Institute of Medicine (IOM) Consensus Study on Accessible and Affordable Hearing Health Care for Adults

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Today’s Talk: Two sections

• Background Material: Accessible and Affordable Hearing Health Care (AAHHC)
  • Hearing Loss (HL) as a Public Health Issue
  • Hearing Health Care (HHC)
    • Access
    • Affordability
    • Technology and Models of Service Delivery
    • Professional Tensions

• IOM Statement of Task: AAHHC for Adults
  • Introduction to Statement of Task
  • Charge to the Committee
    • Provide a Contextual Background
    • Address Federal Regulations for Hearing Aid Dispensing
    • Address Access and Affordability (devices and services)
    • Recommendations
HL is a Public Health Issue

• Approximately 15% of American adults (~40M) report some trouble hearing

• Strong relationship between HL and age
  • 50% ages 75 years and older have significant HL
  • 25% ages 65-74
  • Various causes: aging, noise, genetics

• Adult HL also a concern for younger than 65
  • ~3.5M ages 55-64 have significant HL (8.5%)
  • ~1.0M ages 45-54
    (Better Ear PTA >= 35 dB HL)

• Ages 12-19 (~1/1,000) have significant HL
  • Transitioning from child-service provisions to adult care system
HL is a Public Health Issue

- America is aging, more individuals with HL
  - Most initial HL of mild to moderate - many active in the workforce
  - Some will transition to severe HL, requiring more complex professional services

- Psychosocial health declines with increasing HL
  - HL linked to increased risk of depression
  - Increased social isolation

- Intervention at the earliest stages may lead to better outcomes
  - Beneficial to initiate care early, maintain quality of life
  - Intervention assures that the loss of hearing need not equate to loss of communication
HL is a Public Health Issue

- HHC remains an unmet public health need
- Many individuals are reluctant to admit/treat HL
  - Most hearing aid users have HL for several years and progressed to moderate-severe before acquiring a hearing aid
- Only 20% of those with HL who could benefit from hearing aids actually use them
  - 30% ages 70 and older; 16% ages 20 to 69
  - Perceived benefit, cost, value, stigma, belief they can get along without help
- The needs of the majority of adults with HL are not being addressed
Individuals with HL Have Personalized Needs

- Adults with HL differ in many different dimensions
  - Degree of HL (mild/severe)
  - Communication needs (situational/constant)
  - Communicative difficulties (minimal/consequential)
  - Societal engagement (very/less so)
  - Access to health care system (high/low)
  - Economic situation (disposable income/not)
  - Technologic comfort zone (very/none)

- HHC includes a spectrum of both devices and services
  - Beyond hearing aids, can include other assistive technologies as well as aural rehabilitation (counseling, hearing management groups)

- A continuum of care is required to meet these personalized needs
  - Minimal technology for occasional use - no additional services needed
  - Greater difficulties require more complex devices and services
HHC Access

• Access can be confusing, with competing interests and multiple entry points
  • Audiologist, hearing instrument specialist, family physician, otolaryngologist (differing education/training requirements)
  • Direct web access, magazine and newspaper ads

• Screening
  • For those who think they have HL and want screening, no readily accessible, low-cost screening available

• Devices
  • Traditional hearing aid delivery model is multi-visit process - physician and dispenser (hearing instrument specialist or audiologist) required
  • The primary source for low(er) cost aids is direct-to-consumer advertising (internet, magazine, newspaper) - “buyer beware”
  • Alternate assistive listening devices (ALD) are available outside HHC system on internet or electronics store
HHC Affordability- Device and Services

• Hearing aid is frequent recommendation
  • Expensive to acquire and maintain
  • No/limited incentive for manufacturer or dispenser to reduce cost

• Peer-reviewed studies show acquisition/use associated with income, education and cost as reason for not obtaining device

• Out-of-pocket cost for individual with HL
  • Often spend $4,000-6,000 for a pair of hearing aids
  • Repeat expense: Hearing aid replacement 4-6 years

• What is “affordable”?  
  • Socioeconomic status varies
  • Especially challenging for limited disposable income or medically underserved (rural and inner city)

  Household income: 35% of households <$35,000/yr; Median = $52,000/yr
  20% of Americans live in rural America: more likely to be older, poor, in fair or poor health, and to have chronic conditions
HHC Affordability- Device and Services

