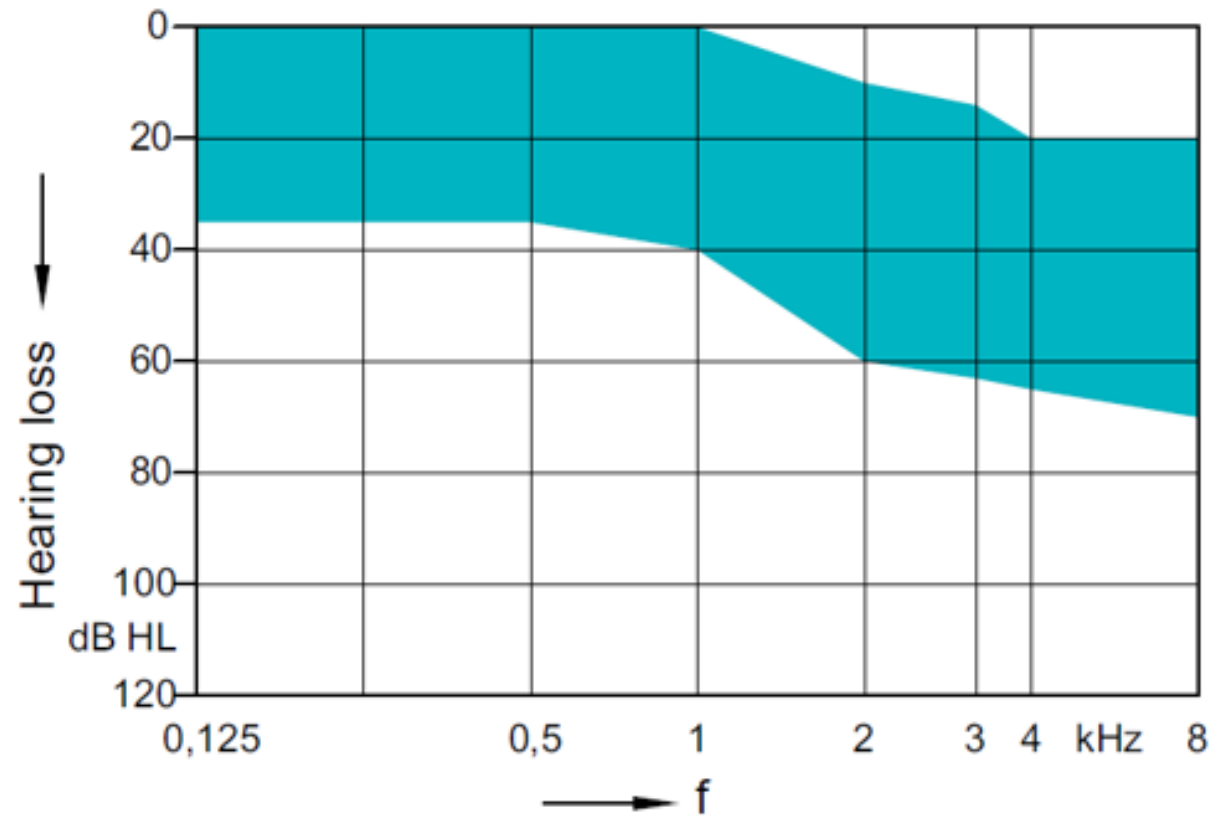
# SECONDARY

- **Hearing Aid Benefit Objectives:**
  - To score each of the following hearing aid benefit performance measures when the subject is using the OTC and current device fit hearing aids:
    1. Sound quality, speech understanding and hearing aid satisfaction real-time assessment,
    2. Speech-in-noise recognition performance, and
    3. Hearing disability in communication situations.
  - **Secondary Gain Selection Objective:**
    - Individual frequency-specific real-ear gain comparison of the two different fitting strategies
- **Secondary Preference Objective:**
  - Fitting strategy preference reported by the subject.
- **Secondary Safety Objective:**
  - To estimate the rate of adverse device effects (ADEs) when the subject is using the OTC.

