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Considerations in Over-the-Counter Hearing Aids: Past, Present, and Future

David Akbari, Au.D., CCC-A, F-AAA, F-ADA

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David Akbari, AuD, CCC-A, F-AA, F-ADA

Award-winning audiologist and public policy advocate Dr. David Akbari is a key opinion leader and advocate for evidence-based best practices. His opinions and policy recommendations have been published in the Star Tribune, MedCity News, The Hearing Review, Hearing Health & Technology Matters, the ASHA Leader, and the Wall Street Journal. Dr. Akbari is also seen as a thought leader within the profession of audiology and has appeared on the talk show programs "This Week in Hearing," "Audiology Talk," the "Hearing Journal Podcast," and "ListenUp!" Dr. Akbari currently serves on the ANSI/ASA S3 WG48 working group where he has contributed substantively since 2013, and is currently the Chairman. Dr. Akbari also serves on the Editorial Advisory Board for The Hearing Review, as well as on the Academy of Doctors of Audiology (ADA) Task Force on OTC Hearing Aids

Agenda

Agenda

- Introduction
- OTC Hearing Aid History, Timeline, and Impetus
- OTC Hearing Aid Legislative Outcomes and Technical Details
- OTC Hearing Aid Contemporary Analysis
- Electro-acoustic Test Methods Supporting Self-Fitting
- Wireless Test Methods Supporting Self-Fitting
- Answering Your Questions / General Q&A

Introduction

Who is David Akbari?

- Current Chairperson of ANSI/ASA (American National Standards Institute/Acoustical Society of America) S3/WG48 (which authors S3.22 standard among others)
- US delegate for ANSI TAG (Technical Advisory Group) to IEC
- Recipient of ADA “Industry Leadership Award” in 2022; first time award was given in 10 years, and first individual to ever win
- Editorial Advisory Board Member, “The Hearing Review”
- Podcast appearances on “ListenUp!”, “This Week in Hearing”, “The Hearing Journal Podcast”, and more
- Employee of Intricon Corporation

OTC Hearing Aid Impetus and Timeline

Why OTC Hearing Aids?

- Windmill and Freeman (2013) and more recently Bray and Amlani (2023) looked at the workforce projections and population incidence of AuDs, HIS, and the hearing impaired
- In summary, the findings were consistent with the idea that there is a huge and growing unmet need for hearing healthcare in the United States
- Projected Need far outweighs Projected Growth of hearing healthcare providers

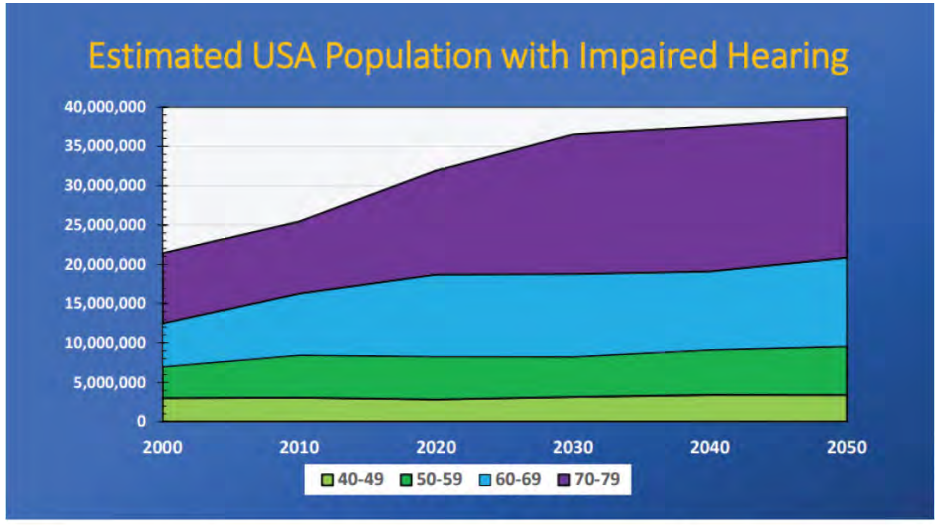


Figure 8. Graying of America: Predicted number of persons in the USA with impaired hearing (ages 40 to 79) between 2000 and 2050.

