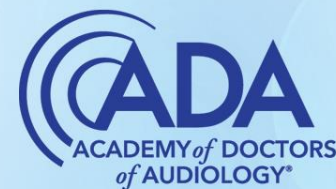


**EARSHOT**

*Webinar Series*



# Groundhog Day--Dynamics, Disruptions and Making the Case for Change

Alicia D.D. Spoor, Au.D.



# A Climate for Change

- The Aging of America
- Research & Data
- Consumer-driven Care
- Disruptive Technologies/Models
- Changing Paradigms, Changing Policies?

# The Aging of America

- 10,000 persons become Medicare-eligible every day.
- With 37 million members, AARP is the 4<sup>th</sup> most powerful special interest group in the nation
- Hearing loss is the third most common chronic condition for those over age 65, behind diabetes and high blood pressure
- An estimated 37.5 million American adults report some trouble hearing
  - 25 percent of those over 65 years have 'disabling' hearing loss
  - 50 percent of those over 75 years have 'disabling' hearing loss
  - Less than 30 percent of those who would benefit from hearing aids, use them

# Research Demonstrates Need, Presents Opportunities

- Untreated hearing loss tied to increased risks of falls, decreased brain volume, dementia cognitive decline.
- Treatment of hearing loss through amplification reduces cognitive decline.
- Medicare (Part B) “Direct Access” to audiology services does not compromise patient safety.
- Studies suggest minimal (if any) differences in real world outcomes among basic and premium hearing aids and even high quality personal sound amplification products (PSAPs).

# Increased Executive Branch Government Focus on Hearing Loss

- CMS' Physician Quality Reporting System (PQRS)
- President's Council of Advisors on Science & Technology (PCAST)
- Food & Drug Administration (FDA)



# Increased Executive Branch Government Focus on Hearing Loss

- National Academy of Medicine/Institute of Medicine (NAM/IOM)
  - Workshop on Hearing Loss & Healthy Aging (January 2014)
  - Committee on Accessible and Affordable Hearing Healthcare in Adults (April, 2015 – Present)
  - Expected Committee report Spring 2016

# PQRS

- Created by Centers for Medicare and Medicaid Services
- Goal: improve the quality of care to Medicare beneficiaries by tracking patterns
  - May apply to other payers in the future
- Reporting now tied to payment penalties

# PCAST Study: Aging America & Hearing Loss

- Part of PCAST's broader examination of technology and aging
- PCAST was charged with assessing access to the technological environment related to hearing amplification devices



# PCAST Study: Aging America & Hearing Loss

- The Council was not tasked with considering access to or the provision of hearing healthcare services as part of its assigned task
- PCAST's stated goals are:
  - Reduce cost (of hearing technology) to the consumer
  - Increase the number of people (with hearing loss) who use hearing technology
  - Stimulate innovation and new technologies

# PCAST Recommendation I

- FDA should designate as a distinct category “basic” hearing aids—non-surgical, air-conduction hearing aids intended to address normal, bilateral, gradual onset, mild-to-moderate age-related hearing loss—and adopt distinct rules for such devices. The FDA should approve this class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser, and should also approve for OTC sale (retail and online) tests appropriate to the self-fitting and adjustment of OTC devices by the end user.

# PCAST Recommendation 2

- The FDA should withdraw its draft guidance document regarding Personal Sound Amplification Devices (PSAPs) and reference this new category as “devices for discretionary consumer use.” PSAP manufacturers should continue to be able to make truthful claims about their use in normal settings, and FDA should not require language in PSAP labeling or advertising that excludes their use by individuals with age-related hearing loss no worse than mild-to-moderate.

# PCAST Recommendation 3

- FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and/or hearing aid vendors. Additionally, the availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test.

# PCAST Recommendation 4

- The FTC should define a process analogous to contact lenses (i.e., “Contact Lens Rule”) by which patients may authorize hearing aid vendors (in-state or out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any dispensing professional who performs such a test, and it should require that the testers furnish such results at no additional cost.