# METHODOLOGY

- Screening
- Placed into group
  - OTC first
  - HA first
- Fit with device
  - 2 week trial
  - Pushed questionnaires
- Return for booth testing and questionnaires
- Wash out
- Cross over
- Return for more testing

# PARTICIPANT CRITERIA



- Non-users (with less than 20% of previous experience)
- Over 18 YOA
- Self-perceived difficulty
- Fluent in English (reading and speaking)
- Meets audiometric criteria

# EXCLUSION

- The device does not fit in the ear
- Other criteria
  - Severe hearing loss or deafness in at least one ear.
  - A steep decline in hearing ability within the last 90 days in one or both ears.
  - Active discharge within the last 90 days.
  - Dizziness.
  - A visible deformity of the ear.
  - Pain, or discomfort in the ear, or significant ear wax accumulation.



# QUESTIONNAIRES

- Rate hearing 1-4
  - No Trouble
  - A little trouble
  - A lot of trouble
  - Cannot hear
- APHAB
- SSQ
- Factors speech hearing, spatial hearing, qualities of hearing, and listening effort

# TESTING

- Field testing
  - Random questions from device
    - Ecological Momentary Assessment (EMA) ratings
      - Situation
      - Difficulty
- Booth testing - QuickSIN
  - Aided
  - Unaided

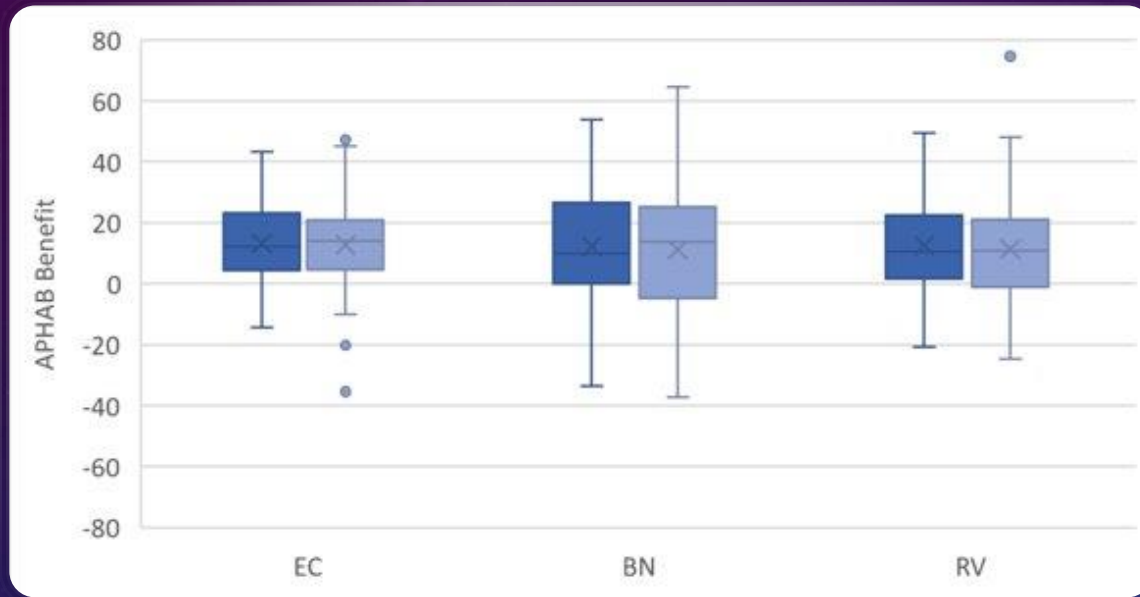
# FITTING

- Hearing aid
  - RECD
  - REM
    - 55, 65, 75, MPO within 3 of NAL-NL2 through 4k
- OTC
  - Handed it to the participant (good luck)
  - Self-fitting
    - In-situ
    - Put into one of four hearing loss fittings

