Hearing Health Care for Adults: Priorities for Improving Access and Affordability





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Committee on Accessible and Affordable Hearing Health Care for Adults

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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

Abbreviated Statement of Task

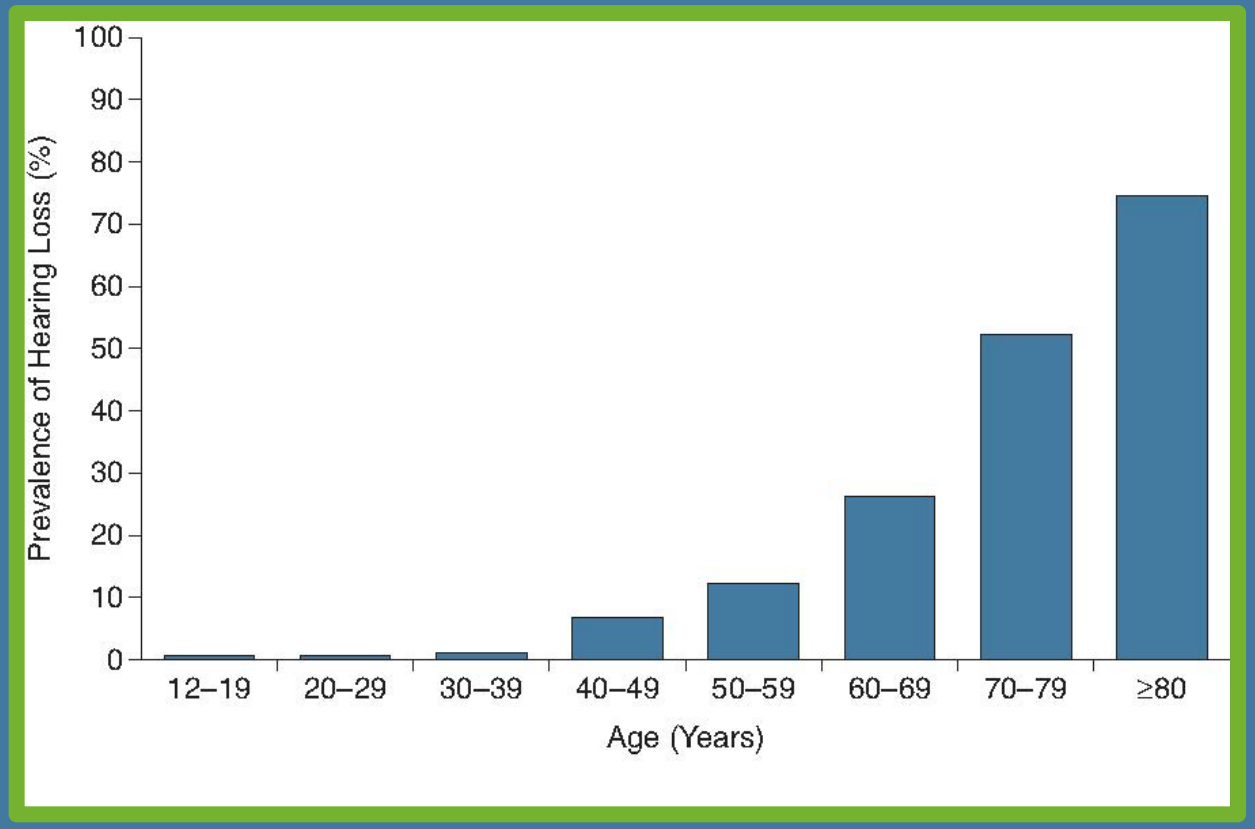
An ad hoc committee will address how to improve accessibility to and affordability of hearing health care for adults, excluding surgical devices and related services and pharmacological therapies. Specifically, the committee will:

- Provide a contextual background addressing the importance of hearing to individual and societal health, productivity and engagement.
- Address federal regulations for hearing aid dispensing.
- Address hearing health care access and affordability
- 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.