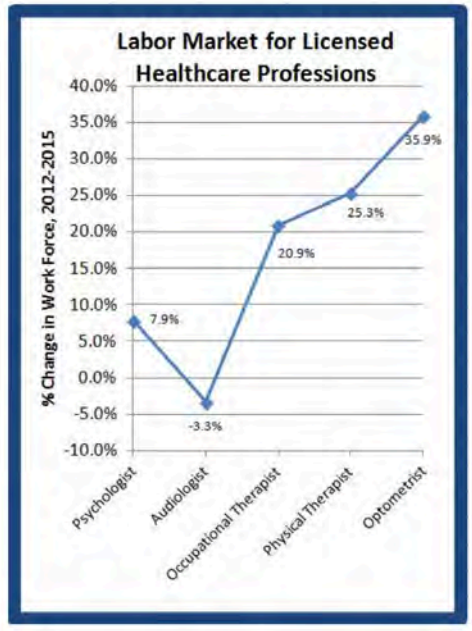
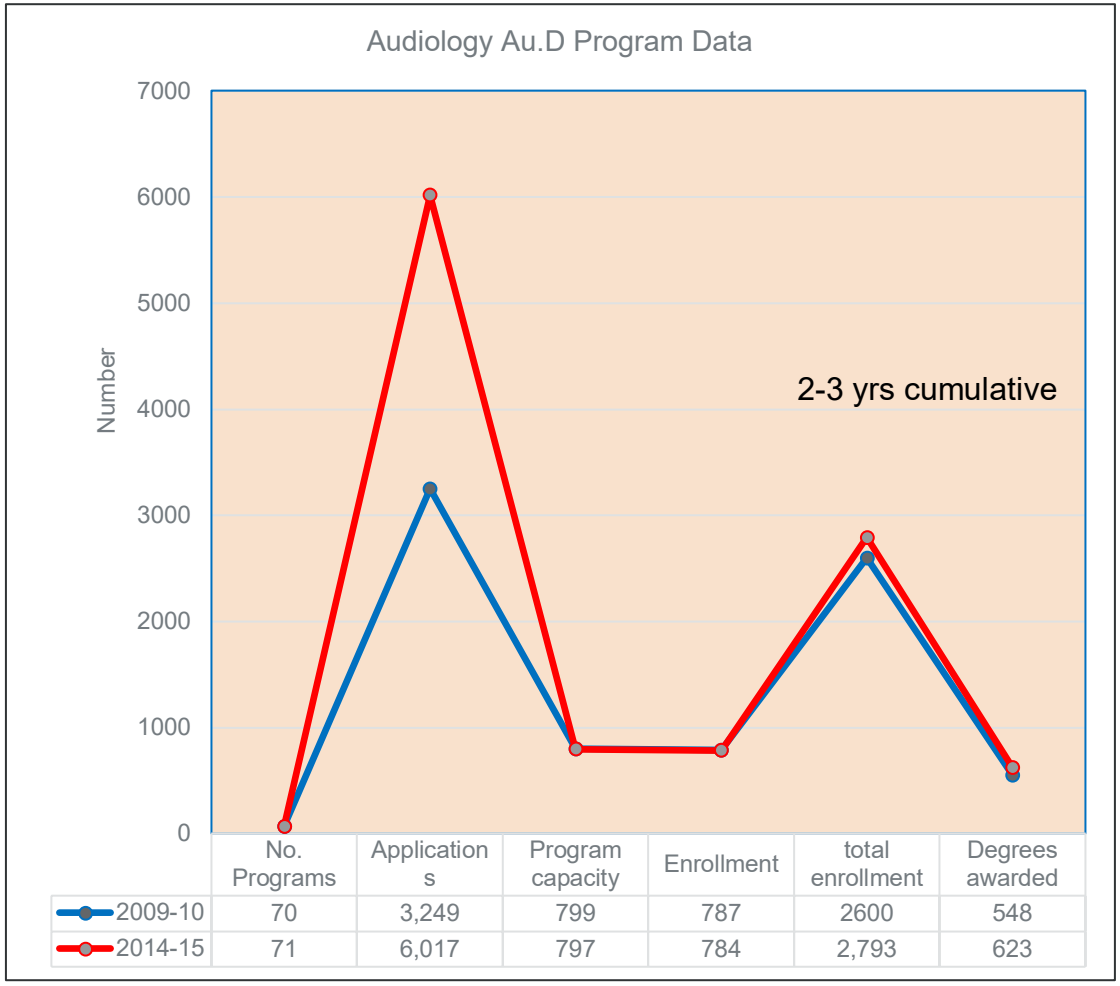


Fig 2. Percentage change in professional work forces from 2012-2015. (Source OES databases, Bureau of Labor Statistics).

Why Not More Audiologists?

- Insufficient clinical placements (#1 Reason)
  - Require 1 year of internship
  - Many audiologists do not want an intern, especially if they are selling hearing aids
- University audiology training programs are people/money intensive
  - Student/faculty ratios often end up at about a 2:6 ratio
  - Universities do not like these ratios
- Many programs have difficulty attracting patients for student training



	No. Programs	Applications	Program capacity	Enrollment	total enrollment	Degrees awarded
2009-10	70	3,249	799	787	2600	548
2014-15	71	6,017	797	784	2,793	623

ASHA Higher Education Services (HES)

