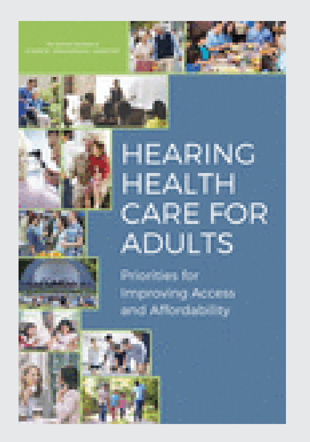

Hearing Health Care for Adults: Priorities for Improving Access and Affordability

DETAILS

324 pages | 6 x 9 | PAPERBACK
ISBN 978-0-309-43926-8 | DOI: 10.17226/23446

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HEARING HEALTH CARE FOR ADULTS

Priorities for Improving Access and Affordability

Committee on Accessible and Affordable
Hearing Health Care for Adults

Dan G. Blazer, Sarah Domnitz, and Catharyn T. Liverman, *Editors*

Board on Health Sciences Policy

Health and Medicine Division

The National Academies of
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THE NATIONAL ACADEMIES PRESS
Washington, DC
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, NW Washington, DC 20001

This project was supported by the Centers for Disease Control and Prevention, Department of Defense (Contract No. HHSP233201400020B/HHSP23337039), Department of Veterans Affairs (Contract No. HHSP 233201400020B/HHSP23337040), Food and Drug Administration, Hearing Loss Association of America, and the National Institutes of Health (National Institute on Aging, National Institute on Deafness and Other Communication Disorders) (Contract No. HHSN26300060). Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.

International Standard Book Number-13: 978-0-309-43926-8
International Standard Book Number-10: 0-309-43926-4
Library of Congress Control Number: 2016946879
Digital Object Identifier: 10.17226/23446

Additional copies of this workshop summary are available for sale from the National Academies Press, 500 Fifth Street, NW, Keck 360, Washington, DC 20001; (800) 624-6242 or (202) 334-3313; http://www.nap.edu.

Printed in the United States of America

Suggested citation: National Academies of Sciences, Engineering, and Medicine. 2016. *Hearing health care for adults: Priorities for improving access and affordability*. Washington, DC: The National Academies Press. doi: 10.17226/23446.

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the report before its release. The review of this report was overseen by **Nancy Fugate Woods,** University of Washington, and **Enriqueta C. Bond,** QE Philanthropic Advisors. They were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

For those who can hear, auditory connection to the world is usually taken for granted. Hearing is a complex physiologic process, and when lost or diminished, it can have effects on health, independence, well-being, quality of life, and daily function as well as on everyday communication. This study—focused on improving accessibility and affordability of hearing care for adults—occurs at an opportune time for progress in this field. Hearing technologies are evolving at ever-increasing rates, care is moving into a variety of retail and online settings, and the pricing structures for hearing aids and associated services are being reexamined. Our committee makes its recommendations acknowledging these changes and urging further and immediate action.

The committee grappled with the questions of how and why hearing loss has been relegated to the sidelines of health care. The barriers to access that have been reported include high costs, lack of insurance coverage, the stigma associated with hearing difficulties and wearing hearing aids, and limited awareness of available options. The goals of this report and its recommendations are to increase transparency, expand treatment options, provide the evidence necessary for consumers to make informed decisions about their hearing health care, and examine various health care delivery and payment models. Hearing loss is a significant public health problem that requires actions throughout the health care and broader community.

Our committee's work greatly benefited from the insights provided by the workshop speakers and feedback from the report reviewers as well as from comments from many others who provided information to the committee. We especially thank the study sponsors for their work on hearing health and for their support of this study (listed alphabetically): the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, the Food and Drug Administration, the Hearing Loss Association of America, the National Institute on Aging, and the National Institute on Deafness and Other Communication Disorders.

I am truly grateful for having had the opportunity to work with this dedicated committee which undertook this study with great energy, intellect, and commitment. This was a complex task full of details and nuances, and the committee members stepped up to meet the challenge—so much so that even a blizzard did not stop them—meeting by Web conferencing and then rearranging their schedules to meet in person 2 weeks later. Their level of engagement in the study and their reasoned and thoughtful discussions made this report possible. Committee members balanced their deeply held individual views with the overarching goal of improving hearing health care. We were all fortunate to work with an intrepid and skilled team of the National Academies of Sciences, Engineering, and Medicine staff, and we deeply thank Sarah Domnitz, Cathy Liverman, Claire Giammaria, Sophie Yang, and Judy Estep, led by Andrew Pope, board director. Without their outstanding support, this report would have been impossible. We also thank Andrea Schultz for her writing and editing work and Ellen Kimmel of the Academies library staff for her assistance throughout the study process. The committee greatly appreciates the efforts of Teresa Meyer-Clemens and Deanna Baker in providing captioning.

As noted above, improving communication for individuals with hearing loss was the goal of the committee's work. It is the committee's hope that the many organizations, agencies, and individuals working on or interested in hearing health care will find this report a source of common ground from which they can work together to keep moving this field forward.

Sincerely,

Dan G. Blazer, *Chair*
Committee on Accessible and Affordable
Hearing Health Care for Adults

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Abbreviations and Acronyms

AAA	American Academy of Audiology
ACA	Patient Protection and Affordable Care Act
ACL	Administration for Community Living
ADA	Americans with Disabilities Act
AHRQ	Agency for Healthcare Research and Quality
ANSI	American National Standards Institute
ASA	Acoustical Society of America
ASHA	American Speech–Language–Hearing Association
BLSA	Baltimore Longitudinal Study of Aging
BMHS	Blue Mountains Hearing Study
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CI	confidence interval
CMS	Centers for Medicare & Medicaid Services
CQI	continuous quality improvement
CTA	Consumer Technology Association
CVAA	Twenty-First Century Communications and Video Accessibility Act of 2010
dB	decibel
dB HL	decibel hearing level
dB SNR	signal-to-noise ratio in decibels

dB SPL	decibel of sound pressure level
DoD	Department of Defense
DOJ	Department of Justice
EHLS	Epidemiology of Hearing Loss Study
EMC	electromagnetic compatibility
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment (program)
ERISA	Employee Retirement Income Security Act of 1974
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FM	frequency-modulated
FR	Final Rule
FTC	Federal Trade Commission
HEDIS	Healthcare Effectiveness Data and Information Set
HIPAA	Health Insurance Portability and Accountability Act
HHS	Department of Health and Human Services
HLAA	Hearing Loss Association of America
HMO	health maintenance organization
HR	hazard ratio
HRSA	Health Resources & Services Administration
Hz	hertz
ICF	*International Classification of Functioning, Disability and Health*
IOM	Institute of Medicine
kHz	kilohertz
LACE	Listening and Communication Enhancement (program)
NHANES	National Health and Nutrition Examination Survey
NHS	National Health Service
NIA	National Institute on Aging
NIDCD	National Institute on Deafness and Other Communication Disorders
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health

OSHA	Occupational Safety and Health Administration
OTC	over the counter
PCAST	President's Council of Advisors on Science and Technology
PMA	premarket approval
PQRS	Physician Quality Reporting System
PSAP	personal sound amplification product
PTA	pure tone average
QSR	quality system regulation
RERC	Rehabilitation Engineering Research Center
SE	standard error
UIB	user instructional brochure
USPSTF	U.S. Preventive Services Task Force
VA	Department of Veterans Affairs
WHO	World Health Organization

Summary

The loss of hearing—be it gradual or acute, mild or severe, present since birth or acquired in older age—can have significant effects on one's communication abilities, quality of life, social participation, and health. Despite this, many people with hearing loss do not seek or receive hearing health care. The reasons are numerous, complex, and often interconnected. For some, hearing health care is not affordable. For others, the appropriate services are difficult to access, or individuals do not know how or where to access them. Others may not want to deal with the stigma that they and society may associate with needing hearing health care and obtaining that care. Still others do not recognize they need hearing health care, as hearing loss is an invisible health condition that often worsens gradually over time. Finally, others do not believe that anything can be done to help them or they feel that the perceived benefit or value of intervention will not be significant enough to overcome the perceived barriers to access.

In the United States, an estimated 30 million individuals (12.7 percent of Americans ages 12 years or older) have hearing loss. Globally, hearing loss has been identified as the fifth leading cause of years lived with disability. Age-related hearing loss is of increasing public health concern as the older adult population grows. The prevalence of hearing loss rises steeply with age, from approximately 3 percent among adults 20 to 29 years of age to an estimated 45 percent among the 70- to 74-year age group and more than 80 percent in the 85-years-and-older age group. The unmet need for hearing health care is high. Estimates of hearing aid use are that 67 to 86 percent of adults who may benefit from hearing aids do not use them.

This study focuses on improving the accessibility and affordability of hearing health care for adults of all ages. This report uses the term "hearing health care" to encompass the range of services (e.g., diagnosis and evaluation, auditory rehabilitation) and hearing technologies (hearing aids and hearing assistive technologies) relevant to hearing loss. Hearing health care is viewed through the social-ecological model that emphasizes the multiple levels of support and action needed throughout society to promote hearing and communication and reduce hearing loss and its effects. The report does not address surgical devices such as cochlear implants.

To address the statement of task, the National Academies of Sciences, Engineering, and Medicine appointed a 17-member committee with expertise in hearing health care services, audiology, otology, hearing loss advocacy, primary care, geriatrics, health economics, technology policy and law, and epidemiology. The study was sponsored by (alphabetically) the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, the Food and Drug Administration, the Hearing Loss Association of America, the National Institute on Aging, and the National Institute on Deafness and Other Communication Disorders.

In examining the complex issues around hearing loss in adults and hearing health care, the committee developed a set of principles that helped shape its work:

- *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*

UNDERSTANDING THE EXTENT AND IMPACT OF HEARING LOSS

Hearing loss may develop at any time during the life course. The onset can be sudden or gradual, and it can affect one or both ears. Hearing loss can result from a variety of causes (e.g., trauma, infection, genetic syndromes, aging, excessive noise exposure), and the pathological changes can occur in one or more regions of the auditory system. Although some hearing loss can be temporary or treatable using medical or surgical methods, most hearing loss in adults is permanent and managed as a chronic condition. Presbycusis, or age-related hearing loss, has been documented in many mammalian species and is characterized in humans by increased hearing thresholds, impaired processing of higher-level sounds (including reduced frequency and temporal resolution), and difficulty understanding speech, especially in noisy or complex listening environments.

Much remains to be learned about the extent and impact of hearing loss, particularly from a population perspective. The effects of hearing loss on communication and, as a consequence, social interactions and functional abilities have serious public health implications for adults of all ages. Among older adults—a growing demographic in the United States and globally—hearing loss is a common, chronic disability that escalates especially in those over 80 years of age. A link between hearing ability and cognitive function and dementia has long been recognized but has only recently begun to be systematically studied. Cross-sectional studies have examined the association of hearing loss with falls, declines in physical functioning, and hospitalization, but population-based longitudinal studies are lacking. The potential economic impacts of hearing loss, including reduced income and increases in unemployment or underemployment, have been modeled, but population-based longitudinal data are needed.

Goal 1: *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 comorbidities 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.

HEARING HEALTH CARE SERVICES: IMPROVING ACCESS AND QUALITY

Although it is widely recognized that hearing aids and hearing assistive technologies can be key components to improving hearing and communication abilities, the critical role that hearing-related services can play in hearing health care is often overlooked. These services include the systematic and comprehensive assessment of an individual's hearing and communication difficulties (e.g., at home, in the workplace, participating in the community), the diagnosis of underlying medical conditions, evaluation of the individual's hearing loss and treatment needs, auditory rehabilitation, and counseling and other services that help the individual to maximize his or her hearing and communication abilities.

Navigating the hearing health care system can be confusing. Entry into the hearing health care system can occur through multiple pathways (audiologists, hearing instrument specialists, otolaryngologists, primary care providers, self service, and others). Consumers can be left with no clear guidance on what will best fit their financial, health, social, and hearing needs. When consumers are left to traverse this complex system, they can find the process and outcomes to be frustrating and unsatisfactory. For the most part, little is known about the relative effectiveness or quality of these services. Guidelines, standards, and metrics must be regularly reviewed and updated to ensure that the most recent evidence is translated into best practices for hearing health care professionals and is disseminated to people with hearing loss and their families.

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.**

Although the hearing health care system is intended to help individuals maximize their hearing and communication abilities, manage their health and well-being, and find ways to compensate for their hearing loss through the use of services and technologies, many individuals report dissatisfaction with the U.S. hearing health care system. Multiple barriers prevent the system from being person centered and person directed. Instead, much of the direction lies in the hands of hearing aid manufacturers and hearing health care professionals, which results in challenges for individuals who want to switch providers, and in challenges for professionals trying to help individuals who seek their assistance with a hearing device that can only be programmed by certain providers. Individuals who need hearing health care services and technologies should be at the center of their own care, with the option to make decisions about what is the most appropriate care for them. In examining the Food and Drug Administration's (FDA's) requirements for physician evaluation prior to obtaining hearing aids, the committee finds no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit. In weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver, the committee recommends removing this regulation to serve consumers' best interests. Relatedly, individuals should be able to obtain their hearing health care records, including audiogram and hearing aid programming history, from their hearing health care professional to enable them to be better informed about their health and change providers if they so choose.

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 government 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.

Similar to many other sectors of the U.S. health care system, hearing health care does not reach all who need it. Residents of rural and low-income urban areas are at a particular disadvantage in accessing care. Furthermore, the minimal diversity in the hearing health care workforce does not mirror the wide diversity in the population of adults this workforce serves. With the high incidence of hearing loss in the adult population and the low utilization of the hearing health care system, efforts should be made to provide easier access for all, especially those for whom socioeconomic barriers exist.

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.**

Effective communication is key both for emotional well-being and for participating in making decisions about one's own health care plan. Hearing is often overlooked in adult medical and wellness visits because of the large number of other health conditions and concerns that must be assessed or, in the case of older adults, because of the assumption that hearing loss is typical and cannot be helped. However, increasing evidence shows that hearing is important for health, and the potential for miscommunication with health care providers due to hearing loss demonstrates the importance of paying attention to hearing ability during medical and wellness visits. Furthermore, health care providers should be aware of the importance of hearing and the need to emphasize, rather than dismiss, hearing concerns during health care visits.

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.

HEARING TECHNOLOGIES

The hearing technology landscape is ever-evolving and encompasses a wide range of products from traditional hearing aids regulated as medical devices to consumer-technology products and hearing assistive technologies. The broad spectrum of types and severity of hearing loss necessitates a wide range of technologies to meet each individual's needs while also meeting requirements for safety and interoperability with other technologies (e.g., cell phones, televisions, and emergency alert systems).

Hearing aids, currently the primary set of devices used for the treatment of hearing loss, are regulated by FDA as Class I or Class II medical devices. In the United States, as in many countries, hearing aid use is low compared to the high prevalence of hearing loss. Estimates of hearing aid use are that 67 to 86 percent of adults who might benefit from hearing aids do not use them. Among the numerous reasons given by individuals for not using hearing aids are the high cost; a lack of effectiveness; challenges with fit, comfort, and use; side effects such as rashes or itching; stigma; challenges with care and maintenance (e.g., changing batteries); and not recognizing that there is a need for hearing assistance.

FDA has established regulations for hearing aids, including quality system regulation requirements, mandatory labeling, and pre-purchase medical evaluation (or a documented waiver). These regulations, along with a number of state regulations, have largely restricted the availability of hearing aids to being mainly dispensed through medical, audiology, or hearing instrument specialist venues. To date, proposals for over-the-counter (OTC) or direct-to-consumer hearing aids have not been approved. Consumer technology products, including personal sound amplification products (PSAPs), have been developed. PSAPs are not considered medical devices, and FDA guidance documents specify that PSAPs cannot be marketed in the United States as products intended for improving hearing loss.

The committee identified the need for FDA to create a category of OTC wearable hearing devices intended for use by individuals with mild or moderate hearing loss. These devices would need to meet specific safety and quality standards and labeling specifications. This regulatory approach would be similar to FDA's regulatory approach of creating separate device classification regulations for prescription eyeglasses and reading glasses (a parallel drawn here specifically to the regulatory approach and not the performance of the devices). A category of OTC wearable hearing devices could provide an additional, easy-to-access option with the potential for lower cost to meet the hearing needs of adults with mild or moderate hearing loss.

Individuals with hearing loss frequently use hearing aids with telecoils or other hearing assistive technologies that couple with cell phones and a range of other communications systems. Efforts are needed to standardize the interfaces and connection of hearing aids, hearing assistive technologies, and OTC wearable hearing devices with other types of technologies and communications systems.

Goal 7: *Implement a New FDA 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, 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 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, and
  - 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 ear tips (e.g., maximum depth for insertion into the ear canal),
  - amplification via air conduction only (wireless technology for programming and connectivity should be permitted), and
  - 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.

Currently, the settings on many hearing aids can only be adjusted by hearing health care professionals who have an agreement with a given manufacturer or distributor to sell that brand of hearing aid. Furthermore, many hearing health care professionals only sell one or a few different brands of hearing aids. A consumer who purchases a hearing aid from one hearing health care professional may find that the manufacturer or distributor has restricted access for adjusting the settings, and thus, the consumer may have to seek all additional programming services from the same distributor that originally sold him or her the product. An open platform approach would provide consumers with greater portability in their hearing health care including increasing the options for choosing their hearing health care professional. Consumers should be notified prior to the point of sale regarding the portability of hearing aid programming.

Greater public awareness and user-friendly instructions about the availability, portability, connectivity, and use of hearing aids and hearing assistive technologies, as well as comparable details on product features, are needed to enable informed decision making.

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, the Federal Trade Commission, the Food and Drug Administration, the 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 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 portabil-**

ity of hearing aids in order to enable more informed purchasing decisions.

IMPROVING AFFORDABILITY OF SERVICES AND TECHNOLOGIES

For many people cost can be a key factor in making health care decisions; for some people cost can be the driving factor, including determining whether to forego the care entirely. The cost of hearing health care includes the cost of services and technologies, and these costs may be incurred multiple times over a period of many years in order to maintain and replace hearing aids and other technologies, to continue to monitor hearing status, and to retain the benefit from auditory rehabilitation and other services. The average retail price for a pair of hearing aids in 2013 was $4,700 (bundled price including the costs of services).

In the hearing health care system that serves adults, nearly all costs are covered by the individual. Third-party payment for hearing health care is limited and many employers do not offer hearing health care insurance options. Currently Medicare Part B covers only diagnostic hearing tests; it does not cover other services or technologies, although some Medicare Advantage plans do. Only some state Medicaid programs offer hearing health care benefits, and several of those that do offer it have strict limitations on eligibility. Vocational rehabilitation programs offer a tremendous benefit for those with hearing loss who are seeking employment, but many individuals are not even aware that this program exists. Furthermore, young adults who have had hearing loss since childhood can face unique financial challenges in transitioning from programs that provided them with hearing aids and services as children and youth to receiving limited, if any, benefits as adults. Given the high numbers of Americans who have hearing loss and the high cost of hearing health care, changes to the cost of hearing health care are needed.

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;**
- **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.**

There are many unknowns in the hearing health care system. The comparative effectiveness of different care delivery models, the health and economic benefits of identifying and treating adult hearing loss early, and the potential for new technologies to disrupt and improve care are just a few of the areas where more research and evaluation are needed. An understanding of these issues will be necessary to continue making strides forward in improving accessibility to and affordability of hearing health care for all.

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.

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.

ENGAGING A WIDER COMMUNITY: AWARENESS, EDUCATION, AND SUPPORT

Hearing plays a vital role in how individuals experience, interact with, and relate to the people and environment around them. Hearing is sometimes referred to as the “social sense” because of its function in developing and maintaining intimate relationships and social connections with family, friends, coworkers, and acquaintances. Supporting individuals with hearing loss requires adaptable solutions that span society—not just solutions within the context of a medical model that revolves around delivery of care and services in a health care setting. These solutions should reduce stigma and negative media perceptions and ensure that consumers understand their hearing test results and have the information they need to compare devices and products and to determine pathways to accessing hearing health care services.

People with hearing loss can experience a variety of challenges in terms of employment and the workplace, including obstacles related to finding employment, career development, promotion and career advancement, equitable compensation, and the balance between job demands and a sense of control and confidence in managing work-related situations. The Americans with Disabilities Act and related laws have provisions that improve access to hearing assistance in some settings, but it is not always adequate, and technology in public venues is not always functional.

For people with hearing loss, the acoustics of the places where they live, work, learn, and socialize, the availability of hearing aids and hearing assistive technologies, and the ability to connect to other communications-enhancing systems may mean the difference between participating in and engaging with their community and feeling isolated. Raising public awareness of hearing health and of the range of options to facilitate communication is key and will require the collaboration of many groups. In addition, individuals, family members, employers, and communities can take actions to maximize hearing and facilitate communication for the benefit of all.

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.

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.

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.

- 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 and
    - Research and incorporate features into buildings and public spaces that improve hearing and communication (e.g., universal design, hearing assistive technologies).

OPPORTUNITIES FOR ACTION

With the positive changes in patient engagement and empowerment occurring throughout the health care system and with the rapid pace of evolution in technology, it is an opportune time to explore and implement changes in the way hearing itself is viewed and the way hearing health care as a whole is delivered, valued, and evaluated. With the benefit of key institutional, technological, and regulatory changes to improve access and affordability, hearing health care is poised to undergo advances that will help individuals with hearing loss and their families find and fully utilize the appropriate, affordable, and high-quality services, technologies, and support they need. Fully developing the array of options for adults of all ages and with all levels of hearing loss (mild, moderate, severe, and profound) requires that hearing loss be recognized as a public health concern that demands multidisciplinary and collaborative efforts by all stakeholders working together with the common goal to improve hearing and communication abilities for individuals and across the population (see Box S-1).

Box S-1 KEY MESSAGES FOR IMPROVING ACCESSIBILITY AND AFFORDABILITY OF HEARING HEALTH CARE FOR ADULTS[a]

Findings:

- Hearing is 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.

Recommended Actions:

- Improve population-based information on hearing loss and hearing health care
- Develop and promote measures to assess and improve quality of hearing health care services
- Remove FDA regulation for medical evaluation or waiver of that evaluation prior to hearing aid purchase
- Empower consumers and patients in their use of hearing health care
- Improve access to hearing health care for underserved and vulnerable populations
- Promote hearing health care in wellness and medical visits for those with concerns about their hearing
- Implement a new FDA device category for over-the-counter wearable hearing devices
- Improve the compatibility and interoperability of hearing technologies with communications systems and the transparency of hearing aid programming
- Improve affordability of hearing health care by actions across federal, state, and private sectors
- Evaluate and implement innovative models of hearing health care to improve access, quality, and affordability
- Improve publicly available information on hearing health
- Promote individual, employer, private-sector, and community-based actions to support and manage hearing health and effective communication

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[a] All findings and recommendations are of equal importance and are not prioritized.

1

Introduction

The loss of hearing—be it gradual or acute, mild or severe, present since birth or acquired in older age—can have significant effects on one's communication abilities, quality of life, social participation, and health. Despite this, many people with hearing loss do not seek or receive hearing health care. The reasons are numerous, complex, and often interconnected. For some, hearing health care is not affordable. For others, the appropriate services are difficult to access, or individuals do not know how or where to access them. Others may not want to deal with the stigma that they and society may associate with needing hearing health care and obtaining that care. Still others do not recognize they need hearing health care, as hearing loss is an invisible health condition that often worsens gradually over time. Finally, others do not believe that anything can be done to help them or feel that the perceived benefit or value of the service or technology will not be significant enough to overcome the perceived barriers to access.

In the United States, an estimated 30 million individuals (12.7 percent of Americans ages 12 years or older) have hearing loss.[1] Globally, hearing loss has been identified as the fifth leading cause of years lived with disability (Global Burden of Disease Study 2013 Collaborators, 2015). The unmet need for hearing health care is high. Estimates of hearing aid use are that 67 to 86 percent of adults who might benefit from hearing aids do not use

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[1] The study, based on data from the National Health and Nutrition Examination Survey, found that these estimates of bilateral hearing loss increase to 48.1 million Americans (20.3 percent) when those with unilateral hearing loss were included (Lin et al., 2011).

them.[2] Data on the use of hearing health care are difficult to obtain given the current structure of the hearing health care model.

Successful delivery of hearing health care enables individuals with hearing loss to have the freedom to communicate in their environments in ways that are culturally appropriate for them and that preserve their dignity and function. Key goals in improving hearing health care are that it be affordable, accessible, effective, accountable, person centered, person directed, and transparent while being supported by a larger society that prioritizes communication, reduces stigma, and provides social and environmental supports for hearing health. Embracing such a system goes well beyond the medical model and acknowledges and demonstrates respect for individuals' needs, concerns, and goals.

SCOPE OF THE STUDY AND STUDY PROCESS

This report examines the hearing health care system, with a focus on nonsurgical technologies and services, and offers recommendations for improving the access to, the affordability of, and the quality of hearing health care for adults of all ages.

To address the study's statement of task (see Box 1-1), the National Academies of Sciences, Engineering, and Medicine appointed a 17-member committee with expertise in hearing health care services, audiology, otology, hearing loss advocacy, primary care, geriatrics, health economics, technology policy and law, and epidemiology. Brief biographies for each of the 17 members of the committee can be found in Appendix B. The study was sponsored by (alphabetically) the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, the Food and Drug Administration, the Hearing Loss Association of America, the National Institute on Aging, and the National Institute on Deafness and Other Communication Disorders.

The committee held six meetings during the course of its work; the first four meetings included public sessions with speakers providing their expertise on a variety of topics relevant to the statement of task (see Appendix A). The committee also held a public conference call with invited speakers. In addition, the committee gathered information from the scientific literature and reviewed information submitted by members of the public and from various agencies and organizations.

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[2] These estimates are based on studies of hearing aid use in older Americans. Bainbridge and Ramachandran (2014) reported that 33.1 percent of potential hearing aid candidates (70 years and older) reported using hearing aids. Chien and Lin (2012) reported that 14.2 percent of Americans with hearing loss (50 years and older) use hearing aids.

Box 1-1 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. Specifically, the committee will

- Provide a contextual background addressing the importance of hearing to individual and societal health, productivity, and engagement. This may include issues such as isolation, social connectivity and well-being, and economic productivity.
- Address federal regulations for hearing aid dispensing. The current federal regulations include the requirement for a medical evaluation by a licensed physician (or a signed waiver of this requirement) prior to the dispensing of a hearing aid in order to promptly identify treatable medical conditions that cause hearing loss.
    - Do the current regulations provide a clinically meaningful benefit to adults with hearing loss?
    - If so, does this benefit outweigh any current barriers to accessibility or affordability that may be associated with the current regulations?
    - What should be the required federal regulatory paradigm for the dispensing of hearing aids?
- Address hearing health care access and affordability:
    - How can affordability of hearing health care, including consideration of third-party payment and alternate hearing assistive technologies and services, be improved?
    - How can current delivery models (system and provider) be utilized or modified to improve access to hearing health care?
    - What innovative health care delivery approaches (e.g., telehealth, mobile health, team-based care) can be used to increase both the access to and affordability of hearing health care?
    - What are the specific challenges for select populations (e.g., older adults, transitioning young adults)?
- 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. In the circumstance where robust evidence is lacking or absent, the committee is encouraged to make recommendations based on sound scientific reasoning in the context of the current health care environment.

  The committee will not address pharmacological therapies for hearing health care.

OVERVIEW OF HEARING AND HEARING LOSS

Sound is produced by waves of air pressure that vary in frequency, amplitude, and direction. When working without impairment, the human auditory system—through a series of complex processes that are carried out in the ear and the brain—can quickly detect, distinguish, and interpret complex mixtures of sound waves from spoken, musical, and other types of audible communications (see Box 1-2).

Box 1-2 BASIC PHYSIOLOGY OF HEARING

The ear, the primary auditory sensory organ, converts sound pressure in the air into neural-electrical signals that are interpreted by the brain as speech, music, etc. The three parts of the ear—outer, middle, and inner—have different roles in this process. The pinna of the outer ear collects and focuses sound waves into the external auditory canal. The sound waves travel through the external auditory canal (approximately 2.5 cm) to reach the ear drum (tympanic membrane). The sound waves cause the ear drum to vibrate. The middle ear is an air-filled cavity in which the vibrations of the eardrum are amplified by three tiny bones, the malleus (hammer), incus (anvil), and stapes (stirrup), collectively known as the ossicles. Thus, the sound waves generated by this process are transmitted as pressure waves to the inner ear.

The inner ear plays a role in the vestibular system (vital to balance and equilibrium) as well as in hearing. The inner ear's cochlea consists of fluid compartments with sensorineural hair cells that translate the vibrations generated by sound into electrical signals, which activate fibers of the eighth (auditory) cranial nerve, which in turn transmits signals to the brain, where the signals are processed by the auditory cortex into understandable sound.

SOURCES: Conners, 2003; IOM, 2004; NIDCD, 2014, 2015.

Two dimensions of sound are its frequency (roughly analogous to *pitch*, measured in hertz [Hz]) and its intensity (the main determinant of the loudness of the sound measured in decibels [dB]) (see Table 1-1). Typically, humans can hear sounds from low to high pitch with frequencies between 20 and 20,000 Hz and at levels as low as 0 dB hearing level[3] (dB HL). At high levels of intensity (and depending on the duration of the sound and proximity to the source) there is a risk of permanent or temporary pain or damage to hearing ability (CDC, 2015a). Results of a hearing test are shown in an audiogram, which is a graph that shows the lowest levels in each ear that an individual is able to hear sounds at each of several different frequencies. Other tests of hearing may also be conducted to differentiate between various causes of hearing loss and to better understand an individual's communication challenges and needs (see Chapter 3).

The World Health Organization defines hearing loss as "not able to hear as well as someone with normal hearing—hearing thresholds of 25 dB HL or better in both ears" (WHO, 2015). The threshold is the minimum sound level at which an individual can detect any sound. Hearing loss is often cat-

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[3] The term "dB hearing level" (db HL) is a unit of sound used for pure tone audiograms and is referenced to levels of normal hearing specified in national and international standards. Decibel measurements may also be provided using sound pressure level measures, a logarithmic measure of sound pressure relative to a reference value.

TABLE 1-1
Examples of Sound Frequencies and Intensities

Sound Frequencies (measured in hertz [Hz])	
250 to 1,000	Vowel sounds, such as the short “o” in the word “hot”
1,500 to 6,000	Consonant sounds, such as “s,” “h,” and “f”
20 to 20,000	Typical range of human hearing
Sound Intensities (measured in decibels [dB])	
10	Normal breathing
25 to 30	Whisper
45 to 60	Typical talking
85	Lawnmower
90	Sounds can become uncomfortable to hear
110 to 140	Rock concert (varies)
120 or louder	Sounds may be painful
0 to 140	Typical range of human hearing

SOURCES: CDC, 2015a; NIDCD, 2010.

egorized as mild, moderate, severe, or profound. Individuals with mild to moderate hearing loss may develop strategies to improve communication, such as facing the speaker or speech (lip) reading, and they may use hearing aids and hearing assistive technologies. Hearing aids are the most widely used intervention for adults with mild to severe sensorineural hearing loss. People with severe to profound hearing loss may be candidates for cochlear implants (a surgical intervention not addressed by this committee).

The committee focused on hearing loss, the major population-based hearing concern in adults, but recognized that there are a number of other conditions, such as tinnitus, which affect hearing health. Many of the recommendations in this report will be of benefit to the care of a range of hearing-related conditions.

Causes and Types of Hearing Loss

Hearing loss can be present from birth or can have an onset at any age. The causes of hearing loss are often categorized based on whether they are congenital or acquired. Congenital causes are those that lead to hearing loss or deafness at birth or soon thereafter. Examples of congenital causes of hearing loss or deafness are genetic syndromes; maternal rubella, syphilis, or certain other infections during pregnancy; low birth weight; lack of oxygen at birth; certain drugs used during pregnancy (e.g., aminoglycosides, cytotoxic drugs, antimalarial drugs, and diuretics); and severe jaundice in the neonatal period (birth to 1 month). Genetic factors are responsible for an estimated 50 to 60 percent of childhood hearing loss in developed countries (Morton and Nance, 2006). Universal newborn hearing screening has been the standard of care throughout the United States since the early 1990s (CDC, 2015b; Morton and Nance, 2006).

Acquired hearing loss may be sudden or gradual in onset and may be caused by meningitis; measles and mumps; otosclerosis (progressive fusion of the ossicles of the middle ear); chronic ear infections; autoimmune or inflammatory disorders; fluid or infection in the ear (otitis media); tympanic membrane (ear drum) thickening or perforations; the use of some antibiotic, antimalarial, or cancer chemotherapeutic medications; some head injuries or other trauma; long-term exposure to excessive noise; cerumen (ear wax) or foreign bodies blocking the ear canal; or aging (presbycusis) (WHO, 2015). Some of these conditions (including otitis media, ear canal blockages, and some forms of otosclerosis) can result in conductive hearing loss, which affects the outer or middle ear, and are often medically or surgically treated. Sudden or fluctuating forms of sensorineural hearing loss may improve with medical or surgical treatment. However, most sensorineural hearing loss is the result of permanent changes to the cochlea, auditory nerve, or central auditory nervous system and cannot be repaired using current medical or surgical interventions. Thus, the most common interventions for sensorineural hearing loss are those that amplify sound to provide sufficient audibility of speech and other sounds. These interventions may include technologies, such as hearing aids and hearing assistive technologies, and auditory rehabilitation services, including auditory and speech perception, speech (lip) reading training, and training to improve communication and coping strategies.

Age-related hearing loss (presbycusis) has been documented in many mammalian species and is characterized in humans by increased hearing thresholds, the impaired processing of higher-level sounds (including reduced frequency and temporal resolution), and difficulty understanding speech, especially in noisy or complex listening environments (Yamasoba et al., 2013). The primary pathology of the process is unknown, but age-related hearing loss is a cumulative disorder which may involve both intrinsic and extrinsic factors, including genetic mutations, the degeneration of cellular structures in the cochlear lateral wall, age-related loss of auditory nerve fibers, and neural changes in the brain affecting signal processing and interpretation. All of these affect the ability of the inner ear and higher neural centers to process acoustic signals and effectively separate the primary speech signal from interfering speech and noise. Regardless of which auditory pathways are affected, the functional consequences will likely include an inability to hear some sounds (particularly high-frequency sounds); an inability to understand subtle differences in spoken words (e.g., "desk" and "debt"), especially in noisy environments; a poorer ability to process acoustic information quickly; and difficulty identifying sources of sound (Roth, 2015; Yamasoba et al., 2013). Generally, individuals present with symmetrical loss which is more apparent with high-frequency sounds and which is commonly more severe in men than in women (Van Eyken et al., 2007; see Chapter 2). Age-related hearing loss is very common, but its rate varies across populations (see Chapter 2), and some people retain excellent hearing well into late ages. There is strong evidence that genetic susceptibility contributes to the variation (Cruickshanks et al., 2010). The etiology of age-related hearing loss is not known, but there is emerging evidence that many potentially modifiable factors (e.g., smoking, adiposity, and vascular disease) are associated with the risk of developing age-related hearing loss (see Chapter 2).

DEFINITIONS AND TERMINOLOGY

As it began its work, the committee recognized the need to determine and then convey the definitions it was using for the key terms in its charge ("affordability" and "accessibility") as well as for various hearing-related terms used in the report. This report uses the term "hearing health care" to encompass the range of services (e.g., diagnosis and evaluation, auditory rehabilitation; see Chapter 3) and hearing technologies (hearing aids and hearing assistive technologies; see Chapter 4) relevant to hearing loss. The committee viewed hearing health care through the social-ecological model (discussed later in this chapter) to emphasize the multiple levels of support and action needed throughout society to promote hearing and communication and reduce hearing loss and its effects. 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—and is not meant to imply any other meaning outside of the report context. The committee also notes that its use of the phrase "mild to moderate hearing loss" is inclusive of the spectrum from mild through moderate hearing loss.

Defining Affordability and Accessibility

Because the committee's charge focused on improving the affordability and accessibility of hearing health care, clear definitions of these two terms are critical to the discussions in this report. Access has been defined as "the timely use of personal health services to achieve the best possible health outcomes" (IOM, 1993, p. 33). This definition focuses on both the use of appropriate health services and on improved health outcomes from such services. The 1993 Institute of Medicine (IOM) report goes on to state, "The test of equity of access involves determining whether there are systematic differences in use and outcome among groups in society and whether these differences are the result of financial or other barriers to care" (IOM, 1993, p. 33). Thus, affordability is a part of access. If health care—be it determining the need for health care, visits to the health care provider, or the prescribed treatment—is too expensive for the individuals affected, it will not be accessible. The definition of access used by Healthy People 2020 incorporates four components: reimbursement coverage, services, timeliness, and workforce (HHS, 2015). As will be discussed in this report, if hearing health care (services and technologies) is to become truly accessible, it will be vital to address the geographic, language, and cost barriers to such care.

It is challenging to define affordability in the context of a specific product or service. *Merriam-Webster's Dictionary* defines *afford* as "to be able to pay for (something); to be able to do (something) without having problems or being seriously harmed" and *affordable* as being "within someone's ability to pay; reasonably priced" (Merriam-Webster, 2015). Affordability at the individual or family level thus largely depends on household income versus necessary expenditures. For example, the Department of Housing and Urban Development notes that families who "pay more than 30 percent of their income for housing are considered cost burdened and may have difficulty affording necessities such as food, clothing, transportation and medical care" (HUD, 2015). An estimated 12 million U.S. households (renter and homeowner) pay more than 50 percent of their annual income for housing (HUD, 2015).

As discussed in Chapters 4 and 5, the price of hearing aids (often bundled with the price for hearing health care services) have often been cited as deterrents to purchase and access, and because there is a general lack of options for hearing health care coverage for most adults (e.g., private insurance, Medicare, Medicaid) these products and services are not affordable for many potential users. The median household income in the United States was estimated by the U.S. Census Bureau to be $53,657 in 2014, with 33.7 percent of all American households having an annual income of less than $35,000 (DeNavas-Walt and Proctor, 2015). Among Medicare beneficiaries, half had an annual income below $24,150 in 2014 (Jacobson et al., 2015). The decision of whether to purchase hearing aids and the associated services (often the initial price is several thousand dollars or more, plus there are ongoing maintenance and, eventually, replacement costs; see

Chapter 5) must compete with decisions about whether to purchase other necessities. Thus, many individuals must make choices about what will fit into their budget and may forego hearing health care to meet other needs.

Hearing-Related Terminology

The hearing abilities of individuals can vary widely across the life span. Some individuals are born without the ability to hear any sound, while others may experience hearing loss either acutely or gradually, with the extent of the hearing loss ranging from mild to profound. Thus, appropriately defining and categorizing those various abilities and their effects on communication can be a challenge.

Individuals who are considered to be deaf generally have profound loss of hearing at most or all frequencies. The term "deaf" when used with a capital "d," *Deaf*, often is used to refer to a community and culture of individuals who share a language (American Sign Language) and cultural values and priorities (NAD, 2015; Padden and Humphries, 1988). How individuals choose to refer to themselves is often influenced by the type and nature of the individual's hearing challenges, age of onset of hearing loss, preferred communication methods, personal preferences, and support community (NAD, 2015).

The term "hearing impaired" has been used extensively, especially by professionals who use it as a single term to cover all types and degrees of hearing loss, but for the individual with hearing loss the term may bring with it the connotation of focusing on limitations and functional challenges (NAD, 2015). Although the term "hearing loss" is generally used to indicate hearing function that is poorer than normal in the population, the term may not apply to individuals who were born with some degree of hearing difficulties that remain unchanged over time, as they did not lose an ability they never had (NAD, 2015). The term "hard of hearing" has also been used, often as a way of differentiating the degree of hearing loss from deafness (e.g., "deaf or hard of hearing"), but the committee did not find it to be descriptive of the condition.