- Hearing aids and rehab services are not covered by Medicare
  
  *JAMA 2014 Viewpoint: Whitson and Lin, Hearing and Vision Care for Older Adults- Sensing a Need to Update Medicare Policy*

- No or limited coverage by most insurance plans
- Reliance on Lions Club, loaner bank, philanthropic orgs

- US industry surveys cite cost and lack of coverage as primary barriers to hearing aid adoption

- For individuals with HL, hearing aids/services can be their third most expensive purchase, beyond purchase of home or car
  
  Tens of thousands of dollars on HHC over lifetime
HHC Technologies

• Assessment and fitting automated - PC/tablet
  • Allows for remote and at-home management

• Hearing Aid
  • Open canal fittings - less burdensome, more natural sound
  • Research ongoing for self-testing/self-fitting hearing aid - Sound environment vs. audiogram
  • Performance in background noise remains problematic

• Assistive technologies
  • ALDs include personal amplifiers
  • Hardwired or wireless; High tech (smartphone) or low tech (loop)
  • Many use combination of hearing aid with other assistive devices and change technology in concert with their sound environment

• Future technology - “Hearables”
  • Ear-level wearable computer - capabilities will far exceed “hearing aid”
HHC Technologies

• In 1977 (regulations enacted) a “hearing aid” was distinct
• Now, same digital technologies are being applied in different devices
  • Hearing aids, ALDs, personal sound amplification products (PSAPs)
  • Different marketing, distribution channel, and costs
  • Same electronic architecture

• Controversy on the FDA regulations governing the labeling of devices that amplify sounds:
  • If labeled for HL, it is a “hearing aid” (regulated)
  • If not labeled for HL, it is a PSAP - consumer product (not regulated)

• Is the best HHC synonymous with the most advanced technology?
  • Tendency or belief to treat all HL with one approach: the best HHC necessitates providing the most costly technology
  • For those who can not afford, this makes HHC unattainable
Service Delivery

• **Traditional**
  - Audiologist/hearing instrument specialist or ENT office dispensing various manufacturer devices

• **Recent**
  - Store front hearing aid sales (e.g., Big box stores)
  - Internet sales - referral or direct to patient
  - “Corporatization” of HHC (rise in industry-owned vs. independent audiologist-owned practice)
  - Insurers - providing aid/services direct to subscriber

• **New/emerging**
  - Smartphone apps - mobile platforms
  - Pharmacy/Retail Clinics
  - Telemedicine - remote testing, fitting and management
Historical Landmarks

• Two events in 1970’s established the HHC system as it exists today

• 1977: FDA hearing aid regulations were enacted

• 1978: Supreme court ruled a professional organization could not limit a professional’s compensation
  • ASHA could no longer stipulate it was a Code of Ethics violation for audiologists to sell hearing aids for profit (i.e., loss of professional certification) and audiologists began to do so
  • Hearing aids are now a primary revenue source for audiologists and an important revenue source for some otolaryngologists
Professional Tensions in HHC

- Many inter-related issues and tensions contribute to the current HHC situation
  - Professional organizations represent member interests - manufacturers, audiologists (may or may not be in private practice), hearing instrument specialists, otolaryngologists
  - Not necessarily aligned with needs of the individual with HL

- Manufacturers vs. Dispensers:
  - Manufacturers dependent upon dispensers to sell their product
    - 6 manufacturers provide >90% of aids
  - Competition for wholesale cost of device - price per aid by large buying practices (Costco, VA) is lower than for independent dispenser
Professional Tensions in HHC

- **Audiologists vs. Hearing Instrument Specialists:**
  - Differing educational qualifications – AuD vs. state licensing
    In 31 states minimum requirement for dispensing is a high school diploma/GED
  - Competition for patient base (revenue)
  - Competing belief systems - “We” provide the better services

- **Audiologists vs. Otolaryngologists:**
  - Major disagreement over gatekeeper status for HHC entry
    - Direct access vs. physician referral
    - Autonomy of practice for audiologists
  - Competing belief systems - “We” provide the best services

- **Introduction of new systems - tensions**
  - United Health - insurer provide aids direct to subscribers (2012)
  - “Texas Hearing Aid Association Sues Walmart” (2014)
Professional Tensions in HHC