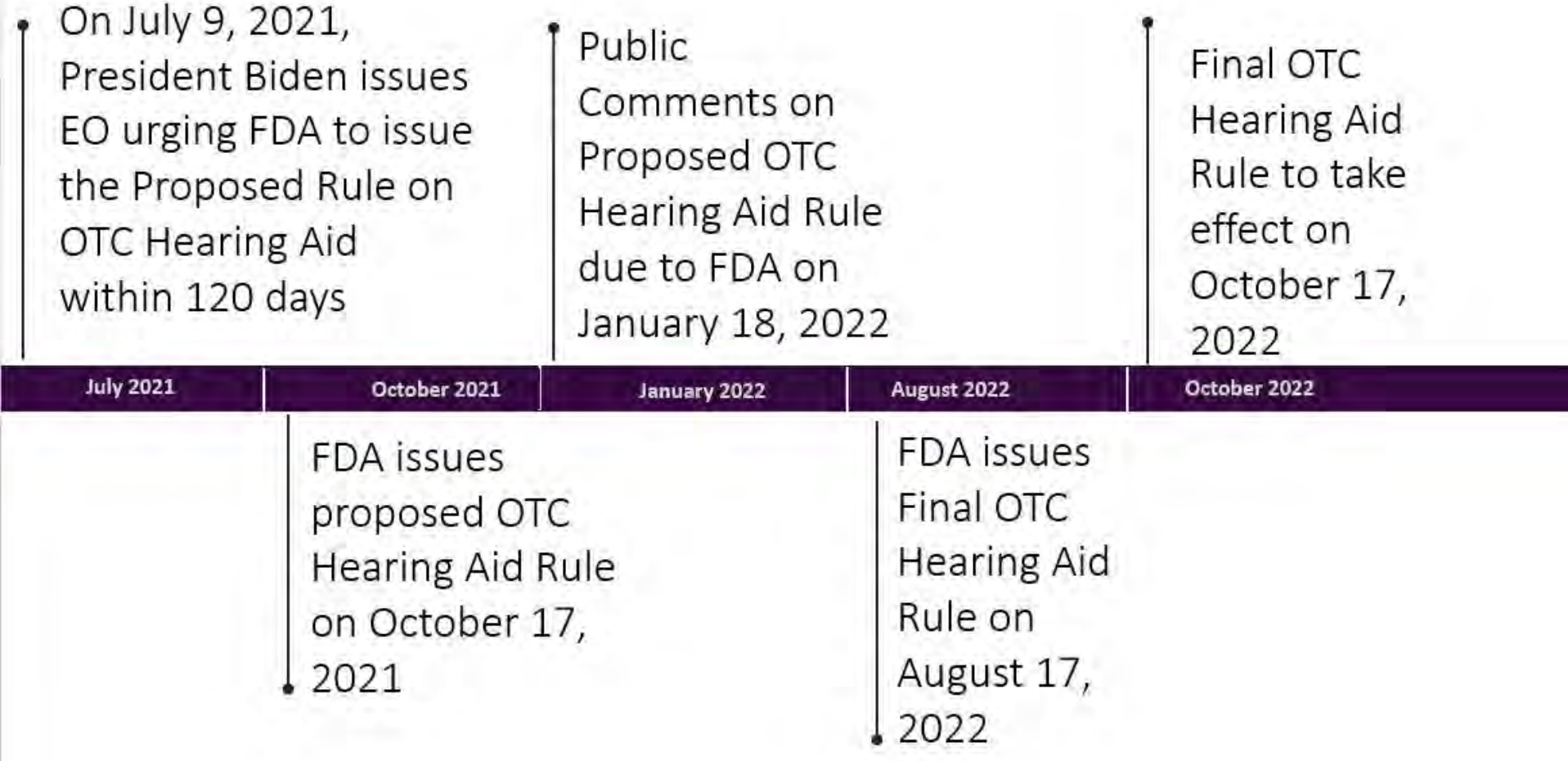
https://www.asha.org/Academic/HES/Archived-Data-Reports/

Data Provides the Answer

- 71 = Au.D. programs
- 8.7= Students/program
- 11= Capacity/program
- 80% = Graduate
- 7 = Per/yr Graduates
- 20% = Attrition
- Maybe half go to HAs?

How did we get to where we are today with the existence of OTC hearing aids?

Source: Academy of Doctors of Audiology OTC Task Force, Sept 2022



Source: Academy of Doctors of Audiology OTC Task Force, Sept 2022

The Bottom Line

- Even if every single AuD program in the country had 100% graduation rates, and all audiologists worked dispensing hearing aids full time, AND HIS did the same, there would still be a huge and growing unmet need for hearing healthcare services in the United States – **This is the impetus for OTC**

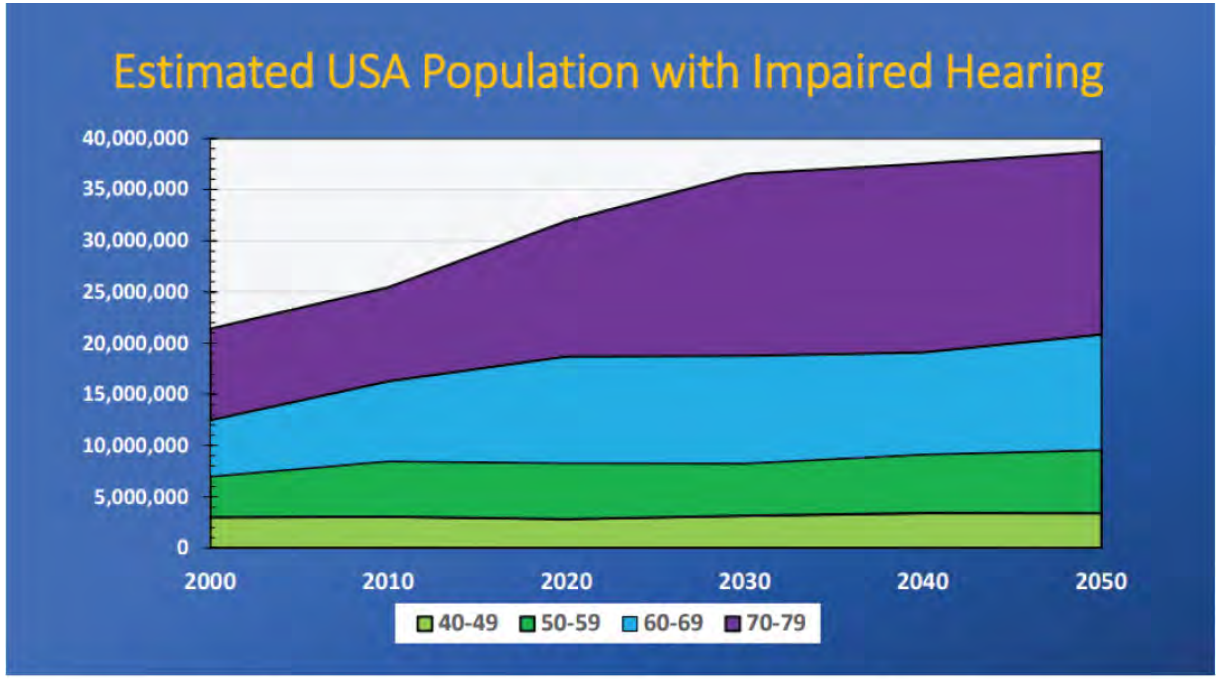


Figure 8. Graying of America: Predicted number of persons in the USA with impaired hearing (ages 40 to 79) between 2000 and 2050.