This report makes every attempt to use hearing-related terms in a manner that is conscientious and respectful of all people who are touched by hearing-related challenges. The committee's task (see Box 1-1) is to focus on adults who use nonsurgical methods to address their hearing conditions; therefore, the committee chose to primarily use the term "hearing loss," while acknowledging that some people who use hearing aids or other nonsurgical 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.

Another question of terminology relates to the different roles people are in when they address hearing loss and interact with hearing health care professionals. 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. A person can be in one, two, or all three of these roles at the same time. The committee uses the terms interchangeably to some extent, while trying to use the terms as appropriately as possible in a given context.

WHY FOCUS ON ACCESSIBILITY AND AFFORDABILITY OF HEARING HEALTH CARE NOW?

Hearing health care is in the midst of many of the same major challenges that the health care system, public health, and society in general are now facing. The following overview briefly explores several reasons why there is a critical need for a comprehensive study of hearing health care focused on improving its accessibility and affordability. Many of the issues discussed here are examined in greater depth in the chapters that follow.

Changing Demographics: Intersection of Hearing Loss and Aging

In the United States, as in many other countries, the median age of the population is increasing, and older individuals are living increasingly longer, during which time aging-associated chronic conditions—and, often, multiple such conditions in a given individual—may emerge and challenge health and social systems (Halter et al., 2009). As a result, it is likely that larger numbers of people will have hearing loss and require and seek care in the coming years. The demographic composition of the U.S. population has been influenced by several factors, including increased life expectancy, improved health care and nutrition, and changes in birth and mortality rates. In 1900, 4.1 percent of the U.S. population (just more than 3 million people) was 65 years or older; by 2012 that age group accounted for 13.7 percent of the population (more than 40 million people); and it is projected that by 2060, individuals 65 years and older will constitute 24 percent of the U.S. population (see Figure 1-1; ACL, 2016; Colby and Ortman, 2015; West et al., 2014). Similar aging trends are occurring around the world (NIA and WHO, 2011).

Hearing loss is a common chronic disability in older adults, can escalate with age, especially in those over 80 years of age (see Chapter 2), and its effects on verbal communication and, as a consequence, on social interactions and functional limitations have serious public health implications. Limitations in activity associated with chronic conditions, including hearing

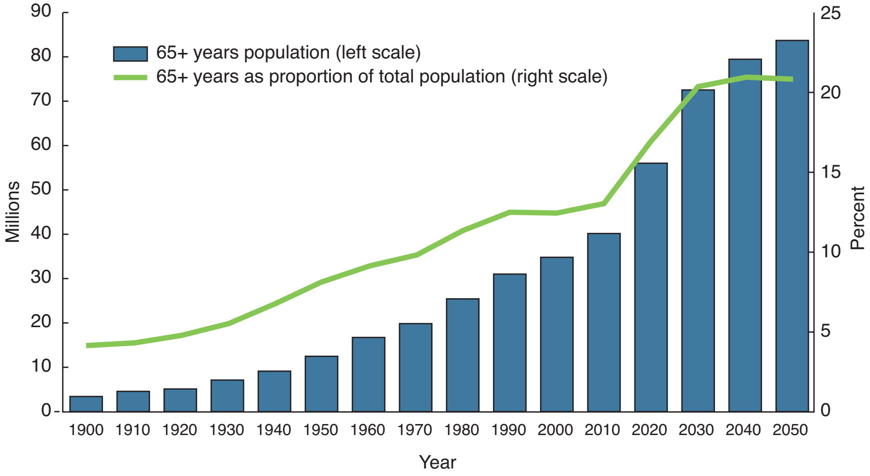

FIGURE 1-1 Population of adults ages 65 years and older in the United States, 1900–2050.
SOURCE: West et al., 2014.

loss, affect greater numbers of older adults as age increases, and the functional impact of hearing loss may be magnified by the coexistence of other such conditions. As the population ages, more people may have moderate to severe hearing loss, which could require more services and potentially more complex services.

Recognizing Hearing Loss as a Public Health Priority and a Societal Responsibility

Long seen as an issue for individuals (and to some extent their families and friends), there is a growing realization that hearing loss is a significant public health concern that is influenced and affected by decisions and actions at multiple levels of society. Loss of hearing may lead to a reduction in quality of life due to communication challenges that can affect interactions with others and that have the potential for effects on cognition, behavior, and other aspects of health (see Chapter 2). However, the application of successful strategies to overcome the functional challenges of hearing loss and enhance communication capabilities can increase an individual's participation in meaningful activities (see more on the *International Classification of Functioning, Disability and Health* in Chapter 3).

Centered on the individual, the social-ecological model (see Figure 1-2) illustrates the relationships and interactions among personal and environmental factors across society that play a role in hearing health: indi-

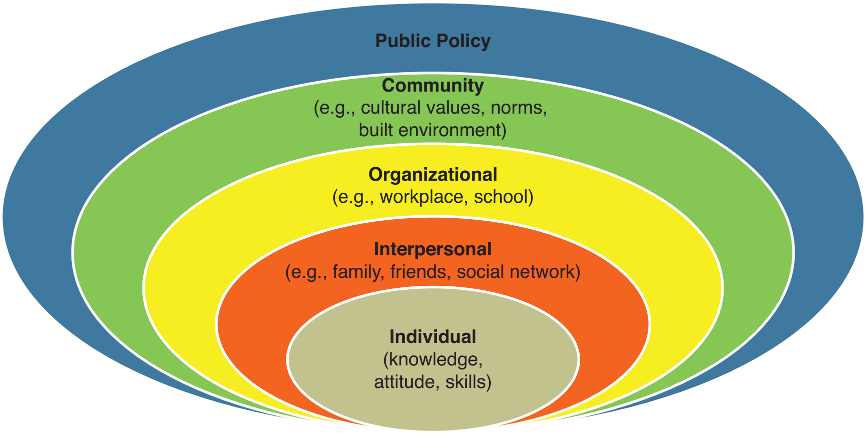

FIGURE 1-2 Social-ecological model.
SOURCE: NIH, 2016. Reprinted with permission.

vidual; family, friends, and other interpersonal relationships (including peer-support groups); organizational (including supports through school, post-secondary education, and workplace); community (ranging from the built environment and acoustics in public spaces to destigmatizing hearing loss); and public policy and regulation (regulations on technologies or policies regarding health insurance coverage or other issues).

The social-ecological model has been more fully developed for other health issues, such as obesity prevention, where factors outside of the individual (e.g., available foods, access to opportunities for physical activity, and public policies on school lunches) play a role in choices, behaviors, and actions (CDC, 2013; IOM, 2005). The relevance of this model to hearing loss can be found in the breadth of responsibilities and actions that encompass successful hearing health care. The committee emphasizes the social-ecological model throughout this report, with particular attention in Chapter 6 to the multiple levels of supports and actions involved in hearing health care.

Rapidly Changing Technologies

The pace of technology change and adoption is accelerating at ever-increasing rates (McGrath, 2013). As discussed in Chapter 4, hearing-related technologies are rapidly evolving and moving toward more wearable and integrated systems. Recently, the President's Council of Advisors on Science and Technology released a report on devices and products for older adults who have mild to moderate hearing loss in which they noted "the unnecessarily high price of hearing aids for individuals and the conspicuously slow pace of innovation by their manufacturers compared with other consumer electronics" (PCAST, 2015, p. 9; also see Chapter 4).

"Hearables" is a relatively new term used to denote a wide range of hearing- and ear-based technologies with various and often multiple purposes which include communication, entertainment, fitness tracking, and physiologic measures in addition to enhancing hearing capabilities. Technologies specific to hearing include hearing aids as well as personal sound amplification products and hearing assistive technologies that connect the user with the television, the telephone, and public sound systems. It is critical that all sectors of hearing health care are fully engaged in these advances and are fully utilizing effective technologies to improve hearing and communication and to assure interoperability and connectivity. These new opportunities and technologies necessitate a call for a critical review of current policies and approaches and increased attention to fully informing the public, particularly those with hearing loss, about the range and capabilities of the options.

Changes in Health Care Paradigms

The hearing health care system is largely unknown to or difficult to penetrate by the general public. Routes for accessing hearing health care go through both business-driven and health care-driven pathways, with sparse information available on the appropriate pathways for individuals to gain access to the services and technologies best suited to meet their needs (see Chapter 3). Health care in general is also undergoing transformations that can propel hearing health care forward, and priorities have been identified which can be applied and incorporated into hearing health care (see Box 1-3).

Efforts are focused on patient-centered care that is evidence-based with attention to quality, safety, and value. Team-based care is also a priority, with teams that include the patient and family in addition to the relevant health care professionals. Principles identified as key to team-based health care are shared goals, clear roles, mutual trust, effective communication, and measurable processes and outcomes in a continuous loop of improvement (Mitchell et al., 2012). Additionally, emphasis on a learning health care system will be of great benefit to hearing health care. As defined, a learning health care system is "one in which science and informatics, patient–clinician partnerships, incentives, and culture are aligned to promote and enable continuous and real-time improvement in both the effectiveness and efficiency of care" (IOM, 2013, p. 17).

Health care encompasses a broad network with widely varying resources and skills applied to a vast array of health concerns. Neverthe-

Box 1-3 HEALTH CARE GOALS

Health care should be

- *Safe*—avoiding injuries to patients from the care that is intended to help them.
- *Effective*—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
- *Patient centered*—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- *Timely*—reducing waits and sometimes harmful delays for both those who receive and those who give care.
- *Efficient*—avoiding waste, including waste of equipment, supplies, ideas, and energy.
- *Equitable*—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

SOURCE: IOM, 2001.

less, progress is being made and efforts put forward that coordinate and integrate hearing health care into the evolving broader health care system. Hearing health care, throughout all of its diverse professional and patient care pathways, offers a wealth of opportunities for fully engaging in changing the paradigms and embracing the quality measures and actions that can improve care for individuals with hearing loss. Opportunities include the exploration and evaluation of diverse delivery and payment systems (see Chapters 3 and 5).

GUIDING PRINCIPLES

In examining the complex issues around hearing loss in adults and hearing health care, the committee developed a set of principles that helped shape its work.

- *Prioritize the needs of individuals with hearing loss*—The committee's priority was concern for individuals with hearing loss and, in particular, on ensuring that these individuals have opportunities for accessible and affordable services and technologies to meet their communication needs. Accordingly, the committee's work focused solely on what it deemed best for consumers/patients/individuals and not on meeting the needs of specific professions or industries.

- *Emphasize hearing as a public health concern with societal responsibilities and effects*—Actions needed to improve hearing and promote communications for individuals with hearing loss require a public health approach that involves efforts across multiple levels of communities and society. The impacts of hearing loss on individuals, families, and society require broad attention to this public health issue, including reducing the stigma often associated with hearing loss. Efforts to improve hearing environments and promote communication can yield benefits for all members of society.
- *Move toward equity and transparency*—Opportunities for improving hearing health care will require that services and products are available to those who need them across the socioeconomic and geographic spectra. Options for selecting those services and products need to be provided in transparent and itemized formats that meet the various health literacy levels of all adults and with data that compare effectiveness based on outcomes and cost using peer-reviewed research.
- *Recognize that hearing loss may require a range of solutions*—No one solution will work for everyone with hearing loss, and therefore the committee emphasizes the range of needs, solutions, and opportunities across the various levels of severity in hearing loss, types of hearing loss, and ways to mitigate hearing loss, maximize hearing, and improve the hearing environment. The goal is a person-centered, person-directed continuum of care across the life span.
- *Improve outcomes with a focus on value, quality, and safety*—Changes are occurring at a rapid rate in hearing health care technologies and in the delivery of hearing health care services, and actions will be required to ensure that these efforts are coordinated, safe, evaluated, and focused on best practices that provide value in improving hearing and communication capabilities for individuals with hearing loss.
- *Work toward an integrated approach that provides options*—The committee provides an approach to hearing health care that integrates services and technologies as appropriate to meet each person's needs. Accessibility, affordability, and awareness are some of the key barriers that contribute to individuals not being able to optimally use hearing health care. Hearing aids and hearing assistive technologies are tools that benefit from careful and unbiased diagnostic and functional assessments of an individual's needs and that can be supplemented by auditory rehabilitation services as appropriate. Creating a variety of options can help enable individuals with hearing loss overcome the specific barriers they face.

ORGANIZATION OF THIS REPORT

This report covers the breadth of the committee's statement of task. Chapter 2 focuses on population-based studies and provides an overview of the evidence on the extent and impact of hearing loss. The focus of Chapter 3 is on hearing health care services, with overviews of the range of hearing health care professionals and the services they provide and with particular attention paid to improving the accessibility of hearing health care services. Hearing technologies are the area of emphasis in Chapter 4, which includes details on current regulations and the committee's recommendations for change. The affordability of hearing health care (technologies and services) is examined in Chapter 5, with discussions of current coverage and exploration of the opportunities to make hearing health care more affordable. Chapter 6 explores issues spanning multiple areas of the community and society that affect access to and use of hearing health care. The report concludes in Chapter 7 with a call to action on hearing health care that will require efforts and collaborations across the range of involved parties, including individuals; families; health care professionals and organizations; employers; insurers; hearing technology industries; government agencies at the local, state, and federal levels; and the general public.

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2

Hearing Loss: Extent, Impact, and Research Needs

Hearing loss may develop at any time during the life course. The onset can be sudden or gradual, and one or both ears can be affected. Hearing loss can result from a variety of causes (e.g., trauma, infection, genetic syndromes, aging, or excessive noise exposure), and the pathological changes may occur in one or more regions of the auditory system. Although some hearing loss might be temporary or treatable using medical or surgical methods, most hearing loss in adults is permanent or slowly progressive. When evaluating the burden of hearing loss in a population, it is important to recognize the heterogeneity in the nature and severity of hearing loss. Individuals also vary in the extent to which auditory rehabilitation, hearing aids, and hearing assistive technologies can improve their communication function (see Chapters 3 and 4). Lessening the effects of hearing loss and improving health and function are the goals of this report's discussions. This chapter begins with an overview of data on the incidence and prevalence of hearing loss in adults and a discussion of the factors associated with the risk for hearing loss in adults and methods for prevention. Subsequent sections discuss the impact of hearing loss on individuals, their families, and society. The chapter ends with the committee's recommendations for next steps in this area.

To develop a full understanding of the public health burden of hearing loss in adults in the United States, the committee gathered information from multiple sources in order to determine the extent to which the U.S. population is affected by hearing loss and the impact of those losses. The committee conducted extensive literature searches, with a focus primarily on articles that relied on audiometric measures of hearing; studies using self-report were included only when they were deemed essential. Cross-sectional epidemiological studies that measure the sensitivity of the auditory system at only one point in time rarely distinguish the pattern of onset or subtype of hearing loss. Because childhood onset of hearing loss as well as most types of acquired hearing loss in adolescence and the early adult years are relatively rare, and because the most common type of hearing loss among aging adults is a slowly developing, symmetrical sensorineural hearing loss called age-related hearing loss or presbycusis, population-based cohorts primarily focus on age-related hearing loss.

Box 2-1 OVERVIEW OF SELECTED STUDIES

Baltimore Longitudinal Study of Aging (1958 to ongoing)—This longitudinal study of adults (531 individuals in the Baltimore–Washington Metropolitan area at baseline) assesses physical and cognitive changes associated with aging (Brant et al., 1996).

Beaver Dam Offspring Study (2005 to ongoing)—The middle-aged adult offspring of participants in the Epidemiology of Hearing Loss Study (described below) were invited to participate in this study which focuses on age-related sensory impairments. The baseline study (2005–2008) had 3,285 participants (Nash et al., 2011). Audiologic assessments were conducted in 2005–2008 with 5-year follow-up in 2010–2013 (Fischer et al., 2015).

Blue Mountains Hearing Study (1997 to 2004)—This population-based study of age-related hearing loss was conducted with a cohort of adults aged 49 years or older living west of Sydney, Australia. From 1997 to 1999, 2,956 individuals underwent audiometric testing, and of those 870 without hearing loss and 439 participants with hearing loss were reexamined from 2002 to 2004 (Mitchell et al., 2011).

Epidemiology of Hearing Loss Study (1993 to ongoing)—Population-based sample of residents of Beaver Dam, Wisconsin, who were 43–84 years of age in 1987–1988. Audiometric examinations to measure the prevalence of hearing loss are ongoing and were conducted in 1993–1995 (n = 3,753), 1998–2000 (n = 2,800), 2003–2005 (n = 2,395), and 2009–2010 (n = 1,812) (Cruickshanks et al., 1998, 2003, 2010a, 2015b).

Framingham Heart Study (1948 to ongoing)—Designed to focus on cardiovascular health in a cohort of residents of Framingham, Massachusetts, with an original cohort of 5,209 individuals who were 30 to 62 years old. Audiologic assessments were conducted in 1978–1979 and 1983–1985 (Gates et al., 1990; Mościcki et al., 1985).

Health, Aging, and Body Composition Study (Health ABC Study) (1997 to ongoing)—This clinical research study is examining changes in body composition and a range of health conditions in older adult residents in the Pittsburgh, Pennsylvania and Memphis, Tennessee areas. At baseline (1997–1998), the sample of 3,075 adults,

DISTRIBUTION OF HEARING LOSS

Studies examining the incidence and prevalence of hearing loss include those that track a number of health outcomes in a cohort (e.g., the Framingham Heart Study, Baltimore Longitudinal Study of Aging) and a few population-based studies that are focused on hearing (e.g., Blue Mountains Hearing Study, Epidemiology of Hearing Loss Study) (see Box 2-1). Information on the extent of hearing loss in military personnel and veterans has been explored in several recent Institute of Medicine reports (IOM, 2006, 2014).

ages 70 to 79 years, had about equal numbers of men and women (33 percent of the men were African American, as were 46 percent of the women) (Kalogeropoulos et al., 2009). Audiometry was included in the examination from 2001 to 2002.

Hispanic Community Health Study/Study of Latinos (2008 to 2011)—This population-based study examined the prevalence and potential risk factors associated with hearing impairment among self-identified Hispanic/Latino adults of ages 18 to 74 years from randomly selected households in four U.S. communities: Bronx, New York; Chicago, Illinois; Miami, Florida; and San Diego, California. Audiometric examinations of 16,415 adults were conducted in 2008–2011 (Cruickshanks et al., 2015a).

Hispanic Health and Nutrition Examination Survey (1982 to 1984)—This multistage sampling study used audiometric and medical examinations to investigate hearing loss and hearing aid use in 1,682 Mexican Americans (Arizona, California, Colorado, New Mexico, and Texas), 441 Cuban Americans (Miami, Florida), and 628 Puerto Ricans (New York City, New York) aged 20–74 (Lee et al., 1991).

Longitudinal Study of Hearing (1983 to 1986)—Using data from two longitudinal studies (one from Great Britain, and one from Denmark), researchers examined the progression of hearing impairment in adults over time. From the Great Britain sample, 98 of the original 432 participants completed the three visits. The second visit was, on average, 2 years after the first, and the third visit was 4.6 years after the first. For the Denmark sample, 206 middle-aged men completed an audiometric assessment at the first visit, 158 at the second visit (3 years after the first), and 135 at the third visit (8 years after the first) (Davis et al., 1990).

National Health and Nutrition Examination Survey (1959 to ongoing)—This program of studies examines the health and nutritional status of adults and children in the United States through interviews and examinations. Each year a representative sample of approximately 5,000 individuals participates in the study (CDC, 2015c). Audiometric assessments of hearing have been included in some years of the examination.

Incidence of Hearing Loss

In addition to providing estimates of the risk of developing a disorder, studies of incidence measure the relative risk associated with such characteristics as age, sex, and race as well as potentially modifiable exposures and other factors that may add prospective evidence for identifying causal pathways. The few studies that have measured the incidence of hearing loss are summarized in Table 2-1. Study designs and methods varied across studies, with only two of the cohorts using traditional population-based designs (Cruickshanks et al., 2003, 2010a, 2015b; Mitchell et al., 2011) and one (Fischer et al., 2015) based on the offspring of one of the population-based cohorts. The other studies employed selection criteria at baseline that may have resulted in a healthier than average sample (Brant and Fozard, 1990; Brant et al., 1996; Gates and Cooper, 1991; Gates et al., 1990; Mościcki et al., 1985) or used very small samples not intended to be representative of the general population of adults (Davis et al., 1990). All but the Baltimore Longitudinal Study of Aging (BLSA), which used Békésy audiometry (a form of automated audiometry), used traditional audiometric assessments of hearing thresholds. The definitions of hearing loss cases varied slightly by frequencies included in the pure tone average. They also differed in that some required bilateral hearing loss (defined by hearing loss in both ears based on the better ear) while others (using the hearing in the worse ear to define cases) included unilateral and bilateral cases. The length of follow-up time varied from 2 to 15 years, with most reporting 5-year event rates. The Epidemiology of Hearing Loss Study (Cruickshanks et al., 2003) and the Beaver Dam Offspring Study (Fischer et al., 2015) cohorts had predominately non-Hispanic white participants. Other cohorts did not report the race/ethnic distributions of their samples, and no data were presented stratifying on race/ethnicity, which suggests, given the demographics of their catchment areas, that the majority of participants also were non-Hispanic white. The committee is not aware of any other published reports of the incidence of hearing loss measured by audiometry in minority populations in the United States.

The reported incidence rates, standardized to annual rates per 1,000 individuals (see Table 2-1), vary from 12 per 1,000 individuals per year in Great Britain to 42.8 per 1,000 individuals per year in Beaver Dam, Wisconsin, and were higher in studies focused on middle-aged and older adults and lower in studies that included younger adults or excluded less healthy participants. The Blue Mountains cohort in Australia was designed to be comparable to the Beaver Dam cohort, and the incidence rates appear remarkably similar when comparing rates using the same pure tone average definition (42.2 per 1,000 individuals per year in the Blue Mountain Hearing Study and 42.8 per 1,000 individuals per year in the Epidemiology of Hearing Loss Study) (Cruickshanks et al., 2003; Mitchell et al., 2011).

However, these comparisons are limited, as no adjustments have been made across cohorts for the actual age and sex distributions of the participants. Nonetheless, the risk of hearing loss was high in all studies of older adults, as can be seen in Table 2-1. Comparing these rates to those for cardiovascular disease (34.6/1,000/year for men and 20.0/1,000/year for women ages 65 to 74 years in the Framingham Heart Study) (NHLBI, 2006), diabetes (7.8/1,000/year) (CDC, 2014), and cancer (4.548/1,000/year) (NCI, 2016) reveals that the risk of hearing loss is up to 2-fold higher than the risk of cardiovascular disease, approximately 5-fold higher than the risk of diabetes, and about 10-fold higher than the risk of cancer. The risk of bilateral hearing loss is approximately 7-fold higher than the risk of bilateral vision impairment (Klein et al., 2001).

Age and Sex

Figure 2-1 shows the age- and sex-specific 5-year incidence of hearing loss in either ear from the Epidemiology of Hearing Loss Study and for bilateral hearing loss in the Blue Mountains Hearing Study (Cruickshanks et al., 2003; Mitchell et al., 2011). Among non-Hispanic white participants in these studies, the incidence of hearing loss was higher at older ages and, within each age group in the Epidemiology of Hearing Loss Study, higher among men than among women. The data on the 80-years-and-older groups have broader confidence intervals because there were fewer participants who did not have hearing loss at baseline and who did have follow-up data.

Although incidence data are scarce and limited to non-Hispanic white populations, the data suggest that the risk of hearing loss increases across the life span and throughout older age and that men have a higher risk of hearing loss than women do. Based on the Epidemiology of Hearing Loss Study data, 18 percent of women aged 60–69 and 35 percent of men aged 60–69 developed hearing loss within 5 years (Cruickshanks et al., 2003).

By 15 years of follow-up, when the participants were 75–84 years of age, 71 percent of the women and 84 percent of the men had developed hearing loss (Cruickshanks et al., 2015b). In models that adjusted for age and sex, the risk of hearing loss nearly doubled with every 5 years of age (hazard ratio [HR] = 1.90, 95 percent confidence interval [CI] = 1.79, 2.02), and men were more than twice as likely as women to develop hearing loss during 15 years of follow-up (HR = 2.23, 95 percent CI = 1.86, 2.66) (Cruickshanks et al., 2015b).

Prevalence of Hearing Loss

In contrast to the limited data on the incidence of hearing loss, numerous cross-sectional studies have described the prevalence of hearing loss.

TABLE 2-1
Selected Studies of Incidence of Hearing Loss

Study and Number of Participants	Definition of Hearing Loss and Participant Age Range at Baseline	Follow-Up Time	Percent Who Developed Hearing Loss During the Follow-Up Time	Estimated Rate per 1,000 Individuals/ Year
Framingham Heart Study N = 1,475[a] (Gates and Cooper, 1991)	PTA of 0.5, 1, and 2 kHz > 26 dB HL Age of participants: 58–88 years	6 years	8.4 (right ear) 13.7 (left ear)	NA
Longitudinal Study of Hearing Great Britain: N = 404 Denmark: N = 157 (Davis et al., 1990)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in better ear Age of participants: Great Britain: 40–65 years; Denmark: 49–69 years	Great Britain: 2 years; Denmark: 3 years	Great Britain: 2.4 Denmark: 6.9	Great Britain: 12 Denmark: 23
Baltimore Longitudinal Study of Aging N = 531 men (Brant et al., 1996)	PTA of 0.5, 1, 2, and 3 kHz ≥ 30 dB HL in either ear (using Békésy audiometry) Age of participants > 25 years	5.1 to 11.2 years[b]	8.7	NA
Epidemiology of Hearing Loss Study N = 1,678[c] (Cruickshanks et al., 2003, 2010a, 2015b)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in either ear Age of participants: 48–92 years	5, 10, or 15 years	5 years: 21.4 10 years: 37.2 15 years: 56.8	5 years: 42.8 10 years: 37.2 15 years: 37.9
Blue Mountains Hearing Study N = 870 (Mitchell et al., 2011)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in better ear PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in worse ear Age of participants: > 49 years	5 years	17.9 21.1	35.8 42.2
Beaver Dam Offspring Study N = 1,984[d] (Fischer et al., 2015)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in either ear Age of participants: 21–79 years	5 years	8.3	16.6

NOTE: dB = decibel (measure of sound intensity or volume); db HL = decibels hearing level; kHz = kilohertz (measure of frequency of sound waves); N = number of participants without hearing loss at baseline; NA = not available; PTA = pure tone average.

[a] Number of individuals followed for progression of hearing decline.

[b] Follow-up times varied by age: < 50 years = mean of 10.9 years; 50–59.9 = mean of 11.2 years; 60–69.9 = mean of 7.8 years; ≥ 70 = mean of 5.1 years.

[c] At baseline, 1,925 individuals had normal hearing. Over the course of the study, 1,678 individuals participated in at least one follow-up examination (1,636 participated in the 5-year follow-up, 1,465 at 10 years, and 1,240 at 15 years).

[d] Number of participants who had 5-year follow-up audiometric testing. Number of participants without hearing loss at baseline = 2,436.

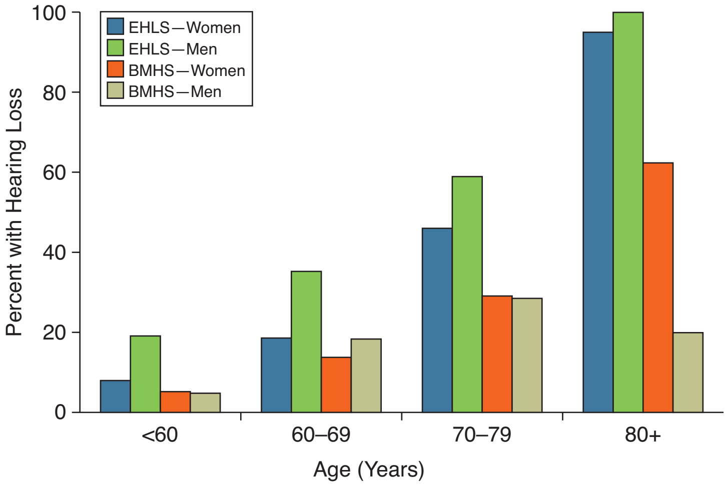

FIGURE 2-1 Five-year incidence in the Epidemiology of Hearing Loss Study and Blue Mountains Hearing Study (Cruickshanks et al., 2003; Mitchell et al., 2011). Incidence rates were found to be greater for men less than 70 years of age than for women in the same age range in the EHLS, but significant gender differences in incident hearing loss were not observed in the BMHS. At the 5-year follow-up examinations, EHLS participants were 53–97 years of age and BMHS participants were 54 years and older.
NOTE: BMHS = Blue Mountains Hearing Study; EHLS = Epidemiology of Hearing Loss Study.

Several large cohort studies carried out in the United States are summarized in Table 2-2. Direct comparisons of the prevalence rates are problematic because of the differences in the age and sex distributions across cohorts. Data from the National Health and Nutrition Examination Survey (NHANES) show that the prevalence of hearing loss rises steeply with age, as shown in Figure 2-2, from 3 percent among adults 20–29 years of age to 49 percent among adults 60–69 years of age (Agrawal et al., 2008). When adults of ages 70 years and older were tested in a more recent wave of NHANES, the prevalence of bilateral hearing loss was found to be 45.6 percent among the 70- to 74-year age group and 80.6 percent in the 85-years-and-older age group (Lin et al., 2011c). These data likely underestimate the true population prevalence since NHANES does not include people living in assisted care facilities, group homes, or nursing homes or those unable to come to the mobile examination center. Insufficient numbers of people from some minority groups and the oldest old are included to produce robust estimates of the prevalence of hearing loss in these subgroups of the population. Using NHANES data, Agrawal and colleagues estimated that 29 million adults ages 20–69 years in the United States have hearing loss, and Lin and colleagues estimated that 30 million people ages 12 and older

TABLE 2-2
Selected Studies of Prevalence of Hearing Loss

Study, Number, Sex, and Age of Participants	Definition of Hearing Loss	Percent with Hearing Loss (%)
Framingham Heart Study N = 2,293; 40.8% men Age of participants: 57–89 years (Mościcki et al., 1985)	PTA of 0.5, 1, and 2 kHz > 20 dB HL in better ear PTA of 0.5, 1, and 2 kHz > 20 dB HL in worse ear PTA of 0.5, 1, and 2 kHz ≥ 25 dB HL in better ear PTA 0.5,1,2,3 > 25 dB HL in better ear PTA 0.5,1,2,4 > 25 dB HL in better ear	35 53 31 36 47
Framingham Heart Study N = 1,662; 40.7% men Age of participants: 63–95 years (Gates et al., 1990)	PTA of 0.5 to 4 kHz > 26 dB HL in better ear	29
Hispanic Health and Nutrition Examination Survey N = 2,751; % men not reported Age of participants: 20–74 years (Lee et al., 1991)	PTA of 0.5, 1, and 2 kHz > 25 dB HL in either ear	Age-, sex-, and ethnic-background-specific rates varied from 2.3 to 48.1
Epidemiology of Hearing Loss Study N = 3,753; 42.3% men Age of participants: 48–92 years (Cruickshanks et al., 1998)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in worse ear	45.9
Health, Aging, and Body Composition Study (Health ABC) N = 2,052; 47.3% men Age of participants: 73–84 years (Helzner et al., 2005)	Low-frequency: PTA of 0.5, 1, and 2 kHz > 25 dB HL High-frequency: PTA of 2, 4, and 8 kHz > 40 dB HL	59.9 76.9
National Health and Nutrition Examination Survey (NHANES) N = 5,742; 46.6% men Age of participants: 20–69 years (Agrawal et al., 2008)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in either ear High-frequency: PTA of 3, 4, and 6 kHz > 25 dB HL in one or both ears	16 32
NHANES 1971–1973: N = 3,192; 47.3% men 1999–2004: N = 4,486; 49.1% men Age of participants: 25–69 years (Cheng et al., 2009)	PTA of 1, 2, 3, and 4 kHz > 25 dB HL in worse ear	1971–1973: 28.5 1999–2004: 21.1
NHANES N = 717; % men not reported Age of participants: over 70 years (Lin et al., 2011c)	PTA of 0.5, 1, and 2 kHz > 25 dB HL in better ear Speech frequency PTA (0.5, 1, 2, and 4 kHz) in better ear	44.8 63.1

continued

TABLE 2-2
Continued

Study, Number, Sex, and Age of Participants	Definition of Hearing Loss	Percent with Hearing Loss (%)
NHANES 2005–2008: N = 3,143; 2001–2004: N = 3,630; 2005–2006: N = 717; % men not reported Age of participants: over 12 years (Lin et al., 2011b)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in better or either ear	Better ear: 12.7 Either ear: 20.3
Beaver Dam Offspring Study N = 2,837; 45.6% men Age of participants: 21–84 years (Nash et al., 2011)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in worse ear	14.1
Hispanic Community Health Study/ Study of Latinos 2008–2011 N = 16,415; 47.97% men Age of participants: 18–74 years (Cruickshanks et al., 2015a)	PTA of 0.5, 1, 2, and 4 kHz > 25 dB HL in better ear; worse ear	Better ear: 8.24 Worse ear: 15.06

NOTE: dB = decibel (measure of sound intensity or volume); dB HL = decibels hearing level; kHz = kilohertz (measure of frequency of sound waves); PTA = pure tone average.

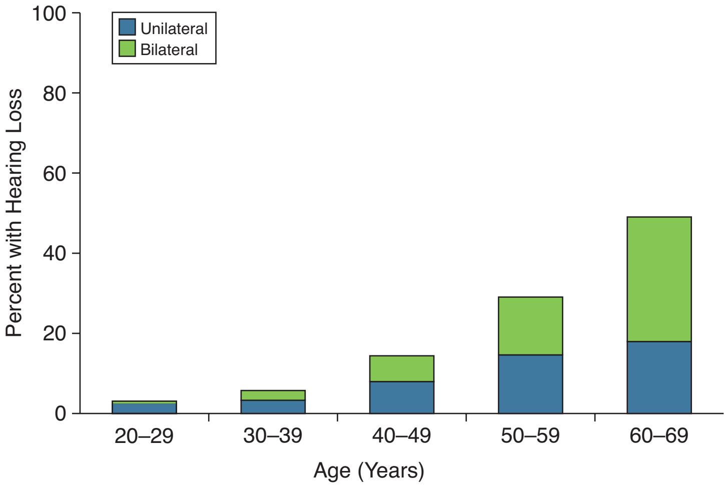

FIGURE 2-2 National Health and Nutrition Examination Survey data on the extent of unilateral and bilateral hearing loss in adults, ages 20–69 years.
SOURCE: Agrawal et al., 2008.

have bilateral hearing loss and 48 million people have poor hearing in at least one ear (Agrawal et al., 2008; Lin et al., 2011c).

In the Epidemiology of Hearing Loss Study cohort, conductive hearing losses were present in 8 percent of participants, with 0.2 percent having a history of otosclerosis (an uncommon but disabling form of hereditary hearing loss that can be aggravated by pregnancy, becomes disabling in mid-life, and in older age is functionally complicated by presbycusis) and 1.9 percent reporting having had an onset of hearing loss before age 20 years (Cruickshanks et al., 1998). Most participants with hearing loss had bilateral symmetrical losses, which is consistent with the predominant type among adults being a sensorineural hearing loss acquired in adulthood.

Severity

The studies described above use a clinically significant cutpoint for defining hearing loss that includes mild losses (26–40 dB HL) as well as moderate and severe or profound losses. The severity of the loss may affect hearing health care needs in various important ways. For example, older adults with profound hearing loss may be candidates for cochlear implants, but this surgical intervention would not be appropriate for someone with a mild loss. Therefore, the committee searched for population-based estimates of the prevalence of hearing loss that were stratified by severity. Cheng and colleagues reported the age–sex–race standardized prevalence of hearing loss by severity in adults 20–69 years of age using data from NHANES I (1971–1973) and NHANES 1999–2004 (Cheng et al., 2009). As shown in Table 2-3, the majority of people with hearing loss had a mild loss, and severe or profound losses were rare in the age range studied, which had an upper limit of 69 years. The Blue Mountains Hearing Study

TABLE 2-3
Age–Sex–Race Standardized Prevalence of Hearing Loss by Severity: Ages 20 to 69 Years

	NHANES I (%)	NHANES 1999–2004 (%)
Normal (< 26 dB)	73.5	78.4
Mild (26–40 dB)	17.3	13.9
Moderate (41–70 dB)	7.8	7.3
Severe or profound (71+ dB)	1.3	0.5

NOTE: dB = decibel; NHANES = National Health and Nutrition Examination Survey.

SOURCE: Cheng et al., 2009.

also reported that the severity of hearing loss increased with age although mild hearing loss was the most common level except in the oldest age group of 85 years and older (Mitchell et al., 2011). Cluster analyses of NHANES data and data from a rural health study described significant variation and gender differences in the shapes of audiogram profiles which may be a useful approach to classifying severity (Ciletti and Flamme, 2008).

Race and Ethnicity

Racial and ethnic differences in the prevalence of hearing loss have been examined in several cross-sectional studies. In the 1999–2004 NHANES, the prevalence of hearing loss among adults 20–69 years was found to be 50 to 60 percent lower among African American participants than among non-Hispanic white participants, and the prevalence among Mexican American participants was similar to that of non-Hispanic white participants (Agrawal et al., 2008). Among older adults (70 years of age or older), this pattern persisted, with non-Hispanic black participants having a lower prevalence than non-Hispanic white participants (Lin et al., 2011c). Similar results were found in the Health, Aging and Body Composition (Health ABC) study (Helzner et al., 2005). In this study of Medicare beneficiaries in two communities (Pittsburgh, Pennsylvania, and Memphis, Tennessee), hearing was tested at the 5-year follow-up visit. Using a pure tone average of 0.5–2 kHz > 25 dB HL cutpoint, they found that the prevalence of hearing loss was 20 to 60 percent higher among white participants than among black participants (Helzner et al., 2005).

In 1982–1984 the Hispanic Health and Nutrition Examination Survey was launched to measure the health of a representative sample of Mexican Americans from the southwestern United States, Cuban Americans from the Miami, Florida, area, and Puerto Ricans from New York City (Lee et al., 1991). Hearing loss (pure tone average 0.5–1, 2 kHz > 25 dB HL either ear) was common in all three groups, but the prevalence was lower among the Puerto Ricans than among the Mexican Americans or the Cuban Americans. More recently, the prevalence of hearing loss was measured in a diverse Hispanic/Latino population as part of the Hispanic Community Health Study/Study of Latinos (Cruickshanks et al., 2015a). In this population-based study in four communities (Bronx, New York; Chicago, Illinois; Miami, Florida; and San Diego, California), hearing loss was common among older adults, and the prevalence was higher among participants with Puerto Rican background than among those with a Mexican background. The prevalence of hearing loss among participants reporting Dominican, Central American, Cuban, South American, or other backgrounds was similar to the prevalence of hearing loss among those with a Mexican background. The report did not include direct comparisons between Hispanic/Latino participants and non-Hispanic white participants. The limited data suggest that there may be a racial/ethnic variation in the prevalence of hearing loss, although the causes and the effects of this difference on individuals' function and activities are not known.

Temporal Population Patterns

A few studies have examined changes in hearing loss prevalence over time in the United States. The evidence from these examinations of temporal trends, secular changes, and birth cohort effects suggests that some cases of hearing loss may be preventable since genetic changes would be expected to accrue quite slowly. Modifiable exposures or risk factors are the more likely explanation for rapid shifts in the risk of developing chronic diseases. Although there are no published longitudinal studies of hearing loss incidence over time, data from the 1971–1973 NHANES and 1999–2004 NHANES suggest that the prevalence of hearing loss (pure tone average 1, 2, 3, 4 kHz) declined 4.8 percent between these two time periods, even after adjusting for age, sex, and race (Cheng et al., 2009).

