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Hearing loss: Public health and consumer perspectives

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Learning objectives

1. Be able to describe the differences between clinical and public health perspectives on hearing loss
2. Be able to describe key public health consequences of hearing loss
3. Provide some examples of common consumer perspectives in hearing loss health care

Disclaimers

- I have no financial connection with the hearing aid, PSAP, or consumer hearing products industries
- I serve on the Board of Directors of the Hearing Loss Association of America (HLAA)
- I am a consumer (I have a hearing loss)

Overview of the hour

- The importance of perspective
 - Clinical, public health, consumer perspectives
- The public health perspective
 - What is it?
 - What do we know about HL from this perspective?
- The consumer perspective
 - What is it?
 - What do we know about HL from this perspective?

Q/A

Perspective

1. Public health perspective

The clinical perspective:

Focus on the individual patient

For instance, asthma

- Problem: this patient is having trouble breathing
- Why? → What's the cause
 - Examination, diagnostic testing
- Clinician's tools
 - Education and treatment now
 - Education and treatment to prevent further episodes
- Clinician advocacy: Work to ensure the best outcome for this patient

Public health perspective

Focus on a community or population

For example, asthma

Problem: A community is having trouble breathing

Why? What is the cause and scope of the problem

- Statistical (epidemiologic) analysis of population-based data

Public health perspective, continued

Public health practitioner's tools

Primary prevention

- Avoid future cases
 - e.g. identify early childhood exposures that are associated with later development of asthma

Secondary prevention

- Detect early for better outcomes
 - e.g. institute screening for kids entering kindergarten

Tertiary prevention

- Provide treatment and maximize functioning for those with the condition
 - e.g. identify environmental triggers of asthma attacks, or identify obstacles to filling of asthma medications, in low income families

Public health advocacy

- Work to ensure best outcomes for the population as a whole

Hearing loss (HL) from a public health perspective

Scope of the problem

Use of the public health practitioner's tools

- Primary prevention
- Secondary prevention
- Tertiary prevention

Public health advocacy

HL: Scope of the problem

In US

- 30 million people with HL
- 12.7% of those age > 12 years

Overwhelmingly, aging most important risk factor

- 3% among adults 20-29 years
- 45% in 70-74 years
- 80% in 85+ years

Noise exposure an important contributor

- Occupational, esp. military
- Recreational 🎵

HL: Scope of the problem

Associated conditions

- Social isolation, depression
- Falls, hospitalizations, increased death rate
- Accelerated cognitive decline
 - vs. cognitive impairment

Note: caution re: association & causation

HL: primary & secondary prevention

Primary prevention

- Reduce noise exposure
- Decrease use of ototoxic drugs

Secondary prevention

- Screen newborns
- Screen for hearing loss in primary care
- Promote public education and recognition/acknowledgement of HL

HL: tertiary prevention

- Increase use of auditory rehabilitation and counseling
- Increase use of hearing aids and hearing assistive devices
- Make environmental changes
 - Quiet the built environment (e.g. quiet hospital initiatives)
 - Install hearing loops
- Ensure compatibility and interoperability
 - Make sure that technology doesn't exclude those with HL
- Educate the public

These are just examples

Before we leave public health ...

OTC sales of acetomenophen (Tylenol)

Acetomenophen is an effective pain reliever

- Acetaminophen overdoses yield > 56,000 ED visits, 2,600 hospitalizations, and 458 deaths due to acute liver failure every year

Public health question: does population benefit outweigh risk?

- FDA says yes
- Risk communication primarily via labelling & package insert
- Public health model assumes informed consumer, in this case

Questions on the public health perspective?

2. Consumer perspective

What do consumers want?