Source: Bray & Amlani (2023)

OTC Hearing Aid Legislative Outcomes and Technical Details

As mandated by FDARA (FDA Reauthorization Act of 2017), the FDA's task was to:

- Provide greater **access** for hearing aids than currently available
- Provide **affordability** of hearing amplification help
- **Increase use** of hearing aids by consumers

In an effort to help improve affordability and accessibility as key goals of “the final OTC rule,” 21 CFR 800.30 was created

- Maintains existing definition and medical device classifications for hearing aids (Class I and Class II) as consistent with FD&C Act
- Creates category of OTC hearing aids, regulatory controls, and conditions for sale (mandated by FDARA)
- Denotes FDARA federal preemptions for OTC hearing aids
- Creates category of prescription hearing aids, regulatory controls, and conditions for sale*
- Replaces 21 CFR 801.420 and repeals conditions for sale for hearing aids under the new CFR Title 21 801.421, as “restricted” devices*
- Removes federal preemptions and 40-year-old exemption decisions for restricted hearing aids*

*There was no Congressional mandate to do this

FDA Exceeded Congress' Mandate Under the OTC Hearing Aid Act/FDARA

- Eliminating the current restricted category of hearing aids and associated regulations
- Creating a prescription category of hearing aids
  - Class I and II Prescription hearing aids did not exist before

OTC Hearing Aid	Prescription Hearing Aid
• Category of hearing aid never existed before • Defined by technical specifications and intended use • May be dispensed by licensed or unlicensed person • Federal preemptions are strong	• Category of hearing aid never existed before for air conduction HAs • Defined by technical specifications and intended use • Must be dispensed by licensed person as governed by State law • Federal preemptions are limited

As a result of the OTC final rule, *both* OTC hearing aids and a newly created Prescription class of hearing aids were defined:

Over-the-counter hearing aid

- "An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment.
- The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs.
- The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section."

Prescription hearing aid

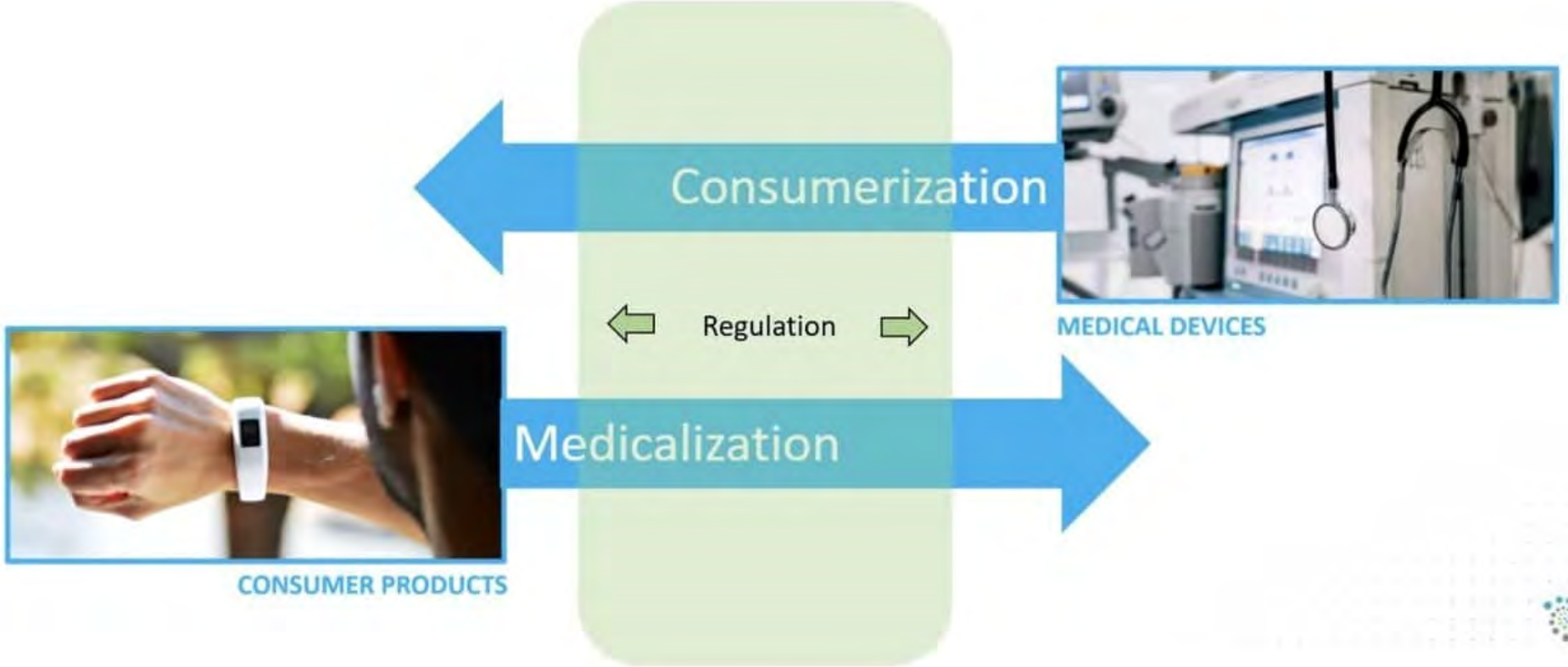
- "A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section."

A Clear Mandate

- OTC hearing aids will be available to consumers through in-person transactions, by mail, or online, without the supervision, prescription, or other order, involvement, or intervention of a licensed person.