A strong birth cohort effect was found using data from the Epidemiology of Hearing Loss Study cohort and their offspring (Beaver Dam Offspring Study) (Zhan et al., 2010). In each generation (defined as a 20-year period of births) the odds of hearing loss were about 50 percent lower for men and 24 percent lower for women than in the previous generation (Zhan et al., 2010). Similar results were found using early National Health Examination Survey data from 1959–1962 and NHANES data from 1999–2004 (Hoffman et al., 2010). In this paper, the odds of hearing loss among 25–64-year-olds were reported to be about 44 percent lower among men and 34 percent lower among women in the second time period compared to the first. A second report by this group used national data for older adults (64–74 years of age) from 1959–1962 and 1999–2006 (Hoffman et al., 2012). This study found that the prevalence of hearing loss among older adults declined about 25 percent between the first time period and the second. The reasons for these declines are not known, but the findings are consistent with the possibility that adult-onset hearing loss is at least partially preventable or that the rate of loss may be slowed or the onset postponed. Whether the trend will continue remains to be seen. Longitudinal data are not yet available on the impact of current listening patterns (e.g., listening to loud music using ear buds).

Progression of Hearing Loss

Several large longitudinal studies have examined the change in hearing thresholds over time. In the Baltimore Longitudinal Study of Aging, it was noted that the rates of change were faster at older ages (Brant and Fozard, 1990). Gates and Cooper (1991) reported that 4 percent of Framingham Heart Study participants experienced a significant decline in hearing during a 6-year follow-up period. Lee and colleagues (2005) followed participants for 3 to 11 years with an average of 10 visits and found that thresholds changed by 0.7–1.2 dB HL per year, depending on the frequency. The rates of change were similar in the population-based Epidemiology of Hearing Loss Study, which tested participants only at 5-year intervals (Wiley et al., 2008). Among participants in that study who had hearing loss at baseline, 53 percent experienced a decline in hearing (> 5 dB HL change in pure tone average) in 5 years. Taken together, these data indicate that hearing diminishes gradually over time, although at an accelerating rate with advancing age. Many, although not all, adults over 80 years of age have some degree of hearing loss (see Figure 2-3). This finding has important implications for hearing health care, as individual needs for amplification and other auditory interventions are likely to change over time and the prevalence of that need will increase as the proportion of the population over 80 years of age increases. Additionally, the surge of older Americans caused by the aging of the boomer cohort raises concerns about the aggregate demands for hearing health care. The slow gradual changes also can mean that adults may not

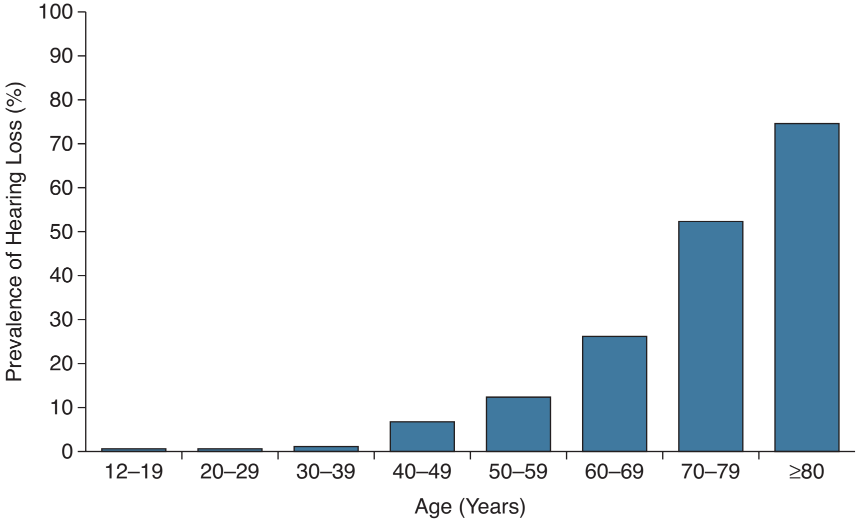

FIGURE 2-3 Prevalence of hearing loss in the United States by age, 2001–2008. Hearing loss is defined by a pure tone average of 0.5–4 kHz thresholds in the better hearing ear > 25 dB HL.
SOURCE: Yamasoba et al., 2013. Reprinted with permission from Elsevier.

recognize the deterioration in their hearing and may delay seeking help. More research is needed on the best approaches for improving awareness of gradual hearing loss.

HEARING LOSS: CAUSES AND RISK FACTORS

The complexity of the physiologic and neural mechanisms that undergird hearing and communication in combination with the numerous genetic and environmental factors that can be associated with or the cause of hearing loss makes it a challenging area for research and one in which much remains to be learned. The major causes and risk factors for hearing loss fall into two major categories, congenital and acquired, although there are complex overlaps between the two, including the potential contributions of genetic susceptibilities to certain risk factors.

Congenital and Genetic Hearing Loss

An estimated 2 to 3 of every 1,000 newborn babies in the United States has hearing loss; of those cases, an estimated 50 to 60 percent result from genetic causes (Alford et al., 2014; Kochhar et al., 2007; Mahboubi et al., 2012). More than 100 genes have been identified as having some effect on hearing ability (i.e., nonsyndromic); in addition, more than 400 genetic syndromes result in other clinical abnormalities that may affect hearing ability (Alford et al., 2014; Kochhar et al., 2007). Newborn hearing screening is the standard of care in the United States and in many other countries; in 2013, the Centers for Disease Control and Prevention (CDC) reported that more than 97 percent of newborns in the United States were screened for hearing loss (CDC, 2015a).

The type and degree of hearing loss that appears in newborns vary. Autosomal recessive hearing loss often results from mutations of the GJB2 gene (estimated as 20 percent of all congenital hearing loss), with variations in severity of hearing loss, but individuals often have nonprogressive, severe hearing loss that manifests early in life, usually prelingual (Mahboubi et al., 2012; Venkatesh et al., 2015). The three genes commonly associated with autosomal dominant causes of hearing loss are WFS1, MYO7A, and COCH. WFS1 mutations, for example, affect hearing at high frequencies, while hearing remains normal in the low frequencies (Mahboubi et al., 2012; Venkatesh et al., 2015). For those with mutations in the MYO7A gene, hearing loss is gradual and progressive and manifests in the first 10 years of life. For those with mutations in the COCH gene, hearing loss begins in the 20s, and while the progression is variable, complete deafness often occurs 20 to 30 years later (Mahboubi et al., 2012; Venkatesh et al., 2015).

Acquired Hearing Loss

As noted in Chapter 1, acquired hearing loss may be sudden or gradual in onset and may be caused by any of a number of exposures, diseases, or health conditions, including meningitis; measles and mumps; otosclerosis (progressive fusion of the ossicles of the middle ear); chronic ear infections; autoimmune or inflammatory disorders; fluid or infection in the ear (otitis media); tympanic membrane (ear drum) thickening or perforations; the use of some antibiotic, antimalarial, or cancer chemotherapeutic medications; some head injuries or other trauma; long-term exposure to excessive noise; cerumen (ear wax) or foreign bodies blocking the ear canal; and aging (presbycusis) (WHO, 2015).

Noise-Induced Hearing Loss

One type of acquired hearing loss is noise-induced hearing loss. Long-term exposure to loud and excessive noise may result in temporary increases in thresholds, or "temporary threshold shifts" (the threshold is the quietest sound that can be heard), and may or may not result in permanent changes in hearing, depending on the level of noise and the length of exposure. Acoustic trauma may result from explosive or impulse noise, with blasts at high intensity levels (~180 dB sound pressure level [SPL]) having the potential to cause hemorrhages, perforation of the ear drum, or impacts on the cochlea (IOM, 2006). As noted in two previous Institute of Medicine reports that reviewed noise exposure data in the context of military service (IOM, 2006, 2014), there are few high-quality prospective studies to quantify the risks associated with these exposures. Most studies of noise in humans have been in occupational cohorts (primarily among men), and few have controlled analyses for factors other than noise or age. One recent report from the Millennium Cohort Study of veterans demonstrated that deployment to combat zones, proximity to improvised explosive devices, and combat-related head injuries were associated with new-onset hearing loss (Wells et al., 2015).

Occupational exposure to noise is regulated in the United States by the Occupational Safety and Health Administration. The National Institute for Occupational Safety and Health (NIOSH) has set recommended occupational exposure limits of 85 dB SPL for an 8-hour time-weighted average (NIOSH, 2015b) and recommends the use of hearing protection measures at higher sound levels. In addition to ear muffs, ear plugs, and other personal hearing protection, workplaces with high noise levels can use environmental (e.g., sound walls or the isolation of loud machinery) and administrative controls (e.g, reduced time worked in noisy environments or increased distance from noise) to reduce exposures (OSHA, 2016). NIOSH estimates that between 5 and 30 million workers in the United States are exposed to occupational noise that puts them at risk for hearing loss, with an additional 9 million potentially at risk due to exposure to ototoxic chemicals, such as certain solvents (Fuente et al., 2013; NIOSH, 2015a). A 30-year review of hearing loss data found that the risk of hearing loss may be declining across occupational groups in many industries (Masterson et al., 2015).

The relationship between noise exposure and the incidence of age-related hearing loss is difficult to determine, particularly as most age-related hearing loss affects hearing ability at high frequencies. Several studies have found that a history of noise exposure was not associated with the rate of later declines in hearing acuity (Lee et al., 2005) or the incidence of hearing loss (Cruickshanks et al., 2003, 2010a; Fischer et al., 2015; Mitchell et al., 2011), even in analyses restricted to those currently employed (Cruickshanks et al., 2010a).

In non-occupational, recreational, and home settings, the levels of noise and lengths of exposure vary widely. Distance from the source of the sound is a factor, as is the volume of the sound and the length of continuous exposure. Target shooting and hunting have been associated with acute onset of hearing loss. Other activities with high and often sustained noise levels that may increase risk for hearing loss include listening to music or other sounds at high volume (including through earbuds or headphones that act to increase the proximity to the source of the sound), participating in a music band, attending loud concerts, and using lawnmowers, leaf blowers, or other high-noise tools (NIDCD, 2014). Ongoing research efforts by the National Institute on Deafness and Other Communication Disorders, the Department of Veterans Affairs, the Department of Defense, and many others are examining noise-induced hearing loss and its etiology and treatment (DoD Hearing Center of Excellence, 2016; NIDCD, 2014; VA, 2015).

Reducing time spent in noisy environments and wearing hearing protection to reduce noise exposure to the ear may help prevent noise-induced hearing loss. Much can be done to alleviate background noises and to promote acoustic environments that have widespread benefit for communication (see Chapter 6).

Risk Factors for Age-Related Hearing Loss

The most common form of acquired hearing loss and the focus of the previously reviewed epidemiological studies is age-related hearing loss. Numerous lifestyle factors, cardiovascular risk factors (including diabetes), medications, neurotoxins, and other factors have been found to be associated with the prevalence of hearing loss (Agrawal et al., 2009; Cruickshanks et al., 2015a; Helzner et al., 2011; Nash et al., 2011). This section focuses on the results of longitudinal studies that have tested associations with the incidence of audiometrically measured hearing loss or with longitudinal changes in hearing thresholds. Although cross-sectional associations are useful for generating new hypotheses, they are considered weak evidence for potential causal mechanisms and prevention. Observational longitudinal studies have the advantage of providing evidence about exposures that precede the development of the disorder but are not sufficient for determining causal pathways. The strongest evidence would come from randomized controlled trials, a study design that has been rarely used in hearing research.

Socioeconomic Status

Indicators of higher socioeconomic status such as higher levels of education or professional occupational categories have been found to be associated with a lower risk of incident hearing loss (or rate of decline) in many (Cruickshanks et al., 2003, 2010a, 2015b; Fischer et al., 2015; Linssen et al., 2014; Mitchell et al., 2011) but not all prospective studies (Kiely et al., 2012). Generational differences in educational attainment explained part of the birth cohort effect on the prevalence of hearing loss discussed above; the impact of birth year was attenuated, although it remained significant (Zhan et al., 2011). This protective pattern is similar to many other disorders of aging, where more highly educated, wealthier people have lower risk of disease, most likely due to a number of factors, but the full reasons are unclear.

Lifestyle Factors

No longitudinal cohort studies have reported significant associations between alcohol consumption and a risk of hearing loss (Brant et al., 1996; Cruickshanks et al., 2015b; Fischer et al., 2015; Gopinath et al., 2010a). One study found that current smokers had a 31 percent increased risk of developing hearing loss during 15 years of follow-up (Cruickshanks et al., 2015b). The risk for former smokers who had stopped 5 or more years earlier was similar to those who had never smoked. Cigarette smoking was not associated with 5- or 10-year risk of developing a hearing loss in this cohort, suggesting that the effects accrue slowly. Consistent with this hypothesis, other longitudinal studies with only 5 years of follow-up have not found significant associations between smoking and risk of hearing loss (Fischer et al., 2015; Gopinath et al., 2010a; Kiely et al., 2012). The Baltimore Longitudinal Study of Aging involving 531 men also found no association between smoking and a risk of incident hearing loss (Brant et al., 1996).

Few dietary factors have been identified as being associated with the risk of hearing loss. In the Blue Mountains Hearing Study, people who consumed fish two or more times per week were 20 percent less likely to develop hearing loss in 5 years of follow-up than those who ate fish less than once a week (Gopinath et al., 2010b). The Nurses' Health Study II found lower risk of self-reported hearing loss among women consuming more fish and long-chain omega-3 polyunsaturated fatty acids (Curhan et al., 2014).

Health Conditions

Blood pressure Population-based longitudinal cohort studies have found no association between blood pressure or hypertension and the risk of hearing loss (Cruickshanks et al., 2015b; Fischer et al., 2015). However, higher systolic blood pressure was found to be associated with hearing loss in the generally healthier Baltimore Longitudinal Study of Aging cohort (Brant et al., 1996). Hypertension was also associated with a faster decline in hearing acuity in a study of Australian participants (Kiely et al., 2012).

Obesity and central adiposity Several longitudinal studies have found obesity or waist circumference—a well-known marker of central adiposity as well as of insulin resistance and cardiovascular risk—to be associated with increased risk of hearing loss (Cruickshanks et al., 2015b; Curhan et al., 2013; Fischer et al., 2015; Linssen et al., 2014). The Maastricht Aging Study reported that a large waist circumference in younger adults and obesity in older adults showed some association with faster deterioration in hearing (Linssen et al., 2014). In the Epidemiology of Hearing Loss Study, there was an 8 percent increased risk of hearing loss for every additional 10 centimeters of waist circumference (Cruickshanks et al., 2015b). Body mass index was significantly associated with a higher (2 percent for every kg/m^2) 5-year risk of hearing loss in the Beaver Dam Offspring Study (Fischer et al., 2015). In the Nurses' Health Study II, body mass index and larger waist circumference were associated with a risk of self-reported hearing loss (Curhan et al., 2013).

Diabetes Although there have been numerous cross-sectional studies reporting a higher prevalence of hearing loss among people with diabetes (Agrawal et al., 2009; Cruickshanks et al., 2010b, 2015a; Helzner et al., 2011; Mitchell et al., 2009), there has been little evidence from longitudinal studies. Diabetes was not associated with incidence of hearing loss in several studies (Cruickshanks et al., 2015b; Fischer et al., 2015; Kiely et al., 2013; Mitchell et al., 2009). However, in the Epidemiology of Hearing Loss Study, highly elevated glycosylated hemoglobin levels were associated with a 2-fold increased risk of developing hearing loss during the 15-year follow-up (Cruickshanks et al., 2015b). As with many other risk factors, it is unknown whether the diabetes itself was the cause or only a correlation.

Atherosclerosis Research in animal models, small clinical studies, and early ecological studies have suggested that cardiovascular disease risk factors and processes may be involved in the pathophysiology of hearing loss with aging (Cruickshanks et al., 2010b). One prospective study reported that the intima-media thickness of the carotid artery—a well-known measure of generalized atherosclerosis—was positively associated with the 5-year incidence of hearing loss (Fischer et al., 2015). The risk of developing hearing loss increased by 28 percent for every 0.2 mm increase in the intima-media thickness, an effect similar to what is seen with 5 years of aging. Plaque, a more advanced stage of atherosclerosis, also was associated with an increased risk of incident hearing loss.

Lipoprotein profiles A longitudinal study of 837 people followed for an average of 3.2 years found no association between hearing and the ratios of triglyceride levels or total cholesterol to high-density lipoprotein (HDL) cholesterol (Simpson et al., 2013). Non-HDL cholesterol was not associated with the incidence of hearing loss in either the Epidemiology of Hearing Loss Study or the Beaver Dam Offspring Study (Cruickshanks et al., 2015b; Fischer et al., 2015).

Chronic inflammation Higher levels of markers of inflammation have been associated with many age-related disorders (Chung et al., 2009; Danesh et al., 2008; Ferrucci et al., 2005; Jenny et al., 2012; Kizer et al., 2011). High concentrations of high sensitive c-reactive protein (hsCRP; a marker for inflammation) were found to be associated with a 2-fold increased risk of hearing loss over a 10-year period among people under the age of 60 years (Nash et al., 2014). The risk also increased with the number of such inflammatory markers that were elevated (hsCRP, interleukin-6, and tumor necrosis factor-α). However, no association was found among people age 60 years or older at baseline. A cross-sectional population-based cohort study has demonstrated associations between certain genetic polymorphisms for tumor necrosis factor-α and tumor necrosis factor receptors and hearing thresholds but no associations between other inflammatory-related polymorphisms and hearing loss (Uchida et al., 2014). Thus, chronic low-grade inflammation appears to play an important role in many degenerative disorders of aging and may be important in aging changes in auditory function, but additional prospective data are needed to evaluate its contribution.

Medications Many medications have potential ototoxic effects; the best known are certain antibiotics and chemotherapy agents (Cruickshanks et al., 2010b). There have been few reports from longitudinal cohort studies with audiometrically assessed hearing of associations between medication usage and the risk of hearing loss. It is not clear if this "absence of evidence" represents a publication bias or the lack of studies assessing medication effects. In the Epidemiology of Hearing Loss Study, no associations were found between the use of nonsteroidal anti-inflammatory medications or lipid-lowering medications (or statins, specifically) and the 15-year incidence of hearing loss (Cruickshanks et al., 2015b). In the study of the offspring of the Beaver Dam participants, statin use also was not associated with the 5-year incidence of hearing loss (Fischer et al., 2015). However, two large cohort studies using self-reported hearing loss outcomes have reported an increased risk of hearing loss to be associated with the use of aspirin, nonsteroidal anti-inflammatory drugs, and acetaminophen (Curhan et al., 2010, 2012). Although it is difficult to study the effects of medications while appropriately accounting for the reasons people use them, for prescription bias, and for polypharmacy, studies are needed to understand the impact of medication usage on changes in auditory function.

IMPACT OF HEARING LOSS

The impact of hearing loss on an individual is highly dependent on the severity of the loss and on the individual's lifestyle, communication needs, and specific environment. Two people with the same degree of hearing loss as measured by audiometry may report very different hearing difficulties. For example, the hearing "demands" may be quite different for a person who lives alone, is retired, and has a group of friends who socialize in only quiet settings than for a person who is working in a noisy office with cubicles, lives with several people, and frequently dines in noisy restaurants with a large group of friends. Additionally, since humans vary in their reactions to challenges and their abilities to find ways to adjust to changes in health, an individual's personality, coping style, resiliency, and duration of hearing loss all may influence how that person perceives his or her hearing abilities. In short, there is tremendous heterogeneity in the challenges in everyday life that are attributed to hearing loss because of the complex interactions of individuals and their environments. This highlights the need for a personalized approach to hearing health care.

From a population perspective, the burden of hearing loss may be hard to detect and quantify even in well-designed prospective studies. Studies that have attempted to measure the impact of hearing loss on communication and quality of life have often used questionnaires that measure the overall health-related quality of life, such as the Medical Outcomes Study-Short Form-36 (Ware and Sherbourne, 1992), which was designed for general population surveys. Other studies have relied on instruments that emphasize difficulties with hearing and communication such as the screening versions of the Hearing Handicap Inventory for Adults or the Elderly

(Newman et al., 1990, 1991; Ventry and Weinstein, 1982; Weinstein and Ventry, 1983). Which outcome methodology is an appropriate metric for measuring impact is open to discussion, and efforts to identify improved "real-world" measures are needed (see Chapters 3 and 6).

Although the committee understands that it is not possible to have perfectly randomized controlled trials to examine the impact of hearing loss, prospective studies (preferably population-based) could be designed and well controlled to examine the associations between newly detected hearing loss and subsequent effects on quality of life and function. Such studies would represent the highest level of evidence possible. Existing studies that use prevalent hearing loss often fail to control for the baseline differences accrued prior to the hearing loss or during the hearing loss. Some studies include "outcome" data collected prior to the measurement of hearing, which obscures the prospective trajectories. The following section briefly discusses some of the limited data available from large studies to highlight the gaps in what is known about the effect of hearing loss on the individual's communication abilities; quality of life; social, occupational, and physical functioning; and health.

Quality of Life and Communication

In the population-based Epidemiology of Hearing Loss Study, participants with hearing loss at the baseline visit had lower quality of life than those with normal hearing, as measured by the 36 item Short Form Health Survey (Dalton et al., 2003). Greater severity of hearing loss also was associated with more communication difficulties, as measured by the Hearing Handicap Inventory for the Elderly, and more limitations in activities of daily living and instrumental activities of daily living (Dalton et al., 2003). Health-related quality of life also was lower in a study of a random sample of people aged 65 and older who had AARP Medicare supplement plans (Hawkins et al., 2012). However, these cross-sectional studies are inadequate for determining the impact of hearing loss as they include both newly detected and longstanding hearing loss and could not adequately control for differences in quality of life that may have preceded the onset of hearing loss.

A longitudinal analysis of data from the Blue Mountains Hearing Study found no difference in the rate of decline in quality of life over a 10-year period between participants with hearing loss and those with normal hearing at baseline, nor was baseline hearing ability associated with the rate of decline in quality of life (Gopinath et al., 2012). Participants who developed a hearing loss during the 10-year follow-up had greater declines in the physical composite score of the Short Form Health Survey than people who retained normal hearing, but there were no differences in the mental composite score (Gopinath et al., 2012).

Cognitive and Mental Health and Depression

A large longitudinal study in Australia found no association between sensory impairments (hearing or vision) and the levels or rates of change in depression during 16 years of follow-up, in multivariable models adjusting for age, sex, and comorbidities (Kiely et al., 2013). The English Longitudinal Study of Aging found no association between self-rated hearing and the onset or persistence of depression (Chou, 2008).

Because hearing loss may burden those people who attempt to communicate with someone who has hearing loss, some studies have measured the impact on the mental health of the spouses of individuals with hearing loss. In the Alameda County Study, baseline self-reported hearing difficulties with communication were associated with the partner's poorer mental health and well-being 5 years later (Wallhagen et al., 2004). The study controlled for age, gender, financial problems, number of chronic conditions, and the hearing loss of the partner. In contrast, the cross-sectional analyses in the large Nord-Trøndelag Health Study found no association between hearing loss measured by audiometry and spousal mental health in 13,678 couples (Ask et al., 2010). It is not clear if the difference in results was due to cultural differences between the United States and Norway, the longitudinal versus cross-sectional designs, or the differences in impact between measured hearing loss and complaints of hearing problems. It is possible that the burden to the spouse is limited to families where the person who has hearing loss is struggling with communication or is dissatisfied with his or her hearing function.

A link between hearing and cognitive function and dementia has long been recognized, as signals transmitted by the ear are processed and recognized by the brain as sounds and words (Humes et al., 2012). Early studies and reviews have reported an association between hearing loss and dementias (Albers et al., 2015; Uhlmann et al., 1989). The association may be bidirectional, as the Australian Dynamic Analyses to Optimise Ageing project found that cognitive impairment was an independent predictor of the rate of decline in auditory function (Kiely et al., 2012). The Maastricht Aging Study analyzed the relationship that hearing and change in hearing, along with vision and change in vision, had with changes in cognitive function as measured with a battery of tests (Valentijn et al., 2005). In this study, declines in hearing were associated with 6-year declines in the Visual Verbal Learning Test (total score and recall), but not with any of the six other tests included in the battery. No effect of hearing aids was seen, but only seven people were fitted, so the power to detect an association was low. In one longitudinal study of people with audiometrically measured hearing loss, there was no difference between hearing aid users and nonusers in cognitive function or mental health after 11 years of follow-up (Dawes et al., 2015).

Several prospective studies of hearing and incident dementia or Alzheimer's disease have been conducted. In a sample of the Baltimore Longitudinal Study of Aging, which excluded people with cognitive impairment at baseline, the risk of dementia was found to be 24 percent higher for every 10 dB of hearing loss after adjusting for age, sex, race, education, diabetes, smoking, and hypertension, and baseline scores on one test of cognitive function (Lin et al., 2011a). Hearing aid use was not found to have an effect on the risk of dementia in this study (Lin et al., 2011a). A smaller association was seen in the Health ABC cohort: The risk of having cognitive impairment increased 7 percent for every 10 dB of hearing loss at baseline (Lin et al., 2013). Baseline hearing loss was also associated with a slightly greater annualized decline in scores on the Modified Mini-Mental State Examination and Digit Symbol Substitution test, although the analyses did not control for baseline scores on those tests, which were worse among those with hearing loss than among those without hearing loss. Hearing aid use was not associated with slower rates of decline or a lower incidence of cognitive impairment in that study (Lin et al., 2013).

A subset of the participants in the Baltimore Longitudinal Study of Aging was followed with magnetic resonance imaging. With a mean follow-up time of 6 years, the rates of whole brain atrophy and atrophy in several regions of the right temporal lobe were greater among people with baseline hearing loss than among normal-hearing participants (Lin et al., 2014). Most participants had only a mild hearing loss, and baseline volumes were similar between those with and without hearing loss. The limited studies published to date provide intriguing evidence suggesting that sensorineural hearing loss and cognitive function changes may co-occur in aging. Mechanisms for these associations are not known although shared pathways such as vascular and inflammatory damage or the effects of hearing loss on social isolation and cognitive load have been suggested (Lin et al., 2011a, 2013, 2014; Panza et al., 2015). Future studies are needed to determine the mechanisms of these possible associations.

Function

Studies using self-reported hearing loss are problematic because of the complex relationship between the severity of loss measured by audiometry and the daily impact on function. It is difficult to separate the effects of the actual hearing acuity from other factors that influence self-perceived problems. In one study that controlled for hearing impairment severity, older adults reported less handicap than younger adults, which may reflect differences in demands on hearing, generational differences in coping, or adaptation to hearing loss over time (Wiley et al., 2000). Future studies based on self-report should include measures of the psychosocial factors that may influence reporting and audiometric testing in order to understand the influences on perceived handicap. Improved measures of hearing are needed—and, in particular, measures that better assess the real-world hearing environment.

The evidence to date on the relationship between hearing loss and social isolation is based on small cross-sectional studies. While it is highly likely that people with severe age-related hearing loss may feel isolated and that some people may respond to changes in hearing by altering their lifestyles, prospective studies are needed to provide stronger supporting evidence. Population-based longitudinal studies of hearing and social isolation are needed to measure the amount of time that adults spend engaging with others or spend in difficult listening conditions in order to determine the effects of different severities of hearing loss and value of treatment.

Other approaches to measuring the importance of hearing loss have evaluated the impact on work. One large study reported finding no association, in a multivariable-adjusted model, between difficulty hearing in noise and the use of sick leave (Nachtegaal et al., 2012). In the Epidemiology of Hearing Loss Study, there was no association between hearing loss at baseline and the 15-year risk of retiring after adjusting for age, sex, self-reported health, and chronic diseases (Fischer et al., 2014).

Cross-sectional studies have examined the association of hearing loss with falls, declines in physical functioning, and hospitalization, but population-based longitudinal studies are lacking. In cross-sectional data from the NHANES study, hearing loss was associated with an increased risk of self-reported history of falls in the previous 12 months (Lin and Ferrucci, 2012). In a subset of the Health ABC study, hearing loss at the 5-year follow-up (2002–2003) was associated with frailty that developed between the baseline examination (1997–1998) and the 10-year follow-up (Kamil et al., 2016). In a study examining hospitalization of the participants in the Health ABC study, participants with hearing loss at the 5-year midpoint examination were likely to have been hospitalized earlier (time to first hospitalization) than those with normal hearing and to have had a higher annual rate of hospitalization over the course of the study (median follow-up was 12 years) (Genther et al., 2015b).

One longitudinal study evaluated the effect of hearing impairment on independence and the use of support services. In the Blue Mountains Hearing Study, 1,457 participants at the baseline hearing test visit reported no use of community support services. Baseline hearing loss was not associated with the 5-year incidence of using community support services, with receiving help from a nonspouse family member or friend, or with an inability to go out alone. However, people with moderate to severe hearing loss had a 2.7-fold increased risk of needing help from family and friends (Schneider et al., 2010). These results provide some evidence that people with severe levels of hearing loss may have a greater need for services than people with normal hearing.

Two studies using self-reported hearing loss analyzed the impact of hearing loss on access to general health care. The Wisconsin Longitudinal Study found that the odds of reporting difficulties and delays in accessing health care in the previous year were 1.85 times higher in the group reporting hearing loss than in those not reporting hearing loss (Pandhi et al., 2011). In the Medical Expenditure Panel Survey, people with hearing loss were found to have better access to health care than those with other disabilities (Horner-Johnson et al., 2014). Several studies (Contrera et al., 2015; Fisher et al., 2014; Genther et al., 2015a; Gopinath et al., 2013; Wahl et al., 2013) have reported longitudinal associations between hearing and mortality risk; however, most showed no association after controlling for confounding factors (Contrera et al., 2015; Genther et al., 2015a; Wahl et al., 2013). The study authors did not speculate on the reasons for these disparities.

Impact of Early Life Onset of Hearing Loss

One subset of adults with hearing loss that deserves particular attention is those adults who had congenital or childhood-onset hearing loss. Programs exist to identify infants and young children with hearing loss who need treatment. Although hearing health care and hearing aids may be provided to these children through private insurance or state and federal programs, coverage changes as these children transition to adulthood (see Chapter 5). Because hearing aids are frequently used by children with hearing loss, long-term hearing health care is needed to help them continue to thrive as adults. Vocational rehabilitation programs provide assistance for some but may be inadequate to provide support for all who need it (see Chapter 5).

The National Longitudinal Transition Study-2 evaluated post-secondary school outcomes for young adults with disabilities (Newman et al., 2011). No information was collected specific to hearing health care needs or current treatments, but a broad array of outcomes was measured. Most analyses focused on comparing the group with disabilities to the general population and then comparing within the group with disabilities by the type of disability. As seen in Table 2-4, young adults with disabilities were as likely to enroll in post-secondary schools as the general young adult population but were slightly less likely to have graduated within 8 years. Employment rates and duration were similar, as were the number of hours worked, but the average hourly wage was slightly lower, possibly reflecting a higher proportion of part-time workers (Newman et al., 2011). A high percentage were engaged in work, education, or training during this early adult period.

TABLE 2-4
National Longitudinal Transition Study-2:
Post-High School Outcomes of Young Adults with Disabilities
Up to 8 Years After High School[a]

	General Population	All Disabilities	Hearing Impairment	Deaf-Blindness
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
Ever enrolled in any post-secondary school	67.4 (0.60)	60.1 (2.63)	74.7 (4.24)	56.8 (7.09)
Graduated any post-secondary school	52.4 (1.02)	40.7 (3.71)	52.9 (6.16)	27.7 (9.14)
Employed at time of interview	66.1 (0.60)	60.2 (2.65)	57.2 (4.89)	30.1 (6.69)
Average duration of employment (months)	21.8 (0.28)	23.5 (1.42)	22.4 (2.59)	19.1 (3.74)
Average hours worked per week	37.1 (0.18)	35.8 (0.88)	31.3 (1.47)	24.7 (2.77)
Average hourly wage	$11.40 ($0.17)	$10.40 ($0.32)	$10.50 ($0.58)	$9.20 ($1.64)
Paid vacation or sick leave	56.6 (0.72)	54.6 (3.31)	49.6 (6.46)	43.8 (10.67)
Health insurance	55.5 (0.79)	47.7 (3.32)	40.4 (6.31)	29.2 (9.78)
Retirement benefits	38.7 (0.78)	39.0 (3.30)	41.5 (6.43)	31.5 (9.99)
Engagement in education, employment, or training since high school		94	95.4 (2.04)	85.0 (5.11)
Lived independently	59.0 (1.63)	44.7 (2.68)	50.5 (5.01)	26.4 (6.56)
Lives semi-independently	1.8 (0.18)	1.7 (0.70)	6.0 (2.38)	8.2 (4.09)
Have had or fathered a child	28.4 (0.57)	29.4 (2.63)	20.6 (4.48)	7.4 (3.95)
Married	19.3 (0.53)	13.4 (1.97)	11.4 (3.50)	3.8 (2.86)
Savings account	63.3 (0.92)	59.0 (2.86)	64.7 (5.32)	64.3 (7.22)
Checking account	73.9 (0.80)	58.7 (2.85)	73.5 (4.89)	46.9 (7.47)
Credit card	61.1 (0.92)	41.4 (2.85)	52.9 (5.59)	29.2 (6.81)
Food stamps			15.1 (5.56)	38.8 (13.13)

continued

TABLE 2-4
Continued

	General Population	All Disabilities	Hearing Impairment	Deaf-Blindness
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
Friends outside of school or work weekly		78	76.3 (4.79)	62.3 (7.31)
Communicating by computer daily		32.0 (2.69)	51.4 (5.50)	41.2 (7.37)
Community participation		51.7 (2.73)	59.3 (4.86)	66.9 (6.78)
Driver's license/learner's permit		77.7 (2.40)	83.5 (4.07)	26.9 (6.64)
Registered to vote		71.0 (2.64)	71.0 (5.04)	56.9 (7.42)

NOTE: SE = standard error.

[a] N = 4,810 in Wave 5 that were out of high school when interviewed in 2009; 13- to 16-year-old students were selected in Wave 1, and their average age was 14.4 years in 2000; 40.2 percent of Wave 5 participants were 24 years or older; 65.6 (2.57) percent white, 20.2 (2.17) percent African American, and 14.2 (1.89) percent identified as Hispanic in Wave 5 interviews.

As young adults, they were becoming independent, forming relationships, moving out on their own, driving, and voting at high rates. The set of young adults with hearing loss appeared to be quite similar to the entire study cohort and to the general population on many measures. The majority of both groups saw friends weekly, engaged in community activities, and were registered to vote. In summary, this study showed that children with hearing loss transition to adulthood similarly to young adults without hearing loss in many ways. However, there are very limited data about their hearing health care needs or how its affordability may limit their access and opportunities.

Economic Burden of Hearing Loss

There are no population-based longitudinal data that measure the economic impact of hearing loss. Modeling the economic cost to society of hearing loss has been approached in several ways with varying assumptions. Mohr and colleagues (2000) focused on severe to profound hearing loss and estimated the costs over a lifetime to an individual to be $297,000 (averaged across age at onset), with most of the losses (67 percent) due to reduced work productivity. The study estimated that persons who experience severe to profound hearing loss before retirement are expected to earn only 50 to 70 percent of what their peers earn who do not have hearing loss. Ruben (2000) used several sources of labor and disability data to look at the economic effects of communications disorders, with some data focused on hearing loss, and found negative impacts of hearing loss on individual income and significant underemployment of individuals with hearing loss. Stucky and colleagues (2010) used a simulation model based on national estimates of the prevalence of hearing loss in individuals age 65 years and older across the range of hearing loss, as well as several sources of economic data, and estimated that the total costs of first-year treatment of hearing loss in 2002 were approximately $1,292 per person, or $8.2 billion nationally, and projected that by 2030 these costs would increase to approximately $51.4 billion nationally. They also estimated the 2002 lost productivity costs attributable to hearing loss in this age group to be approximately $1.4 billion nationally. Simpson and colleagues (2016) examined health care cost data from privately insured adults age 55 to 64 years and found higher health care costs for a number of chronic health conditions for individuals with a diagnostic code for hearing loss as compared with a matched group without that diagnostic code. Emmett and Francis (2015) examined data from the 1999–2002 cycles of NHANES that included audiometric evaluation and a questionnaire on income. Their study found hearing loss to be associated with a 1.58 times higher odds of low income and 1.98 times higher odds of being unemployed or underemployed in adults age 20 to 69 years. The authors noted that these are cross-sectional data that cannot be used to establish causation and pointed to the need for longitudinal studies.

PREVENTION OF HEARING LOSS

Only one small, randomized controlled trial has been conducted to evaluate interventions (other than hearing technologies) for age-related hearing loss (Durga et al., 2007). This trial of folic acid supplementation in the Netherlands demonstrated that in a group of 50- to 70-year-olds, those participants who received 800 µg/day of folic acid experienced smaller declines in hearing at low frequencies (pure tone average 0.5–2 kHz, both ears) during a 3-year follow-up period than did participants who received a placebo (1.0 dB versus 1.7 dB HL, respectively) (Durga et al., 2007). Although this study is not generalizable to the United States where foods are fortified with folate and thus additional supplementation may provide little additional benefit, it suggests that certain nutritional interventions may delay or slow the deterioration of hearing with aging.

Hearing loss prevention efforts targeting all ages largely focus on reducing exposure to intense noise or to sustained high levels of noise by reducing noise volume or increasing the distance from the noise source; by using ear muffs, ear plugs, or other hearing protective devices; and by using other noise-reducing strategies (NHS, 2015; NIDCD, 2008). Additionally, the avoidance of ototoxic medications, some specific chemical exposures, and other environmental exposures of concern can be considered. Whether healthy lifestyles have any benefits in preserving auditory function remains to be seen.

The risk factors and exposures reviewed above preceded the development of hearing loss, but these factors may not cause hearing loss. Evidence that there are modifiable risk factors for hearing loss is limited by the paucity of prospective, population-based data. There is suggestive evidence that socioeconomic status and obesity are associated with a risk of hearing loss. The reported prospective associations summarized above, along with the pronounced decline in hearing loss across generations, suggest there may be ways to reduce the risk or slow the progression of hearing loss with aging. Additional prospective studies are needed to replicate these findings and strengthen the evidence. Randomized controlled trials of interventions to determine the impact of reductions in obesity or waist circumference on hearing may be warranted. Including measures of hearing in trials aimed at reducing hyperglycemia, atherosclerosis, and chronic inflammation for other health reasons may help to elucidate the roles of these conditions in declining hearing acuity among adults.

For age-related hearing loss, there is insufficient evidence to support interventions for primary prevention. However, ongoing research is seeking to identify drugs that act on oxidative stress pathways, inflammation, and hormonal regulation that may have beneficial effects on hearing. Although some surgical and medical treatments are available for some forms of middle-ear disease and sudden-onset hearing loss, there are no medical or surgical treatments to cure age-related hearing loss. At this time, tertiary prevention methods for helping individuals manage their hearing loss and reduce the impact of hearing loss on their quality of life are available (see Chapters 3, 4, and 6).

NEXT STEPS AND RECOMMENDATION

The paucity of data in many areas of hearing health care will be highlighted throughout this report. Given the number of people with hearing loss and the opportunities to improve their function and quality of life, more can be done to strengthen the evidence base. Of the numerous factors that have contributed to hearing health care's lack of a strong research base, the committee describes just a few:

- *Lack of health insurance coverage for hearing health care*—Evidence of improved patient outcomes is a general requisite for health insurers, policy makers, and others making decisions about payment for health care interventions. However, because few health insurance plans or programs provide reimbursement for hearing health care (see Chapter 5), there has not been a demand for this research.

- *Nature of the devices and interventions*—Hearing aids are fairly low-risk medical devices, and the Food and Drug Administration's regulatory processes for approval of hearing aids do not require clinical trial data (unless significant changes are sought to previously approved models). Therefore, randomized controlled clinical trials evaluating the efficacy of hearing aids to improve health outcomes have been limited (see Chapter 4).
- *Research training changes and public health emphasis*—In general, hearing loss has not been viewed as a public health concern, and audiologists and others are often not trained in public health research methodologies. Additionally, health services researchers, health economists, and epidemiologists receive little training about sensory disorders. Strengthening the research training programs and encouraging multidisciplinary teams to address the many research needs will improve the quality of the evidence in hearing health care.

