

RECOMMENDATIONS

Health and Medicine Division

JUNE 2016 • HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY

The National Academies of Sciences, Engineering, and Medicine convened an expert committee to study the affordability and accessibility of hearing health care for adults in the United States. The resulting report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, recommends key institutional, technological, and regulatory changes that would enable consumers to find and fully use the appropriate, affordable, and high-quality services, technologies, and support they need. The committee's recommendations are provided in full below.

Improve Population-Based Information on Hearing Loss and Hearing Health Care

RECOMMENDATION 1

The National Institutes of Health, the Centers for Disease Control and Prevention, the Patient-Centered Outcomes Research Institute, the Department of Defense, the Department of Veterans Affairs, state public health agencies, and other relevant government agencies, as well as nonprofit organizations, hearing health care professional associations, academic institutions, and researchers, should strengthen efforts to collect, analyze, and disseminate prospective population-based data on hearing loss in adults and the effects of hearing loss and its treatment on patient outcomes. Specifically,

- Support and conduct studies to develop, evaluate, strengthen, and align metrics for hearing loss and communication abilities;
- Support and conduct studies, including longitudinal studies, in diverse populations to better understand:
 - the risk and natural history of hearing loss;
 - risk factors and co-morbidities of hearing loss;
 - hearing health care needs; and
 - the impact of hearing loss and its treatment on health, function, economic productivity, and quality of life; and
- Develop and strengthen research training programs to address hearing loss as a public health concern with attention to cross-disciplinary training on sensory disorders, epidemiological methods, advanced biostatistics, and health services and health economics research methods.

Develop and Promote Measures to Assess and Improve Quality of Hearing Health Care Services

RECOMMENDATION 2

The Centers for Medicare & Medicaid Services, the National Institutes of Health, the Department of Defense, the Department of Veterans Affairs, other relevant federal agencies, hearing health care professional associations and providers, advocacy organizations, health care quality improvement organizations, health insurance companies, and health systems should collaborate to:

- Align and promote best practices and core competencies across the continuum of hearing health care, and implement mechanisms to ensure widespread adherence; and
- Research, develop, and implement a set of quality metrics and measures to evaluate hearing health care services with the end goal of improving hearing- and communication-focused patient outcomes.

Remove the Food and Drug Administration's Regulation for Medical Evaluation or Waiver

RECOMMENDATION 3

The Food and Drug Administration should remove the regulation that an adult seeking hearing aids be required to first have a medical evaluation or sign a waiver of that evaluation and should ensure consumers receive information about the medical

conditions that could cause hearing loss through continued inclusion of that information in hearing aid user instructional brochures.

Empower Consumers and Patients in Their Use of Hearing Health Care

RECOMMENDATION 4

Hearing health care professionals, professional associations, advocacy organizations, and relevant governmental agencies such as the Office for Civil Rights at the U.S. Department of Health and Human Services should ensure patients are aware of, and

understand how to exercise, their rights of access to information about themselves under the Health Insurance Portability and Accountability Act Privacy Rule (45 C.F.R. Section 164.524), including their audiograms and hearing aid programming history.

NOTE: All recommendations are of equal importance and are not prioritized.

Improve Access to Hearing Health Care for Underserved and Vulnerable Populations

RECOMMENDATION 5

The Health Resources & Services Administration, state health departments, advocacy organizations, and hearing health care professional schools and associations should:

- Collaborate and partner with health care providers to ensure hearing health care accessibility throughout rural and underserved areas using mechanisms such as telehealth, outreach clinics (including federally qualified community health centers), and community health workers;

- Support and promote programs, including incentives such as tuition assistance, to increase diversity in all sectors of the hearing health care workforce; and
- Promote the training of cultural competency in the hearing health care workforce and incentivize practice in underserved communities.

Promote Hearing Health Care in Wellness and Medical Visits

RECOMMENDATION 6

Public health agencies (including the Centers for Disease Control and Prevention and state health departments), health care systems (including those of the Department of Defense and the Department of Veterans Affairs), health care professional schools and associations, advocacy organizations, health care providers, and individuals and their families should promote hearing health in regular medical and wellness visits (including the Medicare Annual Wellness Visit). Specifically,

- Use patient visits to assess and discuss potential hearing difficulties that could affect doctor–patient communication and overall patient well-being, to encourage individuals and their family members and caregivers to discuss hearing concerns, to raise awareness among older adults about age-related hearing loss, and to encourage referral when appropriate; and
- Develop and disseminate core competencies, curricula, and continuing education opportunities focused on hearing health care, particularly for primary care providers.