REM

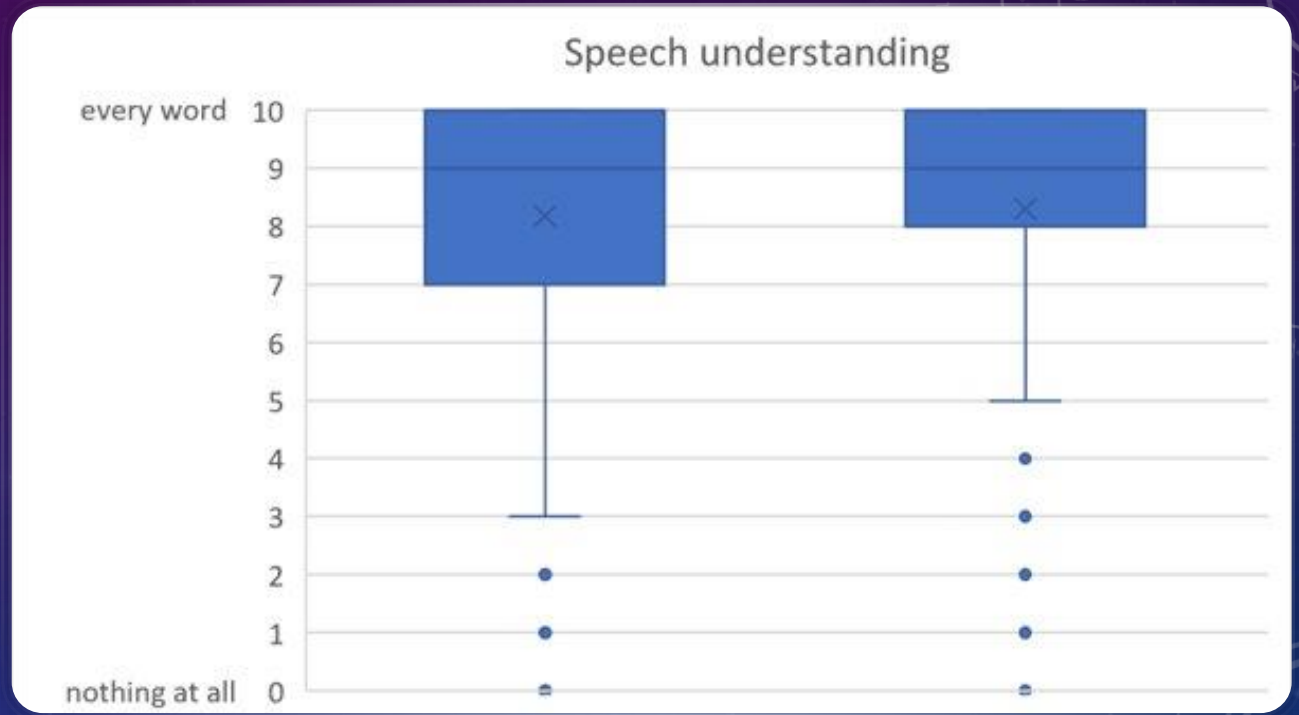
- Hearing aid
  - After fitting before leaving
  - Post fitting after field testing
- OTC
  - After fitting before leaving (not on ear but in box)
  - Post fitting after field testing

# RESULTS APHAB



Characteristic	Hearing aid	OTC
Current listening situation		
Speech in quiet	13.6% (159/1171)	15.2% (166/1091)
Speech in some noise	25.3% (296/1171)	26.2% (286/1091)
Speech in loud noise	7.3% (85/1171)	8.3% (91/1091)
Television	30.3% (355/1171)	32.9% (359/1091)
Listening to music	7.7% (90/1171)	7.1% (78/1091)
Other with speech	3.8% (45/1171)	4.3% (47/1091)
Other without speech	12.0% (141/1171)	5.9% (64/1091)
Sound quality of hearing aid in current situation		
Excellent	32.6% (379/1164)	27.8% (302/1085)
Good	33.8% (394/1164)	47.6% (517/1085)
Fair	25.9% (302/1164)	17.5% (190/1085)
Poor	6.4% (74/1164)	6.5% (71/1085)
Bad	1.3% (15/1164)	0.5% (5/1085)
How much speech is understood		
N	934	945
Mean $\pm$ SD	8.2 $\pm$ 2.0	8.3 $\pm$ 2.0
Median	9.0	9.0
Min, Max	0.0, 10.0	0.0, 10.0
How satisfied are you with hearing aid in current situation		
Very satisfied	29.4% (342/1162)	27.2% (295/1084)
Satisfied	36.1% (420/1162)	48.3% (524/1084)
Neutral	26.2% (305/1162)	16.1% (175/1084)
Dissatisfied	7.5% (87/1162)	7.7% (83/1084)
Very dissatisfied	0.7% (8/1162)	0.6% (7/1084)