The research needed to advance the effectiveness of hearing health care services and technologies, particularly comparative effectiveness studies, is described in Chapters 3 and 4. Chapter 5 discusses cost effectiveness research and details the urgency for demonstration projects and other studies to be conducted to fill the gaps in research on interventions, outcomes, and impacts. In addition, research efforts also need to focus further on improving public awareness, reducing stigma, and engaging community organizations and businesses in ensuring that hearing- and communication-friendly environments are available (see Chapter 6).

Well-designed longitudinal population-based studies that adequately control for confounders are needed to definitively determine the impact of hearing loss on adult individuals, families, and society. Additionally, the gaps in population-based surveillance efforts pertinent to hearing loss include insufficient knowledge about variations in the incidence of hearing loss among and across racial and ethnic populations and across geographic areas and insufficient knowledge about the impact of hearing loss on social function, employment, quality of life, independence, and the need for social services. This absence of evidence is striking given that the Global Burden of Disease project has ranked hearing loss as the fifth leading cause of years lived with disability—higher than other chronic diseases of aging such as diabetes, dementia, and chronic obstructive pulmonary disease

(Global Burden of Disease Study 2013 Collaborators, 2015). Learning more about the economic burden of hearing loss should be a priority.

Strengthening research in hearing health care will need to involve a more robust set of metrics for assessing and defining hearing loss and communication abilities, with a focus on measures that are applicable to communicating in the complex environments of daily life. This goal has also been identified in the NIDCD Strategic Plan (NIDCD, 2015). As noted above, further collaborative and interdisciplinary efforts in hearing loss research are needed. Additionally, training in research methodologies needs to be strengthened for audiologists and other hearing health care professionals. Accreditation organizations involved with monitoring education programs could incorporate requirements for research training into standards for academic programs.

Data sources and research opportunities also need to be expanded. The current focus of the hearing-related programs at the CDC is on childhood hearing loss and newborn screening (CDC, 2015b). In addition to these vital programs, it is important to expand CDC's role and research in adult hearing loss to ensure that this serious public health concern benefits from the population-based approaches and public health opportunities that are available through CDC and through state public health departments.

Goal 1: ***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 comorbidities 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.

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3

Hearing Health Care Services: Improving Access and Quality[1]

Although it is widely recognized that hearing aids and hearing assistive technologies can be key components to improving hearing and communication abilities, the critical role that hearing-related services can play in hearing health care is often overlooked. These services include the systematic and comprehensive assessment of an individual's hearing and communication difficulties, diagnosis of any underlying medical conditions, evaluation of the individual's hearing loss and treatment needs, auditory rehabilitation, and counseling and other services that help the individual to maximize his or her hearing and communication abilities. These services are provided by a range of hearing health care professionals.

Hearing health care is facing challenges similar to those being addressed in many other facets of health care in the United States. Hearing health care is often expensive and underutilized by many of the people who need it. Entry into the hearing health care system can occur by multiple pathways (audiologists, hearing instrument specialists, otolaryngologists, primary care providers, self service, and others) (see Box 3-1). Consumers can be left with no clear guidance on what will best fit their financial, health, social, and hearing needs (NIDCD, 2015). When left to traverse this complex system, even those patients who are fortunate enough to have the time,

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[1] For accuracy when referring to findings and conclusions in published studies on hearing health care services, only the specific professions included in a given study are referred to in the study-related text of this report. However, following the discussion of such studies, the committee's commentary on the larger implications and applications of the study findings are broadened to include all relevant hearing health care professions.

Box 3-1 PROFESSIONS INVOLVED IN HEARING HEALTH CARE

Audiologists

Audiologists are nonphysician health care professionals trained in the assessment, treatment, and rehabilitation of hearing, balance, and related disorders of the ear and hearing. Audiologists offer services to identify individuals with hearing difficulties; determine the cause of hearing loss; assess hearing needs; treat needs using hearing aids, hearing assistive technologies, and/or auditory habilitation and counseling services; and educate individuals and family members about hearing loss prevention and accommodation. Currently, audiology professional organizations, academic accreditation bodies, and the majority of state licensure laws require a doctor of audiology graduate degree, which typically requires 4 years to complete, in addition to a bachelor's degree. All states require a graduate degree, a qualifying examination, and supervised experience in a clinical fellowship as well as continuing education. State licensing requirements vary. There are approximately 12,250 practicing audiologists in the United States, and they are primarily located in urban areas (BLS, 2014a).

Hearing Instrument Specialists

Also referred to as *hearing aid specialists*, hearing instrument specialists are qualified to identify individuals with hearing loss, assess their need for hearing aids, dispense hearing aids, and educate individuals and their family members about hearing loss. In most states, state laws require that hearing instrument specialists have, at minimum, a high school diploma, a 2-year apprenticeship, and a license to practice. The licensure requirement varies between states, but most require completing an annual application form and paying a fee. Some states require certification which is offered through the National Board for Certification in Hearing Instrument Sciences. There are approximately 5,570 hearing instrument specialists in the United States, and most are located in large cities (BLS, 2014b).

Otolaryngologists

Otolaryngologists are physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, throat, and related structures of the head and neck. After an otolaryngology residency, some

finances, knowledge, skills, and patience necessary to navigate the process may find the process and outcomes to be frustrating and unsatisfactory (Pacala and Yueh, 2012). Furthermore, there have been few randomized controlled trials that have examined the degree of relative effectiveness of and the quality of care provided by these various services; much remains unknown. For individuals in need of hearing health care but unable to overcome the time, financial, and information barriers, there is a lack of information about the options available regarding services and technolootolaryngologists obtain further fellowship training in otology or neurotology to focus exclusively on the medical and surgical conditions of the hearing and balance system. These practitioners are eligible for subspecialty board certification in neurotology. Otolaryngologists are trained to evaluate conditions of the ear that could affect hearing or that require further medical or surgical evaluation. In 2009 just over 10,000 otolaryngologists were estimated to be working in the United States, but there has been a decline in the number of residents seeking board certification since 2006. There have also been changes in their geographic distribution in the United States during this time; from 2004 to 2009, 20.9 percent of counties lost otolaryngologists (Neuwahl et al., 2012).

Primary Care Providers

For most people, primary care providers (such as family practice physicians, geriatricians, nurse practitioners, and physician assistants) are the first point of contact with the health care system (Flocke et al., 1998; Green et al., 2001). Many primary care providers practice within a comprehensive patient-centered medical home (Rosenthal, 2008). They establish long-term relationships with patients and provide care across the spectrum of ages, diseases, and social circumstances (DeVoe et al., 2011; Pandhi and Saultz, 2006; Phillips et al., 2014; Saultz, 2003; Saultz and Albedaiwi, 2004; Saultz and Lochner, 2005; Worrall and Knight, 2006), which can put them in a position to help identify their patient's hearing loss as a possible cause of or confounding factor for social withdrawal, depression, or reduced interactions with family members (Bagai et al., 2006). Primary care providers can be the first to assess and diagnose patients with hearing loss and, in some cases, may be able to treat the patient without a referral to a hearing health care professional. For example, blockage of the ear canal with cerumen can be easily remediated. It is also within a primary care provider's scope of practice to treat outer or middle ear infections as well as to identify and discontinue ototoxic medications, such as certain antibiotics or high-dose nonsteroidal anti-inflammatories. They are also trained to conduct simple hearing screening tests and primary otologic examinations. If the examination identifies hearing loss but does not reveal an obvious cause that is treatable in a primary care setting, referrals are provided to the appropriate specialist (Yueh et al., 2003).

gies and little support to help the consumer understand and compare the potential benefit of various services and technologies.

Access to care has been defined as "the timely use of personal health services to achieve the best possible health outcomes" (IOM, 1993, p. 33), and according to Healthy People 2020, it encompasses the components of coverage, services, timeliness, and workforce (Healthy People, 2016). *Quality of care* is the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM, 1990, p. 4). *Equity* is achieved by removing any systematic differences in the use and outcomes among groups regardless of whether these differences result from financial or other barriers to care (IOM, 1993). This chapter will delve into the practice and delivery of hearing health care and the opportunities to improve access, quality, and equity throughout the system.

SERVICES-BASED INTERVENTIONS FOR HEARING LOSS

Understanding the range of hearing health care services can be challenging. Hearing problems sometimes develop rapidly along with other symptoms such as ear pain, dizziness, or tinnitus, which can herald the onset of infection or disease. Sometimes hearing problems develop so slowly that they are not recognized until a family member or friend expresses concern about difficulties carrying on a conversation with someone due to that person's apparent poor listening or inattention. This is often the case in age-related hearing loss. Hearing health care ranges from the identification and management of diseases or conditions that may cause hearing loss, which sometimes require advanced medical or surgical care, to rehabilitation and the use of hearing aids and hearing assistive technologies to minimize the psychosocial and quality-of-life consequences of permanent hearing loss. As a result, the consumers of hearing health care services may require services from physician or nonphysician professionals, depending on the cause of the hearing problem, the ability of modern medicine to treat any underlying condition (if present) and restore hearing, and the person's need for help coping with difficulties experienced in day-to-day listening activities and communication challenges. Individuals with lower levels of health literacy may not understand the different types of, causes of, and service providers for hearing loss, which adds to the confusion these individuals may face when seeking care for hearing problems (Reese and Hnath-Chisolm, 2005). Furthermore, personal preferences, lifestyle, and communication needs, among other things, may drive different individuals with the same type of hearing loss to opt to use different services or different modes of service delivery (e.g., in-person, online, telehealth) to meet their needs.

Understanding the range of hearing health care is also important for identifying key indicators for the quality of care. Hearing loss can be understood in the context of disease, and quality can be defined as accurate diagnosis and appropriate and timely medical treatment within the context of the *International Classification of Diseases*. Hearing loss can also be understood within the context of communicative and psychosocial functioning, and in that case quality can be defined based on the *International Classification of Functioning, Disability and Health* (ICF). Therefore, defining quality depends on the dimension affected by the hearing impairment. Hearing health care refers to services that can be focused on treating disease, function, or both. If the problem is disease focused, quality can be measured in terms of a timely and successful medical or surgical intervention or reduced morbidity associated with the disease. When the problem is function focused, affecting everyday auditory and communicative activities, social participation, and quality of life, the quality of care can be judged by improvement in hearing and communication abilities and in overall function and quality of life; objective measures are difficult to obtain so an individual's satisfaction remains the primary metric. The quality of audiological management might be defined in terms of the degree of restoration of activities and participation (relative to optimum potential). When the problem is multifactorial, a combined approach is indicated.

Under optimal conditions, hearing health care is a coordinated system, capable of addressing hearing loss from both a medical/disease focus and a functional/rehabilitative focus. Thus, the key to offering efficient and effective hearing health care services is assessing hearing-related problems from both a disease and function perspective and accessing the right services and technologies for the specific needs of the individual, at the lowest cost.

Hearing Health Care Utilization

Most data available on the utilization of hearing health care are from surveys asking people if they have had a recent hearing test or about their use or nonuse of hearing aids. In the 2005–2006 and 2009–2010 National Health and Nutrition Examination Survey datasets, only 39.5 percent of adults ages 70 years and older had had a hearing test in the previous 4 years (Nieman et al., 2016). Overall rates of recent hearing testing were similar for white Caucasians, African Americans, and Mexican Americans (39.1 percent, 43.3 percent, and 41.5 percent, respectively). Within the same study population of adults 70 years of age or older, a multivariable model controlling for age, degree of hearing loss, marital status, and self-reported health conditions found that African Americans, people who were widowed, and those with a college education were more likely to have had hearing tests than were white Caucasians, people who were married, and those with a high school education, respectively. There was no difference in the extent of recent hearing testing between Mexican Americans and white Caucasians. These national data do not address disparities for other minority groups and may not reflect regional or local variations in testing.

In the population-based Epidemiology of Hearing Loss Study cohort, whose participants had an average age of approximately 66 years, 36 percent had never had their hearing tested before the baseline examination in 1993–1995 (Cruickshanks et al., 1998). More recently, in the study which followed up on the adult children (with and without hearing loss) of the participants in that study, 78 percent of those adult children had not talked with their doctors about a hearing problem in the past 5 years, and only approximately 34 percent of the adult children ages 21 to 69 years and approximately 55 percent of the adult children aged 70 years and older had had their hearing tested in the previous 5 years (Nash et al., 2013). Among those who had not had hearing testing in the previous 5 years, 9 percent had a mild to severe hearing loss according to the audiometric examination, which was part of the study. Because audiometric testing is not routinely performed in the United States, many adults with hearing loss remain unaware of a decline in their auditory function. With few published studies addressing hearing health care in the general U.S. population, little is known about the factors or types of symptoms or complaints that make individuals more likely to seek hearing health care.

It is well recognized that the prevalence of hearing aid use is quite low in the United States compared with the prevalence of hearing loss. Data on the extent of hearing aid use are discussed in Chapter 4.

Screening and Case Finding

In 2011 the U.S. Preventive Services Task Force (USPSTF) examined the issue of screening for hearing loss as a population-wide measure during primary care visits for asymptomatic adults aged 50 years and older but did not recommend screening due to insufficient evidence to adequately weigh the balance of potential benefits and harms of screening for this asymptomatic population (I Statement[2]) (Chou et al., 2011; USPSTF, 2014). The USPSTF noted that potential harms from screening could include anxiety, labeling, stigma, or other psychosocial effects but that no studies were available at the time of their analysis to evaluate these outcomes. The USPSTF added, “Because screening and confirmatory testing for hearing impairment are noninvasive and serious harms of treatment are rare, there are probably little to no adverse effects of screening for hearing loss” (USPSTF, 2014). The committee for the present report finds that lack of a USPSTF recommendation for population-wide screening for hearing loss in asymptomatic adults (such as has been recommended for colorectal screening) should not diminish the importance of discussing hearing health on an individual basis in primary care visits when patients present with complaints or the provider has reason to be concerned.

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[2] An “I Statement” from the USPSTF means that “the USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined” (USPSTF, 2013).

Hearing difficulties can negatively affect communication in any setting, and effective communication is particularly important in the health care setting both for patient safety (Middleton et al., 2010) and to enable the person-centered approach toward which the U.S. health care system is moving. For these reasons, it is important to consider changes in hearing ability during patient wellness and medical visits for those patients who express concern about their hearing and are seeking help (see section on primary care providers later in this chapter).

Because hearing tests are usually not a routine part of primary care visits, the onus often remains on the individual or family to recognize the symptoms and seek appropriate hearing health care. There are ongoing efforts to improve hearing health literacy, including the development of tools to help individuals determine when their hearing problems might stem from a medical condition and whether the problems can be managed by audiologists or other nonphysician professionals. Development is ongoing, but initial results are encouraging (Zapala et al., 2015).

Evaluation and Diagnosis

Individuals presenting for a hearing evaluation may be seeking audiological services for several reasons, including self-recognized concerns about the ear and hearing; a referral following signs of poor hearing found during a medical evaluation; the request of family members or friends who suspect hearing loss; or as part of routine health care. The evaluation may vary somewhat among individuals based on such factors as risk for ear disease. Regardless, the objective of the evaluation is always to identify treatable conditions and to assess the impact of any hearing loss on overall function.

Patient History and Otoscopic Exam

The first step is to obtain a general medical and hearing history in order to gather information about the duration and severity of hearing loss, hearing-related medical history (e.g., previous ear infections, symptoms of ear pain or drainage, family history of hearing loss, prescription and over-the-counter medication history, etc.), and previous use of hearing loss interventions. Further interview questions and standardized questionnaires may be used to assess the impact of hearing loss on the individual's day-to-day life.

Second, an otoscopic examination is performed to evaluate the pinna (outer ear), external auditory canal, and tympanic membrane for any conditions that could be contributing to hearing loss or that may require further evaluation and treatment (e.g., cerumen impaction, an abnormality of the tympanic membrane, etc.). Based on the findings during the history and exam, it may be appropriate to refer the patient to a physician for additional evaluation.

Diagnostic Testing

Pure tone audiometry Pure tone audiometry measures the lowest intensity level at which an individual can detect calibrated pure tones at specific frequencies between 250 and 8,000 hertz (Hz). The level at which a person is estimated to detect a calibrated pure tone 50 percent of the time is defined as a "threshold." Intensity levels are calibrated in decibels (dB) relative to average normal hearing (dB hearing level or dB HL) and can range from –10 to 120 dB HL. Typically, pure-tone thresholds between –10 and 20 dB HL are considered within normal limits.

Pure tones can be delivered through headphones to the right and left ears individually so that the sound travels through each ear canal and middle ear to the cochlea within the inner ear (termed "air conduction" hearing). Alternatively, pure tones can also be delivered to the skull using a bone oscillator so that the sound passes through the skull and directly stimulates the cochlea, bypassing the ear canal and middle ear ("bone conduction" hearing). By looking at the patterns of air conduction and bone conduction thresholds, the practitioner can make some conclusions about the nature of the hearing loss. When hearing loss is the result of damage to or disease of the ear canal, eardrum, or middle ear, air conduction thresholds will be higher than bone conduction thresholds—termed a "conductive hearing loss." When air conduction and bone conduction thresholds are similar but fall outside the limits of normal hearing, the hearing loss is called a "sensorineural hearing loss."

Speech audiometry In the United States, speech audiometry uses simple, two-syllable words presented via headphones to each ear individually to determine the lowest intensity level at which 50 percent of the words are correctly repeated, termed a *speech reception threshold*. Speech reception thresholds ranging from –10 to 20 dB HL are considered within normal limits. There are also forms of speech-in-quiet and speech-in-noise testing designed to emulate commonly occurring listening environments, which can contribute to functional needs testing and to evaluating an individual's expected benefits from amplification, described below. Disproportionately poor speech recognition performance in relation to an individual's thresholds for pure tones may suggest changes to the function of the cochlea, auditory vestibular nerve, brainstem, or central processing.

Immittance audiometry Immittance audiometry (sometimes referred to as "acoustic impedance" or "admittance testing") includes tympanometry and assessments of the acoustic reflex threshold. These tests are typically used to establish middle ear pressure and to estimate the transfer of acoustic energy through the middle ear system, which can help differentiate between different disorders.

Functional Communication Assessment

The aims of a functional communication assessment are to define an individual's audiologic and nonaudiologic needs related to hearing and communication, establish the impact of hearing loss on the individual and his or her communication partners (e.g., family), and to determine from which services and technologies the individual may derive benefits (ASHA, 2016f; Valente, 2006). When there is a strong relationship between measured hearing impairment and reported hearing and communication difficulties, managing the hearing difficulties through technologies and/or rehabilitation may be beneficial and sufficient. When there is a mismatch between reported difficulties and the magnitude of measured hearing difficulty, other factors must be explored, including the unique environments that the individual may operate in, the behaviors of other people who frequently interact with the individual, and psychological and cognitive factors such as intellectual capacity, anxiety, and depression. These factors match the biopsychosocial model underpinning the ICF.

Along the lines of the ICF framework, audiological testing captures primarily the impairment aspect of auditory function. However, audiologists must be mindful of hearing difficulties that arise with *noncommunicative activities* such as the detection of threats and alarms; the ability to localize sounds in space; and recognizing the sounds of events in the surrounding environment (a coin dropping on the floor, for example, or an automobile accident outside of the building). There are also *communicative activities* that can be difficult to assess and quantify because each individual lives in a unique auditory environment, but there are several touchstone conditions, such as the ability to understand a conversation in one-on-one and group settings, and the abilities to recognize and understand low-level or whispered speech, speech presented in background noise, and speech presented at high intensity levels.

Individuals being evaluated for the functional consequences of hearing loss most likely have a chronic problem, which is unlikely to improve spontaneously or through medical or surgical treatments. Consequently, treatment must focus on maximizing residual capacity to facilitate participation to the greatest extent possible.

Evaluation and Diagnosis Summary

The results of the audiological evaluation should answer the following questions:

- Is the hearing loss or other form of hearing loss a result of a disease process that requires medical care?
- Is the magnitude of any measured hearing loss sufficient to create a functional deficit, and if so, can diminished function explain the concerns of the individual being evaluated?
- If there is a mismatch between the magnitude of the hearing loss and the concerns of the individual being evaluated, are there identified psychosocial factors to explain the mismatch, and are any additional investigations or referrals necessary?
- If there is no mismatch, which strategies will be the most effective for maximizing function (e.g., technologies, rehabilitation)?
- If the magnitude of any hearing loss or other form of auditory impairment is not sufficient to cause concern about disease or impaired function at present, what is the risk for developing hearing loss in the future, and are there any health or lifestyle changes that might mitigate future risk?

The answers to these questions drive the individualized audiological treatment plan. When an audiological evaluation is performed as an adjunct to a physician's medical evaluation, some of these questions may be deferred to the referring physician. The same set of tests of auditory function can be used to evaluate both the possibility of disease and the effects of hearing loss on function, although most of the traditional test battery is focused on the diagnosis of disease. Additional tests, such as otoacoustic emissions tests and tests for the characterization of tinnitus, may be used to distinguish between more complex forms of otologic disease or auditory dysfunction and are not reviewed here.

Treatment

Treatment for hearing loss can take many forms and will differ based on an individual's type of hearing loss, unique needs in daily life, personal preferences, and financial means. Treatments can include such services as auditory rehabilitation and counseling as well as various technologies (see Chapter 4), although not every person with hearing loss is a candidate for a hearing aid or other assistive technologies. Medical and surgical treatments are not part of this report's statement of task and will not be discussed.

Selection, Fitting, Maintenance, and Use of Hearing Technologies

Many hearing health care professionals provide services and support to users of hearing technologies. The most common device-related services are the provision of and assistance with using hearing aids (see Chapter 4 for a discussion of hearing aids and hearing assistive technologies), which includes hearing aid selection, fitting, verification, and validation within the context of the functional communication assessment (for best practice guidelines for audiologic management of hearing loss in adults, see ASHA, 2016f and Valente, 2006; for a review of the components of hearing aid fitting management across worldwide guidelines, see Oh and Lee, 2016). Following best practices in audiology in the United States, selection of a hearing aid is based on an individual's needs and requirements for hearing aid gain, ear canal geometry, occlusion, special features (e.g., directional microphone, noise reduction circuit, feedback suppression, telecoil), ease of insertion and manipulating volume controls, and cosmetics. Determination of gain processing is initially based on a validated prescriptive procedure, such as those developed by the National Acoustics Laboratories (Byrne and Dillon, 1986; Byrne et al., 2001; Johnson and Dillon, 2001; Mueller, 2005). Other aspects of the hearing aid evaluation include selection of output limiting and compression features, and consideration of the need for special technologies that go beyond the scope of this report (e.g., bone-anchored hearing aids, contralateral routing of signal fittings, and middle-ear implants). Gain verification using a probe microphone ("real-ear" measures) is the most reliable method to validate that prescriptive gain targets have been achieved (Abrams et al., 2012; Mueller, 2001). Best practices for operating, maintaining, and using hearing aids are then discussed, with emphasis on both the devices and the individual. Device-related orientation includes instruction on hearing aid insertion and removal, use schedule, hearing aid features, reducing feedback, changing batteries, and performing maintenance. Patient-related orientation includes setting goals and expectations, methods for adjusting to amplification, counseling on communication strategies, and considerations for supplementary rehabilitation, such as speech reading or speech-perception training. Finally, a plan for assessment of treatment benefits is initiated using validated subjective and objective outcome measures (for examples, see Cox and Alexander, 1995; Cox et al., 2003; Dillon et al., 1997; Ventry and Weinstein, 1982). Follow-up visits may be required to perform further adjustments and to provide further education on the correct operation, maintenance, and usage of the hearing aid(s) or other technologies, including changing of batteries (Desjardins and Doherty, 2009). In the longer term, additional visits may be necessary to ensure that the hearing aids continue to perform optimally and that hearing remains stable.

Although hearing aids are the more common treatment for which hearing health care professionals provide services and support, these professionals can also provide similar services for hearing assistive technologies (such as products connecting with the television or phone, see Chapter 4) even if they do not sell those technologies. Increased attention to hearing assistive technologies is needed in hearing health care professional training to enable these professionals to provide individuals with hearing loss information on the range of technologies available and to help individuals determine what technologies might be useful to them given the nature and extent of their specific hearing loss and communications needs. Tables 3-1 and 3-2 provide the distribution of hearing health care professionals who fit hearing aids and the distribution of venues that provide hearing aids, respectively, from one survey of the field.

Auditory Rehabilitation

Pharmaceuticals and medical devices cannot always provide definitive solutions for chronic health conditions or meet the specific needs and preferences of every individual. Similarly, for individuals with hearing loss, hearing aids cannot unequivocally address the multifaceted challenges of living with hearing loss, such as the hearing loss itself, communication difficulties, changes in quality of life, and possible comorbidities (see Chapter 2). Like other chronic health conditions, hearing loss requires a holistic, individual-centered approach to care that blends both medical and nonmedical solutions, such as auditory rehabilitation (also referred to as aural rehabilitation or audiological rehabilitation). Overall, auditory rehabilitation is designed to help individuals learn to live with hearing loss, provide information on the use of hearing aids and hearing assistive technologies, teach strategies for better listening and communication, and, in some cases,

TABLE 3-1
Hearing Aid Fittings Dispensed by Profession According to the 2008 MarkeTrak VIII Survey

Profession	Percent of Fittings
Audiologist	62.9
Hearing Aid Specialist	31.1
Physician	1.5
Other	4.5

SOURCE: Kochkin, 2009. Republished with permission of Newstex, LLC.

TABLE 3-2
Hearing Aid Modes of Delivery
According to the 2008 MarkeTrak VIII Survey

Source of Hearing Aid Distribution	Percentage of Survey Takers
Audiologist's office	31.2
Hearing aid specialist's office	27.5
Veterans Health Administration	14.5
Ear doctor's office	9.2
Mail order	4.7
Wholesale club	2.4
Department store	2.1
Clinic	1.2
Military installation	1.2
Hospital	1.1
Family doctor's office	0.5
Home	0.5
Drugstore	0.3
Other	2.4

SOURCE: Kochkin, 2009. Republished with permission of Newstex, LLC.

offer psychosocial support (ASHA, 2016b; Boothroyd, 2007; Sweetow and Palmer, 2005).

Auditory rehabilitation programs can take many shapes and reflect a variety of paradigms. For example, these programs may be offered with a group in a community setting or on an individual basis in an audiology clinic. Sessions may be led by an audiologist, a speech-language pathologist, or a trained volunteer (Bally and Bakke, 2007). Alternatively, individuals may take part in self-paced, multimedia rehabilitation programs from their home. Programs have been designed for an array of individuals with varying degrees and types of hearing loss and across all age groups. These programs may be focused on individuals who are new to using hearing aids, those who are experienced hearing aid users, or those who have hearing loss but do not use hearings aids. An individual's needs, preferences, abilities, and goals, along with the specific characteristics of the person's auditory disorder, should be considered in order to determine the type of auditory rehabilitation program(s) that would be best suited for that individual. This section will discuss the available evidence for auditory-based rehabilitation programs and for counseling-based, supportive programs, both of which may include Internet- and computer-based designs that are becoming more common.

The goal of auditory rehabilitation programs is to improve speech communication through the use of auditory training, and most of the studies that evaluate auditory training focus on measuring the different aspects of speech recognition. This training may be analytic in nature, centered on differentiating and identifying different parts of speech (e.g., vowels and consonants), or it may be synthetic, teaching listening skills and applying linguistic and context-specific techniques. Some auditory rehabilitation programs combine both of these strategies to maximize the opportunities for positive outcomes for individuals with hearing loss. Although an individual's family may be included in consultations and hearing aid orientation, auditory rehabilitation is typically designed to enhance the speech recognition of the individual with hearing loss and does not involve family members or other communication partners (some programs may incorporate family in home-based practice or in communication strategies training). Sweetow and Palmer (2005) conducted a review of available literature on auditory rehabilitation that included randomized controlled trials, cohort studies, and pre/post study designs, regardless of whether the study design included control groups or reported outcomes using subjective or objective measures; only 6 out of 213 studies met these defined inclusion criteria. The outcomes measured in these studies included factors connected to consonant recognition, speech perception with a range of one word to full sentences, and self-perception. Despite finding methodological shortcomings (e.g., small sample sizes, variable demographic data, a lack of long-term measures, a lack of blinding, inconsistent paradigms, variable outcome measures) and a lack of resounding evidence, the authors cautiously concluded based on a qualitative assessment that auditory training, specifically synthetic training, could be beneficial to individuals with hearing loss for the outcomes that were measured (Sweetow and Palmer, 2005).

Chisolm and Arnold (2012) updated the Sweetow and Palmer review and added four more studies to the analysis.[3] To further examine the evidence in the 10 studies, Chisolm and Arnold (2012) conducted a meta-analysis using the studies that included comparable outcome measures (6 out of 10 studies) related to speech recognition, regardless of factors that varied across the studies, such as listening environment and stimuli. The authors found that in the short term there was a small, but reliable, effect for improvements in speech recognition. Based on their findings, they concluded that "clinicians should have increased confidence in recommending

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[3] A comprehensive summary of the studies and the outcome measures that are described in these two reviews can be found in Chisolm and Arnold (2012).

the use of an auditory training program as a part of a comprehensive auditory rehabilitation plan" (Chisolm and Arnold, 2012, p. 249). However, they cautioned against assuming that improvements would be preserved over a longer timeframe, given a lack of data on long-term outcomes. In a more recent study by Kuchinsky and colleagues (2013), researchers used a physiologic measure of cognitive effort—pupil dilation—to study a speech-perception training program, which is a form of auditory training. The researchers found that participation in auditory training resulted in increased word recognition and that it reduced the cognitive effort required to identify words in the presence of background noise, a common complaint of people with hearing loss.

Of the 10 studies reviewed by Chisolm and Arnold in 2012, the authors concluded that only 1 study provided evidence and methodologies that were sound enough to be considered for clinical implementation—the 2006 study of the computer-based auditory training program, Listening and Communication Enhancement (LACE) (Chisolm and Arnold, 2012; Sweetow and Sabes, 2006). LACE is an interactive, adaptive program delivered in home settings that is available via the Internet, DVD, or CD (Neurotone, 2016; Sweetow and Sabes, 2006). The exercises included in the program are intended to produce "better comprehension of degraded speech, enhancement of cognitive skills, and improvement of communication strategies" (Sweetow and Sabes, 2006, p. 543). Studies of LACE have found statistically significant improvements on most of the outcome measures studied (usually tasks taught within the program related to improving speech recognition and the goals listed above), relatively high rates of compliance, better outcomes for new hearing aid users than for experienced users, and better outcomes for those who completed all of the training sessions than for those who did not (Chisolm et al., 2013; Henshaw et al., 2015; Olson et al., 2013; Sweetow and Sabes, 2006). However, a recent randomized controlled trial in a population of veterans found no statistically significant improvement in outcomes among those using LACE when compared to those using standard of care hearing aid intervention alone (Saunders et al., 2016).

Since the development of LACE, other computer-based auditory training programs have been tested with mixed results (Abrams et al., 2015; Dubno, 2013; Saunders and Chisolm, 2015). Henshaw and Ferguson (2013) conducted a systematic review of literature on these types of computer-based programs. The authors reviewed 13 studies out of 229 that were originally identified. These studies were randomized controlled trials, nonrandomized controlled trials, cohort studies, or pre/post studies. Although the authors identified statistically significant improvements on tasks that were taught within the various programs, the evidence was mixed in terms of improved speech recognition. The evidence suggested that, when reported, there were high rates of compliance and that information presented during the training was retained for extended periods of time (up to 7 months). Unlike the Chisolm and Arnold (2012) review described above, a meta-analysis was not possible due to the heterogeneity of the studies. Henshaw and Ferguson also described challenges with the large variability in study design, protocols, outcome measures, participant inclusion, and individual benefits that resulted from the training. However, the authors did highlight the potential of computer-based auditory training programs, noting that these programs are easily accessible, customizable and flexible, and both cost and time efficient (Henshaw and Ferguson, 2013). Additionally, researchers have highlighted patient-perceived benefits associated with the use of computer-based auditory programs which include increased self-confidence and general satisfaction and enjoyment (Saunders and Chisolm, 2015; Tye-Murray et al., 2012). Current and ongoing studies of computer-based auditory programs (Miller et al., 2015; Saunders et al., 2016) hold promise for expanding the evidence base of these programs and informing decisions about the design of future programs.

Counseling-Based, Supportive Rehabilitation

Rehabilitation programs that concentrate on counseling/psychosocial support, personal adjustment/coping, and building communication skills offer a platform for improving attitudes and beliefs, building resilience, reducing experienced and perceived stigma, and empowering individuals to take a more active role in managing their hearing loss (also see Chapter 6). These types of programs are usually offered in a group setting and may be led by an audiologist or a trained health professional. Hawkins (2005) conducted a systematic review of rehabilitation programs of this nature which included randomized controlled trials, quasi-experimental study design, and nonintervention cohort studies. Unlike the case with auditory training, which can be evaluated using objective measures, the outcomes measured in these studies tended to be more subjective, assessing individuals' self-perceived changes in personal adjustment/coping, limitations related to their hearing loss, and overall satisfaction with hearing aids. Based on an evaluation of 12 studies (out of 22 identified), Hawkins concluded that there is some evidence that these types of counseling-based programs had a positive effect on self-perception and self-esteem and also positively contributed to the use of enhanced communication skills and hearing aids (Hawkins, 2005). Most of the available studies identified for this review used nonexperimental designs, had small sample sizes (usually less than 50 people), and did not track long-term outcomes—common limitations in this area of literature. Hawkins (2005) hypothesized that the generally strong support among experts and clinicians for counseling-based group rehabilitation, despite the lack of conclusive evidence, is a result of clinical experience and observed benefits for patients.

In a subsequent review of the literature, Chisolm and Arnold (2012) narrowed the inclusion criteria to randomized controlled trials with control groups that included outcome measures related to quality of life and reductions in limitations related to hearing loss. The authors found three new studies that met their criteria and revisited 7 of the 12 studies originally reviewed by Hawkins (2005). Upon assessment of the methodologies and the evidence presented in the studies, Chisolm and Arnold determined that the evidence for three of the counseling-based programs (i.e., Chisolm et al., 2004; Hickson et al., 2007; Preminger and Yoo, 2010) was supportive enough to warrant consideration for inclusion in clinical practice. To further examine the available evidence, the authors conducted a meta-analysis of the 10 studies and found statistically significant effects—but large variability—when assessing whether these programs reduced perceived limitations related to hearing loss. As with auditory training programs (discussed above), Chisolm and Arnold concluded that counseling-based rehabilitation programs offer small but reliable benefits and that health professionals can recommend these programs to individuals and their families with increased confidence (Chisolm and Arnold, 2012). Roets-Merken and colleagues (2015) conducted a systematic review and meta-analysis of the literature on counseling-based rehabilitation programs for both hearing loss and vision impairment. The authors evaluated the studies for outcomes specifically related to functional and emotional status, social engagement, and self-efficacy. Based on the six hearing loss studies that used randomized controlled trial or control trial designs and met the inclusion criteria, the researchers concluded that there was no statistically significant effect of these programs on the defined measures related to quality of life and well-being.

Since Chisolm and Arnold (2012) conducted their review of the literature, additional studies looking at counseling-based rehabilitation programs have been published. Box 3-2 provides two examples of recently evaluated rehabilitation programs in the United Kingdom and Sweden that employed interactive strategies to boost knowledge and to respond to the psychosocial needs of people with hearing loss. Borg and Borg (2015) described a rehabilitation program oriented toward young adults, using a nonexperimental design with subjective outcomes, and Ferguson and colleagues (2015, 2016) used a randomized controlled trial design to test an Internet-/computer-based educational intervention for new hearing aid users.

Some of the more integrative counseling-based rehabilitation programs have actively incorporated spouses, communication partners, and family members and have identified possible positive outcomes for both the person with hearing loss and the family member participants (Caissie et al., 2005; Habanec and Kelly-Campbell, 2015; Preminger and Meeks, 2010; Scarinci

Box 3-2 EXAMPLES OF RECENTLY REVIEWED COMMUNITY-BASED REHABILITATION PROGRAMS

In Sweden, Borg and Borg (2015) developed a rehabilitation program for young adults with hearing loss called the EC program, which was based on principles of empathy and empowerment (E) and competence and counseling (C). The program used short videos, group meetings, CDs, and DVDs during seven or eight, 2-hour weekly sessions to build self-confidence and competence and to foster independence, creativity, and self-awareness. The ultimate goal was to empower the young adults to educate and counsel others about hearing loss and to respond constructively during sometimes difficult, social interactions—a vital skill for the transition to adulthood. The habilitation/rehabilitation centers that implemented the EC program often adopted parts of the program rather than implementing all aspects of it, thus making comparison and evaluation difficult. Overall, the leaders of the programs rated the interventions positively, with indications that the participants had gained greater knowledge about hearing and about how hearing loss affected their lives and interactions with others. The evaluations also concluded that participants were more confident and could more easily explain the challenges associated with hearing loss to others. When asked about how the program could be improved, participants suggested the development of Web-based courses and chat functions that would allow people to connect more readily across geographic regions (Borg and Borg, 2015).

In the United Kingdom, Ferguson and colleagues (2015, 2016) used a prospective randomized controlled trial to test a multimedia rehabilitation program that was designed for first-time hearing aid users. The program included seven interactive modules that featured videos, pictures, diagrams, animations, testimonials, and quizzes to test the users' comprehension of the material. The program, which required less than an hour to complete, was delivered via DVD (for computers or television) or the Internet and could be used in home settings. Six weeks after the completion of the program, participants demonstrated statistically significant improvements and short-term retention of knowledge related to practical (e.g., earmold cleaning, telephone skills) and psychosocial (e.g., the limitations and benefits of hearing aids) areas that were presented during the intervention. Participants rated the program as highly valuable and indicated a preference for the interactive materials over static written resources. Additionally, almost half of the participants watched the modules two or more times (Ferguson et al., 2015, 2016). In their review of the data, the researchers pointed out that participants had higher levels of knowledge related to the limitations of hearing aids than members of the control group, whereas their knowledge about the benefits of hearing aids was the same as that of the control group (Ferguson et al., 2016).

et al., 2013). These types of inclusive, family-centered rehabilitation programs recognize the effects of hearing loss on family members (often referred to as a third-party disability), take the needs of family members into account, and are intended to increase awareness and enhance communication for everyone who is touched by the hearing loss within the family. Using randomized controlled trials, both Preminger and Meeks (2010) and Habanec and Kelly-Campbell (2015) engaged spouses of individuals with hearing loss in group-based auditory rehabilitation sessions. Following participation in the programs, spouses reported statistically significant reductions in measures of third-party disability and improvements in communication. Despite the potential value of inclusive, group-based programs, this approach may not always be able to respond to the individual needs, circumstances, and preferences of each of the individuals in the group, suggesting that a combined approach to rehabilitation may optimize results.

In recent years, researchers have also explored the use of computer- and Internet-based modules as cost-effective, convenient mechanisms for increasing access to and use of counseling-based, supportive rehabilitation programs. Many of these programs have been developed using models from auditory training programs. Overall, evaluations of Web-based education and rehabilitation programs have identified positive outcomes, including increases in knowledge, decreases in perceived limitations related to hearing loss, and decreases in depression and anxiety (Ferguson et al., 2015, 2016; Laplante-Lévesque et al., 2006; Thorén et al., 2011, 2014). See Box 3-2 for a discussion of an Internet-based rehabilitation program that was recently tested by Ferguson and colleagues (2016) with 203 new hearing aid users. Internet-based education and rehabilitation programs offer a promising opportunity to extend the reach of limited resources, engage people with hearing loss and their families, and bolster knowledge and confidence.