• Lack of agreement on legislative strategies
  • Expansion of VA Hearing Aid Benefits by Hearing Instrument Specialists - Expanding the list of eligible providers to include hearing instrument specialists - (IHS, ASHA, ADA, AAA)
  • Audiology Services Enhancement Act - Recognizes audiologists as diagnostic and treatment providers able to receive Medicare reimbursement (ASHA, ADA, AAA)
  • Medicare Aid Coverage Act - (amend title XVIII of the Social Security Act to remove the exclusion of Medicare coverage for hearing aids and examinations therefore, and for other purposes- see below)

• Hearing specialty orgs have not traditionally supported coverage of hearing aids by Medicare - fear reimbursement rates too low

• Have varying legislative strategies to address coverage of services – disagree on issues regarding physician oversight and “direct access”

• Agreement limited to “Hearing Aid Tax Credit”
  • Does not alter the delivery model or cost of aid/services
  • $500 per device once every 5 years - never enacted
IOM Statement of Task

- Background Material: AAHHC
  - HL as a Public Health Issue
  - HHC
    - Access
    - Affordability
    - Technology and Models of Service Delivery
    - Professional Tensions

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IOM Consensus Study Development

- All sponsors have an interest in adult HL
- NIDCD supports research on all aspects of HL across lifespan

- Specific to AAHHC: 2009 NIDCD Research Workshop on AAHHC for Adults with Mild to Moderate HL
  - Entry to research on HHC system as a whole
  - NIDCD research priority area

- January 2014 IOM Workshop on HL and Healthy Aging
  - Elevated discussion of HL and HHC to a broad audience
  - Workshop discussion included:
    Lack of recognition re: value of hearing and communication
    FDA regulatory environment
    HHC access and affordability
IOM Consensus Study Born...

- Following the 2014 IOM Workshop, coalition and discussion among IOM, federal agencies and others for development of Consensus Study Statement of Task

- Centers for Disease Control and Prevention (CDC)
- Department of Defense (DOD)
- Department of Veterans Affairs (VA)
- Food and Drug Administration (FDA)
- National Institute on Aging (NIA/NIH)
- National Institute on Deafness and Other Communication Disorders (NIDCD/NIH)

- Hearing Loss Association of America (HLAA)
Why an IOM Consensus Study?

- HHC system needs improvement
- HHC involves many government agencies; scientific, technical and economic areas; and clinical and professional organizations
  Beyond mission of any one single agency
- Objective process needed from unbiased panel with broad expertise
- IOM Consensus Report will provide valuable guidance and recommendations for improvement to the government and all stakeholders
Charge to the IOM Committee: Statement of Task

1. Provide a Contextual Background
2. Address Federal regulations for hearing aid dispensing
3. Address HHC Access and Affordability (devices and services)
4. Make Recommendations

Topics intersect each other and are difficult to separate individually
“The value of hearing and the value of intervening for hearing loss is not well recognized.

• **Address importance of hearing to individual and societal health, productivity and engagement.**

• **Include issues such as isolation, social connectivity and well-being as well as economic productivity.”**
Charge to the IOM Committee

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4. Make Recommendations
Address Federal regulations for hearing aid dispensing

• “The current federal regulations include the requirement for a medical evaluation by a licensed physician (or a signed waiver of this requirement) prior to dispensing of a hearing aid in order to promptly identify treatable medical conditions that cause hearing loss.

• Do the current regulations provide a clinically meaningful benefit to adults with hearing loss?

• If so, does this benefit outweigh any current barriers to accessibility or affordability that may be associated with the current regulations?

• What should be the required federal regulatory paradigm for the dispensing of hearing aids?”
Federal Regulations and Hearing aid Dispensing

• In 1977, FDA hearing aid regulations were enacted, making hearing aids “restricted class I devices”
• Addressed labeling and conditions for sale (FDA presentation)
  • Required a medical evaluation within preceding 6 months of purchase, preferably by an ENT
  • Waiver process allowed for adults: requires a signed statement acknowledging that medical evaluation is in his/her best health interest
  • The dispenser may **not** actively encourage waiver
  • Waiver intended to only be used in rare circumstances, such as opposition to medical evaluation for religious purposes
FDA Required Medical Evaluation

- **PRIMARY Issue:** Unclear if serving intended purpose
- Medical evaluation exists for the sole purpose of promptly identifying *treatable medical conditions* that cause HL

- Most causes of adult HL are *not* medically treatable (90-95%?)
- Presumably, many of those with medically-treatable causes go directly to a physician for specific symptoms beyond the HL itself (self-report conditions such as ear pain, drainage, dizziness, sudden HL, etc.)