# ADA Response to PCAST

- Conditional agreement of all four recommendations
- Strongly encourage audiologic examination prior to purchase of **any** amplification device
- Proffers awareness as the key barrier to treatment
- Emphasized role of the audiologist and importance of access to services

# NAM Committee on Accessible Affordable Hearing Healthcare for Adults

- Importance of hearing to individual and societal health
- Affordability of non-surgical devices and services
- Examination of federal regulations for non-surgical hearing aid dispensing
- Innovation and improvement of technology and delivery to optimize hearing health

# Audiology Recommendations to NAM

- ADA and AAA collaboration
- Focused on important role of audiologist
- Focused on evaluation and treatment
  - Removal of FDA waiver
  - Direct Access to Audiologist

# Audiology Recommendations to NAM

- Recommendation 1: *Hearing loss should be considered a chronic medical condition, rather than simply an age-related phenomenon.*
- Recommendation 2: *Eliminate the medical evaluation requirements, including the use of a waiver, for adults as currently required by the Food and Drug Administration.*
- Recommendation 3: *An audiologic evaluation should be obtained prior to obtaining **any** amplification device.*

# Audiology Recommendations to NAM

- Recommendation 4: *Devices should be coupled with audiologic rehabilitation to assure optimal outcomes for patients.*
- Recommendation 5: *Traditional Medicare Part B coverage for hearing services should be revised to remove barriers that impede accessibility or raise the costs of hearing care.*



# 18x18 Movement Aligns with Audiology Recommendations

- Will provide Medicare (Part B) patients with greater accessibility to affordable, high quality hearing healthcare
- Recognizes the valuable role of the audiologist in the provision of successful treatment and outcomes
- Will classify audiologists in the correct category with other doctoral-level clinical providers
- Will better deploy limited healthcare resources

# FDA Reopens Public Comment Period on PSAP Guidance

- The FDA has stated that this action is, at least in part, the result of the PCAST report and recommendations
- FDA seeking information on accessibility and use of hearing aids and PSAPs by consumers with hearing loss
- FDA seeks to “protect the public and foster innovation” on this issue

# Looking Ahead

- Greater accessibility to the ‘device’
  - Patients will have increased access to amplification products (hearing aids and other devices) in every price range
  - Successful audiologists will embrace new and disruptive innovations in amplification, assistive technologies and telehealth
  - Average selling price of the future amplification might be \$0

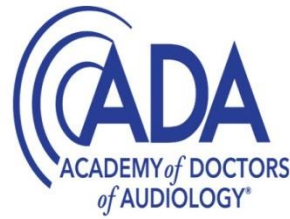
# Charting a Successful Future

- The provision of holistic audiologic care
  - Offer comprehensive evaluative and rehabilitation services for the entire body
  - Viewed as a communication coach/expert
  - Itemization of products and services
  - Payment for expertise and time as is consistent with other successful clinical doctoring professions

# References

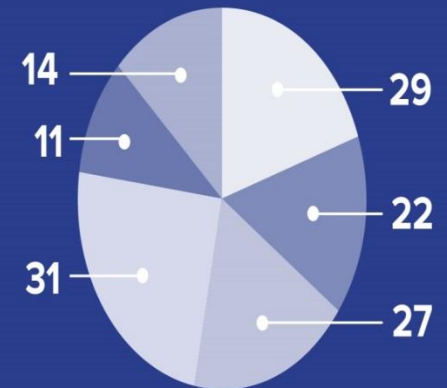
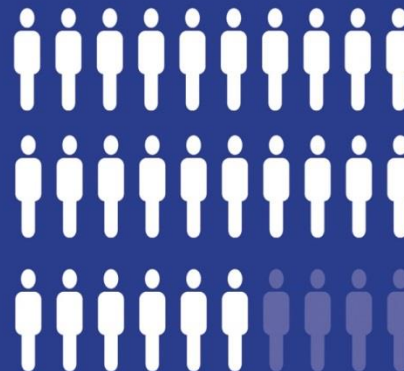
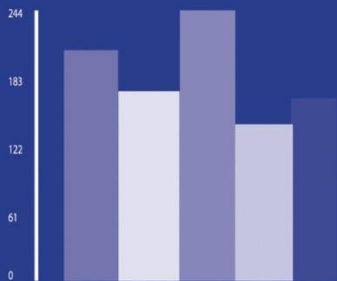
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# Hearables: A business case for adopting in the practice