Overview of Hearing Loss

- Hearing loss can be mild or severe, present since birth or begin later in life, occur gradually or suddenly, result from a health condition or accompany aging; one or both ears can be affected. Most hearing loss in adults is permanent or slowly progressive.
- Hearing loss has been associated with serious health comorbidities such as depression, anxiety, low self-esteem and insecurity, social isolation, stress, mental fatigue, cognitive decline and dementia, reduced mobility, and falls. Both the severity of hearing loss and the impact hearing loss has on individuals' lives vary. More research is needed to better understand the impacts.
- It has been estimated that **30 million people (12.7 percent of Americans ages 12 years or older) in the U.S. have hearing loss.**
- **The unmet need for hearing health care is high.** Estimates of hearing aid use are that 67 to 86 percent of adults (50 years and older) who might benefit from hearing aids do not use them.

Prevalence of hearing loss in the United States by age, 2001-2008

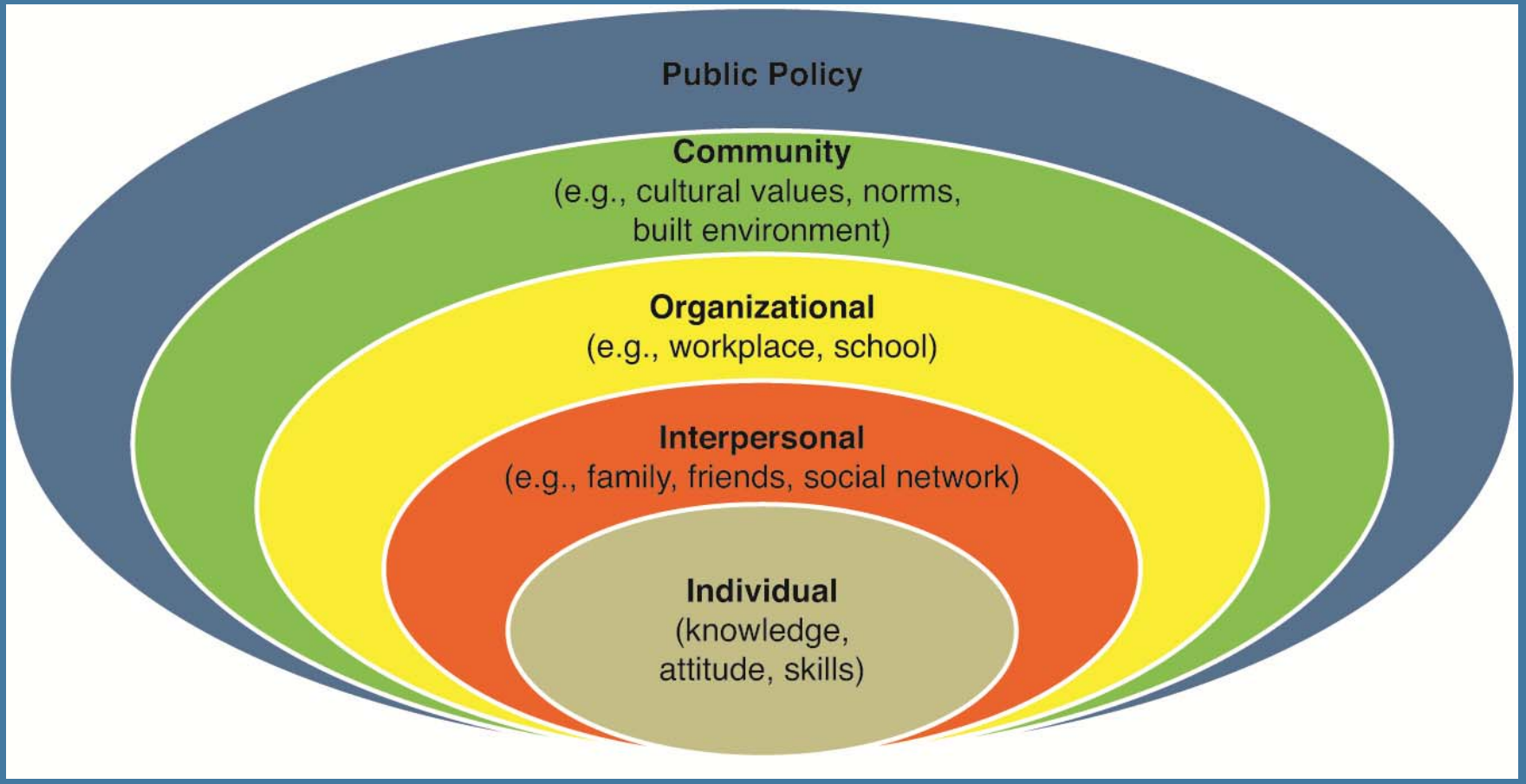


Source: Yamasoba, T., F. R. Lin, S. Someya, A. Kashio, T. Sakamoto, and K. Kondo. 2013. Current concepts in age-related hearing loss: Epidemiology and mechanistic pathways. *Hearing Research* 303:30-38.

