

NIDCD Research Working Group

Accessible and Affordable Hearing Healthcare
for Adults with Mild to Moderate Hearing Loss

Co-Chairs

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*Hearing Loss and Healthy Aging: An IOM-NRC Research Workshop
January 13-14, 2014*

Today's Presentation

- Working Group Background and Rationale
 - Hearing loss is a public health concern
 - Accessibility
 - Affordability
 - Changes in technology and delivery systems
 - Professional tensions
- Working Group Research Recommendations - Gap Areas
- Currently Funded NIDCD Projects
- Challenges and Opportunities

Hearing Loss is a Public Health Concern

- Approximately 17% of American adults report some degree of HL (36 million)
- Yet, only 20% of those with HL who require intervention and treatment seek help for their condition
- Most hearing-aid users had HL for more than 10 years and progressed to mod-severe HL before acquiring a hearing aid
- For many and varied reasons, the needs of the majority of adults with HL are not being met

NIDCD Research Working Group

August 25-27, 2009

- Looked at the hearing healthcare (HHC) system as whole with a public health perspective
 - New direction for NIDCD research
- Overarching goal to increase the number of individuals receiving quality HHC
 - Better understand the current HHC system
 - Identify research gaps, including low cost hearing aids
 - Identify innovations and opportunities for the future

NIDCD Research Working Group

August 25-27, 2009

- To develop a research agenda leading to increased accessibility and affordability of HHC for adults with mild to moderate HL
 - Aimed at delivering better HHC access and outcomes that are effective, affordable, and deliverable to those who need them
 - Implementable and sustainable in clinical and community settings beyond the research environment
 - Complement and supplement, not replace, current paradigms
- Focus was not on research related to
 - Complex technological advancements for hearing aids/implants
 - Adults with severe to profound HL
 - Children
 - Public education

Why Mild-to-Moderate HL?

- Represents the hearing status of many older Americans
- Least likely to have had hearing screening/assessment
- Least likely to use a hearing aid
 - Perceived benefit, cost, value, stigma, believe they can get along without one
- Yet, likely to benefit from amplification
- Psychosocial health declines with increasing HL
- Early intervention may lead to better outcomes
 - Plasticity effects - beneficial to initiate care early, maintain quality of life, before cognitive or other age-related declines occur
- Many will transition to severe HL, requiring more complex interventions and services (device/rehab) in later years

Hearing Health Care Access

- Access is as important as affordability
- Screening
 - No readily accessible, low-cost ways for US adults to get their hearing screened (international screening efforts are ongoing)
- Assessment
 - Multiple entry points with competing interests include family practitioners, audiologists, hearing aid specialists, otolaryngologists
- Devices
 - Obtaining a device through traditional delivery models is a multi-visit process
Audiologist and physician visits required
 - Direct-to-consumer through internet, magazine/newspaper/television advertising
Primary source of low-cost aids - can mean "consumer beware"
 - Internet availability does not make devices "accessible"
Lower incomes have lower internet use; 48% of adults 65+ are not online
 - Better alternatives are needed for necessary healthcare devices

Hearing Health Care Affordability

- Includes devices and professional services
- Average out-of-pocket cost of ONE hearing aid is ~\$1,800
 - Price per aid ranges from \$1,182 - 2,876 (industry survey)
 - 70% require two aids
 - Consumers often spend \$4,000 - 6,000 for a pair of hearing aids
 - Hearing aid life span is 4-6 years - replacement costs repeat expense
- US household income (2009 Census)
 - 35% of households <\$35,000/yr; Median household income = \$50,000
- What is "affordable"?
 - Different price points for different segments of the population
 - Limited scientific data on specific impact of cost on adoption rates
- US industry surveys of "non-adopters" - Cost is cited as a primary reason
 - Of those most in need, 64% said price was an obstacle to adoption
 - 66% said likely to get a hearing aid if 100% coverage by insurance
 - 47% said likely to adopt a hearing aid if price did not exceed \$500