*Brian Taylor*



# Who is Brian Taylor?

- **25 years of clinical and business experience**
- **Senior Director, Clinical Affairs, Hypersound**
- **Consultant for Fuel Medical**
- **Adjunct Professor, A.T. Still Univ.**
- **Editor, Audiology Practices**
- **Editor, HHTM Hearing News**



# Over the next 20 minutes:

- What is a hearable?
- Why hearables need to be embraced?
- Thoughts on how to successfully integrate hearables into your practice

# 2010 - The Rise of the PSAP



# 2016 - The Rise of Hearables





# “Show Me the Money”

- A recent TechCrunch report indicates that funding for hearables has nearly tripled from \$12.6 million in 2014 to over \$32 million in 2015.

## Hearables: Morphing of Two Different Technologies



# The Spectrum of Hearables

1. Made for iPhone Hearing Aids
2. PSAPs
3. Directed Audio
4. Augmented Reality Devices
5. Amplification Apps

# “Made for iPhone Hearing Aids”



# High Quality Personal Sound Amplification Products



SoundHawk



Sound World Solutions



ER Bean





# PSAPs

- Alango Technologies: HearPhones



HearPhones are really 3 in 1:

1. Personal Hearing Enhancer
2. Assistive Listening Device
3. Advanced Bluetooth Headset



# Directed Audio

Alango Technologies



## SALT

Smart Assistive Listening Transceiver

Switch hearing aid to T-coil

A revolutionary combination of truly Personal Sound Amplifier  
with a versatile Assistive Listening Device

# Directed Audio

- Hypersound Clear 500 P
- Ultrasonic Sound System



# EarMachine App



“When you move an EarMachine wheel, you are changing more than 100 different values that control our state-of-the-art signal processing”