OPPORTUNITIES TO IMPROVE HEARING HEALTH CARE SERVICES

In considering its task of improving accessibility and affordability of hearing health care, the committee identified a number of opportunities to change hearing health care services for the benefit of the patient and consumer. These opportunities, which are discussed in the sections that follow, include

- Enhance quality in patient–provider interactions
- Involve primary care providers in hearing health care
- Empower consumer and patient use of hearing health care
- Support and engage in quality improvement
- Overcoming disparities in services delivery and access
- Improve and expand the use of auditory rehabilitation programs
- Develop and evaluate innovative models of hearing health care delivery
- Examine the Medicare requirement for physician referral for diagnostic hearing testing

Enhance Quality in Patient–Provider Interactions

As is the case with other chronic health conditions, the effective diagnosis, treatment, and management of hearing loss is best achieved using a patient-centered approach to care and a collaborative and supportive relationship with the professionals who provide that care. However, interviews of individuals with hearing loss and their families indicate that interactions with health care providers and hearing professionals do not always meet their needs and expectations (Kelly et al., 2013; McCormack and Fortnum, 2013; Southall et al., 2010). Anecdotal evidence from people with hearing loss has shown that some health professionals, like their patients (see Chapter 6), may maintain the beliefs that hearing loss is a natural part of aging and that hearing aids and other treatment options have low levels of efficacy (Gilliver and Hickson, 2011; van den Brink et al., 1996; Wallhagen and Pettengill, 2008). Studies also indicate that hearing loss is often neglected or dismissed in primary care settings, implying that it is not always viewed as a priority despite the potential health implications (see Chapter 2).

Whether increasing slowly over time or occurring with a sudden onset, hearing loss is a condition that needs to be processed and accepted before an individual can be fully ready to take action and consider and adopt treatment options (see the discussion of the transtheoretical model in Chapter 6). Health care professionals can play a positive, supportive role in helping individuals accept and adjust to a diagnosis of hearing loss. However, a review of first-time consultations with audiologists in Australia found a lack of demonstrated empathy and a divergence between the patients' needs and the goals of the audiologists (Ekberg et al., 2014). For example, when the audiologists delivered the diagnosis, two-thirds of them directly transitioned into a recommendation for hearing aids, without allowing the patient time to react or ask questions about the diagnosis and without discussing other available treatment options (e.g., hearing assistive technologies, communication programs, support groups) (Ekberg et al., 2014). Furthermore, audiologists in this study often overlooked the psychosocial needs of their patients. In approximately half of the encounters (51 percent), patients voiced psychosocial concerns and negative attitudes toward the idea of adopting hearing aids, sometimes with an emphasis on perceived stigma. However, the audiologists usually redirected the conversation to a discussion of the various models of hearing aids available. Given these unsatisfactory interactions, many patients left the consultation without agreeing to a treatment strategy. To improve these interactions with patients, Ekberg and colleagues (2014) suggested that the principles of personal adjustment counseling and patient-centered care should be emphasized in training for audiologists. Motivational interviewing—a patient-centered approach to counseling and behavior change that has been applied in a number of medical settings (Lundahl et al., 2013)—may also benefit the patient–provider interaction following a diagnosis of hearing loss and in considering patient preferences and needs regarding treatment. At least one study is under way to investigate the potential for using motivational interviewing via the Internet to promote individuals to seek additional hearing health care if they have failed a prior hearing test (Weineland et al., 2015). Optimal patient–provider interactions following a diagnosis require that hearing health care professionals recognize the patient's level of acceptance, adjustment, and readiness for action; identify the patient's information needs; consider whether the patient's level of health literacy may interfere with comprehension (see Chapter 6 for a discussion of health literacy); and provide the appropriate levels of support and empathy to the patient and his or her family, who may also be involved in decision making and care for the individual with hearing loss.

In the context of the social-ecological model (see Chapter 1), the role of health care and hearing health care professionals in educating and supporting individuals and their families about hearing loss, treatment options, and management is critical. The information provided and the attitudes projected by health care providers are consequential in shaping the attitudes and beliefs of individuals and the subsequent actions taken by those individuals. For example, interviews with individuals about the adoption and use of hearing aids indicated that individuals were more likely to pursue the use of hearing aids and overcome challenges in adapting to hearing aids when they developed a good relationship with their audiologist because of such factors as perceived consideration, warmth, and empathy (Dawes et al., 2014). Following a review of available literature, Clements (2015) suggested that the first consultation with an audiologist or other hearing health care professional may have a long-term effect on decision making and outcomes. If the encounter creates a negative patient response, it is more likely that that individual will return to a state of denial about his or her hearing loss (the pre-contemplation phase in the transtheoretical model in Chapter 6, Figure 6-2) and deny the need to take action, further delaying possible opportunities to improve quality of life and well-being (Clements, 2015). The likelihood that an individual will make appropriate decisions about how to move forward in treating hearing loss may be affected by multiple factors, including the cost and convenience of the treatment and the lifestyle and personal attitudes of the patient. One challenge that hearing health care professionals and patients face is ensuring that there is plenty of time for the discussion of options and next steps, particularly regarding the purchase and fitting of hearing aids. The patient may be asked to make a large investment in hearing aids at the same time that the patient is adjusting to a new diagnosis of hearing loss.

The literature on patient-centered care in various areas of health care is replete with examples of the benefits of listening and responding to patients' concerns, considering patients' specific needs and preferences, and engaging them in shared decision making about available treatment options (Epstein and Street, 2007, 2011; IOM, 2001, 2011c, 2014, 2015a; Meyers et al., 2010). Hearing health care professionals—as with other health care professionals—need to engage in best practices in patient-interaction processes and take the necessary time to understand the attitudes, concerns, health literacy needs, and priorities of individuals with hearing loss; discuss all available treatment options, not just hearing aids; know what community-based education and support resources are available both locally and online; educate individuals about the use, operation, and maintenance of hearing aids and hearing assistive technologies at an understandable level; and manage user expectations and beliefs. Providing a written summary of the discussion may also be helpful since an individual's hearing loss can affect communication during the office visit.

Involve Primary Care Providers in Hearing Health Care

Enhancing discussions about hearing loss between patients and health care professionals as a part of regular health assessments in primary care settings could help improve hearing health, promote its importance as a health priority, and decrease delays in referral and treatment. Because primary care providers (such as family practice physicians, geriatricians, nurse practitioners, and physician assistants) are often the first to assess and diagnose patients with hearing loss (Bagai et al., 2006; DeVoe et al., 2011; Flocke et al., 1998; Green et al., 2001; Pandhi and Saultz, 2006; Phillips et al., 2014; Rosenthal, 2008; Saultz, 2003; Saultz and Albedaiwi, 2004; Saultz and Lochner, 2005; Worrall and Knight, 2006), they can play a vital role in referring patients to the hearing health care system and following up to ensure that the patient receives all necessary care. Furthermore, as health care professionals who may have long-term relationships with patients (DeVoe et al., 2011; Phillips et al., 2014), primary care providers can help patients and their family members navigate the hearing health care journey and serve as sounding boards, trusted advisors, and advocates. For example, tinnitus is a hearing concern that patients often present to primary care providers and, although it can occur without hearing loss, it frequently accompanies hearing loss (Hoare, 2013). Primary care providers can help navigate the medical and audiological evaluations that may be required, provide assistance in gaining access to other support services, and help facilitate referrals for patients who may benefit from a community support group or, for those requiring long-term care, a residential facility that specializes in supporting people with hearing loss (McKee, 2013; Yueh et al., 2003). Primary care teams within the medical home can also provide support and education to patients having difficulty with the use of the technologies (e.g., inserting hearing aids, changing batteries, and adjusting hearing aids for different noise environments and to interface with different technologies such as a telephone, television, stereo, and other sources of sound).

In spite of the many opportunities the patient–primary care provider relationship can present for helping identify, inform, and possibly treat hearing loss, substantial evidence shows that hearing loss is often underdetected and undertreated in primary care settings (Cohen et al., 2005; Danhauer et al., 2008; Johnson et al., 2008). There are many reasons for this. Individuals might be reluctant to admit their hearing challenges to their primary care provider or may not experience hearing difficulties in the quiet setting of an exam room even though they do have hearing difficulties in noisier settings (Bogardus et al., 2003). Furthermore, primary care providers might find it challenging to add hearing screening to acute care visits due to time constraints, a lack of reimbursement, or a lack of a structured reminder (Johnson et al., 2008). For older adults, some primary care providers may think hearing loss is simply a normal part of aging and that there are no worthwhile treatment options. Additionally, primary care providers may not be aware of existing hearing health care resources and guidelines. Research is needed to determine how often primary care providers are discussing their patient's hearing concerns, offering hearing assessments, and, ultimately, whether their interventions result in their patients getting the hearing health care they need.

As part of the Patient Protection and Affordable Care Act,[4] the Medicare Initial Preventive Physical Exam and the Annual Wellness Visit include provisions for reviewing patient hearing status in the primary care setting. To make the best use of these provisions and the opportunity to detect hearing loss in any primary care visit, regardless of the type of insurance, studies are needed to identify the most effective methods for improving the likelihood and ease of detecting hearing loss in patients when a patient presents in the office of a health care professional who is not a hearing specialist. Some primary care providers have implemented systems to make hearing screenings a part of routine care. Examples include asking patients to complete a pre-exam survey, training nonphysician personnel to perform basic screenings, conducting an oral history, or exploring the potential for hearing loss concerns through a whisper or a finger rub test. In particular, primary care providers should be vigilant for hearing changes in patients who present with comorbid conditions such as depression or cognitive

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[4] Patient Protection and Affordable Care Act, Public Law 111-148, 111th Cong., 2nd sess. (March 23, 2010).

dysfunction, which may be associated with or exacerbated by hearing loss and therefore might improve with the use of assistive technologies (Mulrow et al., 1990). As the first point of contact that many patients have with the health care system, primary care providers play a critical role in identifying hearing loss and facilitating patient access to additional hearing health care when appropriate, and they could be used more. However, primary care providers are only one part of the hearing health care team, and most individuals with hearing loss would likely benefit from services provided by many members of the team. Primary care providers are increasingly practicing within a patient-centered medical home and could benefit from additional training in supporting a team-based care approach specific to hearing health.

Empower Consumer and Patient Use of Hearing Health Care

There are multiple opportunities to empower consumers in their use of hearing health care which may also reduce barriers and improve access to hearing care.

Food and Drug Administration Regulations on Medical Evaluation or Waiver

Because the sale of hearing aids is regulated by the Food and Drug Administration (FDA) (see Chapter 4 for more detail), a dispenser selling hearing aids must follow the Code of Federal Regulations regarding the conditions of sale of hearing aids. Among other stipulations, FDA's regulations require that prior to obtaining hearing aids, a patient must provide the hearing aid dispenser with a "written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid" (see Box 3-3). The FDA regulation provides an alternative whereby patients 18 years of age or older can sign a waiver of that evaluation (see Box 3-3). This regulation was enacted in 1977 out of concern for the potential of hearing aids to be substituted for the medical or surgical treatment of hearing loss and possibly lead to further declines in patient health (Mann and Nandkumar, 2015). The committee explored this issue, obtained and evaluated data from the available literature and from the Department of Veterans Affairs (VA) and the Department of Defense (DoD), and concluded that the health risks are low, this regulation provides no clinically meaningful benefit, and the waiver presents a barrier to access with no substantial enhancement of patient safety.

First, the committee examined the nature and extent of the medical conditions listed in the FDA regulations as well as others that could be cause for concern. Although not directly tied to the medical evaluation

Box 3-3 CODE OF FEDERAL REGULATIONS ADDRESSING MEDICAL EVALUATION CONDITIONS FOR HEARING AID SALE

21 C.F.R. § 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements—*

> (1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.
> (2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:
>
> > (i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
> > (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
> > (iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by _____ _____ (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

SOURCE: C.F.R. Title 21: Hearing aid devices; conditions for sale § 801.421.

requirement, a separate section of the regulations (21 C.F.R. § 801.420) states that hearing aid dispensers should be aware of eight health concerns and "should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist)" if those conditions are seen through actual observation or learned from other information such as patient history. The eight conditions that have been termed the "red flag conditions" are

- "Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear within the previous 90 days
- History of sudden or rapidly progressive hearing loss within the previous 90 days
- Acute or chronic dizziness

- Unilateral hearing loss of sudden or recent onset within the previous 90 days
- Audiometic air-bone gap equal to or greater than 15 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal
- Pain or discomfort in the ear" (21 C.F.R. § 801.420).

Concerns related to not identifying these conditions prior to the dispensing of hearing aids include the following: (1) the patient's condition could be resolved through medical or surgical procedures or treatments, without the need for hearing aids; (2) given the patient's condition, hearing would not be expected to improve with hearing aids, so the patient would be sold a product he or she does not need; or (3) use of hearing aids could mask an ongoing health condition that could go untreated and possibly cause further detriment to hearing or health.

To determine whether the above-mentioned concerns were significant enough to justify keeping the medical waiver regulation in place, the committee assessed the data available in the scientific literature on the incidence and prevalence of the eight conditions and others that could relate to hearing loss. The committee also obtained data from the VA which reported the incidence of medical conditions in veterans requiring referral to otolaryngologists by audiologists, and the committee obtained data from the DoD on the incidence of hearing-related medical conditions in service members based on a review of medical coding data (see Table 3-3). The data show that these medical conditions are rare. Most of these medical conditions present with symptoms that are obvious to the patient or the provider (e.g., drainage, pain, deformity, conductive hearing loss) or could be symptoms of any number of medical conditions (e.g., dizziness). This is in contrast to the relatively high frequency of untreated hearing loss.

The FDA regulations stipulate that the contents of the user instructional brochure that manufacturers compile as part of the hearing aid packaging contain information about the eight red flag conditions so that consumers will be aware of these potential medical conditions that can cause hearing loss. It is not evident that a required physician evaluation or signing a waiver of that evaluation provides any additional clinically meaningful benefit. The committee was unable to find any analogous examples in health care where a similar waiver is required for adults. In most areas of health care, patients are empowered to seek the care they think they need for their symptoms and are not mandated by any regulation to obtain a physician's evaluation. For example, glaucoma testing is often recommended prior to being fitted for prescription glasses, but it has not been mandated, even though the incidence of glaucoma—1.9 percent of people

TABLE 3-3
Medical Conditions That Can Present with Hearing Loss

Condition	Rates in the Published Literature	Rates in the DoD and VA Populations	Predominant Presentation, Symptoms, and Treatment
Cerumen impaction	~2% of adults (Davis, 1989; Karlsmose et al., 2001)	1.3%[a] (N = 3,500,000) (VA)[b]	Unilateral or bilateral Symptoms: ear fullness, decreased hearing Treatment: Removal with ceruminolytics; irrigation; debridement
Otitis externa	4–8.1/1,000/year[c] (CDC, 2011; Guthrie, 1999) 1.2% (males) 1.3% (females) (Rowlands et al., 2001)	Not provided	Generally unilateral Symptoms: acute ear pain, drainage, decreased hearing, swollen pinna Treatment: antibiotics, debridement
Otitis media (OM)	Acute OM: 5.46%[c] in North America; chronic suppurative OM: 3.06%[c] (for a review, see Monasta et al., 2012)	Not provided	Unilateral or bilateral Symptoms: acute ear pain, fullness, fever, decreased hearing Treatment: antibiotics; drainage with ear tube
Tympanic membrane perforation		2/1,000/year[d] (N = NA) (DoD)[e]	Unilateral or bilateral Symptoms: hearing loss, ear pain, drainage Treatment: observation; surgical repair
Otosclerosis	6.1–13.7/100,000/year (Levin et al., 1988; Pearson et al., 1974)	Not provided	Generally unilateral Symptoms: hearing loss Treatment: observation; hearing aids; middle ear surgery
Cholesteatoma	3.7–13.9/100,000/year[c] (Kemppainen et al., 1999; Tos, 1988; for a review, see Kuo et al., 2015)	Not provided	Generally unilateral Symptoms: hearing loss, ear pain, drainage, dizziness/vertigo Treatment: surgery
Sudden sensorineural hearing loss	10.21–27/100,000/year (Alexander and Harris, 2013; Byl, 1977; Wu et al., 2006)	~0.2/1,000/year (N = NA) (DoD)[e]	Unilateral Symptoms: sudden hearing loss, possible dizziness/vertigo Treatment: observation, steroids

continued

TABLE 3-3
Continued

Condition	Rates in the Published Literature	Rates in the DoD and VA Populations	Predominant Presentation, Symptoms, and Treatment
Meniere's disease	190/100,000/3 years in the United States (for a review, see Alexander and Harris, 2010)	Not provided	Unilateral Symptoms: fluctuating hearing loss, tinnitus, vertigo, ear pressure Treatment: observation, low salt diet, diuretic
Vestibular schwannoma (also known as acoustic neuroma)	0.6–2/100,000/year (Babu et al., 2013; Lin et al., 2005; Propp et al., 2006; Stangerup, 2006, 2010)	0.009/1,000/year (N = 1,313,520) (DoD)[e]	Unilateral Symptoms: hearing loss, vertigo/imbalance, facial weakness, difficulty swallowing Treatment: observation with serial imaging, radiotherapy, surgery

NOTE: DoD = data on military service members; NA = data not available; VA = data on veterans.

[a] Combined rate for cerumen impaction and foreign body removal.

[b] Personal communication. Email to staff for the Committee on Accessible and Affordable Hearing Health Care for Adults regarding incidence of medical conditions in the veteran population, from David Chandler, Deputy Chief Consultant, Department of Veterans Affairs. Received January 15, 2016. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

[c] These estimates include children.

[d] Combined rate for tympanic membrane perforation, ossicular discontinuity, and auditory nerve disorders.

[e] Personal communication. Email to staff for the Committee on Accessible and Affordable Hearing Health Care for Adults regarding incidence of medical conditions in military service members, from Mark Packer, Executive Director, Department of Defense Hearing Center of Excellence. Received August 7, 2015. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

40 years of age and older in the United States (NEI, 2016)—is relatively high compared to the rates for the above-mentioned red flag conditions, there is treatment to slow its progression, and the consequences of the disease can seriously affect vision and are irreversible.

Second, the use of the waiver is common practice, and it is easily selected in online or mail-order sales. The committee could not find a recent peer-reviewed study with reliable data on the overall percentage of individuals who provide proof of a medical evaluation to hearing health care professionals or the percentage of individuals who sign the waiver, but several estimates provided to the committee by professional organizations and anecdotal evidence indicate that approximately 60 to 95 percent of individuals purchasing hearing aids may be signing the waiver[5,6] (Adams, 1995; PCAST, 2015). The FDA regulations require hearing health care professionals to maintain records of the statements or waivers for 3 years (21 C.F.R. § 801.421). Hearing aids are also available for sale online, often with a requirement that the consumer provide an audiogram so that fitting can be done, but consumers are asked only to read the medical evaluation statement and check a box if they choose to waive the medical evaluation. The ease of selecting the waiver, much as in downloading a mobile app or software upgrade, can mean that the consumer does not read it thoroughly but rather agrees to it (or provides an electronic signature) as a routine step in the purchasing process. In addition, the regulations present a barrier to access by requiring a separate appointment (with additional costs that may be at the patient's expense, depending on his or her health insurance coverage) for a medical evaluation that in most cases would not be helpful and would delay a patient from getting much needed assistance with hearing and communication.

In summary, the committee finds no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit. The committee finds that the medical evaluation regulations are not effective, nor are they needed to protect patient health and safety. In weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver, the committee recommends removing this regulation to serve consumers' best interests.

Access to and Portability of Hearing Health Care Records

Access to hearing aid–related records (including audiograms and programming history) and the ability to move those records between hearing aid dispensers is an area of concern. The President's Council of Advisors on Science and Technology recommended that the Federal Trade Commission

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[5] Personal communication. Letter to staff for the Committee on Accessible and Affordable Hearing Health Care for Adults, from Kim Cavitt, President, Academy of Doctors of Audiology; Judith Page, President, American Speech-Language-Hearing Association; and Larry Eng, President, American Academy of Audiology. Received August 27, 2015. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

[6] Personal communication. Letter to the Committee on Accessible and Affordable Hearing Health Care for Adults, from Kathleen Mennillo, Executive Director, International Hearing Society. Received January 15, 2016. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

enact requirements for hearing health care professionals to provide or make available audiograms and hearing aid programming reports and settings to consumers (PCAST, 2015). Such a policy could facilitate consumers' ability to change their hearing health care providers for subsequent care if their providers are not meeting their needs, or it could allow changes in providers if an individual moves to another location or is away from home for an extended period of time. (An additional challenge to changing providers is that hearing aids have proprietary software that can only be programmed by dispensers who have a relationship with the manufacturer of that particular hearing aid. See Chapter 4 for further discussion.)

The portability of and access to an individual's own medical records is a legal right guaranteed under the Privacy Rule of the Health Insurance Portability and Accountability Act[7] (HIPAA). The Privacy Rule grants patients a right to inspect and receive copies of certain health information about them—known as a designated record set—that is held by a HIPAA-covered entity (e.g., a medical office or hospital). The Privacy Rule regulates health care providers that conduct specific types of electronic transactions such as billing for health care services or verifying insurance benefits, so audiologists and hearing instrument specialists typically are subject to the HIPAA Privacy Rule. Under the HIPAA statute, patients have a legally enforceable right of access to their designated record set within 30 days of requesting them, a time limit that is subject to an extension under certain circumstances.

The audiogram as well as other hearing-related health records should be part of the individual's designated record set. The Privacy Rule defines this record set as including medical, insurance, and billing records plus an additional category of other records "used, in whole or in part, by or for the covered entity to make decisions about individuals" (45 C.F.R. § 164.501). This definition strongly suggests that if an audiologist or hearing instrument specialist uses any part of the audiogram to make decisions about an individual, the entire file is part of that individual's designated record set. However, a patient's access may depend on the data retention policy of the audiologist or hearing instrument specialist. The rule allows individual access only to data that a health care provider "actually maintains" at the time that an individual's request is received (79 Federal Register 7289). State regulations typically determine which records each provider needs to maintain.

Despite this broad right of access across all sectors of the health care system, patients report that they have difficulty obtaining access to their health data, and access problems perennially appear as sources of patient complaints under HIPAA. Patients who are denied access can file a com-

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[7] Privacy Rule of the Health Insurance Portability and Accountability Act, Public Law 104-191; 45 C.F.R. § 164.524.

plaint with the Office for Civil Rights at the Department of Health and Human Services, and this office generally will attempt to work with the provider to explain its obligation to provide access. In other areas where patients have encountered difficulty accessing their health records, patient advocacy groups often develop programs to assist patients in exercising their rights and filing complaints if access is denied. Consistent with laws governing access and portability of other health records, hearing health care patients should have access to their audiograms and other hearing health care records held by HIPAA-covered hearing health care professionals.

Support of and Engagement in Quality Improvement

Measuring and Improving Quality

High-quality health care—regardless of the type of care, the geographic location where it is delivered, or the patient population receiving the care—must be safe, effective, patient centered, timely, efficient, and equitable (IOM, 2001, 2006a,b, 2011a, 2012b). Improving and maintaining the quality of care that patients receive can be accomplished through a variety of mechanisms from the individual provider level up through the system level on a national basis. For example, evidence-based clinical practice guidelines and standards of practice can be used to educate health professionals, inform practice patterns, and facilitate widespread adherence to best practices. Performance metrics can be used to standardize and incentivize high-quality care, assess quality in specific areas of care, and compare care across providers. Additionally, continuous quality improvement efforts can be used in practice settings and health care systems to evaluate current practices, inform adjustments in care delivery, and provide data to strengthen the evidence base. Like all aspects of health care, high-quality hearing health care and improvements to that care need to be built on a foundation of scientifically sound data and research methods, as is described throughout this report.

Clinical Practice Guidelines and Standards of Practice

The purpose of clinical practice guidelines and standards of practice is to provide direction for high-quality, evidence-based health care services and established best practices. In the United States, the Agency for Healthcare Research and Quality (AHRQ) catalogs clinical practice guidelines[8]

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[8] AHRQ has adopted the Institute of Medicine definition of clinical practice guidelines, which states, "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (IOM, 2011b, p. 4).

for various health conditions, treatments, and medical specialties in the National Guideline Clearinghouse. A set of stringent inclusion criteria (available at www.guideline.gov) is used to evaluate each of the guidelines submitted for review (AHRQ, 2014). In the case of hearing loss, a few relevant guidelines have met the inclusion criteria and are listed within the clearinghouse under otolaryngology and otolaryngologic health conditions (see Box 3-4; AHRQ, 2016). Typically, health care professional associations collaborate with researchers and clinicians to develop evidence-based clinical practice guidelines in areas where scientifically rigorous data and studies are available.

In addition to the National Guideline Clearinghouse, several professional organizations maintain standards of practice and clinical guidelines for public reference. Box 3-4 provides examples of clinical practice guidelines and standards of practice for hearing loss in adult populations. The American Speech–Language–Hearing Association (ASHA) also maintains an online collection of evidence-based clinical practice guidelines relevant to audiology and speech-language pathology (ASHA, 2016d). In 2005, ASHA's National Center for Evidence-Based Practice in Communication Disorders began evaluating available guidelines and systematic reviews for this collection. To assess the guidelines, the center uses a scoring framework called the Appraisal of Guidelines for Research and Evaluation II framework, and systematic reviews are considered against unspecified quality indicators (ASHA, 2016g). It is important to note that only a handful of the guidelines and reviews listed are directly related to hearing loss, with many of them focused on screening for newborns and children.

To further guide the practice patterns for hearing health care, the American Academy of Audiology's Professional Standards and Practices Committee sets and updates standards of practice for the profession. These standards were developed "to define acceptable standards of practice for services" that fall within the scope of practice for audiologists (AAA, 2012, p. 1). The current standards were updated in 2012 and focus on six areas: education, screening, evaluation and diagnosis, treatment, prevention, and research (AAA, 2012). In the late 1990s (1996–1999), ASHA, the American Academy of Audiology, and the VA convened the Joint Audiology Committee on Clinical Practice Algorithms and Statements to establish a consensus on clinical algorithms for audiology. The joint committee used the best available evidence at the time to develop five practice algorithms: overview of audologic services; comprehensive adult audiologic assessment; comprehensive pediatric audiologic assessment; hearing aid selection and fitting; and cochlear implant assessment, programming, and rehabilitation. Each of the algorithms is presented in a decision tree format with an accompanying practice statement that can be used to guide audiologists through the decision-making process for the specified scenarios (Joint Audiology Com-

Box 3-4 EXAMPLES OF AVAILABLE CLINICAL PRACTICE GUIDELINES AND STANDARDS OF PRACTICE

- **American Academy of Audiology:**
  - Standards of Practice (AAA, 2012)
  - Guidelines for the Audiologic Management of Adult Hearing Impairment (Valente, 2006)
  - Clinical Practice Guidelines Adult Patients with Severe-to-Profound Unilateral Sensorineural Hearing Loss (AAA, 2015)

- **American Academy of Audiology, American Speech-Language-Hearing Association, and Department of Veterans Affairs:** Audiological Clinical Practice Algorithms and Statements (Joint Audiology Committee on Clinical Practice Algorithms and Statements, 2000).

- **American Academy of Otolaryngology—Head and Neck Surgery:**
  - Clinical Guidelines for Tinnitus[a] (Tunkel et al., 2014)
  - Clinical Practice Guideline: Sudden Hearing Loss (Stachler et al., 2012)
  - Clinical Practice Guideline: Cerumen Impaction (Roland et al., 2008)

- **American College of Medical Genetics and Genomics[a]:** Guideline for the Clinical Evaluation and Etiologic Diagnosis of Hearing Loss (Alford et al., 2014)

- **American College of Radiology[a]:** ACR Appropriateness Criteria® for Using Radiological Imaging for Hearing Loss and/or Vertigo (Angtuaco et al., 1996)

- **Royal College of Physicians (United Kingdom):** Hearing and Balance Disorders: Achieving Excellence in Diagnosis and Management (RCP, 2008)

- **Royal College of Speech & Language Therapists Department of Health, National Institute for Clinical Excellence (United Kingdom):** Clinical Guidelines: 5.7 Deafness and Hearing Loss (Taylor-Goh, 2005)

- **U.S. Preventive Services Task Force[a]:** Recommendations on Screening for Hearing Loss in Older Adults (Moyer, 2012)

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[a] As of February 2016, these clinical practice guidelines have met the inclusion criteria for the Agency for Healthcare Research and Quality's National Guideline Clearinghouse (AHRQ, 2016).

mittee on Clinical Practice Algorithms and Statements, 2000). Although these algorithms may be useful in guiding practice, they have not been revisited or updated in almost two decades and may not reflect the most current and best available evidence, which is fundamental for ensuring high-quality, evidence-based care.

Guidelines and standards can only be effective if they are consistently applied across practice settings. Despite the online availability of guidelines and standards related to hearing health care, little is known about whether health care professionals are aware of these resources, how frequently the resources are taught in health professional education, or how often they are applied in practice settings. The possible impact of these guidelines and standards on improving the quality of care is also unknown. In order to understand the reach and limitations of these resources and to develop strategies to ensure that best practices are implemented, surveys and additional research are needed. As new research findings become available, the guidelines and standards need to be updated to reflect best available evidence. Furthermore, efforts to widely disseminate revised guidance; teach students and health care professionals, including primary care providers, about the existence of the guidelines and how to implement them; and modify practice patterns will also be required to ensure that patients fully benefit from evidence-based practices.

Performance Metrics

Another mechanism for ensuring and promoting high-quality health care is the development, implementation, and analysis of performance metrics, which may also be tied to clinical practice guidelines. As broadly defined by previous Institute of Medicine work, performance metrics "encompass the wide range of measures of health care quality that include measures and indicators of clinical care, health care processes, and patient outcomes and satisfaction" (IOM, 2012a, p. 181). Performance metrics can also be used to increase accountability, enhance transparency, standardize care, and incentivize evidence-based care—all of which contribute to the delivery of high-quality care.

Across the health care landscape in the United States, there is a range of organizations, government agencies, insurers, health care systems, researchers, health professionals, and other stakeholders involved in the development and use of performance metrics. When applied nationally, performance metrics can serve as a basis for accreditation, certification, and pay-for-performance programs. Box 3-5 provides examples of organizations that develop and use performance measures on a national scale in order to improve the quality of health care.

In 2005, ASHA's Working Group on Quality Indicators developed quality indicators for audiology and speech-language pathology programs across a variety of settings (e.g., schools and private practice). The indicators were designed to encourage quality improvement efforts; to provide a framework for developing, reviewing and updating programs; and to educate health professionals, students, and consumers about high-quality care. The indictors are grouped into five areas: purpose and scope of services, service delivery, program operations (e.g., administration, human resources, financial management), program evaluation and performance improvement,

Box 3-5 EXAMPLES OF PERFORMANCE METRICS

The Joint Commission: The Joint Commission certifies and accredits health care organizations and programs throughout the United States using specific performance measures and standards as a basis of evaluation. The Joint Commission develops certification and accreditation standards by reviewing available evidence and engaging a broad range of experts and stakeholders in the process. Currently, there are more than 21,000 health care organizations and programs that have met The Joint Commission's certification and accreditation standards for quality and safety (The Joint Commission, 2016a,b).

National Committee for Quality Assurance: More than 90 percent of health plans across the United States measure performance using the National Committee for Quality Assurance's Healthcare Effectiveness Data and Information Set (HEDIS). Participating health plans report on 81 HEDIS quality measures that are categorized into five domains and cover a range of health conditions and processes (e.g., breast cancer screening, immunizations, diabetes care, weight management). HEDIS measures are reviewed on an annual basis and retired when they are no longer applicable, ensuring that the measures are always up to date. The National Committee for Quality Assurance also serves as an accreditation and certification body for health care plans and organizations, requiring compliance with various standards (NCQA, 2016a,b,c).

National Quality Forum: The National Quality Forum uses a defined evaluation process in order to build consensus and endorse evidence-based performance measures, which are then catalogued online. Measures that receive endorsement are reviewed every 3 years to ensure the application of the best available evidence. Each year the National Quality Forum's Measure Applications Partnership provides recommendations and guidance to the Department of Health and Human Services on more than 100 performance measures that are being considered for implementations across 16 federal health care programs, including various programs administered by the Centers for Medicare & Medicaid Services (NQF, 2016a,b,c).

and ethics (ASHA, 2005). As with the discussion of the clinical practice guidelines and standards above, it is difficult to know how these indicators are applied and what impact they have on quality, and it appears that they have not been revisited in more than a decade.

To further promote and ensure the delivery of high-quality care, the Centers for Medicare & Medicaid Services (CMS) launched a voluntary incentive program in 2006 called the Physician Quality Reporting System (PQRS) (formerly the Physician Quality Reporting Initiative), which has implemented performance metrics within the Medicare program. Physicians and various types of practitioners and therapists—including audiologists and speech-language therapists—who provide care to Medicare patients under Medicare Part B's Medicare Physician Fee Schedule are eligible to participate in the PQRS program (CMS, 2016a). The program has evolved through various legislative actions. For example, the Medicare Improvement for Patients and Providers Act of 2008 made the PQRS program permanent and required CMS to report online the participation in the program and some performance measures (AMA, 2015; CMS, 2016c). Additionally, the Patient Protection and Affordable Care Act of 2010 shifted the paradigm of the PQRS program so that, beginning in 2015, increasing penalties for nonparticipation were included rather than incentive payments for voluntary reporting of quality measures (AMA, 2015). In 2016 health care professionals and group practices are required to choose and report on at least nine individual measures and one crosscutting measure from a list of available measures for at least half of all Medicare patient appointments. Selected measures can be reported via Medicare billing claims, a registry-based reporting system, or certified electronic health records (CMS, 2016b). There is a 2-year gap between reporting and possible penalties; for example, health professionals and group practices that did not meet the 2015 requirements will see a downward adjustment in 2017 (AMA, 2015; CMS, 2015).

Because of the possible impact of PQRS requirements on the practice of audiology, 10 audiology organizations[9] came together to form the Audiology Quality Consortium. The consortium develops possible quality measures for PQRS inclusion, monitors the PQRS program and quality measures, responds to proposed changes in the PQRS program, and provides education and guidance on PQRS requirements to audiologists. The consortium also maintains a website[10] that lists the applicable PQRS measures and codes (e.g., Current Procedural Terminology [CPT®], *International Classification of Diseases*, G-codes) for audiologists, provides claims forms, and offers other helpful resources (AQC, 2016a,b). The six PQRS measures relevant to audiology that are currently listed on the consortium's website are (1) documenting current medications, (2) screening for depression, (3) risk assessment for falls, (4) care planning for falls, (5) screening and preventative care for tobacco use, and (6) referral for patients with acute or chronic dizziness (AQC, 2016b). As noted by the consortium, under the 2016 PQRS requirements, audiologists are required to report on all three of the crosscutting measures (i.e., medications, depression screening, and tobacco use), rather than only one, because there are fewer than nine individual quality measures that apply to audiology (AQC, 2016c).

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[9] Academy of Doctors of Audiology, Academy of Rehabilitative Audiology, American Academy of Audiology, American Academy of Private Practice in Speech Pathology and Audiology, American Speech–Language–Hearing Association, Association of VA Audiologists, Directors of Speech and Hearing Programs in State Health and Welfare Agencies, Educational Audiology Association, Military Audiology Association, and National Hearing Conservation Association.

[10] See http://audiologyquality.org.

Audiologists who provide services to fewer than 15 Medicare beneficiaries in a year are exempt from PQRS reporting.

The National Quality Forum estimates that by 2017 approximately 90 percent of Medicare payments will be tied to some form of performance metric (NQF, 2016c). It is becoming clear that performance metrics are driving change in the landscape of health care quality in the United States—within Medicare and beyond—and will also play a role in how hearing health care is delivered in the future. As electronic health records continue to be implemented and evolve, performance metrics and clinical pathways or algorithms will be integrated and used to inform and maximize the quality of care provided. Thus, it is essential that collaborative action, such as that of the Audiology Quality Consortium, be taken in order to develop clearly defined, evidence-based performance metrics that can be adopted for ensuring high-quality hearing health care.

Continuous Quality Improvement

Continuous quality improvement (CQI) is a process- and data-oriented mechanism that is used to enhance the quality of health care delivery and promote excellence. CQI efforts involve "capturing, analyzing, and regularly reporting data; translating the data and resulting information into actionable opportunities to improve performance at the local level; and developing plans for process changes that will further support effective, efficient, and value-added interventions" (IOM, 2015b, p. 338). Like performance metrics, CQI programs are becoming more commonplace among health care systems across the United States, as accreditation bodies (e.g., The Joint Commission, the National Committee for Quality Assurance) continue to emphasize measuring outcomes and CQI processes as part of their accreditation standards. ASHA developed the National Outcomes Measurement System with the goal of collecting and analyzing national outcomes data on the effectiveness of speech-language pathology and audiology services. The initial work focused on speech-language pathology outcomes, but efforts are under way to expand this work into audiology services (ASHA, 2016h; Mullen, 2003; Mullen and Schooling, 2010).

Within the field of hearing health care, the application of CQI principles and programs also holds promise for improving the quality and efficiency of care that patients receive. Under the research section of the American Academy of Audiology's standards of practice, audiologists are called on to measure and evaluate clinical outcomes and to update practice policies and procedures as part of CQI efforts (AAA, 2012). Recently published literature that was centered on the use of CQI in hearing health care appears to be limited and has primarily focused on newborn screening programs (e.g., Deem et al., 2012) and administrative processes, such as appointment management (e.g., Huddle et al., 2016). For audiologists and other health professionals who would like to implement CQI strategies in their practices, there are numerous resources and guides available (ASHA, 2016d; HRSA, 2016b; IHI, 2016; Taylor, 2013). Successful CQI efforts require proactive leadership, a culture of continuous learning, measurable outcomes, a reliable platform for ongoing data collection and analysis, opportunities to share feedback and exchange ideas, and strategies to implement necessary change (IOM, 2015b).

Summary

Measuring and improving the quality of hearing health care necessitates buy-in and collaborative effort among researchers, health professionals, health systems, insurers, advocacy organizations, people with hearing loss and their families, and experts in performance metrics and health care quality improvement. As described throughout this section, high-quality hearing health care is a multifaceted goal that can be promoted and accomplished through the development and implementation of mechanisms such as clinical practice guidelines and standards of practice, performance metrics, and continuous quality improvement efforts. However, guidelines, standards, and metrics must be regularly reviewed and updated to ensure that the most recent evidence is translated into best practices. Additionally, once guidelines, standards, and metrics are defined and deployed, a range of strategies—e.g., dissemination, education, and incentives and/or penalties—may be necessary to ensure uptake and implementation by hearing health care professionals.

Overcome Disparities in Services Delivery and Access

Disparities in health care can be defined as inequities in access to care or in quality of care (IOM, 2003). These disparities may contribute to differences in health outcomes across groups of individuals by race, ethnicity, income, education, age, and place of residence, among others. This section addresses the challenges to access and quality for underserved and vulnerable populations of adults with hearing loss, geographical disparities in the location of hearing health care providers, and issues of racial/ethnic and linguistic diversity in the professional workforce serving adults with hearing loss. Expanded health services research is needed to improve understanding of hearing health care disparities and to investigate how economic, racial, cultural, gender, and age-related factors may influence hearing health care use and patient-centered outcomes.

Socioeconomic, Racial, and Ethnic Disparities

A large proportion of the U.S. adult population has not had a recent hearing test (see earlier section on hearing health care utilization). Furthermore, many adults who have hearing loss and may benefit from using hearing aids are not using the devices (see Chapter 4). Only limited evidence is available on the use of hearing health care services by low-income adults and racial and ethnic minorities. Individuals living at or below the federal poverty level were found to be less likely to access hearing health care in the form of using hearing aids than individuals in higher-income populations (Bainbridge and Ramachandran, 2014). African Americans and Mexican Americans are also less likely to report using hearing aids than non-Hispanic White Americans (Lee et al., 1991; Nieman et al., 2016; Pugh, 2004), although one of those studies (Nieman et al., 2016) found that after adjusting for hearing loss, there were no significant differences for African Americans. Full exploration and analysis of the causes and effects of these findings have been hindered by the lack of hearing aid–using adults from racial/ethnic minorities being included in epidemiological studies (see Chapters 2 and 4). Researchers and funding agencies have called for more study of culture-specific interventions to better meet the needs of Hispanic Americans and African Americans (Donahue et al., 2010; Lee et al., 1991; Pugh, 2004). Ongoing research funded by the National Institutes of Health is targeted toward developing affordable and accessible interventions for hearing loss to meet the unique needs of older adults from racial/ethnic minorities.

