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A Quantitative & Qualitative Approach Towards Evaluating OTC Hearing Aids

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Amyl Amlani, PhD

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Kevin Liebe, AuD

Kevin Liebe, AuD, is President and CEO of Hearing Health & Technology Matters (HHTM). As a clinician, he has practiced in a wide range of settings, including private practice, hospital and ENT settings, as well providing clinical education and training for a major hearing aid manufacturer. He is a past president and board member of the Washington State Academy of Audiology and has served as an expert audiology consultant and advisor to hearing technology startups and investors.



Disclosures

- **Presenter Disclosure:** Financial: Aryn Amlani is employed by Otolithic Consulting. He received an honorarium for this presentation. Non-financial: Aryn Amlani is a Member-at-Large, Academy of Doctors of Audiology. Financial: Kevin Liebe is the President and CEO of Hearing Health & Technology Matters. He received an honorarium for this course. Non-financial: Kevin Liebe has no relevant non-financial relationships to disclose.
- **Content Disclosure:** This learning event does not focus exclusively on any specific product or service.
- **Sponsor Disclosure:** There is no external sponsor for this course.

Learning Outcomes

After this course, participants will be able to:

1. Describe the barriers faced by consumers seeking reliable information on different over-the-counter(OTC)/direct-to-consumer (DTC) models.
2. Explain the value of using both quantitative and qualitative measures to understand the performance and perceptual benefits of OTC/DTC hearing aids.
3. Discuss the benefits and features provided to consumers and professionals that engage and utilize a digital platform that provides both audible listening opportunities combined with perceptual written/graphical information as they navigate through the evolving OTC/DTC space.

Outline

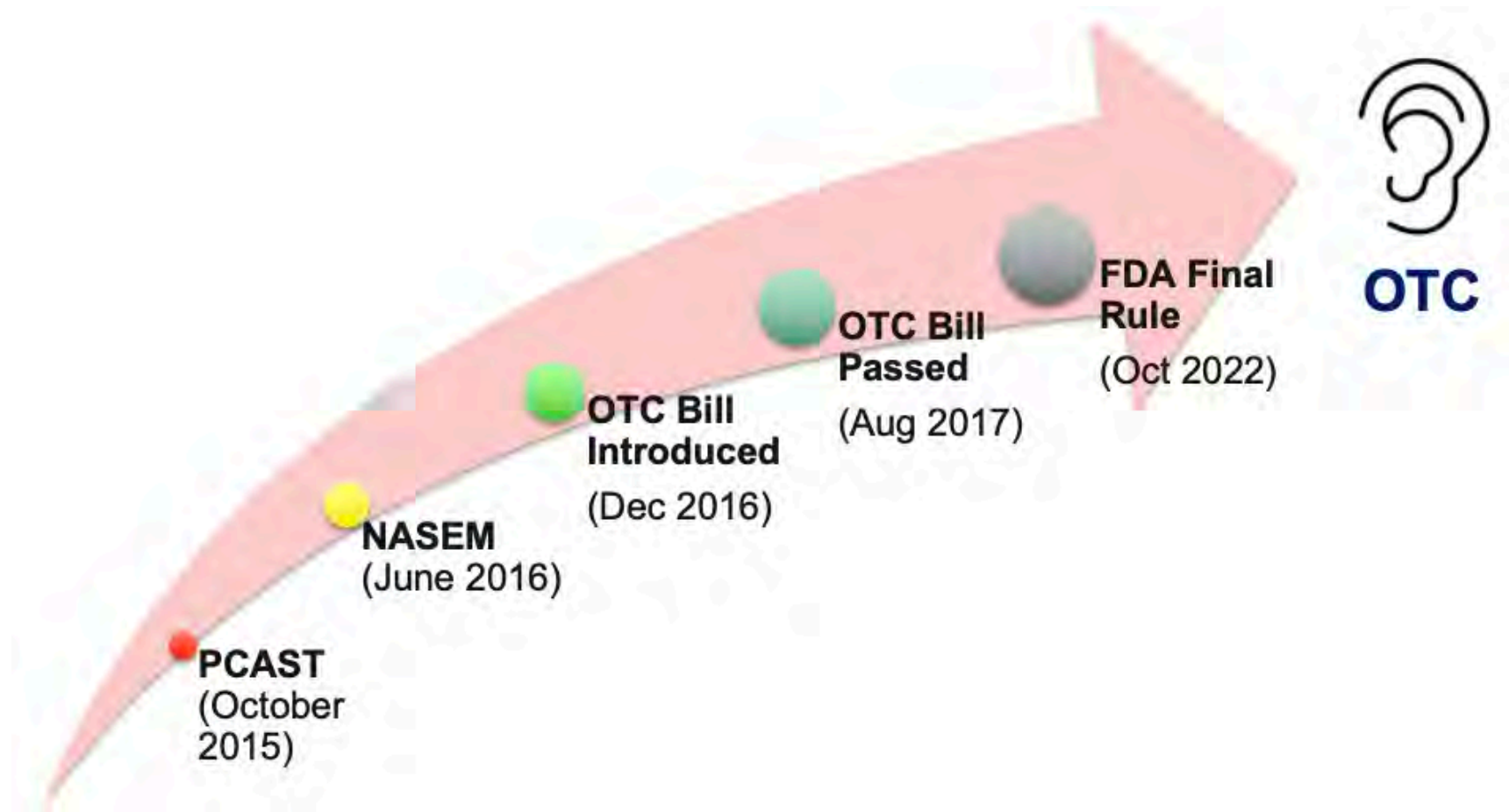
TIME	TOPIC	INSTRUCTIONAL METHOD	RELATED LEARNING OUTCOME NUMBER
0-5	Introduction	Lecture	1, 2, 3
5-20	Consumer + Pro Barriers, including the OTC legislation requirements	Lecture	1
20-30	Existing models for evaluating OTC/DTC, non-hearing-aid-products	Lecture	1,2
30-40	Proposed model for evaluating OTC/DTC hearing aid products	Lecture	1,2,3
40-50	Consumer perception towards consumption in having quantitative and qualitative metrics during the evaluation process	Lecture	2,3
50-55	Summary	Lecture	1,2,3
55-60	Q&A	Interactive	N/A

Today's Consumer is Different

- Consumers are taking a more active role in their healthcare than ever before.
- Thanks to:
 - Frustration with current system
 - Greater access to information
 - Technological innovations
 - New business models

Today's Hearing Care Consumer

- How did we get here?