# Augmented Reality Devices



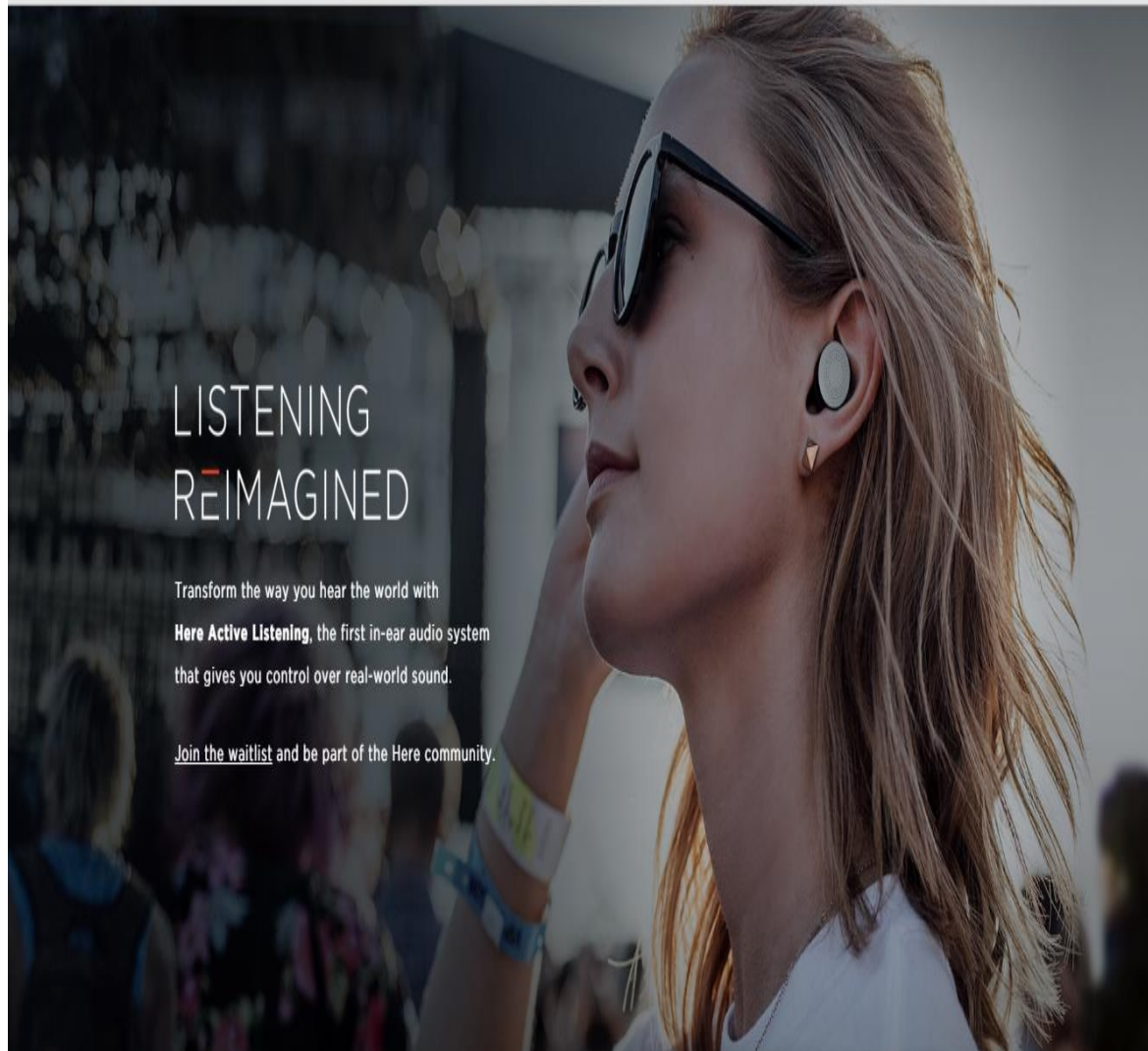
**B** BRAGI PRE-ORDER STORE

**The Dash**  
Truly Wireless Smart  
Earphones.

The advertisement features a woman with dark hair pulled back, wearing a black halter top. She is shown in profile, looking towards the left, with her right hand near her ear where she is wearing a small, black, circular earphone. The background is dark, and the lighting highlights her face and the earphone. The text 'The Dash' is in a bold, cyan font, and 'Truly Wireless Smart Earphones.' is in a white, sans-serif font. The BRAGI logo and 'PRE-ORDER STORE' text are in the top right corner.



# Doppler Labs



## LISTENING REIMAGINED

Transform the way you hear the world with  
**Here Active Listening**, the first in-ear audio system  
that gives you control over real-world sound.

[Join the waitlist](#) and be part of the Here community.



JACOTI Hearing Suite

The video player features a background image of a smiling woman wearing earbuds and holding a smartphone. In the center of the video is a red YouTube play button icon. To the right, there are three mobile devices (two smartphones and one tablet) displaying the Jacoti Hearing Suite application interface. The interface includes a profile picture, a list of contacts, and various control buttons. In the top right corner of the video frame, there is an orange banner that reads "LAUNCH JAN '16 at CES, Las Vegas". In the top left corner of the video frame, there is a blue and white badge that reads "CES INNOVATION AWARDS 2016 WINNER".