Express Federal Preemption

- Prohibits State or local governments from establishing or continuing any law, specifically applicable to hearing products that will:
- *"restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids that is different from, in addition to, or otherwise not identical to, the regulations promulgated under the federal OTC hearing aid regulations"*



Source: Akbari D. OTC hearing aid rule – the impact now and into the future. *Hearing Review*. 2023;30(2):8-11.

In Summary

	Over-the-Counter (OTC) Hearing Aids	Prescription Hearing Aids (Any hearing aids that do not meet OTC requirements)	Personal Sound Amplification Products
Type of Product	Medical device and electronic product	Medical device and electronic product	Electronic product
Intended Users	• People 18 years and older • For those with perceived mild to moderate hearing loss	• People of any age, including those younger than 18 years • For people with any degree of hearing loss, including severe	People of any age with normal hearing to amplify sounds in certain environments
Conditions for Sale	• Purchaser must be 18 years or older • No medical exam • No prescription • No fitting by audiologist • No need for licensed seller	• Prescription needed • Must purchase from licensed seller in some states	No applicable FDA requirements regarding conditions for sale

Source: https://www.fda.gov/medical-devices/consumer-products/hearing-aids

OTC Hearing Aid Contemporary Analysis

Now that OTC is here, what's out there?

- All hearing aids sold in the United States fit into one of the FDA three letter "product codes"
  - Product codes are not meaningful on their own and are just a placeholder for categorization on devices that are the same in a regulatory sense
- Product codes are searchable and public
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
- Not all OTC hearing aids are considered self-fitting
  - In order to be legally marketed in the US, all self-fitting hearing aids need to have a 510(k) marketing clearance prior to sale
  - **NOTE**: FDA does not "approve" or endorse any product, they only "clear" them based on claims and intended use
  - Be wary any time you see the phrase "FDA Approved"

All Air Conduction Hearing Aid Product Codes

Product Code	Device		Regulation Number	Device Class
NIX	Hearing Aid, Air Conduction, Transcutaneous System	Transcutaneous Air Conduction Hearing Ai...	874.3950	2
OSM	Hearing Aid, Air-Conduction With Wireless Technolo ...	Wireless Air-Conduction Hearing Aid	874.3305	2
QDD	Self-Fitting Air-Conduction Hearing Aid, Prescript ...	Self-Fitting Air-Conduction Hearing Aid	874.3325	2
QUG	Hearing Aid, Air-Conduction With Wireless Technolo ...	Wireless Air-Conduction Hearing Aid	874.3305	2
QUH	Self-Fitting Air-Conduction Hearing Aid, Over The ...	Self-Fitting Air-Conduction Hearing Aid	874.3325	2
ESD	Hearing Aid, Air-Conduction, Prescription	Air-Conduction Hearing Aid	874.3300	1
LDG	Kit, Earmold, Impression	Air-Conduction Hearing Aid	874.3300	1
LRB	Face Plate Hearing Aid	Air-Conduction Hearing Aid	874.3300	1
QUF	Hearing Aid, Air-Conduction, Over The Counter	Air-Conduction Hearing Aid	874.3300	1

- In a nutshell
  - QUF and QUG are non-self-fitting OTC
  - QUH and QDD are self-fitting OTC and Rx, respectively
  - OSM and ESD are the Rx products you are used to

= OTC = Rx

What's a 510(k)?

- A "510(k)" refers to section 510(k) of the Food, Drugs, and Cosmetics Act (FD&C Act) and means that a medical device is "substantially equivalent" to another already legally marketed medical device
  - The key element of "substantial equivalence" is:
    - With respect to a device being compared to a predicate device, that the device has:
    - (i) the same technological characteristics as the predicate device, or
    - (ii) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data that demonstrates that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device.

Products

- Search by product code to see 510(k) clearances https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

QUH (OTC Self-fitting)

Device Name	Applicant	510(K) Number	Decision Date
Sontro® Otc Hearing Aids (Ai)	Soundwave Hearing, LLC	K231550	10/26/2023
Lumen 155-Sf	Intricon Corporation	K223911	10/17/2023
Self-Fitting Hearing Aids	Huizhou Jinghao Medical Technology Co., Ltd.	K221052	09/25/2023
Intrisound™ Tuned Lumen® 155 Hearing Aids	Tuned Ltd	K223848	09/08/2023
All-Day Clear Slim Adcs1 Hearing Aid. All-Day Clear Adc1 Hearing Aid	Sonova AG	K230538	06/16/2023
Lexie Lumen Self-Fitting Otc Hearing Aids With Lexie Application	HearX SA (Pty) Ltd.	K223137	03/14/2023
Eargo 5 , Eargo 6	Eargo, Inc.	K221698	12/21/2022
Nuheara Iqbuds 2 Pro Hearing Aid	Nuheara Limited	K221064	10/30/2022
Jabra Enhance Plus	GN Hearing A/S	K213424	01/19/2022

✦ = Both OTC and Rx

Products

- Search by product code to see 510(k) clearances https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

QDD (Rx Self-fitting)

Device Name	Applicant	510(K) Number	Decision Date
Lumen 155-Sf ✦	Intricon Corporation	K223911	10/17/2023
Vibe Sf Self-Fitting Hearing Aid	WSAUD A/S	K220403	08/12/2022
Mdhearingaid App, Mdhearingaid Smart Hearing Aids	MDHearingAid	K220303	08/04/2022
Jabra Enhance Plus ✦	GN Hearing A/S	K213424	01/19/2022
Bha100 Series Braun Clear Hearing Aid	Kaz USA, Inc., A Helen Of Troy Company	K212609	01/05/2022
Bose Soundcontrol Hearing Aids	Bose Corporation	K211008	05/05/2021