Barriers to Hearing Aid Adoption

- **Self-perceived hearing difficulty**
- **Stigma + psychological factors**
- **Cost/Affordability**
- **Accessibility to providers**
 - Geography (Urban vs Rural Areas)
 - Shortage of Providers

- **Archaic service delivery model**
 - Physician referral for Medicare
 - Reliance on insurance/third-party programs
 - New Prescription Category and Reassignment of Preemptions (Federal to State level)
- **Unbiased Resources**
- **Misleading Advertising**
- **Poor Digital Health Literacy**

What does the OTC legislation do?

- Make OTC hearing aids **sale** available for adults (18 and older) who believe they have mild to moderate hearing loss, even if they have not had a hearing exam
 - **Fitting** of an OTC device still requires State Licensure for provider
- Set specific technical requirements (ex: gain/output) for devices to be considered as approved OTC hearing devices
- Set specific labeling requirements for consumers
- The FDA has taken all hearing aids off list of restricted devices, a list reserved for products that can only be sold through state licensed practitioners or under certain conditions of sale.
 - State laws will still restrict the sale of prescriptive hearing aids to licensed hearing care professionals only. The removal of hearing aids from the restricted list also impacts the governing of warranties and hearing aid returns

OTC Legislation: Intent

- Increase competition
- Reduce prices for consumers
- Increase access for those in rural areas
- Reduced stigma
- Empower consumers to take ownership of care

OTC Legislation: Reality

- Jury is still out as to whether the OTC legislation will actually deliver on the promised benefits
- Concerns remain:
 - Candidacy: ‘self-perceived’
 - Pricing
 - Medical conditions missed
 - Lack of counseling and support
 - Underfit or overfit vs. prescriptive target (NL2, etc)
 - Change from federal preemptions to state
 - Creation of a prescription category

OTC Device Electroacoustics

(ANSI/CTA 2051:2017 Standards)

- Output
 - 111 dB SPL (Linear Devices)
 - 117 dB SPL (WDRC Devices)
- Gain
 - No gain limit
- Frequency Response
 - At least 250 to 5000 Hz
- Harmonic Distortion
 - < 5%
- Equivalent Input Noise
 - < 32 dB A

OTC Device Electroacoustics

(ANSI/CTA 2051:2017 Standards)

- User adjustable volume control
- Tools/software to control and self-test
- Insertion depth > 10 mm from eardrum
- Proper physical fit
- Required labeling (inside and outside)
 - Age (18 years and up)
 - Medical warnings
 - Usage cautions
 - Seek professional help

The Newly Empowered Consumer

- As of October 2022, consumers now have the option to purchase over the counter or through a licensed professional
- Professional fitting and follow-up would be gold standard, but we also need to be able to discuss OTC options with our patients.
 - Patients not yet ready for traditional hearing aid may want situational device to use
 - You are the expert!
 - As professionals, we should be able to provide advice as an objective professional, irrespective of manufacturer, etc

The Problem We All Have

- Now that we have OTC hearing aids – how do we know the performance of these devices?
 - Consumers already have difficulty navigating prescriptive hearing aids
 - Professionals likely to lean on brands they know to recommend for patients
 - But, how do we know which ones are best for our patient?
 - Level of loss, sound quality, features, ease of use

Health Literacy (CDC)

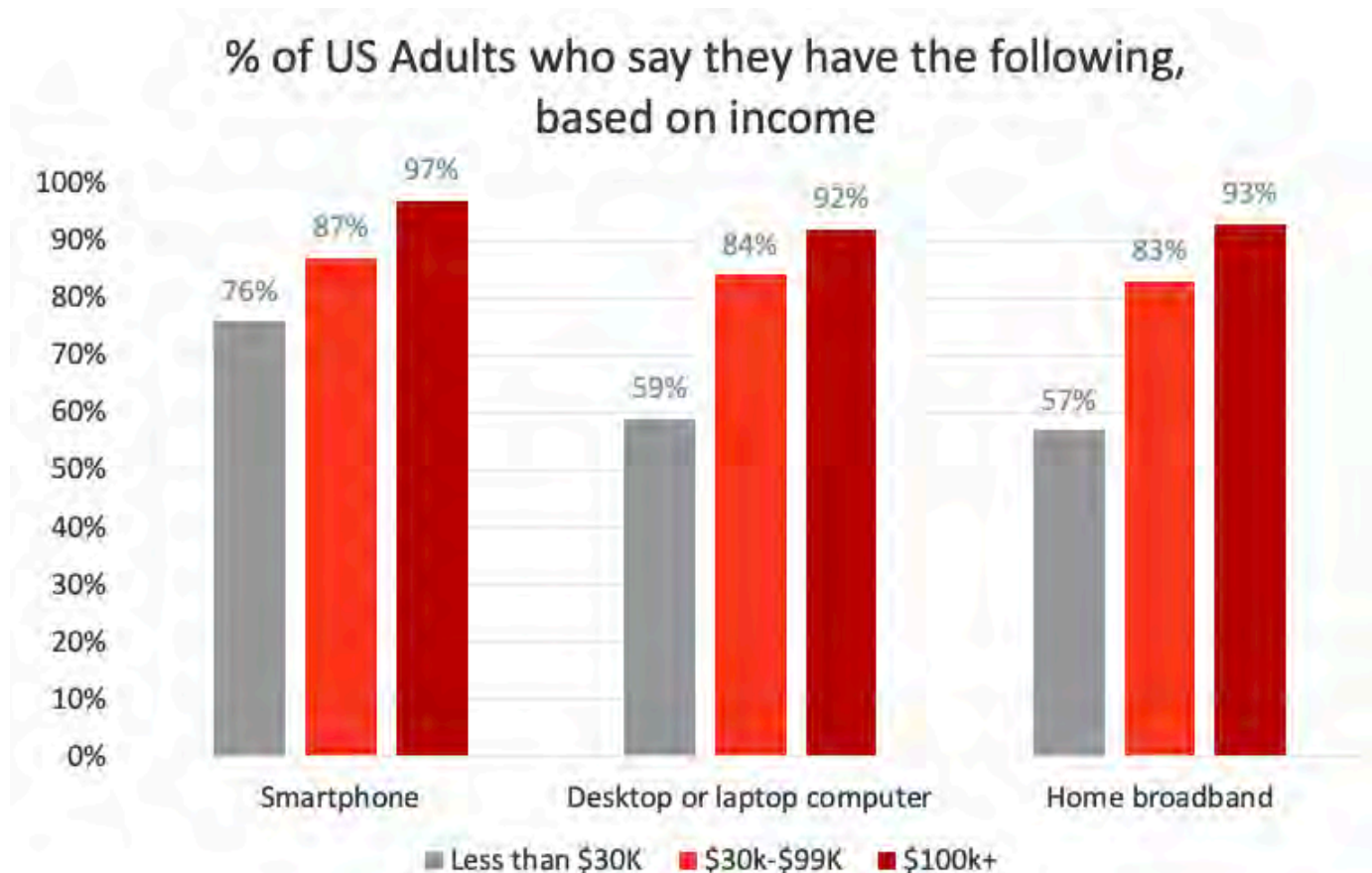
- **Personal health literacy**
 - The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.
- **Organizational health literacy**
 - The degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Barriers to Information