LAUNCH JAN '16 at CES, Las Vegas

Jacoti Hearing SUITE

CES INNOVATION AWARDS 2016 WINNER

# Why hearables need to be part of mix?

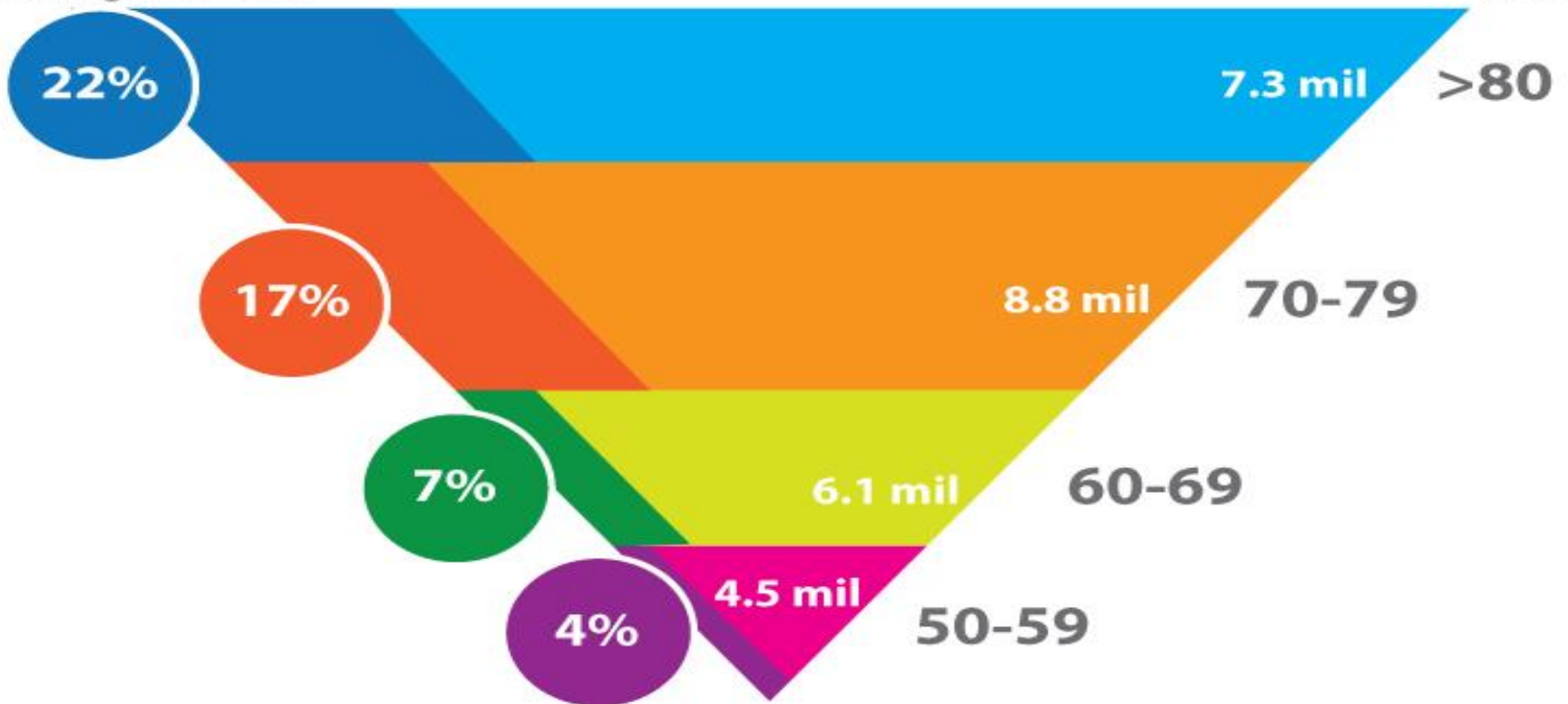


# The Unmet Need

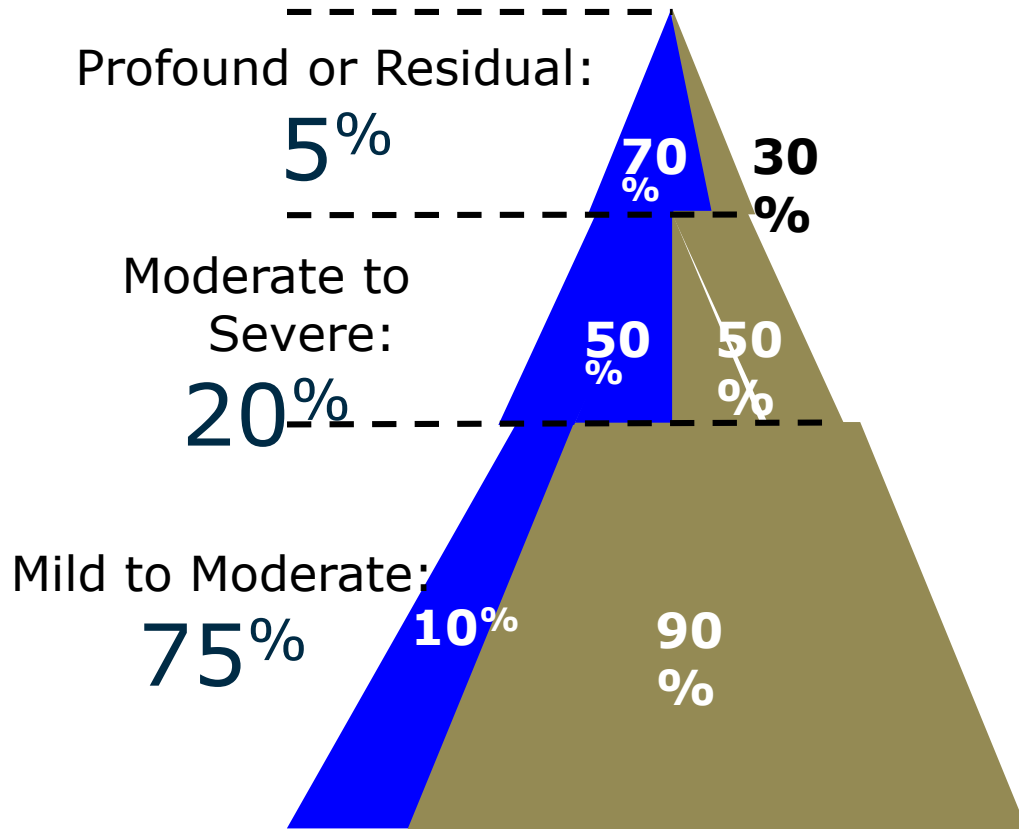
## Prevalence and Number of Individuals 50 years or older with >25dB hearing loss

