

**DRAFT OCTOBER 6, 2009**

**Summary Report from the NIDCD Working Group on  
Accessible and Affordable Hearing Health Care for Adults with  
Mild to Moderate Hearing Loss,  
August 25 - 27, 2009 Bethesda, Maryland**

The National Institute on Deafness and Other Communication Disorders/National Institutes of Health (NIDCD/NIH) sponsored a working group on *Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss* on August 25 -27, 2009. The working group was held in Bethesda, Maryland. The purpose of the working group was to develop a research agenda to increase accessibility and affordability of hearing health care for adults with mild to moderate hearing loss, including accessible and low cost hearing aids.

**Background:**

Hearing loss (HL) is a public health issue and is among the leading public health concerns. Approximately 17% of American adults, or 36 million people, report some degree of HL. Yet, fewer than 20% of those with HL who require intervention and treatment seek help for their condition. Untreated HL has social and economic ramifications. Most hearing aid users have lived with HL for over 10 years and their impairments have progressed to moderate-to-severe levels before seeking a hearing aid. For whatever the reason(s), the current hearing health care (HHC) system in the United States is not meeting the needs of the vast majority of adults with HL. As the lead Federal agency to promote the Nation's HHC, NIDCD has the responsibility, and is actively seeking, to address this problem from the public health perspective.

NIDCD Senate Report Language for FY2010 appropriations "recommends that the NIDCD support research to develop, improve and lower the cost of hearing aids...". Further, Healthy People 2020, a U.S. Department of Health and Human Services (HHS) activity that provides science-based, 10-year national objectives for promoting health and preventing disease, includes increasing the adoption rate of hearing aid usage as a HP2020 goal. NIDCD is committed to addressing these recommendations and goals through well-developed and targeted research initiatives.

**Hearing health care (HHC) access**

For the purposes of the working group, "access" includes hearing screening/assessment as well as acquiring an appropriate device and services for the individual's hearing loss and communication needs. HHC access can be confusing to the consumer, with ill-defined professional roles and competing financial interests among provider groups. Multiple entry points include family practitioners, audiologists, hearing aid specialists, otolaryngologists, and direct web access, as well as magazine, newspaper and television ads.

In the US (in contrast to many other nations) there are no readily accessible low cost hearing screening programs and access to low cost aids exists only on the web, or through newspaper or magazine ads, all of which can be "consumer beware". Hearing aids are necessary healthcare devices, and thus, there is a compelling need for better alternatives for accessing these. It is important to note that the availability of a product on the web, does not ensure its "accessible". In late 2007, for ages 65 and older, 63% of Americans and 84% of British do not use the Internet. Individuals of lower income have particularly low internet use.

**Hearing health care affordability**

The definition of "affordable" remains undetermined. There are likely different price points for different segments of the population. Limited data are available on the specific impact of cost on hearing aid penetration/adoption rates. Yet, cost is considered to be one of the primary reasons for non-adoption of hearing aids. From MarkeTrac VII Survey of "non-adopters", 76% mentioned finances as a barrier to adoption, 64% said they can not afford aids, and half indicated cost as a definite reason why they don't use hearing aids.

Average out-of-pocket cost of one hearing aid (including the device and professional services) is approximately \$1,800. This price includes free, direct mail and discounted aids (not through the Department of Veterans Affairs) meaning the actual cost is higher for most patients. Prices range from \$1,400 to \$5,000 apiece. Consumers often spend \$4000 to \$6000 for a pair of hearing aids. Hearing aid life span is 4-5 years. Batteries add additional costs. A hearing aid wearer, over his/her lifetime, may spend tens of thousands of dollars acquiring hearing aids. Beyond purchase of a home or car, hearing aids can be the 3rd most expensive purchase for many Americans with HL.

Medicare does not cover the cost of hearing aids. Most insurance programs do not cover hearing aids and of those that do, most pay only a portion of the costs. In addition, approximately 46 million Americans (15%) are uninsured. Many individuals who cannot afford hearing aids rely on Lions Clubs, hearing aid loaner banks, and various other philanthropic organizations. This is not an acceptable public health solution for a necessary health care device.