✦ = Both OTC and Rx

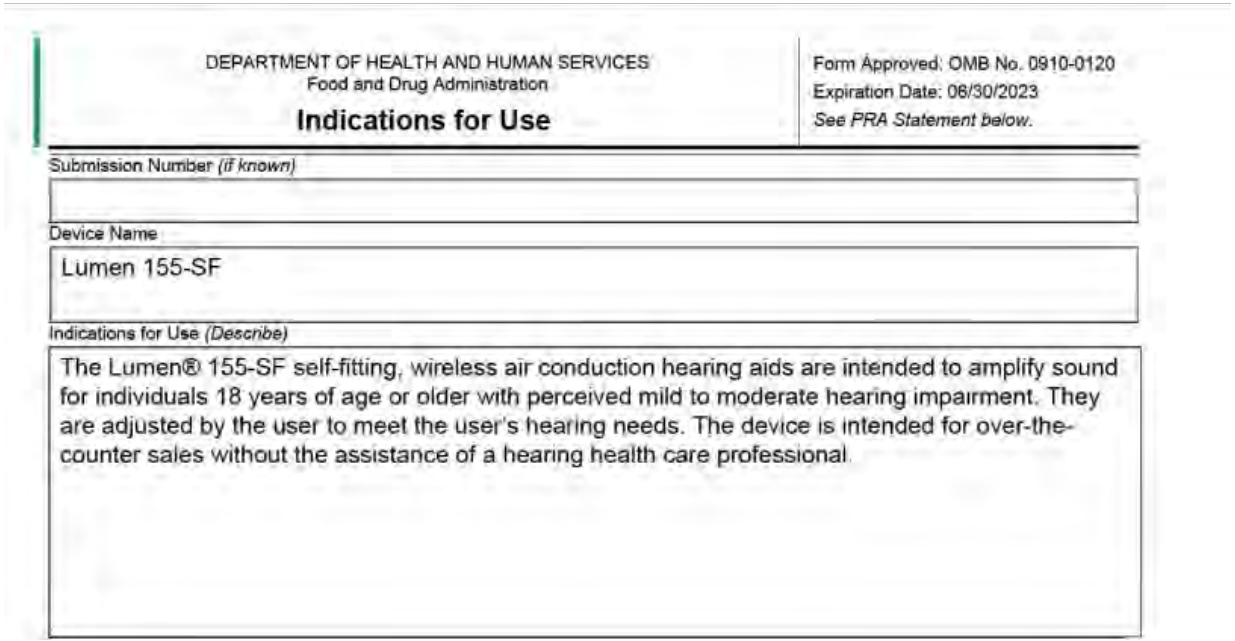
Looking Deeper

- K223911 – Lumen 155-SF

Device Classification Name	self-fitting air-conduction hearing aid, prescription
510(k) Number	K223911
Device Name	Lumen 155-SF
Applicant	Intricon Corporation 1260 Red Fox Road Arden Hills, MN 55112
Applicant Contact	David Akbari
Correspondent	Intricon Corporation 1260 Red Fox Road Arden Hills, MN 55112
Correspondent Contact	David Akbari
Regulation Number	874.3325
Classification Product Code	QDD
Subsequent Product Code	QUH
Date Received	12/29/2022
Decision Date	10/17/2023
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Ear Nose & Throat
510k Review Panel	Ear Nose & Throat
Summary	Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

Deeper into OTC

- All 510(k) cleared OTC hearing aids have to provide clinical data, robust labeling, claims, and intended use which are all evaluated by the FDA
- Each cleared 510(k) has a publicly available summary posted on the searchable database



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

Lumen 155-SF

Indications for Use *(Describe)*

The Lumen® 155-SF self-fitting, wireless air conduction hearing aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for over-the-counter sales without the assistance of a hearing health care professional.

Deeper into OTC

- All but one of the cleared self-fitting devices is based on the NAL-NL2 fitting rationale
  - K223911 is not based on NAL-NL2
- All clinical data summaries typically use deviation from NAL-NL2 prescriptive targets along with similar performance to recognized consensus standards to establish substantial equivalence
- Primary endpoints are typically APHAB or some other similar self-reported outcome measure along with real-ear

Deeper into OTC – What's out there? Product code: QUH

Device Name	Self-Fitting Rationale	Endpoints	Predicate / Reference Devices
Sontro	NAL-NL2	APHAB, QuickSIN, Real-Ear	Bose (K211008)
Lumen 155-SF	Ciletti & Flamme, NHANES based Proprietary	APHAB, SSQ-12, Real-Ear	Nuheara (K221064) Bose (K211008)
Huizhou	NAL-NL2	APHAB, Real-Ear	Bose (K211008)
Intrisound Tuned Lumen 155	NAL-NL2	Real-Ear Mean Absolute Difference from NAL-NL2, COSI and IOI-HA	Braun (K212609)

Continued on next slide

Deeper into OTC – What's out there? Product code: QUH

Device Name	Self-Fitting Rationale	Endpoints	Predicate / Reference Devices
All-Day Clear	NAL-NL2	APHAB, QuickSIN, Real-Ear	Bose (K211008)
Lexie Lumen	NAL-NL2	APHAB, IOI-HA, QuickSIN, Digits-in-Noise	Braun (K212609)
Eargo 5, 6	Proprietary (based on NAL-NL2)	APHAB, Aided Speech Recognition	Bose (K211008)
Nuheara Iqbuds 2	NAL-NL2	APHAB, SSQ-12, BKB-SIN, Real-Ear	Bose (DEN180026), Braun (K212609)
Jabra Enhance Plus	NAL-NL2	APHAB, QuickSIN, Real-Ear	Bose (DEN180026)