Older Americans and low-income Americans are more likely to lack access to reliable information.

- Who most likely will they ask?
- HCP, etc

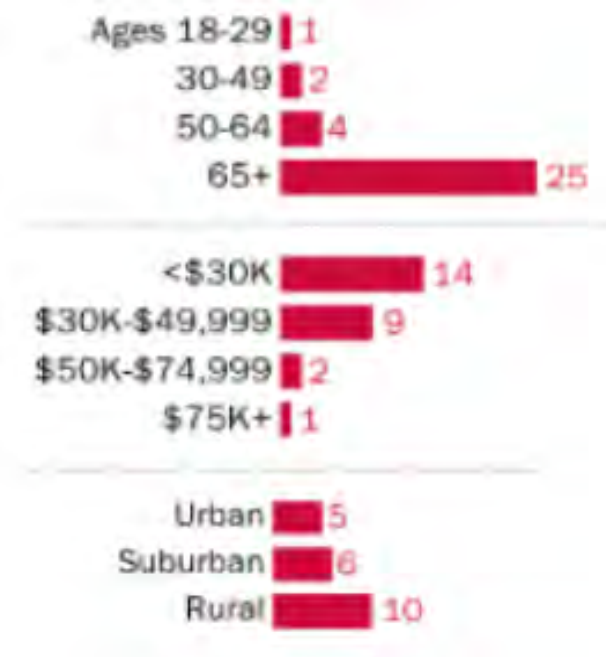
Barriers to Information



Barriers to Information

Percentage of US Adults who say they don't use the internet, based on:

- Age
- Income
- Geography



Google: Example #1a

Google

hearing aids

[All](#)
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About 244,000,000 results (0.54 seconds)

Results for [redacted] [Use precise location](#)

Ads · Shop hearing aids

 Zepp Clarity Hearing Aid... \$1,699.00 Zepp Clarity Free by 1...	 Jabra Enhance... \$1,995.00 Jabra Enha... 100-day ret...	 Audien Atom Hearing Aid... \$99.00 Audien Hear... ★★★★★ (420)	 Hearing Aids, Invisible... \$199.95 Neptune He... ★★★★★ (3k+)	 Nano CIC Completely i... \$297.00 Nano Hearin... ★★★★★ (942)
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Ad · <https://www.simple-sound.com/otc/store>

SimpleSound OTC Hearing Aids - Welcome to SimpleSound™

Will OTC **hearing aids** work for you? Book a free appointment for SimpleSound. Pick up your new **hearing aids** at a local Miracle-Ear store today! Find A Store. Cheap **Hearing Amplifiers**.

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Google: Example #1b

Google otc hearing aids

[All](#)
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About 38,500,000 results (0.46 seconds)

Ads · Shop otc hearing aids

 Free 3-day Jabra Enhance Select 200... \$1,995.00 Jabra Enhance 100-day retu...	 Zepp Clarity Hearing Aids... \$1,699.00 Zepp Clarity Free by 1/...	 Free 3-day Jabra Enhance Select 50... \$1,195.00 Jabra Enhance 100-day retu...	 MD VOLT: OTC Rechargeabl... \$299.98 MDHearing ★★★★★ (5k+)	 Free 3-day Jabra Enhance Select 100... \$1,595.00 Jabra Enhance 100-day retu...
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Ad · <https://www.overhearing.com/>

Overhearing - No Audiologist Visit Needed

We're Bringing the OTC Hearing Aid Market Into the Modern Age w/ Simple Online Shopping.

Over-The-Counter or OTC, Hearing Aids Are Now Available In The US To People Over 18...

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Ad · <https://www.simple-sound.com/otc/product>

SimpleSound OTC Hearing Aids - No Prescriptions Required

Visit SimpleSound OTC hearing aids website and book your appointment in 2 minutes. Try...

Amazon: Example #1a



Hearing Aids, Rechargeable Hearing Aids for Seniors & Adults with Volume Control, Small Completely-in-Canal Digital Hearing Amplifier,...

★★★★☆ - 338

\$199.99

Save \$50.00 with coupon

prime



EarCentric EasyCharge Rechargeable Hearing Aids (Pair) for Seniors, Behind-The-Ear BTE Ear Aid PSAP...

★★★★☆ - 1,791

\$219.00

Save more with Subscribe & Save



Hearing Aids, Hearing Aids for Seniors Adults Hearing Amplifier with Noise Cancelling, Hearing Aid Amplifier with 3 Sizes Ear Tips Mini...

\$69.99

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Hearing Aids, HaYue Hearing Aid for Seniors Rechargeable with Noise Cancelling Hearing Amplifier with AI DSP Chip for Adults Hearing Loss B...