### **External Influences**

Beyond the public health urgency, four external factors influenced the compelling need and timing of the working group. These were changes in the demographics and socioeconomics of the US as well as new and emerging technologies and evolving service delivery paradigms.

#### ***Changing Demographics***

There is a strong relationship between age and reported HL: 18% of adults aged 45-64, 30% of adults aged 65-74, and 47% of adults 75 years or older report a HL. America is aging, and by 2026, 30% of the US population will be over 55 and 18% will be over 65. A concomitant increase in hearing aid candidates is expected. Many will have an initial hearing loss of mild to moderate level and will be active in the workforce.

#### ***Changing Socioeconomics***

The mission for both HHS and NIH includes closing the gaps in health disparities. NIH held an international Summit on Eliminating Health Disparities in December 2008. The Agency for Healthcare Research and Quality periodically issues a "National Healthcare Disparities Report"; the most recent version released in 2008.

It is a public health need and mandate to address health care disparities in underserved populations. 20% of Americans live in rural America; these individuals are more likely to be older, poor, in fair or poor health, and to have chronic conditions. Inner city individuals are also underserved. Many in America have limited disposable income. Median household income (2007 Census) is \$50,000. 35% of Americans have household income < \$35,000. The current unemployment rate is more than 9.0%. Socioeconomic disparities in health care likely also exist in HHC. The estimate of underserved for HHC could be higher than for health care in general because of the high cost of hearing aids and complex access to these devices. It is important to remain conscious of the underserved, economically disadvantaged and less advantaged. NIH/NIDCD research and the emergent solutions should address the needs of all Americans.

#### ***Changing Technologies***

Auditory assessment is being automated. Automated hearing tests (telephone/computer/web-based) including speech-in-noise are now a viable possibility and in some cases are already available as are hand-held pure-tone hearing screeners and screeners for middle ear conditions using otoacoustic emissions. Hearing aid component costs are minimal (<\$150) and evolving downward with technological and manufacturing advances. "System on a chip" technology (ASIC, Analog VLSI, DSP) offers new possibilities. Hearing aid fitting is being automated with fitting programs/algorithms routinely run on PCs. Open canal fittings offer less burdensome fitting possibilities. Research and development leading to a self-testing and self-fitting hearing aid is ongoing. Technological advances make it likely that audiometry, real-ear measurements, hearing aid programming and fitting can be packaged and performed on one chip.

#### ***Changing Service Delivery Paradigms***

Beyond the traditional audiology / hearing aid specialist / otolaryngology office offering hearing aids from various manufacturers, there are now store-front hearing aid sales (e.g.,

Cosco) as well as internet sales, including direct-to-patient as well as internet referral/consolidators. Telemedicine opportunities now exist for remote audiometric testing and hearing aid fitting and management. The unbundling of costs for hearing health care services is being actively discussed (currently products and services are combined for a single fee so the consumer is unaware of the cost for individual audiological services vs. the device). Professional workforce demographics are also changing. There is a shortage of primary care physicians and a shortage of audiologists to meet needs of all individuals with HL. Professional organizations are now discussing the training and certification of audiology assistants and technicians (not unlike OT/PT technicians) in an effort to maximize productivity of the most highly trained individuals. Convenient care clinics, providing convenient access to basic care for the most common acute conditions, are now a part of the healthcare access landscape and provide an example of new routes of access and service delivery paradigms.

### **Professional Issues**

Many interrelated issues, tensions and conflicts across provided groups have contributed to the current HHC situation. The willingness of manufacturers to produce lower cost hearing aids and the willingness of audiologists to sell low-cost aids in the traditional distribution system is debated within and among the professions. Direct access for patients has long been a tension among professional groups (otolaryngologists and audiologists), as have the differing educational qualifications and credentialing standards of hearing aid dispensers (audiologists and hearing specialists).

The value of current Food and Drug Administration (FDA) regulations requiring a medical evaluation has also been debated. Some support the current regulations, while others believe they add unnecessary burden and cost to the patient/consumer. Many of the medical clearances/evaluations that do occur are not full otologic evaluations and come instead from a primary care physician. Further, many patients sign a medical waiver.