Why Focus on Hearing Health Care Now?

- *Changing Demographics: Intersection of Hearing Loss and Aging*
- *Recognizing Hearing Loss as a Public Health Priority and a Societal Responsibility*
- *Rapidly Changing Technologies*
- *Changes in Health Care Paradigms*

Social-Ecological Model



SOURCE: NIH (National Institutes of Health). 2016. Social and behavioral theories: Social ecological model adapted from U. Bronfenbrenner, 1977.

Guiding Principles Developed by the Committee

- *Prioritize the needs of individuals with hearing loss*
- *Emphasize hearing as a public health concern with societal responsibilities and effects*
- *Move toward equity and transparency*
- *Recognize that hearing loss may require a range of solutions*
- *Improve outcomes with a focus on value, quality, and safety*
- *Work toward an integrated approach that provides options*

Definitions

- **Hearing loss** - The committee chose to primarily use the term "hearing loss," rather than "hearing impaired" or "hard of hearing," while acknowledging that some people who use hearing aids or other non-surgical services and technologies have had hearing difficulties since birth. The report addresses issues of importance to individuals with deafness and to the Deaf community; however, deafness is not the focus of this report.

- **Roles** - A person with hearing loss may at various times be a ***patient*** seeking care and treatment options, a ***consumer*** making purchasing decisions, or an ***individual*** participating in his or her community and seeking the best ways to meet his or her communication needs. The committee uses the terms interchangeably to some extent, while trying to use the terms as appropriately as possible in a given context.

- **Hearing health care professionals** - For the purposes of this report the term "hearing health care professionals" is used broadly to encompass those who work in hearing health care (including audiologists, hearing instrument specialists, and otolaryngologists). The term is used throughout the report primarily for ease—that is, one collective term, rather than listing each group repeatedly throughout the report.

Findings

- Hearing can be vital to communications, health, function, and quality of life. Individuals need to be alert to their hearing health, as hearing loss can range from mild to profound and tends to increase with age, onset can be gradual, and each individual's hearing needs are unique.
- Hearing health care involves a wide range of services and technologies with ever-expanding and evolving options, however, many people do not have access to these options or cannot afford them.
- Hearing loss is a public health and societal concern; engagement and action are needed across the spectrum of relevant stakeholders, including individuals and families, professionals, nonprofit organizations, industries, government, and the health care community.

Overview of Recommended Actions

Expand data on hearing loss

1. Improve population-based information on hearing loss and hearing health care

Improve access and quality of hearing health care services

2. Develop and promote measures to assess and improve quality of services
3. Remove FDA regulation for medical evaluation or waiver of that evaluation
4. Empower consumers and patients in their use of hearing health care
5. Improve access for underserved and vulnerable populations
6. Promote hearing health care in wellness and medical visits

Expand options for hearing technologies

7. Implement a new FDA device category for over-the-counter wearable hearing devices
8. Improve the compatibility and interoperability of hearing technologies

Improve affordability of services and technologies

9. Improve affordability by actions across federal, state, and private sectors
10. Evaluate and implement innovative models of hearing health care

Engage the wider community

11. Improve publicly available information on hearing health
12. Promote individual, employer, private sector, and community-based actions

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Goal 1*: Improve Population-Based Information*

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.

Specific actions detailed in bullet points that follow the recommendation.

Goal 2: *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.**

Goal 3: *Remove FDA Regulation for Medical Evaluation or Waiver to Purchase a Hearing Aid*

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.

Goal 4: *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 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.

Goal 5: *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.**

Goal 6: *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.