★★★★☆ - 111

Save 20%

\$59.99

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Rechargeable Hearing Aids for Seniors & Adults with Noise Cancelling, Digital Hearing Amplifier with Into Ear No Squealing, Magneti...

★★★★☆ - 384

\$109.99

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MORE RESULTS



Hearing Aids, Hearing Aids for Seniors Adults Hearing Amplifier with Noise Cancelling, Hearing Aid Amplifier with 3 Sizes Ear Tips Mini...

★★★★☆ - 95

\$71.00

Save 5% with coupon

prime

FREE delivery Sun, Jan 22

More Buying Choices \$69.99 (2 new offers)



Hearing Aids, Newest 16-Channel Digital Rechargeable Hearing Aids with Charging Box Indicating Remaining Power Percentage...

★★★★☆ - 12

\$139.99

Save 10% with coupon

prime

FREE delivery Mon, Jan 23



Rechargeable Hearing Aids for Seniors Severe Hearing Loss, Earrrck Digital Hearing Amplifier with Noise Cancelling, BET Hearing Aid with...

★★★★☆ - 22

\$199.00

Save more with Subscribe & Save Save \$20.00 with coupon

prime

FREE delivery Fri, Jan 27



Lentorgi Hearing Aids for Seniors, Virtually Invisible, Noise Reduction, Omni-Directional Microphone, Rechargeable, Completely-in-Canal...

★★★★☆ - 5

\$799.99

Save \$150.00 with coupon

FREE delivery for Prime members



Audien ATOM Rechargeable Hearing Amplifier to Aid and Assist Hearing, Premium Comfort Design and Nearly Invisible

★★★★☆ - 980

\$99.00

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Small Business

Amazon: Examples



Sponsored

Rechargeable Hearing Aids for Seniors Severe Hearing Loss, Earrrck Digital Hearing Amplifier with Noise Cancelling, BET Hearing Aid with...

★★★★★ ~ 22

\$199⁰⁰

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Prime
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 Only 9 left in stock - order soon.



Sponsored

Lentorgi Hearing Aids for Seniors, Virtually Invisible, Noise Reduction, Omni-Directional Microphone, Rechargeable, Completely-in-Canal...

★★★★★ ~ 3

\$799⁹⁹

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FREE delivery for Prime members

Best Seller



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Audien ATOM Rechargeable Hearing Amplifier to Aid and Assist Hearing, Premium Comfort Design and Nearly Invisible

★★★★☆ ~ 980

\$99⁰⁰

Save more with Subscribe & Save
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FREE delivery **Sun, Jan 22**

Small Business ~

Clinic Example

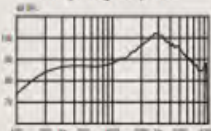
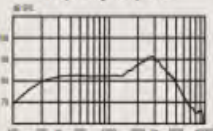
- Even with professional guidance, it's challenging for patients to navigate available devices and options
 - Multiple brands
 - Opaque industry jargon
- Clinicians face many of the same challenges

Today: Limitations Persist

- Subjective reviews of hearing devices – like other consumer products – can be useful, but have limitations
 - Trustworthy source?
 - Motivation & bias?
- You don't know what you don't know
 - Important factors omitted or neglected?