Hearing Health Care Affordability

- Beyond purchase of home or car, hearing aids/services can be the third most expensive purchase for many with HL
 - Hearing aid value (benefit relative to cost) is a factor in return and non-use rates
 - Quality HHC is assumed to be the most advanced technology, thereby reducing access to HHC for those who can least afford it
- No coverage by Medicare
- No coverage or limited coverage by most insurance plans
- Instead, reliance on Lions Clubs, loaner banks, and philanthropic organizations
- Not an acceptable public health solution
- Better alternatives are needed for necessary healthcare devices
- Spectrum of socioeconomic capacities
 - NIH mission includes closing the gaps in health disparities, includes racial and ethnic minorities, urban and rural poor, medically underserved
 - Acquiring HHC may be especially challenging for the “working poor”
 - Important to remain conscious of the underserved, economically less advantaged

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New and Emerging Technologies - Rapid Changes

- Auditory assessment and hearing-aid fitting is being automated and routinely conducted on PC/tablet
 - Allows remote fitting, consumer programming, other
 - PC/Internet use for at-home aural rehab program
- Hearing aids
 - Component costs are minimal
 - Open canal fittings less burdensome
 - Research ongoing for self-testing and self fitting hearing aid
- Smartphone entry into health care - rapid development
 - NIH priority area in "mhealth": Smartphone as a mobile platform to improve healthcare
 - Eclipsing hearing aid functionality
 - Wireless link to many devices - including hearing aids
 - Ownership rising: age and income variables influence ownership rates

Service Delivery Paradigms - Rapid Changes

- Traditional paradigms
 - Audiology / Hearing aid specialist / ENT office with various manufacturer devices
 - Limited manufacturer direct to patient
- New Paradigms
 - Store front hearing-aid sales (e.g., Big box stores)
 - Internet sales - direct to patient and to referral/consolidators
 - Telemedicine - remote testing, fitting, management
 - Entry of insurers into the delivery paradigm - direct to patient
 - “Corporatization” of HHC (rise in industry owned and branded outlets vs. independent audiologist-owned practices) - manufacturer as provider
 - mHealth - mobile platforms
 - Convenient care clinics
- New delivery paradigms will require changes in workforce demographics and training

Professional Tensions in HHC

- In 1977, FDA regulations enacted
- In 1979, audiologists began selling hearing aids for profit
 - Now an important revenue source for HHC professionals
- Professional tensions among HHC providers:
Manufacturers - Audiologists - Hearing Aid Specialists - Otolaryngologists
 - Disagreement over gatekeeper status (direct access) for HHC entry
 - Differing educational/credentialing requirements (MD/AuD/state licensing)
 - Competition for the patient base (revenue)
 - Unique belief systems (“We” provide the best services)
 - Debate on value of current FDA regulations
- Lack of agreement on legislative strategies for HHC
 - Various legislative strategies re: direct access and coverage of services
 - Professional organizations have not uniformly supported reimbursement of hearing aids by Medicare
 - Agreement limited to legislation supporting a “hearing aid tax credit” - \$500 per device / once every 5 years

Charge for Research Recommendations

- Aimed at technologies or delivery strategies that are effective, accessible, and affordable to those who want and need them
- Take advantage of current and evolving technologies and health care delivery models
- Consider innovative and creative solutions with potential for implementation
- Reflect current demographics and the varying socioeconomic capacities of the US population
- Practical and feasible undertakings for the near future

Research Recommendations - Gaps

- From a list of more than 70 recommendations, working group members selected their highest priority, in terms of importance and immediate feasibility
- Organized into 10 general areas
 - Access
 - Screening
 - Assessment
 - Hearing Aid Technologies
 - Patient Variables
 - Aftercare Needs
 - Delivery Systems
 - Workforce and Training of HHC Professionals
 - Medical Evaluation/Regulatory Issues
 - Overarching Topics