### **Working group focus:**

The working group specifically focused on adults with mild to moderate hearing loss. This group is least likely to have had hearing screening/assessment and is least likely to be using an aid (due to one of many reasons including perceived benefit, cost, stigma, value, etc.). Yet, individuals with mild to moderate hearing loss can obtain benefit from amplification strategies. Research has demonstrated that psychosocial health declines with increasing hearing loss. Earlier hearing aid users may have better eventual outcomes with amplification, and plasticity effects may require less auditory retraining. It may be beneficial to initiate hearing health care, maintaining quality of life, before cognitive or other age-related health declines occur. In addition, many individuals with mild to moderate HL will progress to severe hearing loss (HL), requiring more complex professional services in later years.

The working group focus was not on identifying research needs related to the development of increasingly sophisticated or technologically complex hearing aids. In addition, the focus was neither on children nor on adults with severe hearing loss or complex or extensive hearing health care needs. NIDCD sought research needs that would complement and supplement, not replace, current paradigms and services. Ensuring quality was paramount in all considerations and deliberations. Research recommendations were designed to lead to outcomes increasing accessibility and affordability of hearing health care, ultimately leading to an increase in the number of hearing-impaired adults receiving quality hearing health care in the United States.

### **Participants:**

The workshop was co-chaired by Drs. Amy Donahue, NIDCD/NIH, Judy Dubno, Medical University of South Carolina and Lucille Beck, Department of Veterans Affairs. Twenty individuals, from US and international institutions, bringing varied expertise and experiences to the working group, were invited as participants. Two guest speakers from Food and Drug Administration also participated ([view roster link](#)).

Accessible and affordable hearing healthcare for adults with mild to moderate hearing loss is a pressing public health issue in the US. Working group participants were instructed that their role was to address this pressing public health issue and to consider the needs of all adult patients with mild to moderate HL, bringing their individual knowledge and experiences to this working group. Participants were charged not to represent the needs/agenda of the professional organizations, institutions or industries to which they belong. Professional issues of roles and “turf” in the HHC landscape, noted above in the background section, were to be put aside. This was a necessity if the working group was to make any traction in articulating opportunities, barriers and research needs for promoting accessible and affordable HHC for individuals with mild to moderate hearing loss.

Representatives from the American Academy of Audiology (AAA), American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS), American Speech-Language-Hearing Association (ASHA), Better Hearing Institute (BHI), Convenient Care Association (CCA), Hearing Loss Association of America (HLAA), and the Hearing Industries Association (HIA) were in attendance as observers. Invited government agencies included the Agency for Healthcare Research and Quality, the Maternal and Child Health Bureau and the Food and Drug Administration.

### **Agenda and Working Group Format:**

Briefly outlined below is the agenda and session content ([view the full agenda](#)). Working group participants were provided numerous articles and other related documents to read and review prior to the meeting.

The first evening began with introductory and keynote presentations. The background and purpose (see Background section above) and charge to the working group were presented from the public health perspective by Dr. Donahue. The specific charge was to develop a research agenda leading to increased accessibility and affordability of hearing health care for adults with mild to moderate hearing loss, including accessible and low-cost hearing aids. Participants were also charged to remember the broad public health mandate and to be interactive, transparent, and collaborative.

The session then proceeded with two keynote presentations on changes in healthcare and healthcare delivery and one presentation on hearing loss, hearing aids and quality of life. The second day consisted of presentations and discussion related to accessible and affordable hearing screening and hearing aids. Topics included hearing healthcare bottlenecks, telehealth opportunities, rehabilitation needs, US and international perspectives on hearing screening, affordable hearing aids, and hearing aid delivery systems, audiology workforce needs, and medical and regulatory considerations. The second day concluded with an active discussion session among working group participants. The third day began with additional group discussion with the aim of articulating future research directions.

Three break-out groups were then formed to develop research questions in three areas:

1. Access (at all stages of hearing health care)  
(Leader: Davis, including Herer, Krumm, Mann, Weinstein and Yueh)
2. Assessment (including screening)  
(Leader: Margolis, including Derebery, Dhar, Freeman and Peng)
3. Intervention (not limited only to hearing aids)  
(Leader: Dillon; including Dalzell, Humes, Killion, and Preves)

Following group discussion, the working group reconvened as a whole, and the leader of each group presented their recommendations/suggested actions, during which there was additional group discussion.