# SPEECH UNDERSTANDING

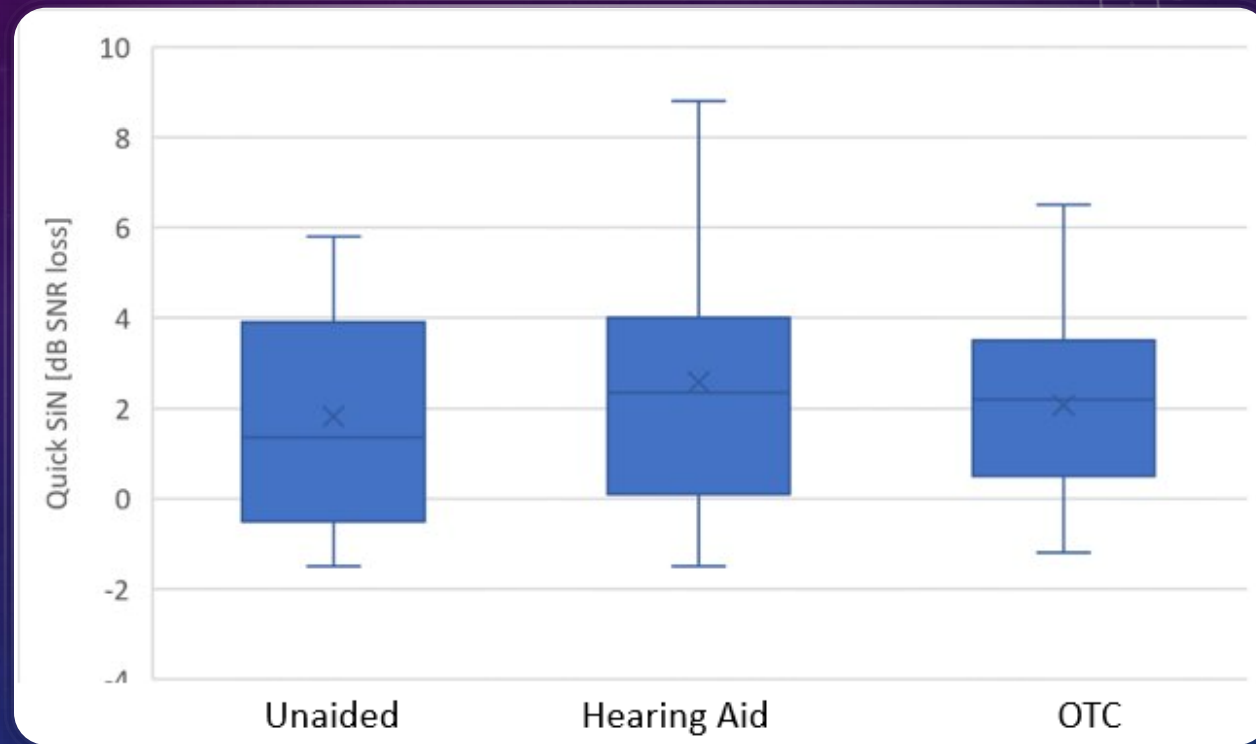


# EMA RESULTS

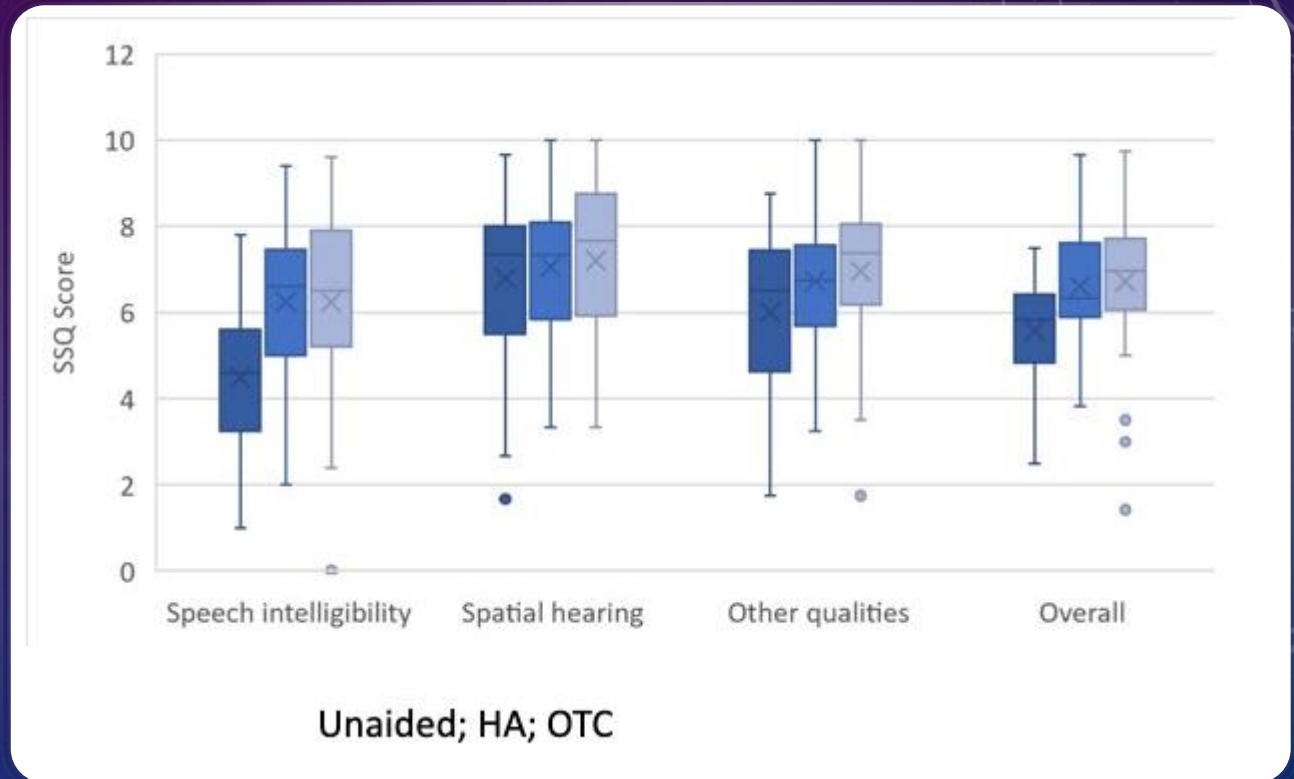
- Sound quality
  - Highest for “speech in quiet” for both fitting strategies followed by “television” (OTC) or “other with speech” (HA) and “other without speech” (both devices).
  - Rated as good or excellent in over 70% of the questionnaires.
  - Ratings were lowest in the “speech in loud noise” situation where less than 40% of questionnaires showed a “good” or “excellent” rating.
- Biggest difference between the fitting strategies was observed for the television situation