Older Adults in Long-Term Care Facilities

Obtaining adequate hearing health care can also be challenging for the approximately 1.4 million older Americans who reside in nursing homes or other long-term care facilities (Cohen-Mansfield and Infeld, 2006; Harris-Kojetin et al., 2013). Several cross-sectional studies have shown that although the majority of older adults in nursing homes have hearing loss and many of them might benefit from hearing aids, only 14 to 30 percent of these residents use hearing aids (Cohen-Mansfield and Taylor, 2004a; Culbertson et al., 2004; Jerger et al., 1995). Potential barriers to hearing aid use among residents of nursing homes include individual-specific factors such as manual dexterity challenges that limit the use of hearing aids without assistance; institutional factors, such as a lack of knowledge among staff and a lack of care procedures to assist and support resident communication; and societal factors such as high costs of hearing aids (Carson and Pichora-Fuller, 1997; Cohen-Mansfield and Taylor, 2004b). Furthermore, hearing loss may be under-reported by residents of nursing homes and under-recognized by staff in the absence of objective screening measures (Cohen-Mansfield and Taylor, 2004a; Corbin et al., 1984; Hoek et al., 1997). An additional challenge for staff and family members is to distinguish miscommunication related to hearing loss from miscommunication related to dementia (Haque et al., 2012; Slaughter et al., 2014). In one study of nursing home residents who used hearing aids, the vast majority (86 percent) needed help with the use and care of the devices, especially changing batteries, and the incidence of problems was high, with approximately two-thirds (69 percent) of hearing aids that belonged to the residents malfunctioning, and nearly half of the staff not having any training in how to use or maintain the devices (Cohen-Mansfield and Taylor, 2004b).

Further development of learning objectives and curriculum regarding hearing health care is needed across multiple disciplines, both within professional training programs and the continuing education of those who work with older adults in long-term care settings, to address the access, follow-up, and quality improvement challenges. A number of continuing education opportunities are regularly available to audiologists on issues related to geriatrics and aging through audiology professional organizations. Limited large-scale research exists on the impact of continuing education and interprofessional training on improving hearing health outcomes, but several examples in the literature have shown positive effects for residents and employees of long-term care institutions (Cohen-Mansfield and Taylor, 2004b; Hoek et al., 1997; Jennings and Head, 1994; Linssen et al., 2013; Robertson et al., 1997). Guidelines for delivery of audiology services in nursing homes were developed by ASHA and include discussion of the potential value of using a variety of hearing assistive technologies in addition to hearing aids (ASHA, 1997). Twenty years later, challenges persist. It is noteworthy that with more older adults choosing to stay in their homes as they age rather than move into long-term care facilities, some of the challenges highlighted in this section will also apply to individuals living in settings other than long-term care facilities.

Rural Populations

A higher percentage of older adults live in rural than in urban areas, and analyses of population changes suggest a migration of baby boomers to rural and small-town communities (Cromartie and Nelson, 2009). One factor that may affect access to hearing health care for rural populations is practice location. Residents of rural areas may not have a choice among providers or may have to travel greater distances than their urban-dwelling peers to access health services or in-network providers.

Further research is needed into the rural health issues potentially affecting hearing health care utilization and the unique needs of rural populations. Older adults in rural communities perceive a number of barriers to general health care access, including problems with transportation, limited health care supply, a lack of quality care, social isolation, and financial challenges (Goins et al., 2005; IOM, 2006c). There is also evidence that older adults in rural areas are more socially isolated than older adults living in urban areas, with the suggestion that infrastructure and health care providers should plan for rural older adults' needs and prevent isolation (Baernholdt et al., 2012). Given the potential association between hearing loss and social isolation in older adults (Mick et al., 2014), greater attention to the hearing health care needs of rural older adults may be an important consideration. Evidence of successful rural hearing health promotion programs from other countries suggests this may be a promising approach. For example, the development of a sensory support center in rural Scotland reduced social isolation and increased the functional independence of older adults (Smith et al., 2015) and the Farmsafe Australia project increased access to screening services in farming communities (Lower et al., 2010). Existing programs to address hearing conservation among farming communities, which have focused on young farmers (e.g., Ehlers and Graydon, 2011), might provide a bridge to increase rural community awareness on hearing health issues in the United States (see also Chapter 6). Tele-audiology programs at the VA and Alaska Federal Health Care Access Network have also been developed and implemented to begin to address rural health needs (Jacobs and Saunders, 2014) (see later section in this chapter for more information on tele-audiology).

Audiology Workforce Diversity

Racial and ethnic diversity within the hearing health care workforce is limited. Although not all audiologists are members of ASHA, member counts provide data that cover most of the audiology workforce. Racial data from a dues notice survey conducted in 2012 showed that of the audiologists certified by ASHA in audiology only, approximately 92 percent were white Caucasian and 3 percent were Hispanic/Latino (see Table 3-4; ASHA, 2016c). The most recent available data on gender are from the dues notice survey conducted in 2009, indicating a primarily female audiology workforce (84.6 percent of 11,867 respondents) (ASHA, 2016c).

These data are similar to demographic data from other health care professions. For example, Sánchez and colleagues (2015) note that even though the Latino population is the second-fastest growing nonwhite population in the United States, there has not been growth in the number of Latino physicians. Furthermore, nurses from minority backgrounds represent only 19 percent of the nursing workforce (American Association of Colleges of Nursing, 2015). At the same time, the United States is undergoing major demographic shifts that are projected to result in more than half of the

TABLE 3-4
Profile of American Speech–Language–Hearing Association Member and Nonmember Certificate Holders in Audiology Only, by Race and Ethnicity

Race	Percentage (n = 9,270)
American Indian or Alaska Native	0.2%
Asian	3.3%
Black or African American	2.4%
Native Hawaiian or other Pacific Islander	0.1%
White	92.1%
Multiracial	1.8%
Ethnicity	**Percentage (n = 9,837)**
Hispanic or Latino	3.1%
Not Hispanic or Latino	96.9%

SOURCE: ASHA, 2016c. Printed with permission from ASHA.

country's population being from minority populations by 2044 (Colby and Ortman, 2014). It is not simply in the audiology workforce, then, that the match between health care professionals and the U.S. population is out of balance.

This shortage of health care professionals from minority communities has serious implications for health care access as well as health care outcomes. According to the Sullivan Commission report (2004), "studies suggest that increasing the diversity of the health workforce can improve patient access, patient satisfaction, and improve quality of life for all patients" (p. 15). More specifically, minority patients report better communication with their providers when the patient and the provider are from the same racial/ethnic group. Minority group patients tend to prefer physicians from their same racial/ethnic background and report higher levels of satisfaction when this occurs (Sullivan Commission, 2004).

Equally important to improving access to care is the promotion and support of increasing the number of providers in underserved communities. Zayas and McGuigan (2006) report that half of the medical school graduates expecting to practice in medically underserved areas are African American. A 2002 survey found that 45 percent of Hispanic/Latino dental school student seniors planned to provide dental care to underserved populations after graduation (Sullivan Commission, 2004) while another study found Latino physicians to be more likely to provide health care for Latino communities and for populations that are medically underserved (Sánchez et al., 2015). Given minority patients' preference for race-concordant health care professionals, increasing diversity in the hearing health care workforce has the potential to help reduce racial and ethnic hearing health care disparities.

This lack of diversity is unlikely to change in the near term due to the lack of diversity in the current audiology student population. Table 3-5 provides enrollment data for students in audiology graduate degree programs. In the 2013–2014 academic year, 69 out of 75 doctorate graduate degree programs in audiology responded to the Communication Sciences and Disorders Education Survey (CAPCSD and ASHA, 2015). According to the survey results, the clinical doctorate, entry-level programs had a total of 1,781 white Caucasian students (87.35 percent), 205 racial/ethnic minority students (noninternational, 10.05 percent), and 53 international students (2.6 percent). The group was also predominantly female (84.7 percent). The limited gender, racial, and ethnic diversity among recent graduates and enrolled students demonstrates that the audiology workforce will not mirror the gender and racial/ethnic diversity of the U.S. population with hearing loss for the foreseeable future. Recruitment and retention of diverse students to professional training programs in hearing health care would likely boost the diversity in the hearing health care workforce over time.

Increasing the diversity in the hearing health care clinical and research workforce has a number of benefits similar to increasing the diversity in other areas of health care, including increasing access to health services, improving equity (Cohen et al., 2002; IOM, 2003; Valantine and Collins, 2015), increasing patient satisfaction, and ensuring better patient communication with providers.

TABLE 3-5
Total Enrollment in Audiology Graduate Degree Programs for the Clinical and Research Doctorates by Gender and Race/Ethnicity, 2013–2014

Audiology Graduate Degree Program	Male	Female	White	Racial/Ethnic Minority (Non-International)	International
Clinical doctorate: entry-level	312 (15.3%)	1,727 (84.7%)	1,781 (87.35%)	205 (10.05%)	53 (2.6%)
Clinical doctorate: post-entry level	27 (28.42%)	68 (71.58%)	46 (48.42%)	5 (5.26%)	44 (46.32%)
Research doctorate	15 (23.44%)	49 (76.56%)	41 (64.06%)	6 (9.38%)	17 (26.56%)

SOURCE: CAPCSD and ASHA, 2015. Printed with permission from ASHA.

Linguistic diversity also affects audiologic care and management because language proficiency can affect performance on some clinical tests of speech recognition and outcomes (Reel et al., 2015; Warzybok et al., 2015). Data from ASHA's 2015 member counts indicated 726 ASHA-certified audiologists self-identified as bilingual service providers, as defined by native or near-native proficiency in a second language. Of these bilingual audiologists, 266 ASHA-certified audiologists were Spanish-language service providers. State-level data indicated that the most bilingual ASHA-certified audiologists living in the United States were located in California, Florida, New York, and Texas. In 6 states, there were 10 or fewer bilingual service providers (ASHA, 2016e). International efforts are under way to develop valid and reliable multilingual test materials (Akeroyd et al., 2015). Academic and clinical training in cultural competency is required within audiology training programs (ASHA, 2014, 2016i). Cultural competencies are part of the knowledge and skills for national certification in audiology from both ASHA and the American Board of Audiology (ASHA, 2004).

The workforce and student enrollment data suggest the need for training programs and professional organizations to develop strategies to recruit and retain minority and bilingual audiologists and other hearing health care professionals. Enhancing and sustaining diversity in the hearing health care workforce will likely require the efforts of multiple stakeholders. Valuing cultural sensitivity and diversity is within the strategic plans and core values of audiology professional organizations (AAA, 2016; ASHA, 2016j). Increasing diversity among the audiology workforce is a stated goal of ASHA's Envisioned Future 2025, both for gender and multicultural diversity. Funding to promote diversity in the hearing health research workforce is available through administrative supplements and individual training fellowships through the National Institute on Deafness and Other Communication Disorders (NIH, 2015; Valantine and Collins, 2015). However, there are no current, clear mechanisms targeted to increase the workforce diversity among audiologists or other hearing health care professionals. Incentive programs, such as tuition reimbursement used for those practicing in other areas of health care, might help diversify the hearing health care workforce. Strengthening cultural competency training and programs is another area that could help the hearing health care workforce fully address the issue of providing high-quality services to diverse and underserved populations (Awosogba et al., 2013; Shaya and Gbarayor, 2006).

Improve and Expand Use of Auditory Rehabilitation Programs

Although consumer organizations (e.g., the Hearing Loss Association of America and AARP) are actively engaged in advocating for the use of auditory rehabilitation and patient choice for hearing health care, rehabilitation programs, such as those described earlier in this chapter, are not widely available (Hawkins, 2005; Sweetow and Palmer, 2005; Thorén et al., 2011). Furthermore, little is known about what proportion of people diagnosed with hearing loss participate in such programs, despite supportive expert opinion across the field. In their literature review, Sweetow and Palmer (2005) indicated that the use of rehabilitation services by audiologists decreased in the 20 years preceding their work due to a number of factors, including a lack of reimbursement and time constraints.

The available evidence supporting auditory rehabilitation programs is generally favorable (see the section on auditory rehabilitation earlier in this chapter) and suggests that these types of programs would likely provide some short-term benefits (Chisolm and Arnold, 2012). However, the evidence is neither robust nor definitive. Reviews of both auditory training and counseling-based, supportive rehabilitation programs describe variability across individuals in terms of outcomes and possible benefits (Chisolm and Arnold, 2012; Hawkins, 2005; Henshaw and Ferguson, 2013; Saunders et al., 2016; Sweetow and Palmer, 2005). This variability may be the result of individual differences (e.g., baseline performance, functional abilities, communication needs, age, severity of hearing loss, motivation, support). These differences require audiologists and health professionals to match individuals with specific interventions—both rehabilitation services and technologies—in order to optimize the outcomes (Abrams and Chisolm, 2013). The development of metrics and biomarkers that could predict which individuals would benefit most from which interventions would greatly simplify decisions about appropriate hearing health care options. In advising their patients, audiologists and health professionals also need to consider the timing of rehabilitation programs. Studies have concluded that the first few weeks to the first few months of hearing aid adoption represent the timeframe when usage patterns are established (Dillon, 2012; Laplante-Lévesque et al., 2014; Ng and Loke, 2015). Also, individuals with new hearing aids are typically encouraged to schedule follow-up appointments within the first 6 months or sooner, as needed. Therefore, this may be a timeframe during which individuals' information needs and receptiveness to rehabilitation efforts are heightened.

In the design phase of auditory rehabilitation programs, there are a number of foundational principles that could be used to promote successful uptake. For example, these programs should be designed to

- meet the needs and individual preferences of the person with hearing loss;
- be cost effective for both individuals and the care provider;
- be easily accessible and convenient;
- be functional, useful, and engaging;

- be interactive;
- provide sufficient feedback and reinforcement; and
- provide perceived value and positive outcomes to the user (Boothroyd, 2010; Henshaw et al., 2015; Laplante-Lévesque et al., 2010; Sweetow and Palmer, 2005; Sweetow and Sabes, 2006).

To promote wider acceptance and implementation of auditory rehabilitation programs, the efficacy and efficiency of the programs should be evaluated in a large-scale, long-term, and systematic way, using standardized outcome measures whenever possible in order to fully meet tests of scientific rigor. The evidence base needs to be bolstered and widely disseminated, and additional research efforts need to determine which individuals will derive the greatest benefit from these programs. Additionally, steps to expand the use of evidence-based auditory rehabilitation programs need to be taken, including the use of large-scale pilot programs. Where evidence-based programs are available, audiologists, health professionals, and advocacy organizations need to be aware of them and be encouraged to recommend them to their patients and constituents.

Develop and Evaluate Innovative Models of Hearing Health Care Delivery

As described earlier in this chapter, obtaining treatment for hearing loss in the United States generally follows a medical model of clinic-based care in which an individual visits a hearing health care professional for diagnostic evaluation, assessment, and care. While this model may be necessary for individuals with medical conditions requiring care by an otolaryngologist or for individuals with complex or more severe forms of hearing loss, this level of care may not always be required for all adults with hearing loss (AAA, 2006; Valente, 2006). For example, an individual with a longstanding age-related hearing loss that only moderately interferes with daily functioning may be reluctant to commit the resources and time needed to pursue this level of care given the multitude of steps required to obtain basic amplification (Cox et al., 2014; Donahue et al., 2010).

Alternative care models for other types of common and chronic medical conditions (e.g., presbyopia, diabetes, etc.) have rapidly expanded with the use of community health workers and retail clinics located in drugstores to complement the traditional medical model of care (Iglehart, 2015; Perry et al., 2014; Villaseñor and Krouse, 2016). Although these and other alternative models of care have not yet been widely used or investigated for hearing loss management specifically, these options may provide effective models for delivering more hearing health care to more people (see below and Chapter 5). In order to maximize the potential of these innovative models and ensure that they are implemented where appropriate and most effective, the models will need to be evaluated for possible risks to safety, quality, value, and cost effectiveness.

Community Health Workers

A community health worker has been defined as a public health worker who is a trusted member of the community or who has an unusually close understanding of the community served (APHA, 2016). They can implement programs for and conduct outreach to community members with the goal of promoting, maintaining, and improving individual and community health (BLS, 2016). Community health workers have been used in many other health care sectors to increase access to care, improve the use of health services, and enhance successful chronic disease prevention and management (Johnson et al., 2012; Perry and Zulliger, 2012; Rosenthal et al., 2010). They may be trained and supervised in the provision of basic services to the community and serve as liaisons between the health care system and the community.

With regard to hearing health care in global settings, community health workers have been taught skills in basic audiometry using automated or manual audiometers, which can use a widely accepted threshold-finding algorithm (the modified Hughson-Westlake bracketing procedure) to generate an audiogram that meets current calibration standards and is consistent with ASHA guidelines (Shaw, 2015). Community health workers have also dispensed basic hearing assistive technology that may be pre-programmed or "ready-to-wear" (WWH, 2016).

Community health workers have the potential to play a role in helping an individual and his or her family cope with hearing loss as a chronic condition, potentially by teaching them about hearing strategies and effective communication skills, maximizing the use of hearing aids by pairing them with other assistive products and with other communications and emergency alert systems (see Chapter 4), and understanding their rights through disability and other relevant policies and laws. Basic hearing assessments might be able to be performed at the community clinic or in the home. In order to serve as an effective tool for community health workers, audiometric equipment should be reasonably priced, portable, and easy to use; and it should be calibrated according to American National Standards Institute specifications and any relevant state requirements. Quality assurance, adequate supervision, and ongoing training would also be important considerations. More research will be needed on the development of potential roles for integrating community health workers into hearing health care teams.

The community health worker model is also consistent with the trend toward providing initial health care services closer to the patient's residence, rather than requiring the patient to engage the health care system in large, complex facilities, such as academic medical centers and full-service outpatient clinics and hospitals. There is evidence that community health workers can successfully facilitate access to health care for subpopulations and deliver health education in a culturally appropriate manner (Brownstein et al., 2007; Ingram et al., 2012; Postma et al., 2009; Staten et al., 2012). Community health workers could serve as a conduit and liaison to the hearing health care system and the health care system as a whole. Given the prevalence of hearing loss in the United States and the multiple follow-up visits that are often needed for comprehensive hearing health care, community health workers offer a potentially beneficial mode of extending hearing health care to a broader segment of the U.S. population, and additional research is needed to further explore this model. Chapter 5 discusses the potential costs associated with the use of community health workers as well as possible reimbursement challenges and opportunities of this model.

Mobile Health Applications

Mobile health, or mHealth (and now "connected health"), typically refers to the use of mobile and wireless technologies to improve the delivery of health care to patients and to improve health and behavioral outcomes and prevention. Together with biological sensors that can collect and store data, these technologies have the potential to add value to hearing health care delivery and hearing health outcomes (HIMSS, 2016; WHO, 2011).

In an effort to improve health care delivery, mHealth applications and intelligent communication systems have been developed to increase access for patients by providing links to health care providers for reviews of symptoms, remote application of diagnostic tools, and ongoing medical management and treatment. In addition to tools that provide remote access for patients to health care providers through smartphones and tablets, diagnostic tools have been developed for mobile devices and their high-quality built-in cameras, microphones, and loudspeakers (Weinstein et al., 2014). Given the need for delivering and recording sound when providing hearing health care, these advances in mobile technologies expand the suite of options for hearing health care to include mHealth. Thanks to their portability, ease of use, and potential to lower costs, mobile devices can serve critical roles for delivery of hearing health care to underserved populations, military conflict locations, rural and remote regions, and low- and middle-income areas of the United States (Källander et al., 2013; Osborn and Mulvaney, 2013; Pew Research Center, 2015). These technologies can be used in real time to (1) perform an otologic examination (as with an otoscope); (2) assess the magnitude of hearing loss; (3) determine an individual's ability to understand speech against various backgrounds (using a digits-in-noise or similar task); (4) perform a self-assessment of communication skills; (5) conduct self-paced speech-perception training or listening and communication training; and (6) engage with others in peer-support groups for patients and family members (Moren, 2014; Olson, 2015). Smartphone apps have recently become available that enable individuals to systematically adjust the gain and frequency response of their hearing aids during the hearing-aid selection process, with the assistance of their audiologist (Paglialonga et al., 2015). Evaluations of these various uses in improving hearing health care are critical.

Some applications are designed to be used without direct access to hearing health care providers and instead employ algorithms that evaluate images (such as audiograms or the results of video otoscopy), determine diagnoses, and recommend treatments or referral (Hussein et al., 2015). Applications are also available to determine if patients' hearing aids are in good working order, to allow audiologists to remotely set certain hearing aid features, and to enable individuals to adjust their own hearing aids as they move in and out of different environments (Picou, 2014). In the immediate future, self-fit or pre-programmed hearing aids will become more widely available, and these options could be fit with the assistance of a smartphone app and a remote connection to an audiologist (as needed) (Romano, 2014). However, just as each individual's hearing loss and hearing needs are unique, a self-fit or pre-programmed option may work well for some and not for others.

Mobile technologies and wearable devices are creating new opportunities for personal health monitoring, tracking, and management, which in turn should lead to improved health behaviors, outcomes, and prevention and also reduced health risks (Bastawrous and Armstrong, 2013; Hall et al., 2015). These devices make it possible to apply mobile technologies to personal or family activities related to health and wellness, which can include communication abilities. At the same time, they can monitor the indoor environment, such as levels of environmental noise. Some devices can serve as health assistive technologies, including for hearing and communication. The large amount of data collected and aggregated by devices creates potential options for health assessments and might be adapted to improve communication-related outcomes (Gay and Leijdekkers, 2015). Because technology advances quickly, the development of many more uses for mHealth in hearing health care is likely.

Research on the benefits, risks, and cost effectiveness of mHealth is lagging behind the use of mHealth technologies by consumers. Research questions for mHealth systems science concern the technologies' efficacy, or the extent to which the use of mobile technologies improve health and wellness outcomes, as well as the validity and reliability of mHealth technologies (Conroy et al., 2014; Knight et al., 2015; Payne et al., 2015; Stoyanov et al., 2015; Yang et al., 2015). Evidence of the effects of mobile technologies and mobile networks on access to hearing health care across demographic groups is also needed. It will also be of interest to determine how mHealth technologies can best be deployed to motivate people to engage in healthy behaviors related to hearing and communication and the impact of changing communication patterns between patients and providers. Other questions include (1) the effects on the hearing health care provider workforce; (2) the need for regulatory controls to ensure information privacy, confidentiality, and security of mHealth data; (3) the risks to user safety from health behavior and engineering perspectives; and (4) technical challenges, such as the need for interoperability among networks. Because research is already lagging behind consumer use, and because technology evolves quickly, it is critical that research into mHealth use for hearing care be given much more attention (Bastawrous and Armstrong, 2013).

Tele-Audiology

One of the earliest forms of "connected health" was telehealth, which is the exchange of health information across remote sites through various forms of telecommunication technologies, such as smartphones, live video conferencing, asynchronous (cloud-based) services for the "store-and-forward" communication of records, email, and other forms of wireless communication. These systems have been used in some form for decades, primarily to connect hospitals in large urban centers to rural areas where health care services may be limited (especially specialty services), with the goals of improving access, reducing cost, and increasing efficiency, while maintaining the quality of care. The use of telehealth technologies has grown rapidly in recent years due to the widespread availability of Wi-Fi and Internet access to support these services. Telehealth options are now available beyond hospitals, such as in private practice offices, assisted living centers, business centers, and patients' homes.

As telehealth has grown, tele-audiology services provided by audiologists have become more widely available in some areas, according to a professional association survey (ASHA, 2016a). Tele-audiology fills a specific need for people who live in rural areas, for those who do not have transportation or are not physically able to travel to obtain audiology services, and for those who move to other locations and wish to maintain a relationship with their hearing health care provider. Current tele-audiology technologies provide capabilities for audiometry, obtaining case histories and completing self-report questionnaires, Web-based support groups, professional-to-professional communication, hearing screening, auditory rehabilitation programs, video otoscopy, and the programming of hearing aids.

One of the leading users of tele-audiology services is the VA, which serves a large number of patients who live outside urban areas and far from VA medical centers (West et al., 2010). Access to audiology services is provided by 455 VA clinical facilities and 132 sites with telehealth carts containing audiology equipment; more than 16,000 tele-audiology patient encounters were completed in fiscal year 2014 (Chandler, 2015). A pilot program launched in 2009 used community-based outpatient clinics as tele-audiology sites and focused on the remote programming of hearing aids. Starting from 10 pilot sites, the program has expanded to 71 sites across the country and has evolved to include remote audiometry with calibration capabilities. Tele-audiology outcomes in the VA are reported to be as good as or better than traditional face-to-face encounters (Beck, 2015). Among the innovative tele-audiology technologies that may increase access in the future are home hearing tests, the scanning and transmission of ear canal images, and the programming of hearing aids in the home through smartphones or tablet computers. The VA has demonstrated that tele-audiology can be a successful program (Gladden et al., 2015). In order to realize the full potential of tele-audiology services, a number of questions will need to be resolved, including how to ensure the accuracy, reliability, and quality of diagnostic evaluations; how to provide high-quality communications between patients and providers; how to confirm patients' understanding of the results; and how to promote patients' acceptance of technologies and auditory rehabilitation services. Questions also remain regarding the costs of the required technologies; cost effectiveness of telehealth and tele-audiology (see Chapter 5); maintenance of confidentiality; and data security. There may also be challenges connected to state licensure laws—e.g., if a hearing health care professional provides care via tele-audiology to a patient located in another state; possible effects on malpractice risk; and reimbursement regulations (see Chapter 5).

Retail Clinics

Among the newest innovations in health care delivery is the trend to provide simple services at lower cost using new technology, staff with less training (e.g., less expensive providers), and increased automation through the use of strict protocols, algorithms, and clinical practice guidelines. As has been the case with the remote services provided by mHealth applications and telehealth, in-person health care visits at sites other than traditional provider offices (such as retail clinics) have been growing in popularity. For example, there were an estimated 10.5 million visits at retail clinics in 2012 (Bachrach et al., 2015). These in-person visits at community locations provide many of the same benefits as remote services (mHealth and telehealth), including decreased overall costs, lower overhead, reduced patient out-of-pocket costs, improved access, increased efficiency, and reasonably short wait times (Salinsky, 2009; Thygeson et al., 2008). Furthermore, although retail clinics were originally viewed as a place to provide basic care for health concerns that were not likely to require follow-up care (e.g., sore throat, ear infection, urinary tract infection, flu vaccination), these clinics are evolving to also manage chronic conditions (e.g., diabetes) (Bachrach et al., 2015). Some evidence suggests that the quality of care in retail clinics is the same as, or better than, that provided in physician offices, urgent care clinics, and emergency departments while the per-episode costs are lower (Mehrotra et al., 2009). Customer satisfaction with retail clinics has been reported to be high. In one national online survey, nearly 80 percent of respondents who had been to a retail clinic rated their experience as being the same as or better than previous interactions with a traditional site of care (Smith et al., 2016). In the same survey, one quarter of respondents reported that they would be willing to use a retail clinic to manage a chronic condition (Smith et al., 2016). However, thus far, retail clinics appear to attract a younger population of patients who do not have existing relationships with primary care providers, which may increase overall utilization but may not improve access to underserved communities or older adults (Mehrotra, 2015).

Within the realm of hearing health care, retail clinics are beginning to explore opportunities to gain a share of the market and expand services for hearing loss. For example, in 2014, Walgreens (with 8,000 locations in the United States) merged with Alliance Boots (a large pharmacy chain based in the United Kingdom) to form Walgreens Boots Alliance. In the United Kingdom, Alliance Boots manages approximately 390 hearing care practices within its pharmacies (SEC, 2014). Since the companies joined forces, Walgreens launched an evaluation of a concept for offering hearing health care services and technologies within its pharmacies at four locations in the United States: Chicago, Dallas, Orlando, and Phoenix (Taylor, 2015). Connect Hearing (Sonova) is working with Walgreens to manage the hearing aid satellite clinics at these four locations, but no decision on future activities between the two companies beyond this limited time project has been announced. In addition to this pilot, Costco Wholesale has opened hearing aid centers in approximately 500 of its warehouses across the United States (see Chapter 5 for additional discussion of the Costco Wholesale model). It remains to be seen whether these clinics are successful in terms of health outcomes, consumer satisfaction, and improving accessibility and affordability. Chapter 5 discusses cost and reimbursement for care that is provided in retail settings.

Research on retail clinics is limited, and little is known about their effects on quality (a potential problem because of the limited availability of local supervision), their impact on long-term outcomes and follow-up care, or their effects on downstream costs (Iglehart, 2015). In order to integrate retail clinics into the hearing health care system and maximize their value for people who have hearing loss, the clinics will need supporting technology and infrastructure to provide basic levels of hearing health care. Care providers who work in retail clinics will need training and support to perform hearing tests, discuss treatment options with patients, and serve as a link to the health care system when referrals are needed for follow-up care.

Summary

The emergence of innovative models of hearing health care and hearing technologies (described in Chapter 4) necessitates research to investigate the relative risks and benefits of these new approaches in comparison to the traditional models of hearing health care delivery, which include hearing aids that are dispensed by hearing health care professionals. A 2009 IOM report that identified priorities for comparative effectiveness research highlighted the importance of investigating and understanding different hearing loss treatments as a priority (IOM, 2009). Since the release of that report, there has been scant new published research investigating these treatment options, particularly on broader and more critical patient-centered outcomes. While there have been several studies on tele-audiology (Blamey et al., 2015), there has been limited research on other hearing health care delivery models (e.g., community health workers, retail clinics) or on direct comparison of different technologies (e.g., over-the-counter devices, high-versus low-end hearing aids) (Cox et al., 2014). Comparative effectiveness research needs to focus on patient-centered outcomes, such as the benefit to real-world communicative function and health-related quality of life, rather than focus on traditional audiologic outcomes, such as hearing and speech tests that are performed in a sound-treated booth.

Examine the Medicare Requirement for Physician Referral for Diagnostic Hearing Testing

The pathway by which an individual enters the hearing health care system can depend on whether that person has insurance coverage that dictates the terms for reimbursement. Individuals who do not have hearing health care insurance coverage can enter the hearing health care system by seeing an audiologist without first obtaining a referral from a physician or nonphysician medical practitioner and pay for all of the services out of pocket, i.e., without reimbursement. Being able to see an audiologist without first obtaining a referral is commonly referred to as “direct access.” In contrast, if an individual has Medicare coverage, an audiologist-provided diagnostic hearing testing will be covered by Medicare only if the individual first obtains a referral from a physician or nonphysician medical practitioner (e.g., a physician assistant or a nurse practitioner).[11] In cases where a Medicare beneficiary expresses concern about his or her hearing to a primary care provider, the provider could choose to refer the patient to an audiologist for diagnostic hearing testing or to an otolaryngologist for an initial evaluation, and then a provider in that otolaryngology practice—likely an audiologist—in turn may conduct a diagnostic hearing test. In the case of either referral pathway, the Medicare beneficiary must go through at least one provider visit to obtain the referral before any hearing evaluation is performed by an audiologist that can be covered by Medicare. The nature of the hearing evaluation covered by Medicare is limited to tests needed "for the purpose of obtaining information necessary for the physicians' diagnostic medical evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem" (CMS, 2008, p. 6). The referral pathway to access diagnostic hearing testing follows Medicare policy for all diagnostic testing (CMS, 2007). Audiologist-provided evaluations designed to assess an individual's functional or communicative abilities or auditory rehabilitation candidacy are not covered by Medicare. Nor is any care related to obtaining a hearing aid covered by Medicare because of the explicit exclusion in the Social Security Amendments of 1965.[12]

Other federally funded programs with hearing health care coverage provisions include the Federal Employees Health Benefit plans (plans approved through the Office of Personnel Management and offered by individual carriers), the Department of Defense Medical Health System, and the Veterans Health Administration. As of 2005, approximately 60 percent of the Federal Employees Health Benefits plans, which cover many federal employees and members of the U.S. Congress, provided coverage for hearing testing performed by an audiologist without requiring a referral from a physician or nonphysician medical practitioner; the coverage depends on the individual plan, similar to the case with insurers in the private sector (CMS, 2007). Coverage of audiologist-provided diagnostic testing for active duty military (provided through the Department of Defense Medical Health System) and for veterans (provided by the Veterans Health Administration) follows a similar model of not requiring a referral from a physician or nonphysician medical practitioner (CMS, 2007; Packer and Henselman, 2015). The Veterans Health Administration employs its own licensed audiologists who work in the same facilities as other health care providers, so this model is different from a community care model.

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[11] Centers for Medicare & Medicaid Services, 42 C.F.R. § 410.32.

[12] Social Security Amendments of 1965, Public Law 89-97, 89th Cong., 1st sess. (July 30, 1965).

For patients, there are advantages and disadvantages with both the referral pathway and the direct access pathway. The disadvantages of referral can include a lack of access to medical providers due to financial barriers, appointment wait times, or transportation difficulties. Hence, if medical referral is thought to be advisable, it should be balanced by a benefit to the consumer in the form of better, more coordinated primary and specialty health care. For those who have limited access to transportation or who rely on others to accompany them to provider visits, each trip to see a provider can present a burden. Patients generally develop hearing impairment slowly over time, so appointments are usually not needed urgently. However, the average wait time to see a family physician is approximately 19.5 days, and a shortfall in primary care physicians by 2020 has been projected—both of these factors may delay the time it takes to get evaluated and receive a diagnosis (HRSA, 2016a; Twiddy, 2014). In one recent study, 71 percent of members of the American Academy of Otolaryngology—Head and Neck Surgery reported being able to see a new patient in 2 weeks or less.[13] Studies have demonstrated that the overall ear disease prevalence in the population of adults with age-related hearing loss is low (Zapala et al., 2015) and that patient populations in health systems that do not require a referral do not have higher rates of missed disease (Zapala et al., 2010) (see Table 3-3).

Conversely, the current medical model in which Medicare coverage for hearing health care requires a referral follows the “medical home” model (NCSL, 2012), which ensures that those with hearing loss see a physician or nonphysician medical practitioner who can assess the possible relationship between the individual’s general health and hearing loss. Given the negative health outcomes that can be associated with hearing loss (see Chapter 2), ensuring that a physician or nonphysician medical practitioner stays involved with and informed of a patient’s hearing ability and any diagnosis may be important for overall health. The medical home model ensures that older adults with hearing loss receive coordinated care for their hearing loss, and also ensures that providers are aware of communication limitations with their patients to whom they must convey critically important health information (such as instructions for medications, etc.). Geriatric medicine is characteristically interdisciplinary, due in part to the interplay of reduced function in multiple physiological systems in older adults and the impact on sensory systems, including hearing and balance.

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[13] Personal communication. Letter to the Committee on Accessible and Affordable Hearing Health Care for Adults, from James Denneny III, Executive Vice President/CEO, American Academy of Otolaryngology—Head and Neck Surgery. Received January 22, 2016. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

In addition to having an increased incidence of hearing loss, the Medicare population is more likely to have problems with dizziness and imbalance, and those who do have an increased incidence of falls (Agrawal et al., 2009). While inner ear vestibular disorders are thought to account for some of the cases involving dizziness that are presented to primary care providers, other causes include cardiovascular disease, systemic infection, psychiatric conditions, metabolic disturbances, and medications (for a review, see Sloane et al., 2001). The association of hearing loss with these conditions may indicate that the primary care provider should be an integral part of the initial episode of care related to any diagnosis of hearing loss, and thus direct access, which bypasses general medical providers, may not be in the patient's best interests.

The committee considered direct access versus requiring a referral with particular focus on how it relates to the committee's task of increasing access and affordability of hearing health care for adults. On one hand, the current Medicare policies requiring a referral may help ensure coordination and completeness of care for older adults who are Medicare beneficiaries and may help preserve a primary care provider as a central repository of all of an individual's health care information. On the other hand, providing a direct pathway to audiologists without requiring a referral might safely decrease the burden on Medicare beneficiaries while increasing accessibility to hearing health care, and communication between audiologists and primary care providers could accomplish the same team-based approach that the current Medicare referral requirement provides. Both pathways have their merits in terms of patient health and hearing health care access. Some committee members thought there were sufficient data to support recommending direct access without referral for Medicare beneficiaries. Other committee members were concerned about removing medical practitioner involvement and did not think there were sufficient data to understand how direct access would impact the effectiveness of the medical home for Medicare beneficiaries. Consequently, the committee could not come to a consensus on this issue. The committee thought that additional evidence might clarify these benefits and challenges for Medicare beneficiaries.

NEXT STEPS AND RECOMMENDATIONS

This chapter has covered a large number of critical issues regarding hearing health care services, and it has reviewed opportunities to improve these services, including needed areas of research. As new programs and delivery models are explored, it will be critical that research be conducted to support evidence-based practice. Ensuring that consumers are informed about their options and that they receive quality services that meet or exceed performance standards and also reach diverse and underserved populations will require coordinated efforts among federal, state, and local government agencies and a range of professional organizations, manufacturers and other private-sector businesses, health care providers, and advocacy organizations. The committee offers the following goals and recommendations for improving hearing health care services. In addition, in Chapter 5 the committee recommends demonstration projects and studies that tie health care service delivery to affordability.

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 government 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.

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4

Hearing Technologies: Expanding Options

The hearing technology landscape is ever evolving and encompasses a wide range of products—from traditional hearing aids regulated as medical devices to consumer-technology products and hearing assistive technologies—with the overall goal of enabling the user to hear and communicate better in their homes (e.g., television), in public spaces (e.g., movies and lectures), and through phones or other communications products and systems. Both the access to and the affordability of these technologies are a concern in the United States and across the globe. Many people with hearing loss do not have hearing aids or other technologies. Of those who do have hearing aids, some choose not to use them. There are regulatory and policy challenges as well as research and design opportunities for improving hearing technologies so that they better meet the needs of individuals with hearing loss.

This chapter examines the broad range of hearing-related technologies. After a brief overview of the hearing technology landscape, including a discussion of the extent of use of these technologies and user satisfaction, the chapter examines studies on hearing aid efficacy and effectiveness (the nature and scope of the market is discussed in Chapter 5). The chapter then delves into the U.S. regulatory structure for hearing aids and other products that address hearing loss. The chapter closes with the committee's recommendations on next steps for improving the accessibility and availability of hearing health care technology. Because the committee was charged to focus on nonsurgical interventions, the chapter does not address cochlear implants or implantable bone conduction hearing aids in detail.

OVERVIEW OF HEARING TECHNOLOGIES

The recently coined term *hearables* has been used to refer to a wide range of hearing- and ear-based technologies (Cannington, 2015; Hunn, 2015) that have been defined as "wearable technology for the ear" (Chandran, 2014; Hosford-Dunn, 2015). Hearable technologies include the devices and products relevant to hearing loss that are discussed in this report (see Box 4-1) as well as other products used via the ear, such as health-related technologies (e.g., monitors for heart rate and other health parameters) and the large variety of headphones, ear buds, and other music and streaming technologies. One estimate projects that the market for hearables will be more than $17 billion by 2020 (Hunn, 2015). Hearables can combine multiple functions and often feature innovations in style, color, and accessibility. The interest in audio technologies suggests a general public that has, and will increasingly have, personal familiarity with technologies that are for hearing or that are worn in the ear.

Hearing technology is undergoing rapid change as great advances in technologies and design features result in new products. Clayton Christensen used the term "disruptive innovation" to describe "a technology that brings a much more affordable product or service that is much simpler to use into a market. And so it allows a whole new population of consumers to afford to own and have the skill to use a product or service, whereas historically,

Box 4-1 TYPES OF HEARING-RELATED TECHNOLOGIES

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

the ability to access was limited to people who have a lot of money or a lot of skill" (Smith, 2007, p. w288). Examples of disruptive innovations include personal computers, cell phones, and retail medical clinics, all of which are products or services that have increased consumer options, generally at lower cost. To disrupt an industry, an innovative technology needs to be coupled with business-model innovation to harness the full potential of the technology (Christensen et al., 2009). Outdated regulations and reimbursement models have the potential to entrench older technologies, even as more cost-effective and more accessible technologies become available. Thus, innovations in hearing technology create a potential for disruptive change in the market for hearing devices, products, and services, but whether the market transitions may depend on additional regulatory, business, and reimbursement factors. This complex topic has been the subject of recent recommendations by the President's Council of Advisors on Science and Technology (PCAST) (Cassel et al., 2016; PCAST, 2015).