- Do the regulations provide a significant *protection* to the individual (i.e., increasing patient safety by identifying the relatively few medically treatable causes of HL in adults who present to get a hearing aid) OR

- Do they create a significant *barrier* (increased cost and access complexity) for the majority of adults *without medically treatable HL*, thereby delaying necessary intervention with a hearing aid?
FDA Required Medical Evaluation

• Appropriate if necessary and justified for patient safety

• However, there are no data to support or refute the requirement for medical evaluation
  • No risk-benefit assessment (patient level) or cost-effectiveness analysis (system level)
  • No FDA enforcement and many (most?) sign the waiver
  • Of the medical clearances that do occur, many are not full otologic evaluations - referrals from primary care
Signed Waiver Process

“I have been advised by _____ (Hearing aid dispenser’s name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.”

• Requires an individual to sign a statement when they choose not to see a medical professional against government advice
  • Unlike most other health concerns where determination of when to seek medical care is a personal decision and no signed statement is required

• Consider possible implications for the:
  • The individual (psyche of refusing medical evaluation)
  • Dispenser (utilizing waiver process far more than regulations intended)
  • System (noncompliance and/or burdensome)
“What should be the required federal regulatory paradigm for the dispensing of hearing aids?”

- Extraordinarily important question with major implications: Intersection of HHC, technology, and FDA regulations
  - Central question is whether the incidence and severity of the diagnoses that would be missed or delayed, and the consequences of such, require medical evaluation/clearance prior to dispensing
  - Discussion should be framed in the context of the current system where the majority of individuals do not acquire medical evaluations as was intended when the regulations were created
“What should be the required federal regulatory paradigm for the dispensing of hearing aids?”

• Are individuals with HL “patients” or “consumers” or “both”?
  • Important yet critical distinction in how one may view regulation and marketing

• Issues to consider may include:
  • Patient safety
  • Access/affordability
  • Innovation
  • Delivery systems
  • Consumer needs and access to health information
  • Available/new technologies
  • Other
Charge to the IOM Committee

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Address HHC Access and Affordability (devices and services)

• “How can HHC affordability, including consideration of third-party payment and alternate hearing assistive technologies/services be improved?

• How can current delivery models (system and provider) be utilized or modified to improve access to HHC?

• What innovative approaches (e.g., telehealth, mhealth, team-based care) can be used to increase both the access to and affordability of HHC?

• What are the specific challenges for select populations (e.g. older adults, transitioning young adults)?”
How can affordability be improved - including consideration of third-party payment?

- HHC not integrated into overall health care arena
  - Evidenced by lack of third-party payment (insurance and Medicare) for devices and services
  - Evidenced by lack of engagement of other healthcare professionals (e.g., primary care, nurses) in HHC (screening/preventive measures/follow-up)
  - Audiology is unlike many other allied health fields (i.e., Occupational/Physical Therapy) with a more integrated care model with greater reimbursement

- What strategies and actions could lead to increased coverage?
- Could an integrated care model lead to or allow for greater third-party reimbursement?
How can affordability be improved - including consideration of alternate hearing assistive technologies/services?

- Alternate technologies are available, yet there is not a clear entry system into HHC for alternate technologies (i.e., labeled for HL and available OTC)

- Consider how best to support the individual who wants some hearing assistance in some listening situations
  - Can’t afford traditional HHC system
  - Not ready for the full spectrum of services audiologists provide
How can current delivery models (system and provider) be utilized or modified to improve access to HHC?

- Health care delivery landscape has changed
  - Move to patient-centered care away from provider-centered
  - Move to integrated or coordinated care
  - Move to population health approach - acknowledgement that factors outside health care system impact health

- HHC System is provider-centered
  - Is this provider-centered approach (regulatory/dispensing/medical) appropriate?
  - Can this approach work equally well for all individuals with HL regardless of:
    - Degree of HL
    - Communication needs and abilities with technology/services
    - Access to health care system and economic situation
How can current delivery models (system and provider) be utilized or modified to improve access to HHC?

• Can other delivery models improve access; and if so, how might they be implemented?
  • Patient-centered approach
  • Integrated/coordinated care
  • Medical home
  • Community-based care programs
  • Home as a location for care delivery

• Inter-professional practice: Can engaging other healthcare professionals in HHC improve access (e.g., nursing, pharmacist)?
  • Expand capacity
  • Reduce burden on audiologists for better utilization of their expertise and skills on more complex cases
How can current delivery models (system and provider) be utilized or modified to improve access to HHC?