Goal 7: *Implement a New FDA Device Category for Over-the-Counter Wearable Hearing Devices*

Recommendation 7: The Food and Drug Administration 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, OTC devices that can assist adults with mild to moderate hearing loss.

Specific actions detailed in bullet points that follow the recommendation.

Goal 8: *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 over-the-counter (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.**

Expanding the Types of Hearing-Related Technologies and Interoperability Between Communications Systems

Medical devices for hearing loss
- Hearing aids
- Over-the-counter wearable hearing devices (proposed)

Consumer electronics not intended for hearing loss
- Personal sound amplification products

Hearing assistive products and technologies
- FM receiver systems
- Infrared receiver systems
- Hearing induction loop technologies
- Other assistive technologies

Communications technologies
- Captioning
- Interoperability technologies
- Emergency information technologies

Goal 9: *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;** ***(Cont'd.)***

Goal 9: *Improve Affordability of Hearing Health Care (cont'd.)*

- **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.**

Goal 10: *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.

Specific actions detailed in bullet points that follow the recommendation.

Goal 11: *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.

Specific actions detailed in bullet points that follow the recommendation.

Goal 12: *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.

Specific actions detailed in bullet points that follow the recommendation.

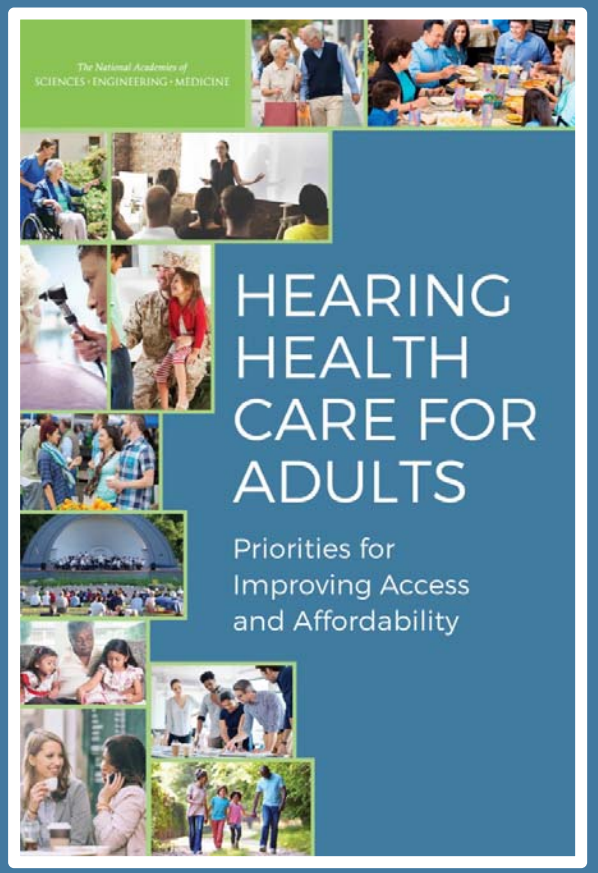
Thank you!

Free PDF of the report:

- www.nas.edu/hearing

Additional materials (also online):