Quality/effectiveness

Safety

Affordability

Informed choice

HLAA is the leading consumer voice for people with HL

- Hearing Loss Association of America
- Founded in 1979 as Self-Help for Hard of Hearing People (SHHH)
- For people with HL, provides
 - Fellowship/support thru local chapter meetings
 - Advocacy thru national office

Membership not representative of people with HL

- Typical HLAA member has longstanding hearing loss, often moderate to severe

Some highlights of HLAA's consumer advocacy

Advocacy for device quality

- Assistive Device Warranty or "Lemon Laws" for hearing aids

Advocacy to lower the cost of services (via wider insurance coverage, tax rebates)

- Medicare coverage of hearing aids (> 10 years)
- Medicare coverage for aural rehabilitation
- Private insurance coverage

These are just a few examples ...

Hot button topic: OTC hearing aids

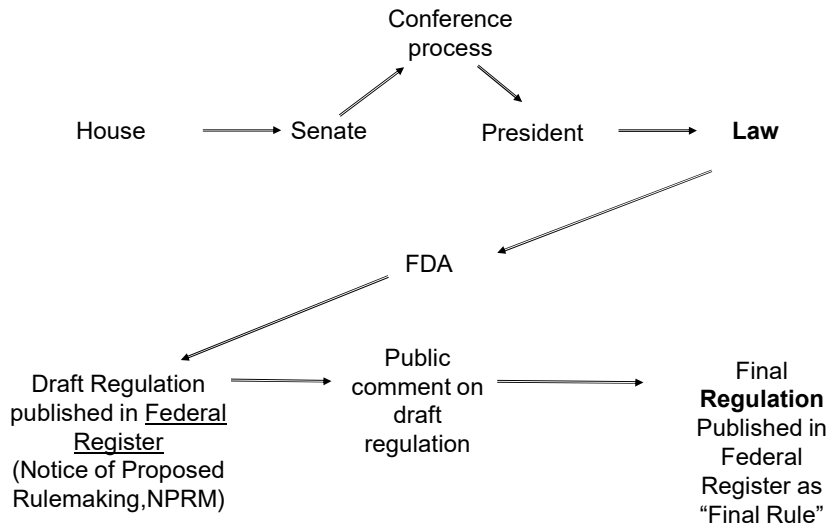
- According to Ian Windmill, Ph.D., President of the AAA, “Half of audiologists are in favor of OTC hearing aids, half are opposed, and a third say that they don’t know.”
- OTC aids = Devices marketed to those with mild/moderate hearing loss

Bill passed by the House and Senate

Over-the-Counter Hearing Aid Act of 2017

- This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to categorize certain hearing aids as over-the-counter hearing aids and issue regulations regarding those hearing aids. The regulations for over-the-counter hearing aids must: (1) provide reasonable assurances of safety and efficacy; (2) establish output limits and labeling requirements; and (3) describe requirements for the sale of hearing aids in-person, by mail, or online, without a prescription.

Legislative & regulatory process

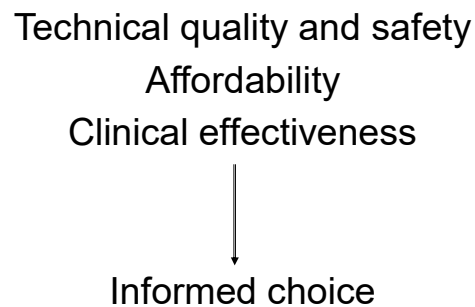


Why OTC hearing aids? The consumer perspective

- Need. Few people who could benefit from hearing aids have and use them
- Cost. Hearing aids are out of reach of many
- Frustration with lack of market competition
 - 21% of audiologists offer just one brand; many offer just two or three; trend over time is for practices to offer fewer choices of brand¹
- Opportunity
 - Technology explosion: Less cost to make highly effective devices

¹Hearing Review, April 2014

OTC hearing aids: Can they meet consumer goals?