Implement a New Food and Drug Administration Device Category for Over-The-Counter Wearable Hearing Devices

RECOMMENDATION 7

The Food and Drug Administration (FDA) should establish a new category of over-the-counter (OTC) wearable hearing devices. This device classification would be separate from “hearing aids.” OTC wearable hearing devices would be defined as wearable, over-the-counter devices that can assist adults with mild to moderate hearing loss. These devices would:

- Explicitly be defined by the FDA as intended for over-the-counter sale;
- Be able to be marketed as devices that may assist with hearing loss and be sold over the counter, by mail, or online; and would include mobile apps and associated wearable technologies intended to function as an OTC wearable hearing device for mild to moderate hearing loss;
- Be subject to regulatory requirements that would explicitly preempt current state laws and regulations for hearing aids and dispensing and preempt potential future state laws and regulations seeking to limit over-the-counter access;
- Be exempt from 510(k) premarket review to the extent that the technology is not fundamentally different from air conduction hearing aids;
- Include thorough consumer labeling, including information on:
 - frequency gain characteristics
 - adequate directions for use
 - communication challenges for which it may be helpful to seek professional consultation
 - medical situations, symptoms, or signs for which to consult with a physician
- Meet minimum safety requirements and standards, including but not limited to:
 - safe maximal sound output (e.g., upper limit for dB SPL [decibel of sound pressure level] peak output) at levels to be determined in conjunction with national experts in hearing conservation

- criteria for eartips (e.g., maximum depth for insertion into the ear canal)
- amplification via air conduction only. Wireless technology for programming and connectivity should be permitted
- American National Standards Institute or other voluntary standards for audio characteristics and performance as determined by FDA, as appropriate for this category
- Be subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category; and
- Have the option to include accessory tests for self-assessment of mild to moderate hearing loss for purposes of selecting and fitting an OTC hearing device.

To further clarify the types of hearing technologies and their oversight and regulation:

- FDA should retain a guidance document on personal sound amplification products (PSAPs) that describes PSAPs as products that are not to be offered or promoted to address hearing loss and are subject to the electronic product provisions of the Federal Food, Drug, and Cosmetic Act through its 2009 PSAP guidance document or a revision of its 2013 PSAP draft guidance document. The PSAP guidance document would establish the distinction between PSAPs for normal hearing and the OTC wearable hearing device category for hearing loss.
- The Consumer Product Safety Commission and the Federal Trade Commission should exercise their respective authorities in the regulation of consumer products marketed as PSAPs.

Improve the Compatibility and Interoperability of Hearing Technologies with Communications Systems and the Transparency of Hearing Aid Programming

RECOMMENDATION 8

The Federal Communications Commission, Federal Trade Commission, Food and Drug Administration, National Institutes of Health, and other relevant federal agencies; the American National Standards Institute and other standards-setting organizations; manufacturers; and industry, professional, and consumer advocacy organizations should:

- Develop standards that ensure that hearing aids and OTC wearable hearing devices are compatible and interoperable with other technologies and communications systems;
- Increase public awareness and consumer-friendly information on the availability, connectivity, and use of hearing aids and hearing assistive technologies; and
- Develop and implement standards for an open platform approach for hearing aid programming that allows any hearing health care professional (or, as evolving technology allows, the device owner) to program the device settings, and require point-of-sale information about the programming features and programming portability of hearing aids in order to enable more informed purchasing decisions.

Improve Affordability of Hearing Health Care

RECOMMENDATION 9

The Centers for Medicare & Medicaid Services (CMS), other relevant federal agencies, state Medicaid agencies, health insurance companies, employers, hearing health care providers, and vocational rehabilitation service agencies should improve hearing health care affordability for consumers by taking the following actions:

- Hearing health care professionals should improve transparency in their fee structure by clearly itemizing the prices of technologies and related professional services to enable consumers to make more informed decisions;
- CMS should evaluate options, including possible statutory or regulatory changes, in order to provide coverage so that treating hearing loss (e.g., assessment, services, and technologies, including hearing aids) is affordable for Medicare beneficiaries;
- CMS should examine pathways for enhancing access to assessment for and delivery of auditory rehabilitation services for Medicare beneficiaries, including reimbursement to audiologists for these services;
- State Medicaid agencies should evaluate options for providing coverage for treating hearing loss (e.g., assessment, services, and hearing aids and hearing assistive technologies as needed) for adult beneficiaries;
- Vocational rehabilitation agencies should raise public awareness about their services that enable adults to participate in the workforce, and they should collaborate with other programs in their respective state to raise this awareness;
- Hearing health care professionals and professional associations should increase their awareness and understanding of vocational rehabilitation programs and refer as appropriate; and
- Employers, private health insurance plans, and Medicare Advantage plans should evaluate options for providing their beneficiaries with affordable hearing health care insurance coverage.