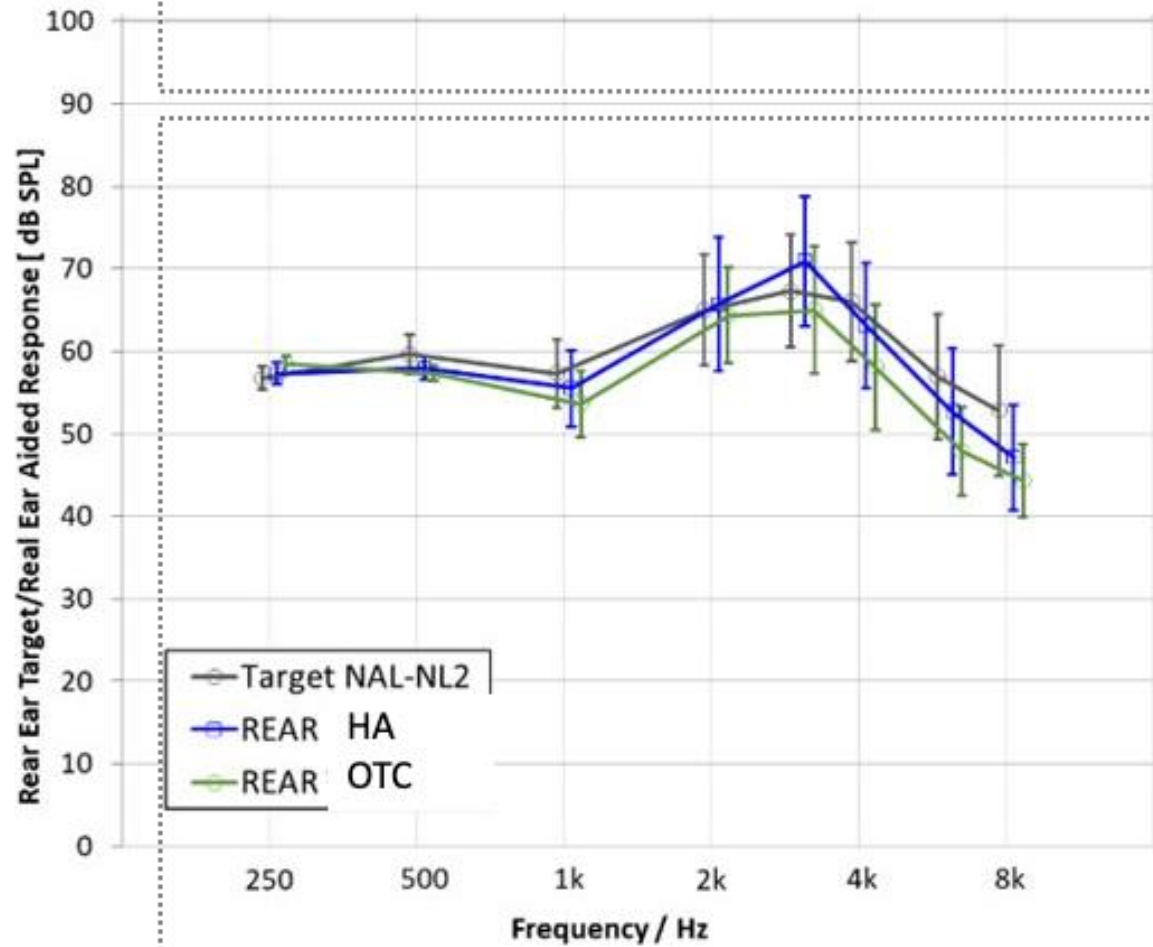
# QUICK SIN



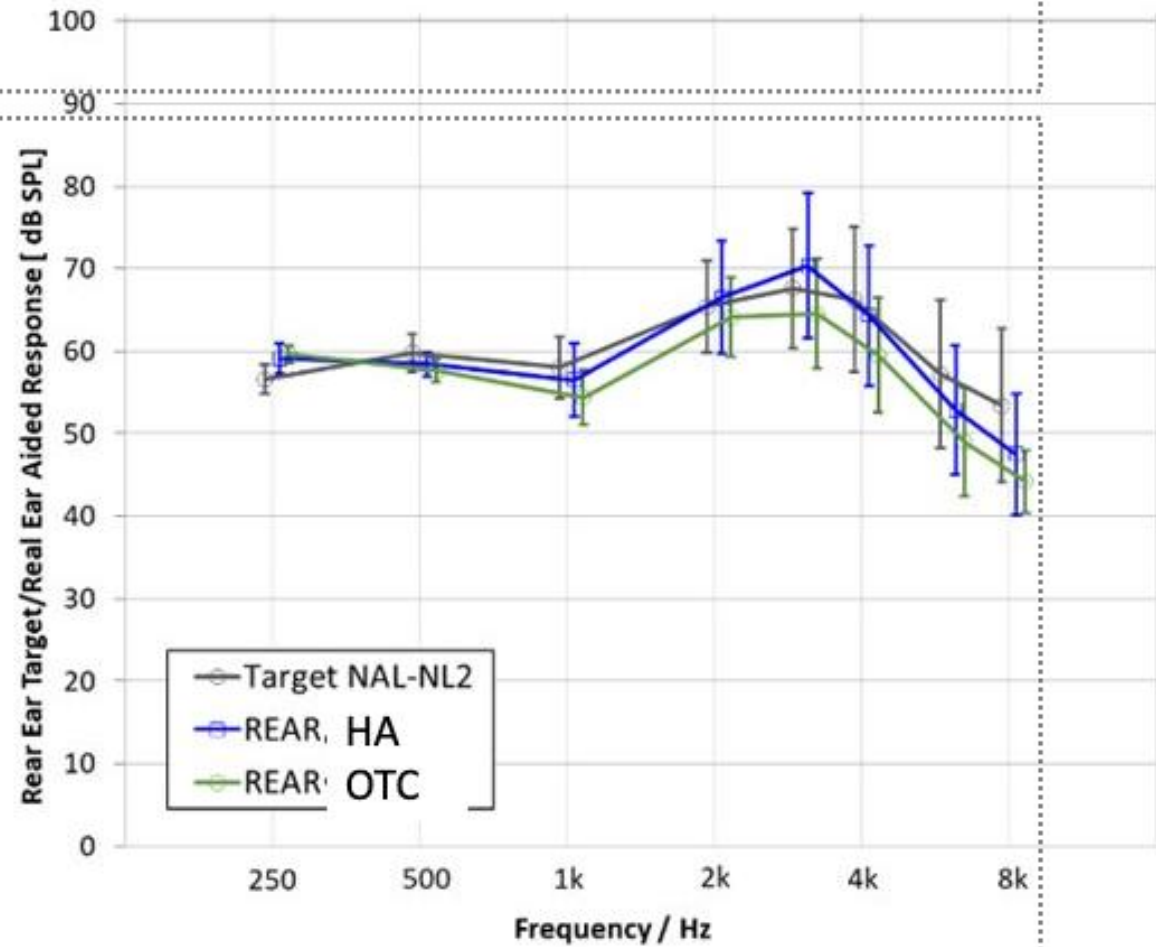
# SSQ



Left Ear 65 dB



Right Ear 65 dB



# FINDINGS

- The *OTC fitting* strategy was not inferior to the traditional fit strategy in each of the 3 benefit scores for each communication subscales in the Abbreviated Profile of Hearing Aid Benefit ( $p < 0.001$  for each subscale).
  - Therefore, the *OTC fitting* strategy demonstrated non-inferiority to the HCP fit strategy in participant's perceived hearing aid benefit (combined p-value  $< 0.001$ )
- What does this mean?
  - The device is not any more harmful

# SECONDARY

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- EMA
  - Variety of listening situations and show similarly good satisfaction
  - Both provided good sound quality and high speech understanding
  - Sound quality was rated fair to excellent in over 90% of the questionnaires
    - Median speech understanding was 8 or above on a scale of 0 – 10 (10 signifying “understand every word”)
    - Satisfaction was neutral to very satisfied in over 90% of the questionnaires
- Quick SIN
  - OTC and HA are similar and show that neither fitting strategy resulted in a degradation of speech understanding in noise
  - With devices - normal/near normal signal-to-noise ratio loss (0-3 dB)
    - Remember what they can do without aids given their hearing losses

# SECONDARY

- SSQ-12
  - In all domains the scores show a benefit of HA and OTC compared to the unaided condition.
  - Virtually no difference in SSQ scores between the devices
- Gain Production
  - REAR similar frequency response shape, consistent with that of the NAL-NL2 targets.
  - Both pairs of devices provided amplification across all audible frequencies
    - Hearing aid fit devices providing greater amplification at higher frequencies
- Fitting device preference
  - Equal numbers preferred each of the two devices (40%) and 20% did not have a preference

# CONCLUSIONS

- Final: No device related adverse reports
- Primary objective was met and demonstrated that the OTC is not inferior to the HA fitting strategy in perceived HA benefit after wearing both devices in real-life conditions.