Technical quality

Details to be decided by the FDA (NPRM process)

- ANSI standards for PSAPs have been developed by the consumer technology industry, and they are reportedly quite stringent
 - These could be adopted by the FDA for OTC HA, or
 - The FDA could modify the standards

Safety

Device safety

- Concerns about maximum sound output standards
- Issue of device safety is FDA's purview
 - Input during NPRM period

Personal safety

- Concerns about people purchasing HA without seeing clinician
- Mandating labelling/warnings (e.g. red flags) is FDA's purview
 - Input during NPRM period

Clinical effectiveness

Since OTC aids have not yet been marketed, this is uncertain.

However, research evidence is positive. For example:

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.

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. AR

Humes et al's study: Design

- Random assignment of 154 adults with mild-moderate hearing loss
- All subjects bilaterally fitted with mini open-canal hearing aids.
- Three groups, with different approaches to fitting:
 1. BP: Fit using audiology Best Practices
 2. SF: Self Fit, with subjects choosing from among three pre-programmed aids
 3. P: Placebo: Given aids programmed to provide no acoustical benefit
- Six week follow up; Primary outcome: Profile of Hearing Aid Benefit (PHAB)
- Other outcomes: hearing aid benefit, satisfaction, desire to purchase

Humes et al's study: Main findings

- Both BP and SF outperformed placebo on Profile of Hearing Aid Benefit (PHAB)
- BP = SF for 5 of 6 measures of PHAB
- BP group more likely to purchase hearing aids (81%) versus SF (55%) versus 36% (placebo)
- After 6 weeks, SF and P were offered hearing aids fitted under audiology BP.
 - Satisfaction with HA increased for those who continued with an audiologist's care, and there was a greater interest in purchasing hearing aids

Humes et al's study: Implications for OTC HA

- Just one study – more research is needed
- But suggests that self-fitting of hearing aids can work well, for some patients, in some circumstances
- Suggests that audiologist's care increases the value that patients place on their hearing aid
 - Better fit?
 - More confident?
 - More informed, better user?

Important OTC effectiveness issue: Recourse if device isn't effective?

- Trial periods with recourse (returns without penalty) have been offered by some higher-end PSAP manufacturers. For example:
 - Sound World Solutions CS50+ – 45 days, full refund less postage
 - Etymotic Bean – 30 days, full refund less postage
- If OTC hearing aids come to market, it is unclear whether recourse will be mandated by law, or whether the market will be allowed to play it out

Informed choice

- If OTC bill passes and devices are marketed, how will consumers make choices?
- Who will provide education/information?
 - Initiative following the NASEM process
 - Online sites with ratings
- **The BIG question: How will audiologists be involved?**
 - Consumers value the services that audiologists provide.
 - How can audiologists monetize this?

After the passage of the OTC bill: Audiologists

- “With the passage of the OTC legislation, we, as audiologists, must continue to lead through consumer education, outreach to other providers, and partnerships with federal agencies. Our efforts will now shift towards directly engaging with the FDA and FTC to shape new OTC hearing aid device regulations that will be developed and implemented in the coming months and years.”

–Ian Windmill, PhD, AAA President

After the passage of the OTC bill: HLAA

- “HLAA has been working diligently with lawmakers to have the consumer voice heard. We are currently working with the FDA on labeling of OTC products, product safety and consumer protection. The future of hearing health care is changing, allowing people to make informed choices. HLAA will ensure consumers have unbiased and factual information and updates about new products, regulations, and legislation as they develop.”

--- Barbara Kelley, Executive Director, HLAA

The End

Additional Reading: Audiology Online

- Ian Windmill: “The Future of Audiology”
<http://www.audiologyonline.com/articles/20q-predicting-future-audiology-16867>
- Brian Taylor: “Interventional Audiology”
<http://www.audiologyonline.com/articles/20q-interventional-audiology-17080>

More slides

Consumerism is about who decides

Clinician
decides

Shared decision

Patient
decides

Patient
complies

Clinician offers
choices
transparently,
patient makes
informed
choice

Off
the
grid