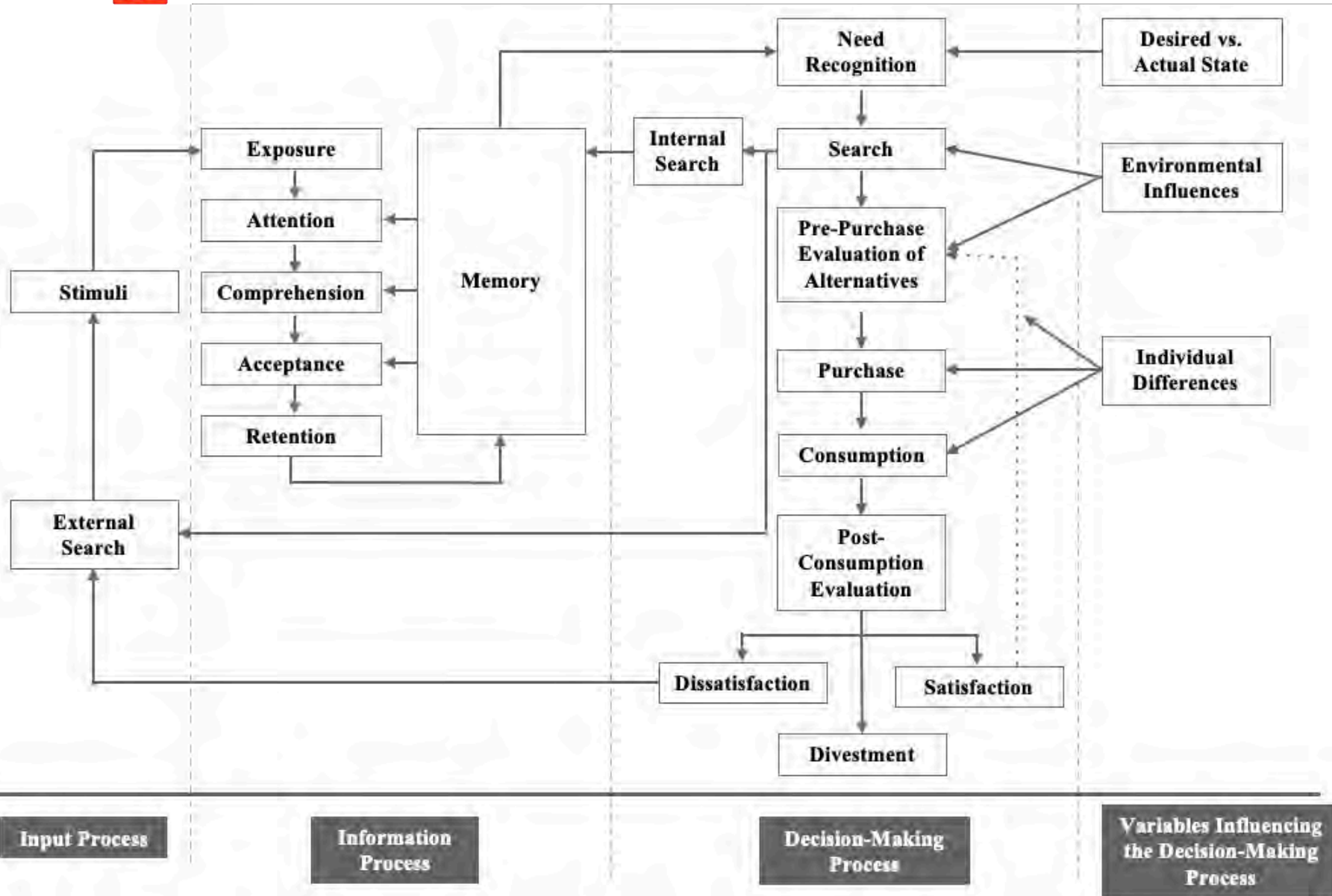
Analyzing Hearing Devices

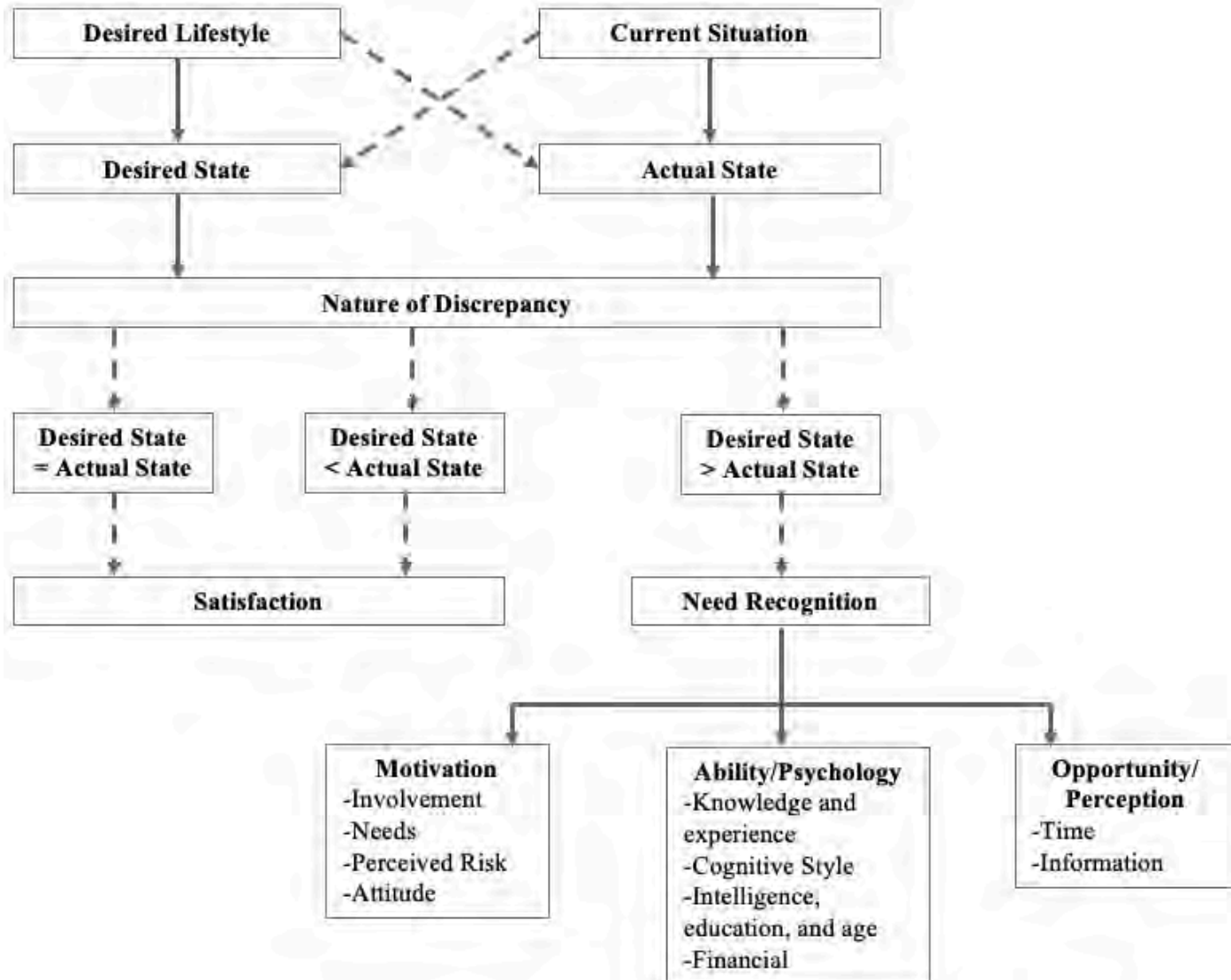
- For traditional hearing aids, datasheets can be obtained that provide specs for a given device
- The datasheet provides us with things like
 - Gain
 - Frequency range
 - Harmonic Distortion
 - Battery drain