This Working Group was intended only as the first step to addressing this important public health problem. NIDCD staff will be thoughtfully considering these research recommendations. Future activities and initiatives seeking to address these research recommendations will be forth coming.

The workshop adjourned at 1:00 pm on August 27th.

**Research Recommendations:**

Drs. Donahue, Dubno and Beck subsequently compiled the recommendations for this report ([link to Research Recommendations](#)).

Recommendations were made in 10 areas: Access, Screening, Assessment, Innovative Hearing Aid Technology and Outcomes, Patient Variable and Outcomes, After-Care, Delivery Systems, Workforce and Training of Hearing Health Care Providers, Medical Evaluation/Regulatory Issues and Overarching Topics.

## **Research Recommendations**

### **Access**

- What are the most appropriate points of access to hearing health care and do these differ for different populations (self-referral, identification by screening program, direct access, referral to hearing health care professionals)?
- What are the unique needs and concerns of populations across the lifespan and among different cultures that impact access?
- What are the barriers for patients accessing the hearing health care system (e.g., personal attitudes, cost, subsidy available, complexity, market forces, location, referral network)?
- Who comprises the unserved and underserved populations?
- What are the effects of culture, socioeconomic status and healthcare insurance coverage on access to hearing health care?
- Can new technology be used to increase awareness of hearing, hearing loss and access to hearing health care for young and middle-aged adult patients?
- How can access to hearing health care be improved for the oldest old population?
- Does early access to hearing health care change outcomes later in life?
- Would information/education about hearing loss prevention early in life increase access to hearing health care later in life or change other outcomes?
- What are the benefits of hearing health care to general health, economic health, lifestyle, well being, and family?

### **Screening**

- Develop accessible hearing screening paradigms, considering both available technology and target populations.
- What variables influence and what factors promote access to hearing screening for different age and hearing loss groups?
- What is the effect of hearing screening on entry into the medical/hearing healthcare system, access to treatments (hearing aids, assistive listening devices, aural rehabilitation, medical/surgical management), and success of treatments?
- Which hearing screening method (face-to-face, telephone, internet, language-free, emerging technologies, questionnaire, audiometric, speech in noise) results in the highest rate of follow-up of individuals seeking interventions and for what populations?
- What are the barriers to hearing screening (cost, insurance policies, capitation, financial disincentives for referral) in various health care settings (primary care offices, geriatric centers, pharmacies, convenient care clinics)?
- Can screening programs be developed with micro-financial incentives?
- What methods and dynamics reduce losses to follow-up (increase accessibility, reduce cost, improve education, patients' perceived need)?
- Do special populations have unique screening requirements (co-morbid diseases/conditions, oldest old, cultural, language)?
- What factors will influence/increase patient awareness/demand of the need for hearing screening?
- What is the cost-benefit of hearing screening programs?

### **Assessment**

- Is an audiogram needed to fit a hearing aid? If so, does it matter how or by whom the audiometry is performed?
- Are there differences in accuracy and quality (i.e. test operating performance) between automatic and manual audiometry?

- Are there differences in accuracy and quality between audiometry conducted in various healthcare settings and using various modalities (face-to-face, language-free, internet, telephone)?
- What are the environmental requirements for valid hearing tests?
- What calibration systems are required for automatic audiometry, and for telephone and internet screening systems?
- How can we increase patient awareness or demand for the need for hearing assessment?
- What assessments (auditory, cognitive, psychosocial, other) are needed to fit a hearing aid (as evidenced by impact on outcome)?

### **Innovative Hearing Aid Technology and Outcomes**

- What variables (technology-centered and patient-centered) predict success with amplification?
- What are the technology- centered factors (cost and other) that determine the penetration and utilization rate of hearing aids and how do these vary among various age, cultural and socio-economic groups?
- What is the difference in outcomes between very low cost one-size-fits-all, low cost try-and-select, entry-level individually programmed, trainable, and full-feature high-cost devices for varying patient population groups and for individual patients?
- What is the effectiveness and patient satisfaction of entry-level (low cost) hearing aids and full-feature hearing aids?
- What characteristics should direct-to-consumer hearing aids have to provide benefit?
- Develop a self-testing, self-fitting hearing aid, considering technology and patient characteristics, selection, fitting and aftercare.
- Can currently available entry-level hearing aids be used to increase access and to reduce cost?
- What is the minimal technology that will achieve a user's success with hearing aids?
- Does trial and rejection of hearing aids cause subsequent delays in reconsidering amplification in the future?