# MY THOUGHTS

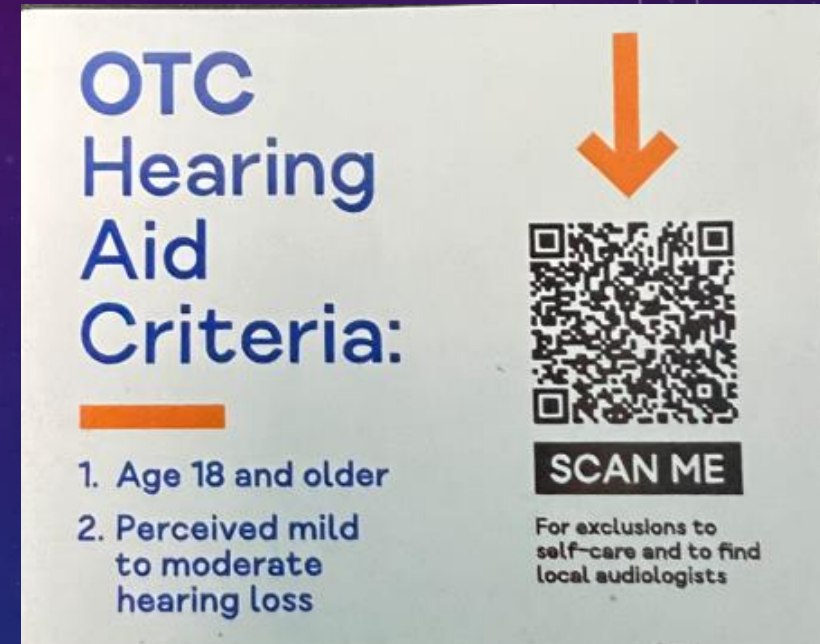
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- What defines as better?
- What are the personality differences?
- Aided is better than not!
  - Yeah!
  - But what is better?



# SO IN THE CLINIC....

- What are you going to offer?
- How can you work with your local pharmacy?
  - [Pharmacy-based OTC hearing aids \(pharmacist.com\)](http://pharmacist.com)
  - Use their language - exclusions for self care



**OTC  
Hearing  
Aid  
Criteria:**

**1. Age 18 and older**

**2. Perceived mild to moderate hearing loss**

**SCAN ME**

For exclusions to self-care and to find local audiologists

The poster features a large orange arrow pointing down to a QR code. Below the QR code is a black button with the text 'SCAN ME' in white. The background of the poster is white with blue text and an orange bar under the title.

# VERIFICATION (OF COURSE)

- Appropriateness
- Verify in the box
  - ANSI standards
    - There are some different requirements for OTC vs prescription (ANSI CTA-2051)
    - NOTE – if using VF2 – use the 0.4 coupler
- Verify on the ear
  - Reprogram to meet targets

# ANSI/CTA 2051

- **Frequency Response Bandwidth:** Standard band: 250 Hz – 5 kHz | Wide band: 250 Hz – 10 kHz
- **Frequency Response Smoothness:** No single peak in the 1/3 octave frequency response shall exceed 12 dB relative to the average levels of the 1/3 octave bands 2/3 octave above and below the peak.
- **Maximum Acoustic Output:** The maximum output sound pressure level shall not exceed 120 dB SPL measured in a 2cc coupler. Note: This is equivalent to a level of roughly 115 dBA referred to the sound field.
- **Input Distortion:** THD+N = 5% or less with 500 Hz tone applied to microphone at 100 dB SPL
- **Output Distortion:** THD+N = 5% or less at 70 and 100 dB SPL output with 500 Hz input
- **Self-Generated Noise:** No more than 32 dBA (equivalent SPL) referred to the input

# WHAT TO DO NEXT?

- Satisfaction
  - Where can it help – where can it not?
- Follow up care
- Work with them on transitioning in the future?
  - If we meet their needs now, they will become patients
  - 60-70% of purchases are current patients