- 4-page report brief
- Action guides
- Recommendations summary



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Extra Slides

Study Timeline

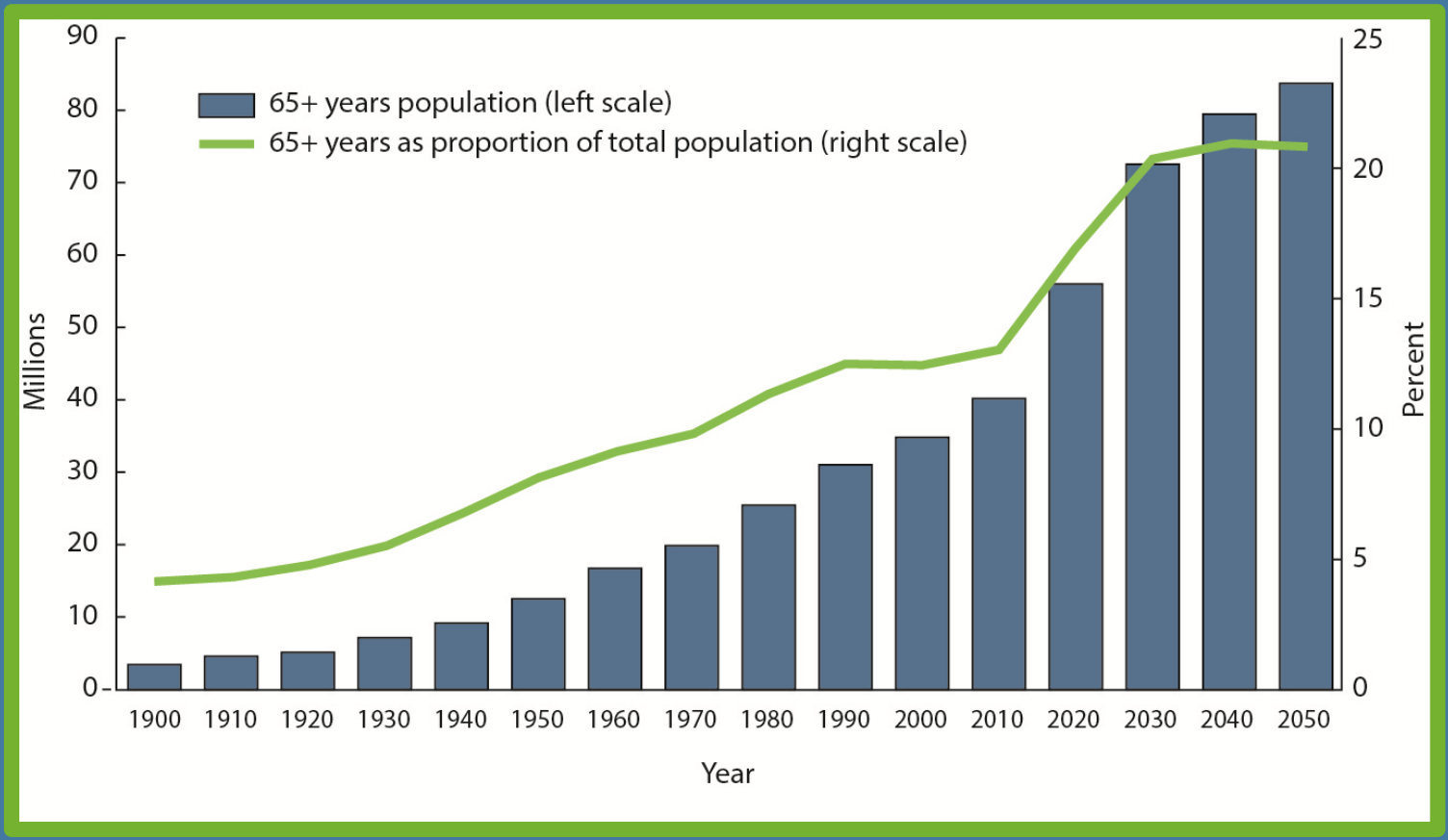
2015

April – First committee meeting
June – Second committee meeting and workshop
September – Third committee meeting and workshop
November – Fourth committee meeting

2016

January – Fifth committee meeting
February – Sixth committee meeting
March/April/May – Report review and response
June – Release to public
June and on – Report dissemination

Population of adults ages 65 years and older in the United States, 1900–2050



SOURCE: West, L. A., S. Cole, D. Goodkind, and W. He. 2014. 65+ in the United States: 2010. U.S. Census Bureau special studies. http://www.census.gov/content/dam/Census/library/publications/2014/demo/p23-212.pdf

Opportunities for Action at Multiple Levels

- **Individuals and families**
- **Communities**
- **Consumer advocacy and support organizations**
- **Hearing health care providers and professional associations**
- **Health care, health care schools, and health care systems**
- **Health care insurers**
- **Federal, state, and local government agencies**
- **Media**
- **Employers**
- **Research funders and researchers**
- **Hearing technology manufacturers and industries**

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.

Recommendation 7: The Food and Drug Administration 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, OTC devices that can assist adults with mild to moderate hearing loss.

These devices would:

- Explicitly be defined by FDA as intended for OTC sale;
- Be able to be marketed as devices that may assist with hearing loss and be sold as OTC, 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 OTC 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 **(cont'd)**

- 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.

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.

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.

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).