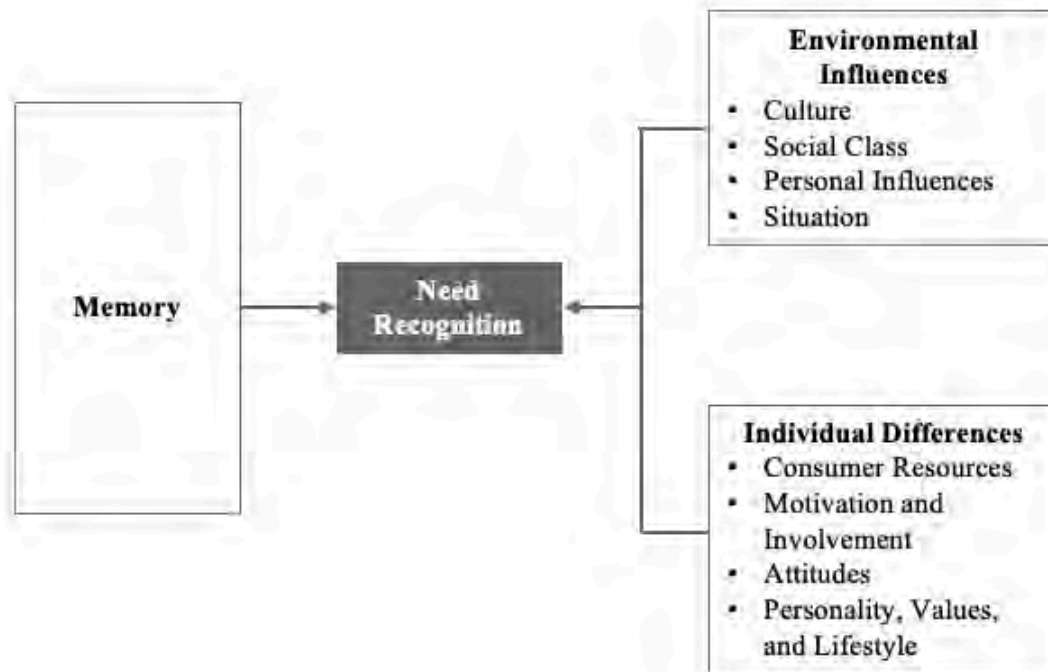
		Frequency Response	Frequency Response
			
OSPL90	Peak	116 dB SPL	105 dB SPL
	1600 Hz	109 dB SPL	100 dB SPL
	HFA-OSPL90	110 dB SPL	102 dB SPL
Full-on gain ¹	Peak	46 dB	35 dB
	1600 Hz	37 dB	29 dB
	HFA-FOG	38 dB	30 dB
Reference test gain		30 dB	26 dB
Frequency range		110-9700 Hz	100-9200 Hz
Telecoil output (1600 Hz)	1 mA/m field	-	-
	10 mA/m field	-	-
	SPLITS L/R	-	-
Total harmonic distortion (Input 70 dB SPL)	500 Hz	< 2 %	< 2 %
	800 Hz	< 3 %	< 2 %
	1600 Hz	< 2 %	< 2 %
Equivalent input noise level	Omni	21 dB SPL	18 dB SPL
	Dir	28 dB SPL	27 dB SPL
Battery consumption ²	Typical	1.5 mA	1.6 mA
	Quiescent	1.5 mA	1.5 mA

Consumer Purchasing Behavior

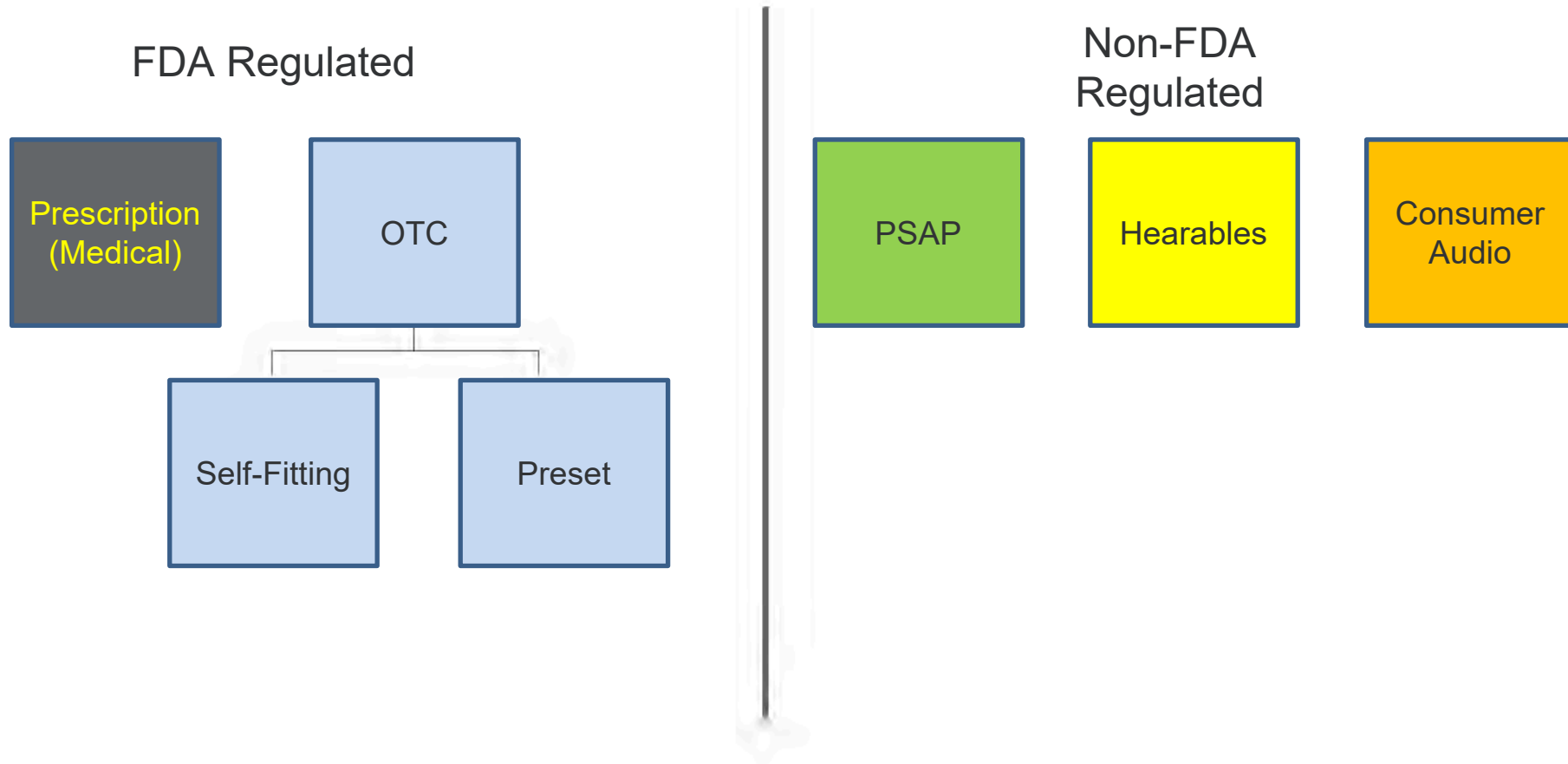
Source: Pexels







Development of a Tool for Consumers and Providers



A vs. B?