Research Recommendations - Overview

- Benefits of HHC
 - General health, economic health, lifestyle, well-being, family
- Access
 - Understand HHC system variables
 - Availability and complexity of services
 - Cost, insurance/subsidy
 - Location, referral networks
 - Understand patient-centered variables
 - Including unique needs and concerns across the lifespan
 - Degree of hearing loss, age, general health, cognitive function
 - Perceived need, value, socioeconomic status
 - Personal attitudes, stigma, culture

Research Recommendations - Overview

- Screening
 - Evaluate barriers to hearing screening
 - Availability
 - Cost/insurance coverage
 - Referral patterns/disincentives
 - In various health care settings (primary care, community center)
 - Determine best screening methods
 - Specificity/sensitivity
 - Follow-up rates
 - Long-term benefit to hearing health
 - Develop accessible screening paradigms
 - Emerging technologies
 - Consider target populations

Research Recommendations - Overview

- Assessment
 - Determine accuracy and quality of audiometry
 - In different health care settings
 - For different means of delivery (in person, internet, emerging technologies)
 - Determine necessary components of assessment batteries to fit hearing aids and guide other interventions (rehab)
 - Evidence by impact on outcome
 - Auditory
 - Cognitive
 - Psychosocial

Research Recommendations - Overview

- Hearing Aid Technologies and Outcomes
 - ID variables that predict success
 - Technology factors (cost, appearance, performance) that influence penetration and utilization rates
 - Differences by age, cultural and socioeconomic groups
 - ID minimal technologies to achieve success
 - Compare effectiveness of various technologies for various populations
 - Low cost, one-size-fits-all
 - High cost, full feature
 - Develop self-testing, self-fitting hearing aids

Research Recommendations - Overview

- Patient Variables and Outcomes
 - ID variables that predict success
 - Factors that influence perceived need and motivation for HHC
 - Patient factors (age, degree of HL, socioeconomic) that influence penetration and utilization rates
 - Characteristics of those who benefit from hearing aids and other interventions
 - Better outcome measures
 - Develop standard set to determine success of HHC
 - Determine how and when to measure outcomes
- Aftercare Needs
 - For different HHC service delivery models
 - Needs for follow-up services, information and patient education
 - Effect on benefit and outcomes

Research Recommendations - Overview

- Delivery Systems
 - Utilize innovative HC delivery models and methods (telehealth, mhealth) for HHC
 - Utilize or modify current models (system and provider) to increase HHC access and affordability
- Workforce and Training of HHC Providers
 - Necessary knowledge, skills, abilities
 - Professionals and others providing HHC
 - Training needs for non-traditional settings

Research Recommendations - Overview

- Medical Evaluation/Regulatory Issues
 - FDA regulations to rule out contra-indications for using hearing aids
 - Provide protection for patients?
 - Create barrier for access to HHC - thereby delaying intervention?
 - Evidence needed
 - What is the appropriate medical evaluation for using H Aid
 - Percentage opting for medical waiver and of these, what percentage is subsequently diagnosed with medically treatable HL
 - Prevalence of medically/surgically treatable causes of HL in adults seeking hearing aids
 - Ability of consumers to detect treatable HL

Follow-up Actions

- Widely distributed Working Group Summary Report
 - Full workshop report: NIDCD Website
<http://www.nidcd.nih.gov/funding/programs/09HHC/Pages/summary.aspx>
 - Open access editorial in *Ear and Hearing* (Donahue et al. 31, 2-6, 2010)
 - Article in ASHA's E-newsletter, *Access Audiology*
- From 2009 to present, research initiatives encouraging grant applications and engagement of the larger research community
- Both traditional and unique NIH funding mechanisms through PAs and special RFAs, such as R01/ R21/ SBIR

Follow-up Actions

- Research in Hearing Health Care (R01/R21)
 - Broad focus - includes entire range of research recommendation
 - Traditional NIH funding mechanisms
- Phased Research Grants for HHC (R21/R33)
 - Allows exploratory phase for conducting pilot work, research or infrastructure
- Outcomes for HHC (R01)
 - Specific to developing measures to determine successful HHC outcomes
- Small Business Innovative Research Grants (R43/R44)
 - Designed to lead to commercialization of new technologies
- Crossed into Health Services Research (HSR)
 - Follow-up working group on HSR in 2012
 - Offered administrative supplements to current grantees
 - NIDCD Program Announcement on Outcomes / Effectiveness / HSR

Many NIDCD staff involved in various initiatives

Active HHC Projects Include...