Hearing Aids

Hearing aids are medical devices defined by the Food and Drug Administration (FDA) as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing."[1] As detailed below, FDA regulates hearing aids as Class I or Class II medical devices. Hearing aids generally have a number of components including a microphone, analog-to-digital converter, digital sound processor, output transducer, and battery. Although often compared to glasses (termed "spectacles" in FDA regulatory language), current hearing aids cannot correct or restore normal hearing acuity to the extent that glasses or contact lenses can correct vision loss or restore normal visual acuity for many people. The general goal of well-fit hearing aids is to improve the audibility of even soft speech, music, and other sounds while assuring that these same sounds and other already audible sounds do not become uncomfortably loud. Hearing aids can be customized to meet the needs of the individual (see Chapter 3) including customization of the frequencies and intensities of sound and other adjustable parameters in the processing of algorithms.

Technological efforts to address hearing loss have a long history. Early hearing trumpets and other "hearing aids" focused on increasing the volume and directionality of sound. With a series of advances in technology (carbon transmitters in the late 1800s, vacuum tubes in the early 1900s, transistors beginning in the 1920s and in more common use in the 1950s, microprocessors in the 1970s and 1980s, and digitalization of sound in the

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[1] 21 C.F.R. 801.420.

1980s and 1990s), the size of hearing aids has decreased, while the capabilities to provide clearer sound have greatly improved (Mills, 2011; Mudry and Dodele, 2000; Washington University School of Medicine, 2016). In addition, advances in signal processing and other technologies, improvements in battery capabilities, and the advent of wireless access have made it possible for hearing aids to include telecoils (for coupling with compatible electronic products; see further description later in the chapter), directional microphones, noise reduction circuitry, direct audio input and processing algorithms that are intended to minimize background noise and maximize conversational sound, and capabilities for wireless signal reception for interactions with televisions, phones, computers and tablets, and other communication and hearing assistive technologies. The extent to which these components (and other innovations) are included in specific hearing aid products varies across the range of basic to premium level aids. Upgrades and variations include the extent and nature of Bluetooth capability, the inclusion of a telecoil, the number of channels, automatic switching among programs, feedback reduction, and smartphone applications to program or personalize the device (*Consumer Reports*, 2015; HLAA, 2016; Mamo et al., 2016; McCormack and Fortnum, 2013). Research and design efforts continue to focus on improvements in various capabilities.

The different types of air conduction hearing aids are distinguished primarily by the location where the device is placed—behind the ear, in the ear, or in the ear canal—with the various types providing varying levels of visibility, ease of control, and features (*Consumer Reports*, 2015; NIDCD, 2013). The literature on the effectiveness of hearing aids and an overview of the regulatory landscape is described later in this chapter.

For most adults with mild to moderate sensorineural hearing loss, a common complaint is difficulty in understanding speech, especially in noisy environments. When measured using a speech-in-noise task (see Chapters 3 and 6), the results may indicate that a more advantageous signal-to-noise ratio is required to understand speech than for individuals with normal hearing. In some cases, given that the hearing aid is well fit and improves speech audibility in higher frequencies, the signal-to-noise ratio may be improved. However, under certain conditions, even well-fit hearing aids may not necessarily improve the signal-to-noise ratio to result in improved speech recognition in noise. For these individuals with mild to moderate hearing loss, hearing assistive technologies and/or auditory rehabilitation may provide additional benefit.

FDA has established regulatory requirements for hearing aids that include technical standards, quality system regulation (including good manufacturing practice requirements), requirements for mandatory labeling and user instructional brochures, and requirements for a pre-purchase medical evaluation (or documented waiver) (see Chapter 3 and below for further discussion of the medical waiver). These FDA regulations, along with a number of state regulations, have restricted the availability of hearing aids to being mainly dispensed through medical, audiology, or hearing instrument specialists. To date, FDA has not been receptive to proposals for over-the-counter (OTC) or direct-to-consumer hearing aids. This has led to the development of hearing-related technologies that are positioned as consumer electronics products rather than medical devices, including personal sound amplification products, or PSAPs (discussed below).

The immense demand for affordable and easy-to-deliver hearing health care in developing countries is resulting in innovations in the design of hearing aids and hearing assistive technologies aimed at increasing affordability and simplifying use. An estimated 360 million individuals in developing countries live with disabling hearing loss, and in 2004 the World Health Organization set out guidelines for hearing aids and services in an effort to support efforts to meet this demand (Olusanya et al., 2014; WHO, 2004). Although developing countries have a major need for low-cost hearing technologies, they often have a limited health care infrastructure with few audiologists and otolaryngologists. One avenue toward meeting the need would be the refinement of self-fitting hearing aids, which assess an individual's hearing and transfer the resulting data directly to the hearing aid, which sets itself appropriately, ideally without computers or other external requirements (Caposecco et al., 2011; Convery et al., 2011; Wong, 2011). Other avenues being explored include varying hearing assistive technologies and the use of solar power and other innovative power options (McPherson, 2011; Parving and Christensen, 2004). These and other innovations in hearing aid technology and fittings may also increase the options for underserved populations in the United States (Clark and de Swanepoel, 2014).

Access to hearing health care services may also improve with greater availability of hearing aids that have an open platform approach to programming. For the purposes of this report, an "open platform" for hearing aid programming refers to a programming platform that allows any hearing health care professional to adjust the device settings to meet a consumer's needs. "Open platform" does not refer to the proprietary software that confers general hearing aid functionality.

Currently, the settings on many hearing aids can only be adjusted by hearing health care professionals who have an agreement with a given manufacturer or distributor to sell that brand of hearing aid. Furthermore, many hearing health care professionals only sell one or a few different brands of hearing aids. A consumer who purchases a hearing aid from one hearing health care professional may find that the manufacturer or distributor has restricted access for adjusting the settings, and thus, the consumer may have to seek all additional programming services from the same distributor that originally sold him or her the product. In contrast, open platforms allow the hearing aid to be programmed by any provider, increasing the portability of care and the number of professionals from whom the individual can obtain care. This approach allows consumers who want to switch to a different hearing health care professional, who are traveling, or who move to a new location to have their hearing health care needs addressed by the professional of their choice. Additionally, technologies will continue to evolve and may enable individuals to make hearing aid adjustments for themselves directly or through a mobile app or other pathway rather than having to depend on a professional every time an adjustment is needed.

The committee urges the development of the standards needed for an open platform approach and the collaborative efforts by manufacturers, distributors, and hearing health care professionals to ensure implementation. The committee also urges greater efforts on the part of those who sell hearing aids to educate consumers about whether a given hearing aid's programming platform is open or closed. Additionally, consumer-friendly information on the programming parameters and other features of specific hearing aids should be furnished to consumers to allow easier comparisons between the devices (see also Chapter 6). These notifications should be provided prior to sale so that consumers can make informed purchasing decisions.

Extent of Hearing Aid Use

In the United States the prevalence of hearing aid use is significantly lower than the prevalence of hearing loss. In a report examining the results of the 1999–2006 National Health and Nutrition Examination Surveys (NHANES) (audiological testing was conducted from 1999 to 2004 in a sample of participants ages 50 to 69 years and in 2005 was conducted in all participants 70 years of age and older), it was estimated that hearing aids were worn by 3.8 million Americans, or 14.2 percent of those who had hearing loss (Chien and Lin, 2012) (see Table 4-1). An earlier report that was focused on NHANES participants ages 70 and older found a strong gradient of hearing aid use based on the severity of hearing loss, with 3 percent of those with a mild loss, 40 percent of those with a moderate loss, and 77 percent of those with a severe loss regularly wearing hearing aids (Lin et al., 2011). In a multivariable model, the severity of hearing loss, college education, and leisure noise exposure were positively associated with hearing aid use, but race/ethnicity, age, sex, and income were not significantly associated with the use of a hearing aid.

Bainbridge and Ramachandran analyzed NHANES data from 2005–2006 and 2009–2010 and found that among participants 70 years of age and older who were deemed to be hearing aid candidates (pure tone average [PTA] 0.5–2 kilohertz [kHz] > 35 decibel hearing level [dB HL] and who

TABLE 4-1
Prevalence and Number of Individuals 50 Years or Older with Hearing Loss[a] Using Hearing Aids in the United States[b]

	Prevalence of Hearing Aid Use Among Adults with Hearing Loss[a] ≥ 25 dB, Percent (95% CI)[c]						
	Sex		Hearing Loss Severity[d]		Total		
Age, Years	Male	Female	Mild (> 25–40 dB)	Moderate or Greater > 40 dB	Overall Prevalence of Hearing Aid Use	Number with Hearing Aids, Millions	Number with hearing loss[a] ≥ 25 dB, millions
50–59	4.3 (0–9.5)	4.5 (0–13.5)	2.7 (0–6.6)	11.8 (0–27.5)	4.3 (0–8.8)	0.2	4.5
60–69	7.3 (2.5–12.1)	7.2 (1.4–13.0)	2.6 (0–5.2)	23.9 (10.6–37.2)	7.3 (3.6–10.9)	0.4	6.1
70–79	21.1 (14.5–27.6)	12.7 (6.0–19.5)	3.4 (0.3–6.5)	47.8 (37.0–58.6)	17.0 (12.4–21.6)	1.5	8.8
≥ 80	28.1 (20.3–35.9)	17.9 (11.2–24.7)	3.4 (0–7.7)	35.7 (28.7–42.7)	22.1 (18.5–25.8)	1.6	7.3
Estimated total number of individuals with hearing aids and with hearing loss, in millions						3.8[d]	26.7

[a] Hearing loss was defined as a speech-frequency pure tone average of hearing thresholds at 0.5-, 1-, 2-, and 4-kHz tones presented by air conduction in the better hearing ear of 25 dB or greater.

[b] Data were derived from the 1999–2006 National Health and Nutrition Examination Survey.

[c] All values represent percent prevalence unless otherwise noted.

[d] Numbers do not sum to group total because of rounding.

NOTE: CI = confidence interval; dB = decibel; kHz = kilohertz.

SOURCE: Chien and Lin, 2012. Reproduced with permission. Copyright 2012. American Medical Association. All rights reserved.

reported moderate or worse hearing ability), just one-third used hearing aids (Bainbridge and Ramachandran, 2014). In this study, individuals with the highest incomes were more likely to use hearing aids than the poorest group, but these analyses did not adjust for education.

In the longitudinal Epidemiology of Hearing Loss Study, 14.6 percent of people with hearing loss were current hearing aid users, and 6 percent were former users (Popelka et al., 1998). Even among those participants who reported significant communication problems and handicap, only 33 percent reported currently using a hearing aid, while 32 percent of those with moderate to severe hearing loss reported current use. Factors associated with hearing aid use were older age, a greater severity of hearing loss, having a college education, poorer performance on word recognition tests, and self-reported hearing handicap and loss. Similar results of low hearing aid use were seen in a study of the adult children of participants in the Epidemiology of Hearing Loss Study, with only 4 percent of people with mild loss and 23 percent of participants with moderate-to-severe loss using hearing aids (Nash et al., 2013).

Although no race/ethnicity differences in hearing aid use have been seen in the NHANES data, this may be partly due to limited power, as the number of Hispanics/Latinos enrolled in the study was small. Data from the Hispanic Health and Nutrition Examination Survey showed that less than 10 percent of Hispanics/Latinos with hearing loss used hearing aids (Lee et al., 1991). Even among the participants with PTA > 40 dB HL, only 5 percent of men and 11 percent of women used hearing aids. A follow-up report from Lee and colleagues demonstrated that poorer Mexican Americans were nine times more likely to use hearing aids than other participants; the researchers speculated that the introduction of the Medicaid program may have contributed to the accessibility of hearing aids (Lee et al., 1996).

Hearing Aid User Satisfaction and Barriers to Use

To investigate the low use of hearing aids, studies have examined both the barriers to purchasing the devices and the barriers to use of the devices once purchased. The specific issues regarding cost as a barrier are discussed in Chapter 5.

As part of the longitudinal Epidemiology of Hearing Loss Study, Fischer and colleagues (2011) examined factors associated with acquiring hearing aids during 10 years of follow-up. Among participants with hearing loss in their better ear who were not using hearing aids, 36 percent started using them within 10 years. College graduates and people who reported greater hearing loss or judged their hearing as poor were more likely to become hearing aid users. When participants with hearing loss who had not acquired hearing aids were asked their reasons for not purchasing them, the most frequent responses included "did not need it," "cost," "inconvenient to wear," and "poor experience of others."

A review of studies examining the nonuse of hearing aids that were already purchased found that the primary reasons given for nonuse were problems with obtaining improved speech clarity and sound quality and challenges with the fit, comfort, and maintenance of the device (McCormack and Fortnum, 2013) (see Box 4-2). MarkeTrak, an ongoing survey by the Better Hearing Institute, the educational arm of the Hearing Industries Association, has found high levels of satisfaction with hearing aids, particularly with more recent models that have newer technologies, but it also notes challenges (Abrams and Kihm, 2015). In a 2004 MarkeTrak survey, two-thirds of respondents who acknowledged that they had a hearing loss but said that they had not adopted the use of hearing aids reported that their barriers to hearing aid adoption included perceptions of or experiences with problems in hearing aid performance (e.g., whistling, background noise), disappointing results (e.g., hearing not restored), and poor reliability (e.g., due to short battery life or humidity) (Kochkin, 2007).

Knudsen and colleagues (2010) reviewed 39 studies on the correlates of help-seeking behavior, uptake of hearing aids, use of hearing aids, and satisfaction with the devices. The researchers found that those individuals who self-reported that they experienced hearing-related activity limitations or participation restrictions prior to hearing aid fitting had greater satisfaction and higher use. The extent of hearing loss (in the moderate range) was generally associated with seeking help and acquiring a device but was not always associated with increased use or satisfaction.

Box 4-2 EXAMPLES OF REASONS IDENTIFIED FOR NONUSE OF HEARING AIDS AFTER PURCHASE

- Perceived as not effective, particularly in certain situations
- Did not meet expectations
- Challenges with fit, comfort, and use
- Side effects such as rashes or itching
- Stigma
- Challenges with care and maintenance (e.g., changing batteries)
- Ongoing cost of batteries, maintenance, and repair
- Appearance—cosmetic concerns
- Hear well enough without the hearing aid

SOURCE: McCormack and Fortnum, 2013.

Ng and Loke (2015) reviewed 22 studies of older adults and noted a wide variety of audiologic determinants of hearing aid usage (largely self-reported), with the severity of hearing loss being a primary determinant, along with the type of hearing aid (greater use for those with more advanced signal processing features) and a greater tolerance for background noise. Nonaudiological determinants of the extent of hearing aid use included self-perception of a hearing problem, expectations of potential benefit, concerns of perceived stigma, and support from significant others or from group sessions.

One of the usability challenges for hearing aids that is reported particularly by older adults is that the small size of the devices can lead to difficulties with proper insertion, removal, and maintenance of hearing aids and changing their batteries. Limited vision and manual dexterity in older adults can exacerbate these problems (Clements, 2015; Erber, 2003). Furthermore, the hearing aids can be easy to misplace or lose.

The above studies indicate that sound quality, speech clarity, the amount of background noise, the ease and comfort of fit, battery reliability, and user expectations about the benefits and performance of hearing aids may be important factors affecting the use or nonuse of hearing aids. Although analogies have been drawn between hearing aids and eyeglasses, there are significant differences. Eyeglasses have corrective lenses and, when used, can generally correct visual acuity to the point that the user does not need any other assistive devices or strategies to see clearly. By contrast, hearing aids can improve the audibility of sound by amplification but are not able to restore normal hearing or fully improve communication abilities, especially in noise. Great strides have been made in hearing aids in the past 50 to 60 years, but issues regarding background noise and clarity of sound, among others, can limit benefits, particularly in certain situations and locations. Individuals who have hearing loss and use hearing aids can frequently benefit from hearing assistive technologies and from using strategies such as consideration of the location and proximity to (or away from) the source of the sound. Research efforts focused on hearing aid improvements continue to be needed, as are the development of performance standards for hearing aids and related products and the use of standardized terminology regarding device features to assist the consumer in directly comparing products and better understanding what can and cannot be expected from a given product (see also Chapter 6). Consistency across manufacturers in naming and describing the features of hearing aids and hearing assistive technologies will enable consumers to independently compare features and not rely solely on distributors and hearing health care professionals for that information.

Personal Sound Amplification Products

The term "PSAPs" refers to a wide range of consumer products that increase the level of sound sensed by the user. FDA guidance documents specify that to avoid classification as a medical device, PSAPs cannot be marketed in the United States as products intended for individuals with hearing loss or to compensate for hearing loss (FDA, 2009a,b, 2013b). A 2009 FDA guidance document defines a PSAP as a "wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities" (FDA, 2009b). FDA's 2013 proposal for revised draft guidance offered some revisions and characterized PSAPs as products that

> are intended to amplify environmental sound for non-hearing impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss. (FDA, 2013b, p. 5)

Some of these products have technical and performance characteristics quite similar to the hearing aids that FDA regulates. Determinations regarding whether a product is a "device" that FDA can regulate are based on the Federal Food, Drug, and Cosmetic Act (FDCA) definition of a device as "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[2] FDA does not regulate PSAPs as medical devices, although FDA can regulate them under the electronic product provisions of the FDCA. As with other consumer products, the Consumer Product Safety Commission has the authority to examine any safety concerns about PSAPs.

Few data are available on the extent and nature of PSAP use. Additionally, the term PSAP is often used to describe a wide variety of products, so it can be hard to understand or compare consumer surveys. An analysis of a MarkeTrak survey reported that approximately 5 percent of respondents who did not own a hearing aid indicated that they owned a PSAP (Kochkin, 2010b). Those who owned a PSAP reported lower levels of self-categorized hearing loss (mild) and had an annual income averaging approximately $10,000 less than those who owned a hearing aid. When asked what they would do if PSAPs were not available, almost half of the PSAP owners indicated that they would not purchase custom hearing aids (Kochkin, 2010b).

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[2] Federal Food, Drug, and Cosmetic Act (FDCA), Public Law 75-717, 75th Cong. (1938) and amended. 21 U.S.C. § 321(h), 21 C.F.R. § 801.4.

A 2014 online survey by the Consumer Electronics Association (now the Consumer Technology Association [CTA]) found that of 1,551 U.S. adults who had been diagnosed with hearing loss or self-reported that they had trouble with hearing, approximately 30 percent owned a hearing aid, 11 percent owned a television amplifier, 11 percent owned an amplified telephone, and 6 percent owned another sound amplification product (CEA, 2014). Of those individuals who owned a PSAP, 51 percent said they used it to help listen to television, and 10 percent reported using the product every day.

The population-based Blue Mountains Hearing Study in Australia surveyed the use of what it termed "assistive listening devices" and found that out of 2,956 respondents, 4.4 percent reported using such a device in the past year, with the primary uses being to enhance use of the television or telephone (Hartley et al., 2010). Of current hearing aid owners in the study, 25.6 percent reported that they had used an assistive device in the past year.

Studies of the effectiveness of PSAPs and hearing assistive technologies have primarily been conducted using small samples of older adults and have noted a general lack of knowledge about hearing assistive technologies, although some studies with users familiar with the technologies have indicated user satisfaction in improving sound quality and speech understanding (e.g., Aberdeen and Fereiro, 2014; Southall et al., 2006). More research is needed to develop the data necessary for improved capabilities and to provide the information needed for comparisons between products and product features by consumers and professionals.

Hearing Assistive Technologies

Individuals with hearing loss, particularly those with moderate to severe hearing loss, may use a variety of hearing assistive technologies in addition to hearing aids to connect to or receive information from other communication avenues (such as the phone or television) or from sound systems in classrooms, theaters, places of worship, or other public spaces or for emergency alerts (see Box 4-3). Driven by the needs of consumers and the requirements of antidiscrimination laws such as the Americans with Disabilities Act (ADA),[3] hearing assistive technologies span the range of products from those for personal and home use to systems available in public spaces and for larger audiences These services are often termed auxiliary aids and services in the ADA,[4] which requires that

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[3] Americans with Disabilities Act of 1990, Public Law 101-336, 101st Cong. (July 26, 1990).

[4] Revisions to the ADA in 2010 included clarifying the scope of auxiliary aids and services to include providing a qualified note taker or interpreter, captioning (in multiple formats), assistive telecommunications products (e.g., telephone handset amplifiers, hearing aid–compatible telephones, text telephones, captioned telephones), videotext displays, and accessibility features in electronic documents (DOJ, 2014).

Box 4-3 HEARING ASSISTIVE TECHNOLOGIES

- Face-to-face communication
  - Hardwired and wireless auditory technologies
  - Visual technologies (e.g., captioning)
- Reception of media (e.g., television, music)
  - Hardwired and wireless auditory technologies
  - Visual technologies (e.g., captioning)
- Telecommunications
  - Auditory
    - Amplified phones
    - Hardwired and wireless interfaces
  - Visual
    - Video conferencing (personal or group)
    - Captioning for teleconferences
- Alerts
  - Auditory
  - Visual (flashing lights, text)
  - Vibrotactile

> A public accommodation shall take those steps that may be necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently than other individuals because of the absence of auxiliary aids and services, unless the public accommodation can demonstrate that taking those steps would fundamentally alter the nature of the goods, services, facilities, privileges, advantages, or accommodations being offered or would result in an undue burden, i.e., significant difficulty or expense.[5]

These types of products have also been termed "hearing assistance technologies."

Improving the availability and effectiveness of hearing assistive technologies is a priority for achieving better hearing and communication for individuals with hearing loss. Improvements in these technologies and connections need to be accompanied by efforts to raise public awareness on the range of options available and to provide user-friendly instructions for connectivity and use. These efforts could be undertaken by hearing health care professional associations, hearing device manufacturers, and government entities such as the Federal Communications Commission (FCC) and the National Institutes of Health. Additionally, training for hearing

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[5] 28 C.F.R. § 36.303.

health care professionals and for primary care providers and other health care professionals working with adults needs to emphasize the capabilities of hearing assistive technologies and best practices for instructing patients regarding their use and connectivity.

Hearing Induction Loop and Telecoil Technologies

Hearing induction loop technology allows the sound system in a room to connect wirelessly with an individual's hearing aid via the telecoil in the hearing aid or via a neck loop receiver and ear phones, thereby eliminating the background noise and improving clarity of sound. These systems work through the installation of hearing loop wiring around the perimeter of the room that connects to the room's sound system. The electromagnetic signals from the sound system are picked up by the telecoil in the hearing aid or cochlear implant or by the receiver.

Telecoils are available on most but not all types and models of hearing aids, but consumers do not always know that their hearing aid has this feature or that it can be added as an option[6] (HLAA, 2016). Only 34 percent of 1,995 respondents to a 2008 MarkeTrak survey indicated that they were aware that their hearing aid had a telecoil (Kochkin, 2010a). Telecoils also enhance the performance of wired and wireless telephones.

In a survey of audio loop users, approximately 70 percent indicated that the loop significantly improved sound quality and speech intelligibility (Kochkin, 2014). Respondents also noted that hearing induction looping empowers consumers because they can walk into a venue with an induction loop and turn on the telecoil sensor without the need to ask for assistance or ask for another piece of equipment (receiver); by being unobtrusive to use, the technology maintains a user's privacy. Furthermore, performance standards for induction loop technology provide the consumer with a technology that can be used across venues and manufacturers, whereas many other hearing technologies are proprietary. Some states have recognized the value of the telecoil to couple with an induction loop by mandating that consumers be informed about the telecoil when they purchase their hearing aids. Hearing induction loops have been installed in some public spaces, such as movie theaters, places of worship, and other large venues, but they can also be installed in private homes (Shaw, 2012) and vehicles (HearingLoop.org, 2015). Efforts are under way in some communities to expand the use of this technology (see Chapter 6).

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[6] The Consumer's Guide to Hearing Aids notes that the majority of hearing aids have telecoils as a standard feature or as a feature that is available to be added (HLAA, 2016).

FM and Infrared Technologies

FM (frequency-modulated) systems use radio signals to transmit sound directly from the speaker's microphone or other sound system. Some types of hearing aids can process the wireless FM transmissions. In other cases, a body-worn receiver is used that is connected to earphones or a neckloop is used that converts the transmission to an electromagnetic signal that can be picked up by the telecoil in the hearing aid (ASHA, 2016; Chisolm et al., 2007b; Kim and Kim, 2014). These systems are often used in classrooms and places of worship and can be used to transmit sound from radio, television, and other sources. Radio signals are able to penetrate walls, and mixed signals can result unless different frequencies are used. Studies on the effectiveness of FM systems in improving speech perception have primarily examined the use of this technology by children in classroom settings (e.g., Bertachini et al., 2015; Hawkins, 1984; Hawkins and Schum, 1985).

Infrared systems use infrared light waves to transmit to a personal receiver. As with the FM systems, the infrared system uses a receiver and headphones or a neckloop and hearing aid telecoil. The infrared systems have the advantage of containing the signal in the room (and thereby having less interference from other competing signals), but they have the disadvantage of potentially competing with natural light (Holmes et al., 2000; Kim and Kim, 2014).

Captioning

Captioning involves the transcription of discussions or programming into text on a screen and can be done on-site or remotely. Captioning is often done in real time for live events such as sports events or conferences, and it can be projected through television and other media, through a website, or directly onto a screen visible in the location of the event. Beginning in 1993, the ADA required all televisions 13 inches or larger to have closed captioning capabilities with text for the auditory portion of programs (Holmes et al., 2000). Captioned telephones are also available and can be used in conjunction with the Telecommunications Relay Service (see next section).

Interconnectivity—Wireless and Other Information and Communication Technologies

Individuals with hearing loss often face challenges involving the interoperability and compatibility of information and communications technologies (e.g., phones, television, or wireless networks) with hearing aids and other products. Beginning in the 1980s and 1990s a number of laws were passed in the United States that focused on ensuring that telephone and television and other electronic communications would be accessible to individuals with hearing loss and other Americans with disabilities (see Box 4-4).

Efforts by the U.S. Access Board (responsible for issuing standards and guidance relevant to the ADA) and other organizations and agencies include a focus on the issues of compatibility and interoperability between and among wireless communications products and systems and hearing technologies, including revised and common wireless standards (Access Board, 2015).

Mobile apps and smartphones have the potential to offer a variety of options for individuals with hearing loss (Mamo et al., 2016; Paglialonga et al., 2015). Smartphones can be used via Bluetooth to initially set up a

Box 4-4 EXAMPLES OF LEGISLATION TO MAKE COMMUNICATION ACCESSIBLE TO INDIVIDUALS WITH HEARING LOSS

Rehabilitation Act of 1973[a] extends vocational rehabilitation programs in the states, and the Section 508 amendment in 1998 requires federal agencies to ensure that their electronic and information technology is accessible to people with disabilities.

Hearing Aid Compatibility Act of 1988[b] requires that the Federal Communications Commission ensure that new telephones be compatible with hearing aids. Wireless phones were exempt from the requirements, but subsequent changes to the law have extended its provisions to cellular phones.

Technology-Related Assistance for Individuals with Disabilities Act of 1988[c] provides funding to states to develop statewide assistive technology solutions for individuals of all ages with disabilities.

Americans with Disabilities Act of 1990 (ADA)[d] requires that under certain conditions, businesses and public accommodations need to ensure that individuals with disabilities are not excluded from or denied services because of the absence of auxiliary aids. Captions are considered one type of auxiliary aid. Modifications to the ADA were made in 2008 (Public Law 110-325) and subsequently in ADA regulations.

Television Decoder Circuitry Act of 1990[e] requires that all televisions larger than 13 inches sold in the United States after July 1993 have a built-in decoder that enables viewers to watch closed-captioned programming.

Individuals with Disabilities Education Act of 1990[f] (Public Law 105-17) and the **Individuals with Disabilities Education Improvement Act of 2004**[g] (Public Law 108-446) ensure the availability of education services for children and youth with disabilities (ages birth through 21 years of age) and the incorporation of assistive technologies into these services.

hearing aid or to personalize and program the device (Mamo et al., 2016). One analysis of mobile health applications for eight health conditions noted the paucity of mobile applications for hearing loss (Martinez-Perez et al., 2013). The apps related to hearing were primarily for the purpose of hearing checks or providing educational tools. Screening for hearing loss is also a potential use (Peer and Fagan, 2015) (see below for information on FDA guidance documents regarding mobile apps; see also Chapter 3).

Phones are required to meet American National Standards Institute (ANSI) standards specifying the level of volume and other sound parameters that must be attainable. The FCC requires that wireless phones meet the ANSI C63.19 standard regarding compatibility with hearing aids. Additionally, telephones are available that provide greater amplification, and other assistive technologies can also be used in conjunction with phone

Telecommunications Act of 1996[h] added Section 713 to the Communications Act, which requires the Federal Communications Commission to develop rules and implementation schedules for the closed captioning of television video programs, and Section 255, which requires telecommunications equipment manufacturers to strengthen efforts to improve accessibility.

Twenty-First Century Communications and Video Accessibility Act of 2010[i] provides protections to enable people with hearing loss and others with disabilities to access broadband, digital, and mobile innovations and includes a focus on emergency information technologies.

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[a] Rehabilitation Act of 1973, Public Law 93-112, 93rd Cong. (September 26, 1973) and amendments 29 U.S.C. § 794d.

[b] Hearing Aid Compatibility Act of 1988, Public Law 100-394, 100th Cong. (August 16, 1988). 47 U.S.C. § 610.

[c] Technology-Related Assistance for Individuals with Disabilities Act of 1988, Public Law 100-407, 100th Cong. (August 19, 1988).

[d] Americans with Disabilities Act of 1990, Public Law 101-336, 101st Cong. (July 26, 1990).

[e] Television Decoder Circuitry Act of 1990, Public Law 101-431, 101st Cong. (October 15, 1990).

[f] Individuals with Disabilities Education Act of 1997, Public Law 105-17, 105th Cong. (June 4, 1997).

[g] Individuals with Disabilities Education Improvement Act of 2004, Public Law 108-446, 108th Cong. (December 3, 2004).

[h] Telecommunications Act of 1996, Public Law 104-104, 104th Cong. (February 8, 1996).

[i] Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111-260, 111th Cong., 2d sess. (October 8, 2010) and amendments, 124 Stat. 2795 (2010).

calls. The FCC's Telecommunications Relay Service offers a variety of options to assist individuals who have hearing loss with placing and receiving phone calls (see Box 4-5). A recent FCC report to Congress highlighted several consumer-related issues including ensuring seamless connections between smartphones and hearing aids and providing more extensive consumer information online and in retail settings to help customers compare features of phones and other technologies (FCC, 2014). Recent FCC proposed rule making focuses on compatibility issues (FCC, 2015b).

Among the other technologies that offer potential for helping individuals with hearing loss is the expanded use of high-definition voice (also referred to as wide-band audio), which broadens the range of frequencies transmitted and the number of audio samples per call to allow less background noise and provide more easily distinguishable sounds (Chang, 2013).

A 2015 survey by the Rehabilitation Engineering Research Center on Telecommunications Access at Gallaudet University found that among 420 respondents with hearing loss (the majority self-reporting that they had severe or profound hearing loss) who regularly used telephones, the major needs reported for improved phone use were

Box 4-5 TELECOMMUNICATIONS RELAY SERVICE

The Telecommunications Relay Service is a public–private-sector collaboration that provides individuals with hearing or speech disabilities the capabilities to place and receive telephone calls with no additional cost to the user beyond standard telephone service charges. The Federal Communications Commission manages the program, which is run in collaboration with telecommunications companies and state-based programs.

The relay service works primarily through communications assistants who facilitate calls through several mechanisms. A person using a teletypewriter or other text input device can call the relay center (usually by dialing 711), provide the number he or she wants to call, and then the communications assistant provides the link converting text to voice and voice to text. An individual with hearing loss can also dial and speak directly to the called party and hear his or her voice. At the same time the individual can read text of the called party's voice to facilitate the caller's understanding. Captioned telephones are often preferred by people with residual hearing who use their own voices. Video relay that uses sign language interpreters is often preferred by people who communicate using sign language.

Title IV of the Americans with Disabilities Act required the telecommunications relay service to be available nationwide and to be as equivalent as possible to standard telephone services.

- Better telephone sound quality;
- Improved telephone captions, which are more accurate, have shorter delays, or both;
- Better ways to test telephone products to find which work for a given individual;
- More affordable prices for accessories and other special telephone equipment;
- More or better information about telephone communication options for people with hearing loss;
- Better options for listening to voice mail;
- More or better information about hearing aid compatibility for cell phones;
- The ability to hear over the telephone using both of an individual's hearing devices at the same time;
- More training on strategies an individual can use to improve his or her telephone communication with people who are difficult to understand; and
- More attention to assessing an individual's telephone communication needs by the individual's audiologist or hearing instrument specialist.[7]

Emergency Communications

Ensuring accessibility of the nation's emergency communications systems requires that the systems have specific features for those with hearing loss. These systems have three key components: (1) 911 call processing and delivery through public safety answering points and call dispatch; (2) the Emergency Alert System (national and regional); and (3) radio and television station transmission of news and updates regarding emergency information, which are mandated to be provided both aurally and in a visual format (such as closed captioning or other methods) (FCC, 2015a). The FCC requires that 911 landline and wireless services be compatible with text telephone devices. Additionally, efforts are ongoing to update and expand the methods of emergency communications to include text-to-911 capabilities for individuals with hearing loss or other disabilities (FCC, 2015c). An increasing number of public safety answering points (local centers where 911 calls are processed) have the capability to receive text-

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[7] Personal communication, *Voice Telecommunications Access Survey*, from Linda Kozma-Spytek, Senior Research Audiologist, Technology Access Program, Gallaudet University. Received February 19, 2016. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

to-911 (FCC, 2016). Weather emergency information can be provided to those who have hearing loss through connections to the National Oceanic and Atmospheric Administration Weather Radio system which can include providing text displays, alerting lights, or other mechanisms (NOAA, 2015). Smoke and carbon monoxide detectors are available with strobe lights, as are emergency devices that use vibrations to alert the user to emergency situations.

EFFECTIVENESS OF HEARING AIDS AND OTHER ASSISTIVE PRODUCTS

Recent research on the effectiveness of hearing aid use (and the use of other technologies, such as cochlear implants) has largely focused on the impact of that use on speech development and learning in children with hearing loss. Fewer peer-reviewed studies have examined the efficacy (performance under controlled conditions, usually in a clinical trial) and effectiveness (performance in real-world settings) of hearing aid use by adults, particularly comparing various types of hearing aids or comparing hearing aids with PSAPs or hearing assistive technologies. As noted in a 2001 review by Maki-Torkko and colleagues, “only a few studies on HA [hearing aid] outcomes meet strict scientific criteria and even fewer studies correlate rehabilitation outcome with the degree of HI [hearing impairment], disability or handicap” (Maki-Torkko et al., 2001, p. 8). As discussed above, studies have looked at the usage of hearing aids and owner’s satisfaction and barriers to use. However, the outcome measures used to assess the efficacy and effectiveness of hearing aids (e.g., measures of speech recognition) vary widely, and a consensus is needed on standard outcome measures.

Studies of Efficacy and Effectiveness of Hearing Aids

Studies of the effectiveness of hearing aids have been primarily experimental studies that have examined the impact of specific technical aspects or components of the hearing aid device using small numbers of study participants, and many of these studies have been focused on technical rather than clinical or functional outcomes (Humes and Krull, 2012). These studies, which often compare different versions of a technology, have investigated such features as directional and omnidirectional microphones (e.g., Gnewikow et al., 2009; Hawkins and Yacullo, 1984; Keidser et al., 2013; Wu et al., 2013), multimemory and volume controls (e.g., Banerjee, 2011), noise reduction technologies (e.g., Oeding and Valente, 2013), and various types of circuits and compression options (e.g., Hawkins and Naidoo, 1993; Kokx-Ryan et al., 2015; Moore et al., 2001; Shanks et al., 2002). During the transition from analog to digital hearing aids over the past

20 years, studies examining the technologies had varying results, due in part to variation in the outcomes assessed. Johnson and colleagues (2016) reviewed 10 studies of hearing aid use by adults with mild hearing loss and found positive benefits of amplification using a variety of measures. Taylor and colleagues (2001) reviewed one randomized controlled trial and seven randomized crossover trials and found no significant differences in user function and quality of life assessments between analog and digital devices when pooling the data.

Assessing the impact of hearing aids on quality of life is a challenge because of the multiple comorbidities in many participants and the gradual onset of hearing loss in many adults. A meta-analysis of studies examining the impact of hearing aids on quality of life found no effect when using general health-related quality of life measures but a medium to large effect when using hearing-specific questionnaires; however, the meta-analysis included only one randomized controlled trial (Chisolm et al., 2007a).

Only a few studies have used control groups or randomized methodologies. As noted by Van Vliet, "Peer-reviewed publications describing performance of various techniques and hearing aid circuits are available, but high-quality evidence about what works for patients in the form of randomized, blinded studies designed to answer critical questions about candidacy for hearing aids, hearing aid selection, fitting, and rehabilitation are very rare" (Van Vliet, 2005, p. 416). A clinical trial conducted by the Department of Veterans Affairs (VA) and the National Institute on Deafness and Other Communication Disorders (NIDCD) examined hearing aid benefits among 360 participants with sensorineural hearing loss (Larson et al., 2000; Noffsinger et al., 2002; Shanks et al., 2002). The participants were randomized in order to examine the results of using three different hearing aid circuits. At the time the study was conducted, these three circuits made up 70 percent of the U.S. hearing aid market. Each circuit was used for 3 months, six sequences of circuits were used, and the study was double blinded. The major outcomes examined were loudness, noise interference, and overall quality, and the outcome measures involved speech recognition tests, ratings of perceived sound quality, and self-assessed subjective assessments of benefit. When compared with unaided listening, the participants reported substantial benefit with hearing aids using all three circuits. Small differences were noted between the circuits on ratings of loudness and on the distortion of sounds.

A study by Yueh and colleagues (2001) randomly assigned 30 veterans with service-connected hearing loss (and eligible to receive a hearing aid through their veteran benefits) to receive either a programmable hearing aid with a directional microphone or a nonprogrammable aid. Hearing-related quality-of-life measures were compared among those two groups and also with 30 veterans with non-service-connected hearing loss who either did not have a hearing aid or who received a hearing assistive technology product. The greatest improvements in hearing-related quality of life were noted by those using the programmable hearing aids, followed by those who received the nonprogrammable aid and then the hearing assistive product, and the lowest scores were for those with no hearing technologies. Similarly, Humes and colleagues (2009) randomly assigned groups of older adults with hearing loss to four types of hearing aids (varying by single- versus multichannel technology and omnidirectional versus bidirectional microphones) and found improvements in speech recognition in all groups with little difference seen between the technologies.

A more recent study conducted by Cox and colleagues (2014) examined the results of laboratory tests and journal entries of speech understanding for 25 participants with bilateral mild to moderate sensorineural hearing loss who used four types of hearing aids (two basic and two premium level) in a randomized crossover trial. The hearing aid fittings were conducted following a best-practice five-step approach that included programming of the hearing aids using the manufacturer's proprietary algorithm and matching real-ear performance to national prescription goals. Participants ranged from new to experienced hearing aid users (mean age of 70.4 years). Each type of hearing aid was used for 1 month, with participants engaged at the end of each month in laboratory speech understanding tests and responding to a set of standardized questionnaires; the participants also recorded journal entries of their experiences with the hearing aids throughout the month. The study found benefits associated with all four types of hearing aids, with experienced users noting greater benefits than new users. No statistically significant differences were found in speech understanding between those using the premium and the basic hearing aids. The researchers also conducted a single-blinded, repeated, crossover trial in which 45 participants used hearing aids with premium and basic features (participants were blinded to the features) and responded to a variety of quality-of-life and hearing assessments and interviews (Cox et al., 2016). On average, the participants did not note any significant differences between the hearing aids with premium features and those with basic features when assessing their use in daily life. These studies are at the forefront of efforts to provide independent comparative data on the effectiveness of hearing technologies. Additional studies are needed that use larger sample sizes across age ranges and control for prior experience with hearing aids to examine hearing characteristics and use of the broad range of products and devices in laboratory and real-world hearing environments.