Source: Pexels

Our Working Goal

1. Bridge the divide between subjective and objective assessment.
2. To provide quality information to allow clinicians and consumers to make better informed decisions about their hearing health.

Our Working Vision

- Highlight (visual and auditory) device performance in optimal and adverse conditions
- Provide peer- and user-input on device performance in optimal and adverse conditions
- Ensure our protocols are scientifically valid **and** provide clinically application/practicality
- Partner with colleagues to ensure that the “vision” (i) considers all angles, and (ii) can be achieved clinically with efficiency

Test Box

- Output/Gain
- Frequency Response
- Multicurves (compression)
- Noise reduction
- Directional microphones



Verifit[®] 2
Advanced Verification



Test Box

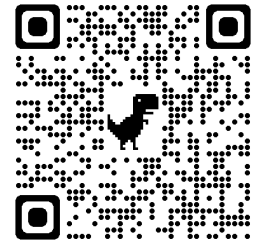
- Create and play WAV files in the Speech Map Mode
 - Quiet
 - Competing noise
 - Reverberation (simulated)
 - Competing noise + Reverberation
- Also allows for device performance recordings under these “real-world” conditions to be stored for additional analysis(es)



Verifit[®] 2

Advanced Verification

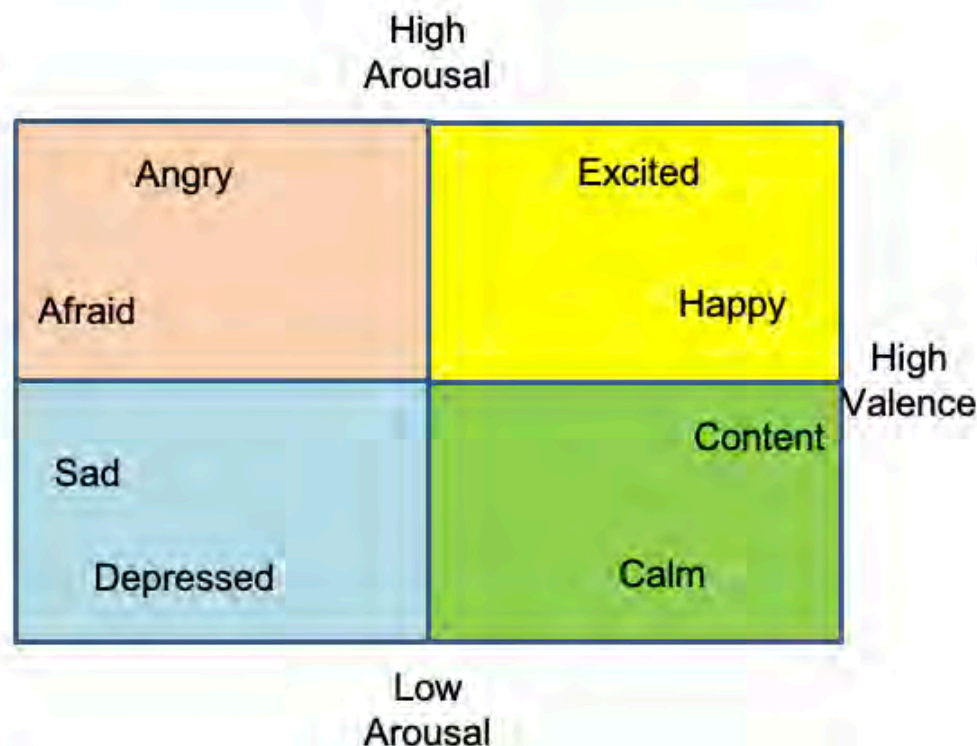




- Place device on Audio Carl
 - Simulate different degrees and configurations of hearing loss for OTC use
- Play out WAV files from loudspeaker array
- Stored for additional analysis(es)

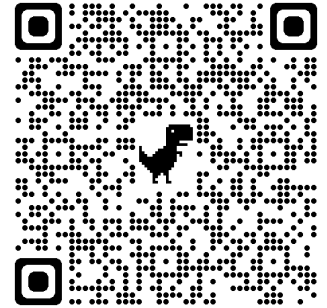
Subjective Rating of Device Performance

*Self-Assessment Manikin
(Bradley & Lang, 1994)*



Why Emotion?

(March 26, 2018)



Inc.

NEWSLETTERS

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SALES

Harvard Professor Says 95% of Purchasing Decisions Are Subconscious When marketing a product to a consumer, it's most effective to target the subconscious mind. 

BY LOGAN CHIEROTTI, CEO OF LOGANCHIEROTTI.COM @LOGANCHIEROTTI

Hearing, Emotion, Amplification, Research, and Training Workshop: Current Understanding of Hearing Loss and Emotion Perception and Priorities for Future Research

Picou et al. (2018)

Rationale:

- Emotions influence behavior
- Hearing loss and amplification characteristics (e.g., compression, noise reduction, directionality, ...) have the potential to influence/evoke emotional response
- Emotion-related perceptions have the ability to represent a novel category of outcome measures that assess the efficacy of treatment methods that alleviate the disability associated with hearing loss

Patient Readiness

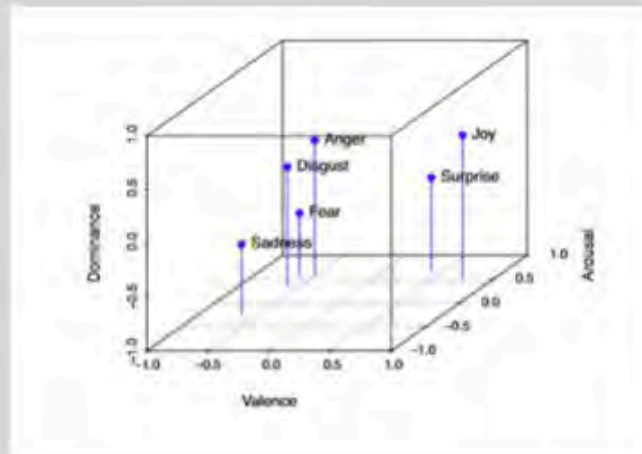
“On a scale from 1 to 10, 1 being the worst and 10 being the best, how would you rate your overall hearing ability?”