### **Patient Variables and Outcomes**

- What are the patient-centered variables that contribute to the penetration rate of hearing aids? Are individual differences related to age and degree of hearing loss?
- How does an individual define hearing-aid value (performance/satisfaction/benefit related to cost)?
- What is the relationship between degree of hearing loss (and its associated audiometric configuration) and attitudes toward hearing health care, including hearing aids?
- What factors motivate individuals to seek hearing health care?
- What factors prevent individuals who are identified by others or self-identify for hearing difficulties from acquiring hearing aids (e.g., cost, attitudes)?
- What factors influence a patient's perceived need for hearing health care?
- What are the concerns of patients who have purchased hearing aids but are not using them?
- What variables reinforce and/or reduce the stigma associated with hearing loss and hearing aids?
- Does early intervention improve long-term outcomes (cognitive, psychosocial, economic, general health) and are individual differences related to age and degree of hearing loss?
- Develop and evaluate an expanded IOI-HA, so that higher sensitivity can be achieved with manageable subject numbers.
- Develop and evaluate a standard set of outcome measures to determine success of hearing health care

### **After-Care**

- What follow-up information and patient education components provide maximum benefit to patients with direct to consumer hearing aids?
- What aftercare is required for various service delivery models and what is the effect on hearing-aid success?
- What are the barriers to follow-up care for users of hearing aids?
- What are the characteristics of people who benefit from auditory training in various settings and what is the role of motivation?
- What is the impact of the hearing-aid orientation to long-term hearing-aid success?
- Do currently available rehabilitation methods (auditory training, LACE) improve long-term success with hearing aids?

### **Delivery Systems**

- How can current delivery systems (including the system and the provider) be utilized and/or modified to increase accessibility and affordability of hearing health care?
- What is the comparative effectiveness between two delivery schemes (current best practice vs. others), with technology held constant?
- What is the effect of patient-centered variables (age, cognitive ability, familiarity with technology) on willingness to access various delivery systems?
- What is the influence of service delivery model on willingness to seek help by patients who report communication difficulties, and on patient outcomes?
- What are the opportunities to use telehealth methodologies for hearing health care?
- What are the opportunities to use new health care delivery models and methodologies for hearing health care?
- What is the minimal hearing health care delivery system needed for successful outcomes?
- Is continuity of care an important variable for hearing health care?

### **Workforce and Training of Hearing Health Care Providers**

- What are the knowledge, skills, and abilities of hearing health care professionals (audiologists and audiology assistants) and other persons providing hearing health care (nurses, nurse practitioners, trained volunteers, caregivers, students, physician assistants)?
- How can caregivers and family members be educated and trained to address the needs of persons with hearing impairment?
- What are the training requirements for hearing health care service delivery in non-traditional settings (i.e., convenient care clinics, pharmacies)?
- What is the capacity and need for hearing screening and assessment services?

### **Medical Evaluation/Regulatory Issues**

- Does the requirement for medical evaluation and clearance prior to hearing aid procurement provide significant protection to patients?
- Does the requirement for medical evaluation and clearance provide a significant barrier to access?
- What percentage of hearing aid recipients opts for the medical waiver?
- What is the patient's understanding of the medical evaluation/clearance and waiver?
- Can different regulatory approaches impact access without compromising hearing health care?
- What decision-making algorithms for "red flag" conditions (requiring medical consultation) are appropriate for different service delivery models (face-to-face, internet, telephone)?
- What is the prevalence of medically/surgically treatable causes of hearing loss in adults with mild to moderate hearing loss and in the subpopulation of adults seeking hearing aids?

- What evidence is available that consumers are unable to identify treatable causes of hearing loss?

### **Overarching Topics**

- Develop research infrastructure supporting research on hearing health care accessibility and affordability (databases, practice networks, multidisciplinary teams).