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# Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss

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The National Institute on Deafness and Other Communication Disorders/National Institutes of Health (NIDCD/NIH) sponsored a research working group on Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss on August 25 - 27, 2009 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. For the purposes of the working group, mild HL was defined as 26-40 dB HL averaged across 0.5 - 4.0 kHz, and moderate HL was defined as 41-60 dB HL averaged across 0.5 - 4.0 kHz.

Why is this working group important at this time? 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<sup>1</sup>. HL is the third most prevalent chronic health condition facing seniors<sup>2</sup>. Yet, fewer than 20% of those with HL who require intervention and treatment seek help for their condition<sup>3</sup>. 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<sup>4</sup>. For many reasons, 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,

Final note from the authors

This working group was intended only as a first step to addressing this important public health problem. We would like to thank *Ear and Hearing* for the opportunity to share the working group purpose and outcome with their readership and encourage *Ear and Hearing* readers and others in the hearing health care communities to partner in future NIDCD research initiatives seeking to increase accessible and affordable hearing health care for adults with mild to moderate hearing loss.

Editor's Note: The guest editorial below is reprinted with permission and some modification from the NIDCD website http://www.nidcd.nih.gov/funding/programs/09HHC/summary.htm. Modifications were made to reduce length and to highlight areas of interest to the readership of Ear and Hearing.

The guest ediorial reflects the thoughtful consideration of a multidisciplinary group (audiologists, otolaryngologists, academics, private practitioners, hearing industry professionals, health services researchers, to name just a few) much like the multidisciplinary membership of the American Auditory Society - Ear and Hearing's parent organization. It reflects important new information that will promote research and attention toward a long-term problem - namely providing effective and low-cost amplification that is readily accessible to Americans. The readership of Ear and Hearing, the field at large, and the hearing-impaired population will benefit from knowledge of this information. Ear and Hearing is pleased to be able to share it with our readers.

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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..."<sup>5</sup>. 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 Healthy People 2020 goal<sup>6</sup>. NIDCD is committed to addressing these recommendations and goals through well-developed and targeted research initiatives.

# Hearing health care access

For the purposes of the working group, "hearing health care" includes assessment and access to hearing aids and non-medical treatment. "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 access. It is important to note that the availability of a product on the web does not ensure it is "accessible". In late 2007, for individuals 65 and older, 63% of Americans<sup>7</sup> and in 2009, 65% of British<sup>8</sup> citizens did <u>not</u> 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 scientific 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. According to the MarkeTrak VII Survey of "non-adopters", 76% mentioned finances as a barrier to adoption, 64% said they cannot afford aids, and half indicated cost as a definite reason why they don't use hearing aids<sup>9</sup>.

In 2004, the average cost of one hearing aid (including the device and professional services) was approximately \$1,800 and 70 percent of individuals with hearing loss require two devices<sup>10</sup>. MarkeTrak VIII lists the 2008 average out of pocket expense for one hearing aid at \$1,600. However, this average price was computed with the inclusion of free, direct mail and discounted aids (but not including those available through the Department of Veterans Affairs) <sup>11</sup> meaning the actual cost is higher for most patients. A recent industry survey found a price range per aid between \$1,182 and \$2,876<sup>12</sup>. A recent consumer survey shows consumers spending \$1,800 to \$6,800 for a pair of hearing aids<sup>13</sup>. While the life span of a hearing aid depends on many factors, in general, hearing instruments have an average life of four to six years<sup>14</sup>. Batteries add additional costs. A hearing aid wearer, over the wearer's lifetime, may spend tens of thousands of dollars acquiring and maintaining hearing aids. Given these factors, hearing aids can be among the most expensive items purchased by many Americans with HL, after their home or car.

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. Since government programs providing hearing aids for adults exist only for the most severely impaired, 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.