Patient Rating of Hearing Ability (#1 = Worst, #10 = Best)	Predicted Probability of Hearing Aid Purchase
1	98%
2	96%
3	92%
4	83%
5	73%
6	58%
7	7%
8	20%
9	10%
10	6%

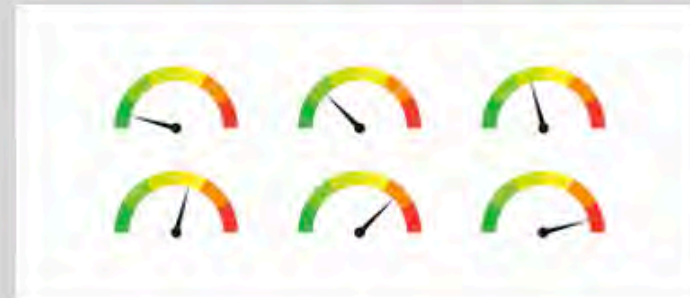
Source: From Palmer et al., 2009.

Dashboard for John Doe

Emotional Comparison



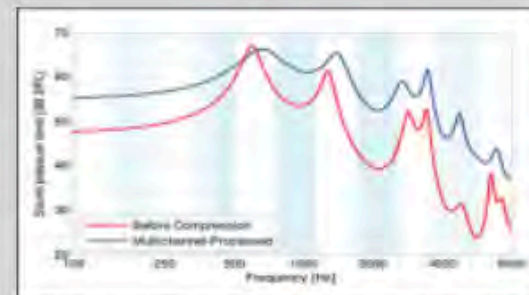
Product Comparison – Testbox and Audio Carl



Patient Readiness Score =

7

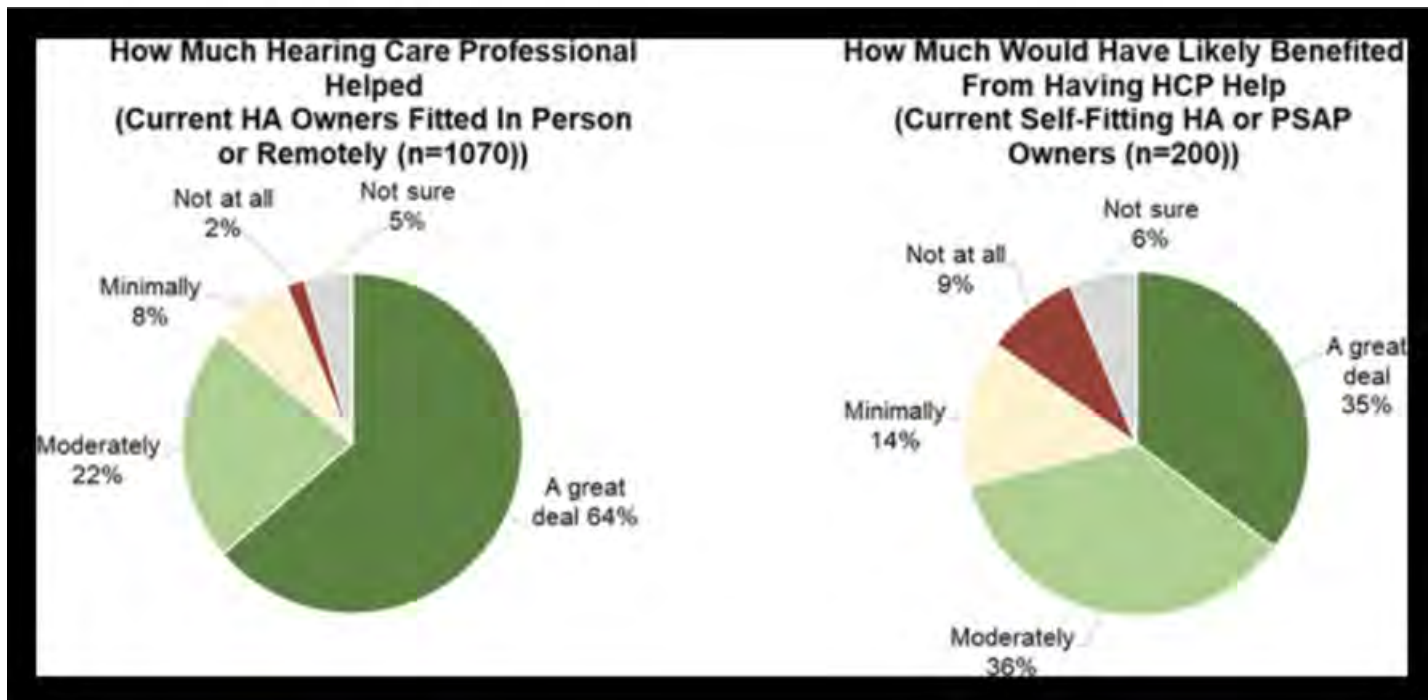
Spectral Differences





Hearing Aid Benefit and Satisfaction Results from the MarkeTrak 2022 Survey: Importance of Features and Hearing Care Professionals

Erin M. Picou, Au.D., Ph.D.¹



Assessment of Consumer Attitudes Following Recent Changes in the US Hearing Health Care Market

Singh & Dhar (2023)

1037 Survey Responses
between March 22 and 25, 2022

- 84% indicated pursuing hearing healthcare in-person
- Older adults were less likely to pursue hearing healthcare via an online service model

Summary: Importance of Qualitative and Quantitative Data

- Affects decision-making for the consumer
- Provides holistic picture of benefits provided by product and professional support
- Deepens connection between provider and consumer, lending to increased likelihood of adoption of product and professional support

References

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- Singh J, Dhar S. (2023, January 19). Assessment of consumer attitudes following recent changes in the US hearing health care market. *JAMA Otolaryngology – Head & Neck Surgery*. doi:[10.1001/jamaoto.2022.4344](https://doi.org/10.1001/jamaoto.2022.4344)

Thank you!

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Kevin Liebe, AuD