• Should there be a “consumer-driven” continuum of care for HL?
  • OTC product specifically labeled for HL (whether an ALD, PSAP, hearing aid, or smartphone app) and/or
  • Hearing aid/services through dispenser and/or
  • Medical professional through self-referral or dispenser referral
  • All available in any order based on consumer decision

• If so, how could such an OTC system be structured to maximize patient safety and protection (through instructions and labeling, referral for medical conditions, etc.) while minimizing risk?
  • Akin to many other diseases/disorders in which OTC products (drugs and devices) are available, e.g., low back pain/vision
  • OTC hearing aids have been discussed many times over past decades
  • Current technology allows low-cost OTC possibilities
How can current delivery models (system and provider) be utilized or modified to improve access to HHC?

- Continuum of Care for Low Back/Knee Pain
  - Home care (ice, heat) and/or
  - Availability of OTC anti-inflammatory drug or product (Advil, Ace bandage, knee brace) - in absence of seeing any professional
  - If continuing concern, may call physical therapist, chiropractor (professional certification - doctorate)
  - Consumer may choose to seek MD at any point in the process

- No signed statement stating they have been told by the government it is in their best interest to go to a physician in case of medically treatable skeletal/muscular injury or pain secondary to serious disease
How can current delivery models (system and provider) be utilized or modified to improve access to HHC?

• Continuum of Care for Vision: Readers or prescription glasses
  • Availability of OTC readers
  • Or to an optometrist for exam/prescription if necessary for glasses (professional doctorate - akin to an AuD audiologist)
  • Consumer may choose to seek MD at any point in the process

• No signed statement stating they have been told by the government it is in their best interest to go to a physician in case of medically treatable optic disease or vision disturbance secondary to serious disease, such as diabetes
What innovative approaches (e.g., telehealth, mHealth, team-based care) can increase access and affordability?

- Telehealth-using web for fitting, user adjustment, rehab

- mHealth- smartphone for health - amazing growth - potential for HL technologies and speech enhancement strategies

- Team-based care
  - Used for improving chronic disease management
  - Hearing health as part of a “care team”

  - Is some care better than no care?
  - Social Enterprise models
    - Sound World Solutions - smartphone app
    - “Hearing Express” - associated with the World Health Organization, community-based program includes a self-programmable hearing aid
What are the specific challenges for **select populations** (e.g. older adults, transitioning young adults)?

- **Older Adults**
  - Needs may range from self-management to professionally-provided care, using simple or complex technology
  - May have co-occurring conditions that complicate care, yet also heighten need for good communication skills
  - Boomers are often tech savvy, yet not true for all

- **Transitioning young adults**
  - Will spend large sums of money throughout their lifetime for HHC
  - Will be experienced in the HHC system

- **Include other special populations**
  - Individuals with low literacy or low income
Charge to the IOM Committee

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Recommendations

• “Provide recommendations aimed both at solutions that are implementable and sustainable in the short term as well as those that may require a longer timeframe for implementation.

• In the circumstance where robust evidence is lacking or absent, the IOM committee is encouraged to make recommendations based on sound scientific reasoning in the context of the current healthcare environment.”
Recommendations

• Keep an eye to the IOM Definition of Quality Healthcare

• Healthcare quality is the extent to which health services provided to individuals and patient populations improve desired health outcomes...

• IOMs six specific aims for system improvement:
  • Safe
  • Effective
  • Patient-centered
  • Timely
  • Efficient
  • Equitable

*Crossing the Quality Chasm: A New Health System for the 21st Century, IOM, 2001*
Recommendations

• Focus on the needs of the individual with HL

• Recognize limited scientific data; use best judgment

• Recommendations will guide follow-up actions by individual agencies as well as trans-agency partnering- both policy and research

• Hope is that the recommendations will provide unifying guidance and motivation for coordinated and sustained action among all stakeholders with an interest HHC

• Respect your time and commitment to this project

• Grateful for your interest and willingness to serve
Take Home Message

- HL is a major public health need affecting millions of people
- Technology and solutions to address the problem are available
- Barriers to access include cost, regulations, business practices, and other systemic factors
- Need to re-examine how to provide access to the range of available solutions to meet the personalized needs of individuals with HL
IOM Consensus Study on Accessible and Affordable Hearing Health Care for Adults

Additional sponsors and discussion/questions