Health care reform is a government priority, with wide-ranging discussions surrounding healthcare costs, burden and treatment effectiveness. The 2009 Institute of Medicine report on Comparative Effectiveness Research lists HL in the top quartile of priority topics noting it is important to "Compare the effectiveness of different treatments... for hearing loss in children and adults, especially individuals with diverse cultural, language, medical and developmental backgrounds."<sup>15</sup> This report not only supports the importance of this issue from the public health perspective but also highlights the need for contemporary data to drive current clinical practice. It is appropriate to question the assumption that the best HHC is synonymous with the most advanced technology, especially for adults with mild to moderate HL. This assumption makes HHC even less accessible for those who can least afford it.

# External factors influencing accessibility and affordability

Beyond the public health urgency, four external factors influenced the timeliness of, and need for, the working group discussion. These factors included 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<sup>16</sup>. America is aging, and by 2026, 30% of the US population will be over 55 and 18% will be over  $65^{17}$ . 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<sup>18</sup>.

#### **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<sup>19</sup>. 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<sup>20</sup>. Many in America have limited disposable income. Median household income (2007 Census) is \$50,000 and 35% of Americans have household income less than \$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. Acquiring appropriate HHC may be especially challenging for the "working poor". 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<sup>21</sup>. Automated hearing tests (telephone/computer/webbased) including speech-in-noise testing are now a viable possibility<sup>22</sup> and in some cases are already available as are hand-held pure-tone hearing screeners and screeners for middle ear and cochlear conditions using tympanometry and otoacoustic emissions<sup>23</sup>. Hearing aid component costs (microphone and other elements) are estimated to be less than \$100 and evolving downward with technological and manufacturing advances<sup>24</sup>. "System on a chip" technology (e.g., 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 trainable and self-testing and self-fitting hearing aid is ongoing<sup>25</sup>. 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., Costco) 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<sup>26</sup>. The unbundling of costs for hearing health care services is being actively discussed (currently products and services are often combined for a single fee so the consumer is unaware of the cost for audiological services and the device). Professional workforce demographics are also changing. There is a shortage of primary care physicians. Further, if all individuals with HL sought HHC, there would be a shortage of audiologists to meet that need<sup>27</sup>. Professional organizations are now discussing the training and certification of audiology assistants and technicians (not unlike existing assistants in occupational therapy, physical therapy and optometry) in an effort to maximize productivity of the most highly trained individuals. Convenient care clinics, providing convenient access landscape and provide an example of new routes of access and service delivery paradigms<sup>28</sup>.

# Professional issues influencing accessibility and affordability

Many interrelated issues, tensions and conflicts across provider 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 those who dispense hearing aids (audiologists and hearing specialists).

The value of current federal 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. The regulation (21 CFR 801.420) specifies that prospective hearing aid users should have a medical evaluation by a licensed physician, preferably an otolaryngologist, otologist or otorhinolaryngologist. However, many of the medical clearances/evaluations that do occur are not full otologic evaluations and are conducted instead by primary care physicians. Further, many patients sign a medical waiver, essentially circumventing the medical evaluation, but exact numbers are unknown.

# Purpose of the working group

The purpose of the working group was to determine and prioritize research needs with the goal of increased accessibility and affordability of hearing health care for adults with mild to moderate hearing loss, including accessible and low-cost hearing aids. The working group specifically focused on adults with mild to moderate hearing loss because this group is least likely to have had hearing screening/assessment and is least likely to be using hearing aids (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<sup>29</sup>. 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 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.

Twenty individuals, from US and international institutions, bringing varied expertise and experiences to the working group, were invited as participants. Two guest speakers from the US Food and Drug Administration also participated. 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 these issues. Participants were charged <u>not</u> to represent the needs/agenda of the professional organizations, institutions or industries to which they belonged. Professional issues of roles and "turf" in the HHC landscape, noted above, 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 adults 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 US government agencies included the Agency for Healthcare Research and Quality, the Maternal and Child Health Bureau and the Food and Drug Administration.