Electro-acoustic Test Methods Supporting Self-Fitting

- A key aspect for achieving a 510(k) marketing clearance is to demonstrate “substantial equivalence” by showing similar results using recognized consensus standards
- There are two main electro-acoustic standard test methods typically leveraged in a 510(k) for documenting hearing aid electroacoustic performance
  - ANSI/ASA S3.22
    - This standard details methods for evaluating hearing aid electroacoustic performance in a coupler, and is used for both prescription and OTC hearing aids for outgoing quality control (QC) inspection
    - Manufacturer sets the limits based on an Operational Qualification (OQ) where a sampling distribution of hearing aids is measured and limits are established
  - ANSI/CTA 2051
    - This standard references ANSI/ASA S3.22 for most of its methods, and adds several criterion-referenced values (manufacturer does not set the limit)
    - This standard was designed with PSAPs in mind that is now used as part of the test requirements for OTC hearing aids

Wireless Test Methods Supporting Self-Fitting

- As part of the test requirements to maintain that consumers will be able to realize safe and effective OTC products, wireless testing is a huge part of FDA's concern
- Among the many potential wireless tests that FDA may require depending on the product, there are two major ones
  - **ANSI/IEEE C63.27**
    - This test is used to document **wireless coexistence** in a medical device (e.g., hearing aids)
    - Coexistence can be thought of as, how does the hearing aid operate in conditions where there are numerous electromagnetic wireless signals operating while the hearing aid is also trying to operate
      - Wi-fi, Bluetooth, and many others
      - Think hospitals, high density housing
    - A failure condition is that the hearing aid cannot operate in the presence of competing wireless signals, and a success is that the hearing aid's designed function is unaffected
    - A summary is required to be found in all applicable OTC hearing aids' user manual

- **ANSI/IEEE C63.19**
  - This test is used to document **<u>wireless radiated immunity</u>** in a medical device (e.g., hearing aids)
  - Wireless radiated immunity focuses more on the hardware susceptibility to unintended wireless signals
    - Think of needing to go into “airplane mode”
  - While coexistence looks at how the hardware/software transmits and works together, wireless radiated immunity has more of a hardware focus and includes the telecoil
  - Unlike coexistence where discrete levels are documented, wireless radiated immunity gets an M/T rating in the range 1-4 where higher rating means that the device is resistant to increasing levels of radio frequency (electromagnetic) field strength
  - M ratings are for the microphone and T ratings are for the telecoil

ANSI C63.19 Category Boundaries	
Category Boundary	Field Strength (V/m)
M1 to M2	35
M2 to M3	40
M3 to M4	45

Answering Your Questions

1. **General knowledge – how do they work, what capabilities, what is currently out there, etc. One person also was curious about average sale price, typical age of those purchasing, and return rates.**

- Most OTC hearing aids work the same as Rx hearing aids, they have the same components and hardware
  - The key difference is software, labeling, and intended use
  - When in doubt, measure SPL on your real-ear system; check against what you expect from NAL-NL2 prescription targets
- Average sale price per pair is between $299 (QUG, QUF) and $1199 (QUH, QDD), with options at the $799 and $899 price point
- Typical age of those purchasing tends to trend older than we would like (75+ as opposed to 55+)
- Return rates are a big mystery; the business model does not work with 50% returns, as high as 60% as low as sub-10%

2. **Even though they are not approved for children, families are going to try (case in point, I have a couple families at my school talking about it). Therefore, how can educational audiologists best counsel families regarding appropriate amplification – i.e., you need to know what is inappropriate about them in order to adequately counsel someone. I would assume this is first and foremost due to the inability to acoustically adjust them and to algorithms on self-fitting devices not being targeted to children, but I will defer to your greater expertise.**

- While the self-fitting ones can be adjusted, the best counseling advice is to point to the labeling and intended use
  - Using a medical device outside of its intended use can have big consequences
- Consider a bottle of Tylenol – It says do not take more than x amount over y hours
  - You cannot stop someone taking a whole bottle, but you can point to the labeling

2. **Even though they are not approved for children, families are going to try (case in point, I have a couple families at my school talking about it). Therefore, how can educational audiologists best counsel families regarding appropriate amplification – i.e., you need to know what is inappropriate about them in order to adequately counsel someone. I would assume this is first and foremost due to the inability to acoustically adjust them and to algorithms on self-fitting devices not being targeted to children, but I will defer to your greater expertise.**

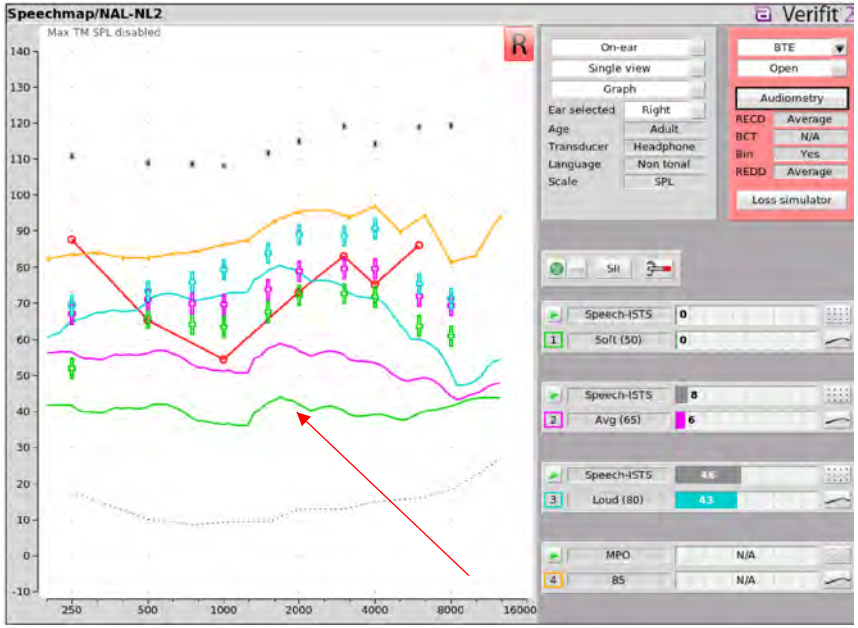
- Another thing to consider is the fitting rationale; as you saw almost all OTC self-fitting products are based on NAL-NL2
- NAL-NL2 as a rationale has the goal of comfort (for adult listeners)
- By contrast DSL v5 m[i/o] has the goal of audibility (for everyone) which is why it tends to be favored in the school system (for learning and access to language)
- When in doubt, the real-ear system can be a powerful tool
  - Even if you do not know the thresholds, showing an SPL plot can help