Prevalence of  
Hearing Aid Use

AGE

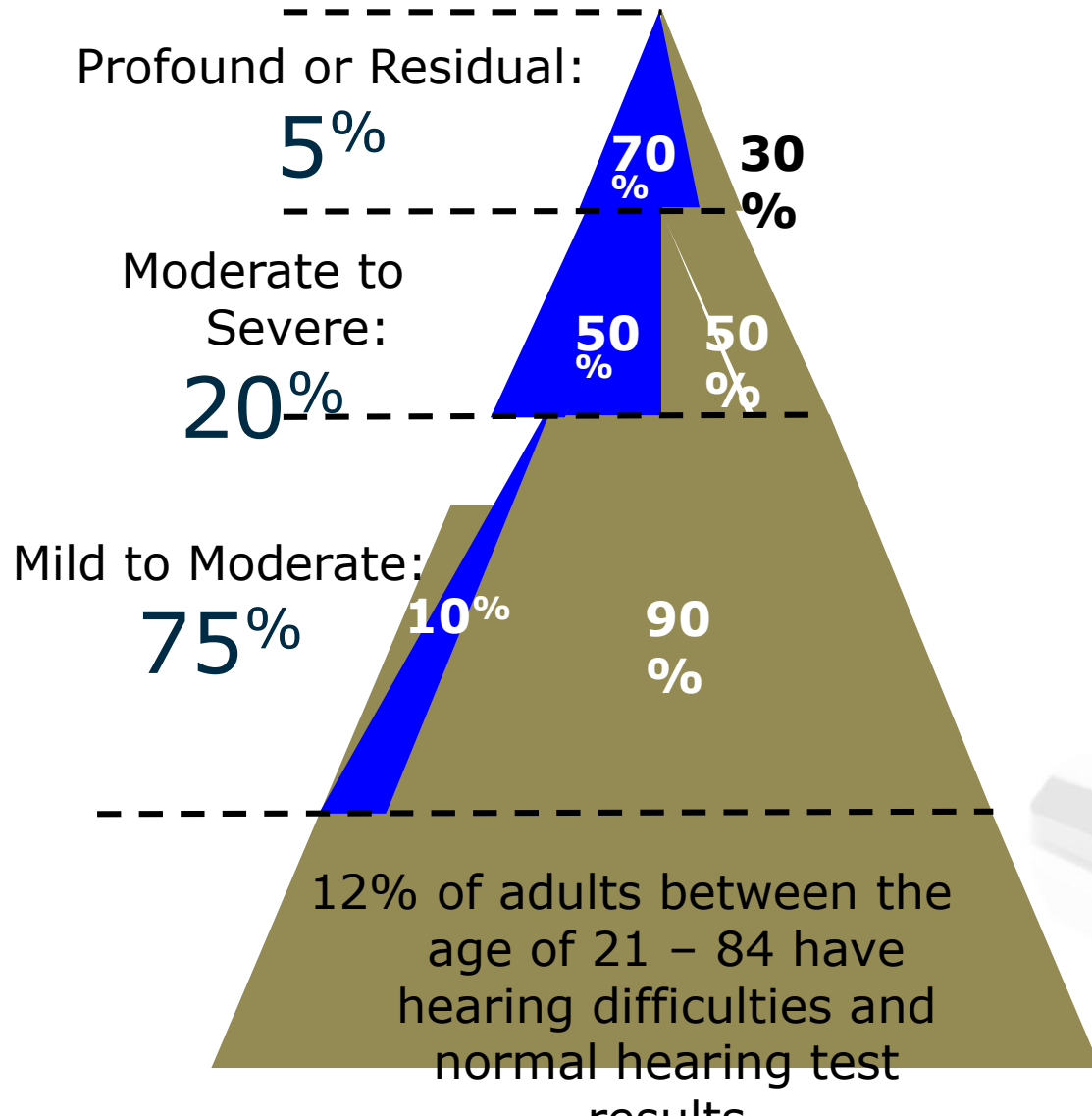


# The Unmet Need

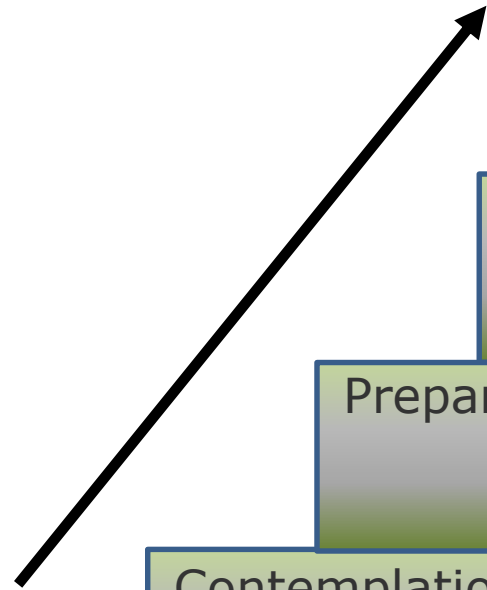




# The Unmet Need



# Stages of Change



**Termination:**  
Behavior fully  
acquired or modified

**Maintenance:**  
Consolidation,  
relapse prevention

**Action:**  
Behavior acquisition  
of modification

**Preparation:**  
Information and advice seeking,  
planning of change

**Contemplation:**  
Problem awareness and ambivalence  
regarding the pros and cons of change

**Precontemplation:**  
Problems denial, lack of awareness,  
no intention to change

Figure 1. Stages of Changes of the Transtheoretical Model

# Moving from one stage to the next?

## **Positive Triggers to Action:**

1. Greater degree of hearing loss
2. Increased difficulty with communication
3. Social pressure to act (encouragement from others)
4. Lesser ability to cope
5. Perception that hearing aid (or other intervention) with help

## **Negative Triggers to Action:**

1. Stigma
2. Passive Acceptance
3. Negative Attitudes about Hearing Aids
4. Cost (Financial and Convenience Costs)

# Solution-based Interviewing

## Uncovering these issues and talking about change

1. Move from biomedical to biopsychosocial talk
2. “Reflect, revise, reflect”
3. Involve significant others
4. Allow patient to set the agenda
5. Use shared decision making

# The Role of Audiology

1. Recognize different skills are needed for relationship-based vs. arms-length transactions
2. Embrace Shared Decision Making (Patient Decision Aids)
3. Demonstrations take on greater importance
4. “Quality control in the ear” to optimize performance
5. Practice Interventional Audiology

# Different Skills Required

## Relationship-based:

- Trust
- Collaboration
- Expertise
- Multiple visits
- Patient-centered

## Arms-length

- One-time transaction
- Anonymous
- Multiple competitive offerings
- Regulated (ADA seal of approval)



# Shared Decision Making

## The Spectrum of Hearing Solutions

Non Customizable Solutions		Customizable Solutions		
At-Home Listening Devices (ALD)	Ear or Body Worn Devices (Hearables)	Directed Audio (Hypersound)	Daily Wear Devices (Multiple Levels of Technology)	Extended Wear & Implantable Devices
	 		 	 

# The dual role of interventional audiology

1. Enhance function for those with “normal hearing for their age”
2. Correct hearing problem related to late stage diagnosis

# Questions?

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See Mamo, et al and Taylor articles for more information