The working group included keynote presentations on changes in healthcare and healthcare delivery, as well as hearing loss, hearing aids and quality of life. Additional presentations were related to accessible and affordable hearing screening, assessment 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. Breakout groups were formed and research recommendations were developed, after which there was additional group discussion.

# **Research Recommendations**

Research recommendations were made in 10 areas: Access, Screening, Assessment, Innovative Hearing Aid Technology and Outcomes, Patient Variables and Outcomes, After-Care, Delivery Systems, Workforce and Training of Hearing Health Care Providers, Medical Evaluation/ Regulatory Issues and Overarching Topics. Numerous research recommendations were made and are available, along with the agenda, roster and working group Summary Report, at

(http://www.nidcd.nih.gov/funding/programs/09HHC/summary.htm). Following the working group meeting, members were asked to select recommendations considered of highest priority, in terms of both importance and immediate feasibility. The selected recommendations, which varied considerably among working group members, are listed below, not in priority order.

- 1. What are the barriers for patients accessing the hearing health care system (e.g., availability of services, cost, subsidy available, complexity, market forces, location, referral network, healthcare insurance coverage)?
- 2. What are the patient centered factors that impact access to hearing health care, including the unique needs and concerns across the lifespan and among different cultures or special populations (e.g., perceived need, personal attitudes, stigma, socioeconomic status)?
- **3.** What are the benefits of hearing health care to general health, economic health, lifestyle, well being, and family?
- 4. Develop accessible hearing screening paradigms for adults with mild to moderate hearing loss, considering both available technology and target populations.
- **5.** Which hearing screening method (face-to-face, telephone, internet, language-free, emerging technologies, questionnaire, audiometric, speech in noise) has the best sensitivity and specificity and also results in the highest rate of follow-up of individuals seeking interventions and for what populations?
- **6.** What are the barriers to hearing screening (availability, cost, insurance policies, capitation, and financial disincentives for referral) in various health care settings (primary care offices, geriatric centers, pharmacies, convenient care clinics)?
- 7. Are there differences in accuracy and quality between audiometry conducted in various healthcare settings and using various means of delivery (face-to-face, language-free, internet, telephone)?
- **8.** What assessments (e.g., auditory, cognitive, psychosocial, other) are needed to fit a hearing aid or guide other forms of intervention (as evidenced by impact on outcome)?
- **9.** What variables (technology-centered and patient-centered) predict success with amplification?
- **10.** What is the difference in outcomes among very low cost one-size-fits-all, low cost try-and-select, individually programmed, trainable, and full-feature high-cost devices for varying patient population groups and for individual patients?
- **11.** Develop a self-testing, self-fitting hearing aid, considering technology and patient characteristics, selection, fitting and aftercare.
- 12. What is the minimal technology that will achieve success with hearing aids?
- **13.** What factors influence a patient's perceived need for hearing health care and motivate individuals to seek hearing health care?
- **14.** What follow-up information and patient education components provide maximum benefit to patients with direct to consumer hearing aids?
- **15.** What are the opportunities to use new health care delivery models and methodologies, including telehealth, for hearing health care?
- **16.** What are the training requirements, 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,

- **17.** What is the appropriate medical evaluation to rule out contra-indications for using a hearing aid?
- **18.** Do the existing FDA requirements for medical evaluation and clearance prior to hearing aid procurement provide significant protection to patients or create a significant barrier to access?
- **19.** What percentage of hearing aid recipients opts for the medical waiver, and of these, what percentage is subsequently diagnosed with medically treatable hearing loss?
- **20.** 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 those adults seeking hearing aids?
- **21.** Develop and evaluate a standard set of outcome measures to determine success of hearing health care and provide guidelines on how and when outcomes should be measured.
- **22.** Develop research infrastructure supporting research on hearing health care accessibility and affordability (databases, practice networks, multidisciplinary teams).

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