Evaluate and Implement Innovative Models of Hearing Health Care to Improve Access, Quality, and Affordability

RECOMMENDATION 10

The Centers for Medicare & Medicaid Services, the Patient-Centered Outcomes Research Institute, the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources & Services Administration, the Department of Defense, the Department of Veterans Affairs, researchers, and health care systems should prioritize and fund demonstration projects and studies, including randomized controlled trials, to improve the evidence base for current and innovative payment and delivery models for treating hearing loss. Specifically,

- Innovative models to be evaluated should include, but not be limited to, community health workers, telehealth, mobile health, retail clinics, and self-administered hearing health care. These projects and studies should include outcomes that are patient-centered and assess value, comparative effectiveness, and cost effectiveness.
- Demonstration projects should evaluate the health impact of beneficiary direct access to audiologist-based hearing-related diagnostic services, specifically to clarify impact on hearing health care accessibility, safety, and the effectiveness of the medical home. This excludes direct access to audiologic testing for assessment of vestibular and balance disorders and dizziness, which require physician referral. Successful outcomes would provide evidence of effective communication and coordination of care with primary care providers within a model of integrated health care, and evidence of appropriate identification and referral for evaluation of medical conditions related to hearing loss and otologic disease.
- Models that are found to be most effective should be widely implemented.

Improve Publicly Available Information on Hearing Health

RECOMMENDATION 11

The National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Department of Defense, the Department of Veterans Affairs, the Administration for Community Living, state public health agencies, other relevant government agencies, advocacy organizations, hearing health care professional associations, hearing technology manufacturers, hearing health care professionals, and media organizations should improve public information on hearing health and hearing-related technologies and services and promote public awareness about hearing and hearing health care. Specifically,

- Strengthen publicly available, evidence-based information on hearing through multiple avenues (e.g., centralized websites, community-based services, local councils on aging) that explain hearing and related health concerns for adults of all health literacy levels, and address the breadth of services and technologies, including their comparative effectiveness and costs;

- Work through media, social marketing, and public education campaigns to disseminate and evaluate key evidence-based messages about hearing and hearing health and to promote accuracy in media portrayals;
- Implement and support a consumer-based metric to enable individuals to understand and track their communication abilities and hearing needs and a consumer-oriented format for audiogram and other hearing test results;
- Adopt standardized terminology across manufacturers about the features and capabilities of hearing aids and hearing assistive technologies so that consumers and hearing health care professionals can make easy, clear, unambiguous comparisons; and
- Develop and disseminate criteria that individuals and families can use to evaluate and compare hearing-related products and services.

Promote Individual, Employer, Private Sector, and Community-Based Actions to Support and Manage Hearing Health and Effective Communication

RECOMMENDATION 12

Individuals, families, community-based organizations, advocacy organizations, employers, private-sector businesses, and government agencies (local, state, federal) should take actions to support and manage hearing health and foster environments that maximize hearing and communication for all individuals.

- Individuals and their family members can
 - Reduce exposure to noise that is at high volume levels for extended periods of time and use hearing protection as appropriate,
 - Be aware of and recognize difficulties in hearing and communication and seek information and care through the range of available services and technologies when appropriate, and
 - Seek out peer-support groups and other opportunities for those living with hearing loss, when appropriate.
- Community-based organizations, advocacy organizations,

employers, private sector businesses, and government agencies (local, state, federal) should promote work and community environments that are conducive to effective communication and that support individuals with hearing loss. Specifically, they should:

- Ensure compliance with the Americans with Disabilities Act and other related laws supporting people with disabilities and strive to exceed their minimum requirements;
- Research and incorporate features into buildings and public spaces that improve hearing and communication (e.g., universal design, hearing assistive technologies).

Study Sponsors

Centers for Disease Control and Prevention
Department of Defense
Department of Veterans Affairs
Food and Drug Administration

Hearing Loss Association of America
National Institute on Aging
National Institute on Deafness and Other Communication Disorders

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