Case Example: 83 y/o Male, Pro-Fit vs Self-Fit

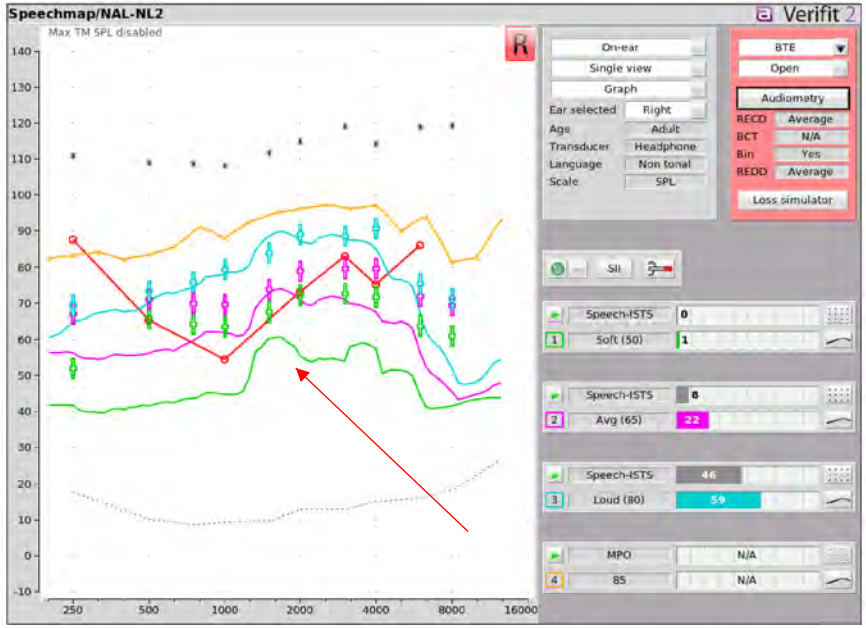
Serial Audiogram (dB HL)

R-250	R-500	R-1000	R-2000	R-3000	R-4000	R-6000	R-8000
70	55	45	60	70	60	70	NR

Pro-Fit



Self-Fit (Non-NAL-NL2)



3. A couple people mentioned working with "student" age 20 or 21 – in educational transition programs. They assumed that they will probably encounter them at some point and maybe even be asked to support them in some way, so I guess care and maintenance?

- In this case, the use of an OTC hearing aid is consistent with the labeling and intended use, but will never be as good as a licensed professional performing evidence-based best practices
- The best thing you can do is to leverage your real-ear system
  - You may also get into features and lifestyle for a person this age, including the use of remote microphones
- One thing to consider about OTC hearing aids is their intended user is someone with "self-perceived mild-to-moderate hearing loss"
  - What I tell audiologists in other settings is that your time is worth something; you can explain care and maintenance, but I would suggest a fee-for-service model if you can do this in your setting
  - You can also say, "I am only able to produce best practices with what I can give you: keep the ones you got but if you want the best results use these"

3. **What algorithms are used for self-fitting? I think you just told me the first self-fitting OTC device is coming out now (I wonder if they are confused with the Jabra clinical device, which has been out for a while now). Nonetheless, pediatric audiologists are very concerned about audibility in fitting, as you know (and as we all should be….) and so are curious about this to whatever extent you can share.**

- This question is the reason I went through this in detail on slides 29 and 30 since it is an important detail related to OTC hearing aids
  - The concerns of pediatric audiologists are quite valid
  - ANY use of ANY OTC product by a minor person is considered off-label use and is not recommended
    - Realistically, you can provide evidence-based reasoning against OTC in peds by showing differences in prescriptive targets between NAL-NL2 and DSL (theoretical) and then showing stock real-ear for any OTC to demonstrate what is missing
      - While SPL should be sufficient, you could use something like SII, AI-DI, or other index measures to demonstrate

3. **What algorithms are used for self-fitting? I think you just told me the first self-fitting OTC device is coming out now (I wonder if they are confused with the Jabra clinical device, which has been out for a while now). Nonetheless, pediatric audiologists are very concerned about audibility in fitting, as you know (and as we all should be….) and so are curious about this to whatever extent you can share.**

- As mentioned NAL-NL2 has the goal of comfort and DSL m[i/o] has the goal of audibility
  - You can drive to get groceries in a luxury party bus with couches, or you can drive to get groceries using a sedan or SUV – use the right tool for the right job!

Learn More

Connect

- Feel free to reach out with any questions, or just to connect
- Check out my articles, podcast appearances, quoted attributions, and more on my LinkedIn page
- https://www.linkedin.com/in/david-akbari-au-d-ccc-a-f-aaa-9aa0869b/

Questions, Comments, Concerns?

Thank you!

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