- Effectiveness of Basic and Premium Hearing Aid Features for Older Adults
 - Comparing the effectiveness of basic-level and premium-level hearing aids
- Minimal Technologies for Hearing Aid Success in Elderly Adults
 - Relationship between technology level and real-world effectiveness - using wireless smartphones as part of outcome measurement system
- Efficacy of a Low-Cost Hearing Aid and Comparison of Service-Delivery Models
 - Clinical trial including service-delivery model (current best practices and over-the-counter simulation) and purchase price (low and typical)
- Can Consumers and Audiologists Detect Ear Disease Prior to Hearing Aid Use?
 - Evidence relevant to FDA required medical evaluation with waiver option

Active HHC Projects...

- Reducing Disparities in Access to HHC on the US-Mexico Border
 - Testing the effectiveness of an innovative community health worker intervention (Promotora), used for other chronic conditions, to expand HHC access among older adults facing health disparities
- User-centered Control of Hearing Aid Signal Processing
 - Allows users to select their desired signal processing parameter values on mobile devices that communicate wirelessly with hearing aids
- Improving Amplification Outcomes in Noise by Self-Directed Hearing Aid Fitting
 - Self fitting with wireless control of hearing aids to explore preferred settings in noise - allow users to custom fit algorithms for greater success in background noise in daily use

Active HHC Projects...

- Primary Care Intervention Promoting HHC Service Access and Use
 - Within a **primary care setting**, testing the effectiveness of three protocols on subsequent access to and use of HHC services
- Community-Based Kiosks for Hearing Screening and Education
 - Within 4 **community based centers**, testing the effectiveness of five hearing screening paradigms for HHC follow-up and hearing aid uptake
- A National Screening Test for Hearing, Administered by Telephone
 - A US version of a **telephone-administered screening test** that has been implemented in the Netherlands, the UK, Australia, Germany and France
- Wireless and Noise Attenuating Headset for Automatic Hearing Screening
 - Development of a **mobile platform** hearing screening device designed for use at point-of-care (POC) locations with very limited personnel resources

Challenges and Opportunities

- Limited pool of clinician-researchers (audiologists, otolaryngologists, hearing aid specialists)
- Limited interest in HL research among other relevant professions: gerontology, primary care, outcomes, health services, public health, epidemiology
- Limited “community participation in research” - research conducted in communities in partnership with researchers
- IOM Workshop is an opportunity to encourage engagement in HHC research
 - Research recommendations remain timely and important
 - Require interaction and collaboration among all relevant parties - expanded cadre
 - Includes data sharing and mining across investigators with multidisciplinary teams
- Reality: Challenging to program build during tight fiscal times
 - Rigorous scientific applications and low funding paylines
 - Yet, program is growing

IHC is Priority Research Area at NIDCD

- Senate Report Language for NIDCD FY2013 appropriations
“The Committee strongly urges NIDCD to support research grants that could lead to less expensive hearing aids, so such aids could become accessible and affordable to more people...”
- Strong support for HHC research from NIDCD leadership, staff, and Advisory Council
- Portfolio growth:

FY	Funded	
	Applications	Total
2011	4	\$739,000
2012	7	\$1,542,000
2013	15	\$4,378,000



Finally....

Thanks to IOM Planning Committee for including
the NIDCD Research Working Group

Acknowledge Drs. Dubno and Beck

QUESTIONS and COMMENTS