Studies of the use of hearing aids have found no clear evidence that hearing aid users become acclimatized to hearing aids or have positive changes in hearing performance over time (Humes and Wilson, 2003; Humes et al., 2002; Turner et al., 1996). While it might be expected that hearing aid users would become more familiar with amplification and would note improvements in understanding amplified speech, the results of studies examining this expectation have not been consistent; however, the numbers of individuals studied has been limited. Further efforts and innovative approaches to understanding and optimizing the benefit of sustained use of hearing aids are needed.

Comparisons of Hearing Aids and Other Products

The evidence base of comparative studies among various types of devices and products is also scant. Studies that have included "non-hearing aid products" have described them in varying ways, making it difficult to distinguish a study examining what in the United States would be considered a PSAP from hearing assistive technologies or from low-cost hearing aids (which in some countries are sold as OTC).

Callaway and Punch (2008) examined the electroacoustic characteristics of 11 types of "OTC hearing aids," although it was not clear which were marketed as hearing aids and sold through mail order or the Internet and which were PSAPs. Eight of the products (termed "low-range" by the authors) were sold for less than $100 and three were in the mid-range group ($100 to $500). The study conducted analyses of gain and output for three hearing loss patterns and found that the low-range products primarily worked for hearing loss at low frequencies and were "electroacoustically inadequate to meet the needs of the hearing impaired" (p. 14), while the mid-range products could meet most or all of the National Acoustic Laboratories parameters. In 2000, Cheng and McPherson reported on a comparison conducted in Hong Kong of 10 OTC hearing aids costing less than $250 each (U.S.). Hearing aids can be purchased OTC in Hong Kong, and some of the products sold there may be more similar to PSAPs or to basic hearing aids. The study found that most of these products performed within the ANSI standards for hearing aids, with several being outside of the equivalent input noise and total harmonic distortion levels, and that most were more appropriate for helping people with low-frequency hearing loss than the high-frequency loss often experienced by older adults (Cheng and McPherson, 2000). An update of this study examined 10 OTC products and found similar results, with little change in electroacoustic characteristics or performance in the intervening decade (Chan and McPherson, 2015).

A study examining the acoustic performance of several more recent direct-to-consumer amplifying products (the authors describe these products as a "newer generation of hearing devices that comprise a higher price point [i.e., cost $200–$400]" found variations in parameters including frequency-specific gain, signal-to-noise ratio, and listening comfort and found that a number met the targeted performance levels (Mamo et al., 2016).

Research Needs

Research on hearing technologies is funded and conducted largely by the private-sector companies that produce hearing aids and hearing assistive technologies. It is estimated that the private sector annually invests $600 million in research and development aimed at improving hearing aids and developing new features, products, and systems (HIA, 2015).

Federal agencies with a focus on research on adult hearing loss include NIDCD, the National Institute on Aging, the VA, and the Department of Defense (e.g., DoD Hearing Center of Excellence, 2016; NIDCD, 2015; VA, 2015). Another avenue for funding university-based research on devices and technologies relevant to hearing loss is through the Rehabilitation Engineering Research Centers (RERCs) (ACL, 2015). These centers are charged with conducting studies of technology, systems, and devices across the range of disabilities. Relevant centers working on hearing include the RERCs on hearing enhancement, on universal telecommunications access, and on wireless technologies (Galludet University, 2013; University of Wisconsin–Madison and Galludet University, 2016; Wireless RERC, 2016). RERCs are supported by the National Institute on Disability, Independent Living, and Rehabilitation Research (formerly the National Institute on Disability and Rehabilitation Research) now located in the Department of Health and Human Services.

Efforts are needed across the academic, private, government, and nonprofit sectors to provide the research, outcome measures, and standards needed to improve hearing health care. Research and standards needs identified by the committee relevant to this chapter include

- Effectiveness and comparative-effectiveness studies of hearing technologies using consumer-relevant parameters across the varying levels of severity of hearing loss;
- Continued innovative research and design of hearing aids and hearing assistive technologies with a focus on improving hearing clarity, facilitating ease of use (particularly for older adults), and compatibility with the other assistive and communications technologies;
- The development of minimum performance standards for examining the effectiveness of hearing devices in real-world situations;
- Consensus criteria for defining an individual with hearing loss as a candidate for a hearing aid or other hearing device; and
- Product labeling comprehension studies.

REGULATORY STRUCTURE AND STANDARDS

Hearing aids, hearing aid compatibility, and to some extent PSAPs are subject to federal regulation in the United States by FDA, the FCC, and Federal Trade Commission (FTC). Hearing aids are also subject to regulation under state regulatory laws, including licensing laws. This section provides an overview of these regulatory laws and describes their impacts on accessibility to hearing health care for adults.

Food and Drug Administration

FDA regulates hearing aids as medical devices under the FDCA. A "device" is defined in the statute as an article or instrument intended for use in the diagnosis of disease or other conditions; intended for use in the cure, mitigation, treatment, or prevention of disease; or intended to affect a structure or any function of the body.[8]

Overview of FDA Regulation of Medical Devices

Under the FDCA, medical devices are regulated under a risk-based framework with three classes of devices:

- Class I devices are considered the lowest risk and are subject to general controls, but they are not required to undergo premarket review by FDA (with some limited exceptions). Although usually exempt from 510(k) requirements, a new device in Class I can lose that 510(k) exemption if it has a different intended use or a "different fundamental technology" than the other devices in that product classification.[9] Examples of Class I medical devices include dental floss, medical gloves, and tongue depressors.
- Class II devices are moderate risk and are subject to general controls, special controls, and premarket review by FDA (with some exceptions where the device is exempted from premarket review). Examples of Class II medical devices include powered wheelchairs and some pregnancy test kits.
- Class III devices are the highest risk, such as implantable devices or life-supporting or life-sustaining devices. Class III devices are subject to general controls and also require premarket approval by FDA prior to marketing. Examples of Class III medical devices

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[8] FDCA § 201(h), 21 U.S.C. § 321(h).
[9] See, e.g., 21 C.F.R. § 874.9 (limitations on exemption).

include replacement heart valves, cochlear implants, and implantable defibrillators.

"General controls" include the registration of the manufacturer's device establishment, listing of the devices in commerce, quality system regulations including design controls and specific requirements for good manufacturing practices (unless exempted), adverse event reporting, labeling, and other requirements.[10] Design controls apply to Class II and Class III devices but not to Class I devices unless the devices are automated with computer software (or otherwise specified in the regulation).[11] "Special controls" include guidance documents, guidelines, performance standards, post-market surveillance, and other controls to provide reasonable assurance of the safety and effectiveness of the Class II device.[12] FDA has three premarket pathways (see Box 4-6).

FDA regulates the labels and labeling of all devices under its jurisdiction. Labeling is information that "accompanies" the device, which can be more than just physical accompaniment. The statute requires that labels and labeling be truthful, accurate, and not misleading. The labeling of a medical device must include adequate directions for use and adequate warnings to protect users.

When FDA authorizes a device for marketing, the device can be limited to use by or on the order of a physician or other health professional (prescription use) or authorized for OTC purchase and use by consumers (OTC use).

FDA also has the authority to impose restrictions on the sale, distribution, or use of a device—making it a "restricted device." Such restrictions can be imposed as a condition of approval in a premarket approval (PMA) order[13] or by promulgating a regulation for devices that undergo 510(k) review or that are exempt from 510(k) review.[14] FDA is authorized to regulate the advertising of restricted medical devices.[15]

Current FDA Regulation of Hearing Aids as Medical Devices

FDA has classified hearing aids under several different classification regulations, based on the intended use and risk of the different technologies. As defined in FDA regulations, a hearing aid is a "wearable sound-

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[10] FDCA § 513(a)(1)(A), 21 U.S.C. § 360c(a)(1)(A).

[11] 21 C.F.R. § 820.30(a).

[12] FDCA § 513(a)(1)(B), 21 U.S.C. § 360c(a)(1)(B).

[13] FDCA § 515(d)(1)(B)(ii), 21 U.S.C. § 360e(d)(1)(B)(ii).

[14] FDCA § 520(e), 21 U.S.C. § 360j(e) and FDCA § 502(q)&(r), 21 U.S.C. § 352(q)&(r).

[15] FDCA § 502(q)&(r), 21 U.S.C. § 352(q)&(r). The Federal Trade Commission otherwise regulates the advertising of medical devices.

Box 4-6 FOOD AND DRUG ADMINISTRATION (FDA) PREMARKET PATHWAYS

510(k) pathway: The 510(k) notification pathway[a] can be used for devices that demonstrate "substantial equivalence" to a predicate device.[b] The new device must have the same "intended use" as the predicate device and either the same technological characteristics as the predicate device or different technological characteristics but information submitted in the 510(k) demonstrates that the new device does not raise different questions of safety and effectiveness than the predicate device. The statute indicates a 90-day review for 510(k) notifications, but in practice the FDA review typically takes 6 months to 1 year or more. If FDA finds that a device is "not substantially equivalent" to a predicate device, the new device is automatically classified as Class III.

De novo pathway: If FDA determines that a new device does not have a predicate device—for example, there is no prior device with the same intended use—and that the new device presents low or moderate risk, FDA can use the "de novo" pathway to reclassify the device from the automatic Class III classification to either Class II or Class I.[c] The petitioner must provide information describing the device and supporting the proposed classification, including proposed special controls that would provide reasonable assurance of the safety and effectiveness of the device.

Premarket approval pathway: This pathway is used for Class III devices, including devices found "not substantially equivalent," implantable devices, and other high-risk devices.[d] A premarket approval application must include labeling, manufacturing information, information to show the device meets any applicable performance standards, preclinical information (bench testing and animal studies, as appropriate), and clinical data that demonstrate the device is safe and effective for the intended use and patient population specified in the labeling.[e]

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[a] FDCA § 510(k), 21 U.S.C. § 360(k).
[b] FDCA § 513(i), 21 U.S.C. § 360c(i).
[c] FDCA § 513(f)(2), 21 U.S.C. § 360c(f)(2).
[d] FDCA § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C).
[e] FDCA § 515(c), 21 U.S.C. § 360e(c).

amplifying device that is intended to compensate for impaired hearing."[16] Air conduction hearing aids amplify and deliver sounds to the external ear canal via air conduction. Bone conduction hearing aids involve an implant that is placed behind the ear, and amplified and processed sound is conducted via the skull bone to the cochlea. An air-conduction hearing aid is a Class I device that is exempt from premarket review but which remains subject to quality system regulation (including good manufacturing practices) and other FDA requirements. As with other Class I devices, a specific

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[16] 21 C.F.R. § 874.3300.

air-conduction hearing aid can lose its 510(k) exemption if it has a different "intended use" or a "different fundamental technology" than other devices in that product classification.[17] A bone-conduction hearing aid is a Class II device, subject to 510(k) notification requirements. FDA has recognized consensus standards that are applicable to both of these classes of hearing aids, including ANSI/Acoustical Society of America (ASA) standards (FDA, 2013a).

FDA has classified wireless air-conduction hearing aids as Class II with special controls.[18] The applicable special controls are testing to validate electromagnetic compatibility; design and performance data to validate wireless technology functions; and labeling that specifies "appropriate instructions, warnings, and information relating to [electromagnetic compatibility] and wireless technology and human exposure to non-ionizing radiation." Wireless air-conduction hearing aids are exempt from 510(k) notification requirements.

A transcutaneous air conduction hearing aid system is a "wearable sound-amplifying device intended to compensate for hearing loss without occluding the ear canal."[19] The system involves of an air-conduction hearing aid attached to tube system that is surgically fitted between the back of the outer ear and outer ear canal. It is Class II, requires a 510(k) notification, and is subject to the special controls specified in an FDA guidance document for this device type (FDA, 2002).

FDA also regulates as devices various testing equipment and accessories. For example, a "hearing aid calibrator and analysis system" is a Class II device, defined as an "electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid."[20]

Cochlear implants and other implantable hearing devices are in Class III and require FDA granting of a PMA prior to marketing. These devices require surgery for implantation and are therefore not part of the charge to the committee and the discussion in this report.

In 1977, FDA issued regulations that made hearing aids "restricted devices" subject to various restrictions on sale, distribution, and use specified in the regulations.[21] These regulations define "hearing aid" as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing."[22] These regulations also set forth labeling requirements for hearing aids,

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[17] 21 C.F.R. § 874.9.
[18] 21 C.F.R. § 874.3305.
[19] 21 C.F.R. § 874.3950.
[20] 21 C.F.R. § 874.3310.
[21] 21 C.F.R. §§ 801.420 & 801.421.
[22] 21 C.F.R. § 801.420(a).

including the requirement for a user instructional brochure, which must be provided to the prospective user by the dispenser of the hearing aid. The brochure must include a "Warning to Hearing Aid Dispensers" that informs dispensers that they should advise prospective users to consult a physician whenever they find the prospective user to have certain medical conditions. The user instructional brochure must also include an "Important Notice for Prospective Hearing Aid Users" that users should have a medical evaluation by a licensed physician before purchasing a hearing aid (see discussion in Chapter 3). That notice also includes the following statement:

> Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

A hearing aid dispenser cannot sell a hearing aid unless the prospective user provides a written statement signed by a licensed physician stating that the hearing loss has been evaluated and the person is a candidate for a hearing aid or, alternatively, the prospective user signs and presents a waiver of the medical evaluation. The prospective user must be given the opportunity to review the user instructional brochure for the hearing aid prior to signing the waiver of medical examination (see Chapter 3).

FDA has permitted the marketing of disposable hearing aids.[23] In addition, FDA has not objected to Internet sales of Class I hearing aids where a mechanism is provided to ensure compliance with the regulations (e.g., FDA, 2005). Often the purchaser is asked to electronically read the waiver form and is given the option to accept the terms of the waiver online.

Over the years, hearing technology companies have petitioned FDA to amend its regulations to eliminate the medical evaluation requirement and to allow the OTC sale of hearing aids (e.g., Etymotic Research, 2003; GudHear, 2003). FDA has denied those petitions. One petitioner argued that OTC hearing aid safety could be ensured by restricting peak OSPL-90 (output sound pressure level with 90 dB SPL input) to 115 dB SPL (sound pressure level) or less in order to prevent hearing damage or tinnitus and by requiring that eartips pass standard tests for allergic reactions and real-world testing for ear canal safety (Etymotic Research, 2003, p. 3). Another petitioner stated that labeling could provide adequate information to educate potential users about hearing loss and when to consult a hearing health care professional. As an example, the petitioner recommended providing

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[23] E.g., FDA-cleared 510(k) notifications K081136 and K021867.

the following information to a prospective hearing aid purchaser in person, by website, or otherwise (GudHear, 2003, p. 4):

- A hearing aid will not restore normal hearing and will not prevent progressive hearing loss, and will not improve the underlying causes of organic hearing loss.
- Some hearing loss is caused by conditions that can be medically corrected. The following signs indicate the need for a medical evaluation by a licensed physician, preferably a physician who specializes in diseases of the ear:

1. Congenital or traumatic deformity of the ear
2. Pain or discomfort in the ear
3. History of active drainage from the ear within the past 90 days
4. History of sudden or rapidly progressing hearing loss
5. Unilateral hearing loss or a difference in hearing between ears in the past 90 days
6. Excessive earwax
7. Foreign body in the ear canal
8. Acute or chronic dizziness

The medical conditions identified above correspond to the “red flag” medical conditions that must be identified in the warning statement to hearing aid dispensers in the user instructional brochure required by 21 C.F.R. § 801.420(c)(2) (for more discussion of the “red flag” medical conditions, see Chapter 3).

FDA denied the petitions requesting an OTC hearing aid classification, citing concerns that a medical evaluation is necessary to ensure that the “red flag” ear conditions would not be “undiagnosed and unevaluated” and to avoid delays in diagnosis and management of medically treatable conditions that cause hearing loss (FDA, 2004a,b).

Current FDA Regulation of PSAPs as Nondevice Articles or Instruments

As noted above, FDA’s regulations define a “hearing aid” as any wearable instrument that is designed, offered, or represented “as aiding persons with or compensating for impaired hearing.” This definition flows from the statutory definition of a medical “device” as intended for use in the cure, mitigation, or treatment of a disease, or intended to affect a structure or function of the body.

Given the technological advances since FDA promulgated the hearing aid regulations in 1977, the interest of consumers in taking more control over their own health and wellness, and FDA’s refusal to create an OTC hearing aid category, some manufacturers have been interested in selling products that enhance hearing without complying with the restrictions on sale, distribution, and use imposed under FDA's hearing aid regulations. As a result, some manufacturers began to market hearing aid devices directly to consumers, sometimes by seeking to comply with the federal restrictions in 21 C.F.R. §§ 801.420 and 801.421 and sometimes not. Some manufacturers sought to market technologies with labeling and advertising claims that the products could help people to hear better, but without calling the products "hearing aids" (FDA, 2009a).

FDA eventually issued a guidance document to address this new category of products that FDA called personal sound amplification products, or PSAPs. As one manufacturer explained, "It is important to realize that the only reason most PSAP manufacturers—including the Petitioner's company—developed PSAPs was to provide a low-cost alternative to hearing aids for those who could not afford hearing aids or did not want to be burdened by FDA regulatory requirements" (Etymotic Research, 2014, p. 15).

FDA issued a guidance document in 2009 to recognize the category of nondevice products called PSAPs that would be distinguished from the medical device "hearing aid" (FDA, 2009b). As defined in that guidance document, a PSAP would be "intended to amplify environmental sound for non-hearing impaired consumers. They are not intended to compensate for hearing impairment." PSAPs would be permitted for uses including "listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations, performances)." That guidance document stated that PSAPs would not be medical "devices" because they were not intended to cure, mitigate, or treat a disease and did not alter the structure or function of the body and thus were not within the statutory definition of "device" in the FDCA.

In 2013, FDA issued a draft guidance document for comment that was intended to supersede the 2009 PSAP guidance document (FDA, 2013b). This draft guidance document retains the same description of uses that would be considered appropriate for a PSAP, but it also includes lists of uses that FDA considers "listening situations that are typically associated with and indicative of hearing loss" and thus within the "hearing aid" device classification. FDA's 2013 draft guidance states:

> Examples of listening situations that are typically associated with and indicative of hearing loss include: difficulty listening to another person nearby, difficulty understanding conversations in crowded rooms, difficulty understanding movie dialogue in a theater, difficulty listening to lectures in an otherwise quiet room, difficulty hearing the phone or doorbell ring, or difficulty listening situations in which environmental noise might inter-

> fere with speech intelligibility. Products making these or similar claims should not be considered PSAPs. In addition, products that are sold as an "over the counter" alternative or substitute for a hearing aid should not be considered PSAPs.

The 2013 draft guidance document has been viewed as more limiting than the 2009 guidance document, in that statements such as that above appear to be further restricting the types of products, claimed uses, and performance claims that would be appropriate for the PSAP product category. Nevertheless, FDA clearly stated in both the 2009 and 2013 documents that the agency's view was that PSAPs were not intended to be used by individuals with hearing loss.

As nondevice products, PSAPs would not be subject to FDA regulatory controls applicable to medical devices. Thus, there would be no FDA control of the design, manufacturing, or labeling of PSAPs (other than to ensure the labeling did not cause the product to be a hearing aid). Nor would PSAPs be subject to the product performance standards that FDA has recognized as applicable to hearing aids (e.g., ANSI voluntary standards recognized by FDA as applicable to hearing aids).[24] Moreover, the FDA regulations imposing the restrictions on sale, distribution, and use—including requirements pertaining to medical evaluations, hearing aid dispensing, and the user instructional brochure—would not apply to PSAPs.

FDA did advise, in both the 2009 guidance and the 2013 draft guidance documents, that PSAPs are electronic products that emit sonic vibrations and thus are subject to the electronic product provisions of the FDCA that apply to both nondevice products and medical devices.[25] Manufacturers of PSAPs are required to report defects (including product failure to perform to design specifications and causing certain types of injury)[26] and adverse events relating to injurious or potentially injurious exposure of a person to electronic product radiation (including sonic, infrasonic, or ultrasonic waves).[27] PSAP manufacturers are also subject to requirements for repurchase, repair, or replacement of products that have a defect or that fail to comply with an applicable federal standard.[28] These regulations for electronic products are far more limited than the medical device regulatory requirements.

At the time it was issued, FDA established a regulatory docket for the public to submit comments on the 2013 PSAP draft guidance. In January 2016, in response to a PCAST report recommending OTC hearing aids

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[24] As noted elsewhere, the Consumer Technology Association has undertaken a project to draft voluntary standards that would apply to PSAPs.

[25] FDCA §§ 531-542, 21 U.S.C. §§ 360hh-360ss; 21 C.F.R. § 1000.15(d).

[26] 21 C.F.R. Part 1003.

[27] 21 C.F.R. §§ 1000.3 & 1002.20.

[28] 21 C.F.R. Part 1004.

(PCAST, 2015) and this ongoing Academies study, the agency reopened the comment period on the draft guidance (FDA, 2016a). FDA asked the public to address the following issues:

1. The degree to which current FDA requirements are a barrier to hearing aid accessibility, affordability, and use;
2. The appropriateness of creating a category of "basic" hearing aids with labeling for OTC sale; and
3. Whether the benefits of OTC hearing aids would outweigh the risks of foregoing the requirement of medical evaluation.

Concurrently with reopening the comment period on the PSAP draft guidance, FDA also announced a public workshop (held in April 2016) to discuss the current quality system and good manufacturing practices requirements that apply to hearing aids (FDA, 2016b). FDA indicated that it would consider proposals for an alternative model for quality verification and quality standards developed by standards development organizations and key stakeholders.

FDA Regulatory Policy for Mobile Apps and General Wellness Products

The proliferation of mobile apps and consumer-oriented products intended for health and medical uses has challenged FDA with regard to where to draw the line between devices and nondevices. Some of the mobile apps under development might be useful in providing hearing assistance or enabling hearing assistive technologies (see Chapter 3). Some mobile apps might be represented as PSAPs. FDA has issued two guidance documents, one on mobile apps and the other on general wellness products (FDA, 2015a,b). As with PSAPs, FDA has tried to distinguish "medical device" products and uses from nondevice products. FDA has also described generic types of products that might be medical devices but that FDA would not affirmatively regulate in its exercise of enforcement discretion.

FDA has long held the view that software can be a medical device when it meets the statutory definition of "device." This includes software that controls a medical device, software that is an accessory to a device, and freestanding software that performs a device function. FDA's guidance document on mobile medical apps states that a mobile app meets the definition of device when it is intended either to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device (FDA, 2015b). For example, the guidance states that a mobile app that functions as a stethoscope would be a mobile medical app subject to device regulation. By analogy, a mobile app that functions as a hearing aid would be a device.

Also relevant to hearing health, FDA's guidance document states that apps intended for use as audiometers are mobile medical apps:

> Mobile apps that use tools within the mobile platform (e.g., speaker) to produce controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders (i.e., an audiometer). Mobile apps that use a microphone or speaker within a mobile platform to serve as an audiometer to allow healthcare providers to determine hearing loss at different frequencies. (FDA, 2015b)

On the other hand, mobile apps that provide a checklist of symptoms to advise a consumer on when to see a physician, general educational tools, or tools that help a consumer communicate with a health care professional would not be medical apps.

To increase the availability to consumers of health-related technologies, FDA's draft guidance document on general wellness products describes categories of low-risk products that would not be subject to regulation as medical devices (FDA, 2015a). A general wellness product is described as having "(1) an intended use that relates to maintaining or encouraging a general state of health or healthy activity or (2) an intended use claim that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions" (FDA, 2015a, p. 3). The former category includes products for weight management, improving mental acuity, and other such claimed effects where there is no reference to a disease, disorder, or medical condition. An intervention or technology that may pose a risk to user safety (such as radiation exposure) or that raises novel questions of usability is not considered to be low risk.

Both the mobile apps guidance and the general wellness guidance indicate that rapid advances in health-related technologies are driving consumer demand and that industry is responding by developing a broad array of products. FDA, in turn, has sought to respond to these products with a risk-based approach to the enforcement of its medical device regulations.

The committee provides details later in this chapter on its recommendation to FDA to establish a new category of OTC wearable hearing devices.

State Laws Relating to Hearing Aids and Hearing Aid Dispensing

Types of State Laws Affecting Hearing Aids and Dispensing

Numerous states have enacted laws that affect sales of "hearing aids" as defined in the state law. These state laws typically define a "hearing aid" as a wearable instrument or device intended for the purpose of "aiding or compensating for impaired human hearing," for improving the hearing of a "hearing-impaired person," or "aiding or improving defective human hearing."[29]

State laws require the licensing of persons who sell, rent, lease, dispense, or otherwise provide a hearing aid to a consumer. Some state laws require an evaluation or measurement of hearing prior to selling a hearing aid. Some state laws prohibit the sale or distribution of hearing aids through the mail or via the Internet, while other state laws permit such sale or distribution under specified conditions.

States also typically have unfair trade practice laws and consumer protection laws that apply to the promotion and sales of products, which could include hearing aids as well as PSAPs. Other state laws of general applicability might also be relevant, but they are beyond the scope of this review.

Relationship Between FDA and State Regulatory Requirements

There is a complicated relationship between FDA regulations and state laws as they apply to medical devices, and this relationship is particularly relevant to the regulation of hearing aids. Section 521(a) of the FDCA contains an "express preemption" provision applicable to medical devices. Under that provision, no state or local government

> may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act [FDCA] and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act [FDCA].

In essence, an FDA requirement applicable to a device that relates to either the safety and effectiveness of the device or a specific requirement for the device established under the FDCA preempts any state or local requirement that is not consistent with the FDA requirement.

State or local requirements are preempted only when FDA has established specific regulations or there are other specific requirements applicable to a particular device under the FDCA. Under FDA's regulations, some state or local requirements affect devices but are not preempted by section 521(a) because they are not "requirements applicable to a device." These include laws of general applicability to device and nondevice products (e.g., unfair

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[29] E.g., California Business and Professions Code § 2538.10(d); Florida Statutes Chapter 484.041(5); Georgia Code Annotated § 43-20-3(5); Michigan Compiled Laws § 339.1301(a).

trade practices) and licensing laws that relate to the practice of medicine or related professions or occupations that administer, dispense, or sell devices.

"Restricted device" regulations issued under section 520(e) may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in state or local requirements. If there is a conflict between such restrictions and state or local requirements, FDA's federal regulations prevail. This would include the restrictions imposed on hearing aid labeling and sales.

Section 521(b) of the FDCA contains a provision whereby FDA may allow the imposition of a state requirement that is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating an FDA regulation exempting the state or local requirement from preemption. FDA's regulations in 21 C.F.R. Part 808 list numerous state requirements that FDA has exempted from preemption, and many of these apply to state requirements applicable to hearing aids and the dispensing of hearing aids.

FDA has treated state licensing laws and terms-of-sale laws as state requirements that are *not* expressly preempted by section 521(a). In contrast, FDA considers that state disclosure and recordkeeping laws, state laws requiring an audiological evaluation before the sale of a hearing aid to a minor, and state laws that are substantially identical to federal requirements *would be* preempted by section 521(a). Nevertheless, FDA has decided affirmatively to exempt these laws from federal preemption through the rule-making exemption procedure.[30]

A manufacturer seeking to market an OTC hearing aid or other innovative hearing assistive technology product thus faces at least four principal hurdles:

1. Federal regulations impose "restricted use" requirements on hearing aid dispensers regarding warnings and information that they must disclose to and obtain from consumers prior to a sale, as well as other conditions on the sale of hearing aids;[31]
2. Federal regulations *exempt* from federal preemption any state laws that (i) require hearing aid dispensers to disclose certain additional information related to the safety and efficacy of hearing aids or that provide consumers with advice at the time of sale, or both; and (ii) impose additional recordkeeping requirements on dispensers;[32]

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[30] See 21 C.F.R. § 808.20 et seq. (describing the exemption procedure); 21 C.F.R. § 808.53 et seq. (listing the exemptions applicable to all states and identifying the specific hearing aid laws of 19 states and the District of Columbia that have been exempted from preemption).

[31] FDCA § 520(e); 21 C.F.R. §§ 801.420-801.421.

[32] 21 C.F.R. Part 808; 45 Fed. Reg. 67326 (1980).

3. Federal regulations *exempt* from federal preemption state requirements that are "equal to, or substantially identical to, requirements imposed by or under" the FDCA;[33] and
4. FDA has by regulation and in statements in the Federal Register interpreted the FDCA as *not expressly preempting* (i) state laws related to the licensing, registration, and certification of hearing aid dispensers; and (ii) state regulations that require hearing aid dispensers to disclose at the time of sale certain information related to the terms of sale (does not include information related to the safety or effectiveness of hearing aids).[34]

In sum, under FDA's current regulations relating to preemption and exemptions from preemption for state laws relating to hearing aids and dispensing, manufacturers would need to consider various state laws and determine whether innovative technologies and marketing approaches would contravene either federal or state regulatory requirements. These state law requirements impose barriers to improving the accessibility and affordability of hearing aids and hearing technologies, in addition to any FDA-related barriers.

Federal Trade Commission

The FTC enforces laws that prohibit fraudulent, unfair, and deceptive trade practices.[35] FTC regulations prohibit the use of misleading sales and advertising practices, including giving inaccurate information about hearing loss, hearing aid performance, refund policies, or warranty coverage.

The FTC website advises consumers that the purchase agreement for a hearing aid should include information regarding the trial period for the product, the warranty, the total price, and what is available during service or repair (e.g., a loaner hearing aid) (FTC, 2016). The FTC also advises consumers about the FDA requirements applicable to hearing aids.

The FTC also provides advice relating to PSAPs. For example, the FTC website states: "Sound Advice: If your hearing is impaired, don't use a PSAP as a substitute for a hearing aid. That may delay the diagnosis of a potentially treatable condition, and cause more damage to your hearing" (FTC, 2016).

Thus, FDA, FTC, and states could bring enforcement with respect to misleading promotional practices for hearing aids and PSAPs.

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[33] 21 C.F.R. § 808.1(d)(2).

[34] 21 C.F.R. § 808.1(d)(3); 42 Fed. Reg. 9285, 9293 (1977); 45 Fed. Reg. 67326, 67331(1980).

[35] Federal Trade Commission Act, 15 U.S.C. §§ 41-58 as amended.

Federal Communications Commission

The FCC is responsible for enforcing several laws intended to enable Americans with hearing loss to have greater access to wire-line and wireless communications services and emerging communications technologies. These laws include the Hearing Aid Compatibility Act of 1988[36] and the Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA),[37] which expanded accessibility laws to newer technologies, including digital, broadband, and mobile innovations (see Box 4-4).

The Hearing Aid Compatibility Act required the FCC to ensure that all wire-line telephones manufactured or imported for use in the United States and all "essential" telephones such as public phones, hospital and nursing home phones, emergency phones, and workplace phones are hearing aid compatible.[38] Cell phones (which were not common in 1988) were exempted, but the statute authorized the FCC to limit or eliminate that exemption.

In 2003, with the widespread availability of wireless phones, the FCC required manufacturers of wireless phones to make available a certain number or percentage of models that are hearing aid compatible.[39] The FCC established rules for hearing aid compatibility of digital wireless phones and to wire-line and wireless communications services through a wide array of phones, including voice-over-Internet protocol telephones and wireless handsets that use advanced mobile technologies.

FCC rules require that phones subject to the Hearing Aid Compatibility Act produce a magnetic field of sufficient strength and quality to permit coupling with hearing aids that contain telecoils. The telecoil picks up the voice signal from an electromagnetic signal from the telephone, enabling users of telecoil-equipped hearing aids to communicate over the telephone without feedback and without the amplification of unwanted background noise. FCC rules also establish technical parameters to ensure that telephones are compatible with hearing aids.[40]

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[36] Hearing Aid Compatibility Act of 1988, Public Law 100-394, 100th Cong. (August 16, 1988). 47 U.S.C. § 610.

[37] Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111-260, 111th Cong., 2d sess. (October 8, 2010) and amendments, 124 Stat. 2795 (2010) (as codified in various sections of 47 U.S.C.).

[38] 47 U.S.C. § 610(b).

[39] The FCC issued a Notice of Proposed Rulemaking in November 2015 to require that all wireless handsets, not just a certain percentage of models, be hearing aid compatible in accordance with a staged plan for implementation. Fourth Report and Order, and Notice of Proposed Rulemaking, FCC 15-155 (November 19, 2015).

[40] ANSI standard C63.19 sets forth the standard for compatibility of digital wireless phones with hearing aids. A digital wireless handset is considered hearing aid compatible for inductive coupling if it meets a T3 (or U3T) rating under the ANSI standard. The ANSI standard also provides a methodology for rating hearing aids from M1 to M4, with M1 being the least immune to radio-frequency interference (including stray signals from the wireless phone) and M4 being the most immune.

FCC rules also generally require that telephones allow the volume to be increased to accommodate individuals with hearing loss, whether or not they use hearing aids. Telephones allowing high volume levels must automatically reset to a lower volume each time the handset is returned to an on-hook condition (unless a waiver is granted in certain conditions).

Telephone manufacturers and wireless service providers are required to provide certain types of information to consumers in their product labeling and packaging for hearing aid–compatible products, and on their websites. Manufacturers and wireless carriers must also file annual reports with the FCC that list their hearing aid–compatible products.

Enacted in 2010, the CVAA updates the FCC requirements to address modern communications. Title I of the statute addresses telecommunications access issues to make advanced communications products and services fully accessible to people with disabilities. These services include voice-over-Internet protocol services and electronic messaging. For example, smartphones are required to be usable by people with hearing aids as well as by individuals who are blind or have vision impairments. Title II addresses video programming to make it easier for people with disabilities to view video programming on television and the Internet. For example, programs shown on television with captioning are required to include the captioning when they are distributed on the Internet. The statute also requires that people with disabilities have access to emergency information, including next-generation 911 services and emergency information on the television.

The FCC recently proposed to amend the hearing aid compatibility rules for wire-line handsets. The proposal would incorporate revised industry standards relating to volume control and set a standard for volume control for wireless handsets intended to ensure more effective acoustic coupling between handsets and hearing aids or cochlear implants.[41]

In November 2015, the FCC adopted new rules to expand hearing aid compatibility requirements to technologies such as Wi-Fi calling and Voice over Long-Term Evolution.[42] To avoid regulatory requirements lagging behind technological advances, these new rules also require that future technologies automatically comply with hearing aid compatibility rules.

One question that arises is whether the FCC regulations would govern compatibility with PSAPs, which are not considered "hearing aid" devices as defined by FDA. The answer to this question might depend on which rules are at issue. The FCC accessibility rules require noninterference with hearing technologies—defined to include hearing aids, cochlear implants, and hearing assistive technologies—to the lowest possible level that allows

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[41] Notice of Proposed Rulemaking, FCC 15-144, adopted October 23, 2015.

[42] Fourth Report and Order, and Notice of Proposed Rulemaking, FCC 15-155, adopted November 19, 2015.

a user to utilize the product.[43] In contrast, hearing aid coupling is defined as applicable to "effective wireless coupling to hearing aids."[44] The hearing aid compatibility rules assume that the ANSI standard applicable to hearing aids would apply in addition to the ANSI standard for handsets to achieve compatibility, which would appear to exclude the possibility of PSAPs not complying with that standard.[45]

Americans with Disabilities Act

The ADA includes requirements for nationwide telecommunications relay services and telephone access to local emergency services (911 call centers). Section 508 of the Rehabilitation Act of 1973 included provisions relating to accessibility to telecommunications technologies that are acquired and provided by the federal government.

Litigation under the ADA has been used to try to expand accessibility to communications technology. For example, there are court decisions with inconsistent outcomes as to whether a website for an entity that does not have a physical location open to the public is subject to ADA requirements relating to public accommodations.[46] The Department of Justice has not issued regulations regarding applicability to websites, but it has suggested that the ADA would obligate public accommodations to make the websites that they use to provide their goods and services accessible to and usable by individuals with disabilities.[47]

These statutes, enforced by private litigants as well as the Department of Justice, might also encourage the development of advanced communications technologies that are accessible and usable by individuals with hearing loss.

Voluntary Standards

Voluntary standards are being developed for PSAPs through the CTA. CTA is accredited through ANSI to develop standards and other technical documents for the consumer electronics industry. CTA voluntary standards committees engage industry, academia, consumers, and other constituencies in the development of performance criteria, measurement protocols, and other specifications. In 2015, CTA committee R6WG20 was finalizing a set of minimum performance metrics for PSAPs and a glossary of PSAP-related terms (Belt, 2015). Discussions are under way regarding the potential for

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[43] 47 C.F.R. § 6.3(a)(2)(viii).

[44] 47 C.F.R. § 6.3(a)(2)(ix).

[45] 47 C.F.R. § 20.19(b).

[46] See discussion in the federal district court's opinion in National Federation of the Blind v. Scribd Inc., Case No. 2:14-cv-162 (D. Vt., March 19, 2015).

[47] 80 Fed. Reg. 35044 (June 18, 2015).

a logo program or other mechanism to identify products that meet the performance standards to aid consumers in comparing PSAPs (Belt, 2015).

As noted above, FDA has recognized consensus standards that are applicable to hearing aids, including ANSI/ASA standards. These standards are intended to ensure the quality and performance of these devices. The standards address issues such as specifications of hearing aid characteristics, signal processing, the computation of loudness and speech intelligibility, measuring the intelligibility of speech over communications systems, and measuring performance characteristics under simulated real-world working conditions.

NEXT STEPS AND RECOMMENDATIONS

The broad spectrum of types and severity of hearing loss necessitates a wide range of hearing technologies to meet each individual's needs with options that adhere to safety requirements and are effective in improving hearing and communication in the complex environments of daily life. Interoperability with other technologies including cell phones, televisions, and emergency alert systems is critical.

Develop and Clarify Hearing Device Options

FDA's hearing aid regulations along with state laws relating to hearing aid sales and dispensing place obstacles in the way of new technologies that could make hearing assistance more easily available and accessible for adults who could benefit from such assistance in connection with mild to moderate hearing loss. As noted throughout this report, innovation in technologies relevant to hearing loss are occurring that can provide affordable, effective, safe, and usable technologies to address the unmet need for hearing health care. The committee carefully examined the regulatory and policy challenges and opportunities for expanding innovative technologies and thus provides a range of options for individuals with hearing loss.

FDA sought to carve out PSAPs as a category of nondevice products that could be more easily marketed. But FDA has defined PSAPs as being intended only for a user population of persons without hearing loss, while hearing aids are intended to compensate for hearing loss. Thus, PSAP manufacturers and distributors are not supposed to be offering their products for the purpose of compensating for hearing loss. This legal and regulatory distinction between hearing aids and PSAPs might not be readily apparent to users, and it might not be fully respected by PSAP sellers who explicitly or implicitly offer their products to compensate for hearing loss.

By taking this approach of removing PSAPs from device regulation, FDA has left PSAPs largely unregulated, without the design control requirements, performance standards, technical standards, or labeling requirements that apply to devices. The FTC would still apply its regulations prohibiting fraudulent, unfair, and deceptive trade practices, but that is a post-market enforcement that might put consumers at risk.

An approach that could better protect consumers and offer options for more informed consumer decision making would be for FDA to create a category of "OTC wearable hearing devices" intended for mild to moderate hearing loss. In order to ensure their safety and effectiveness, these devices could be subject to ANSI and other technical standards applicable to hearing aid performance. They would be exempted from premarket review if the technology was fundamentally the same as Class I air-conduction hearing aids, or else they would be subject to 510(k) notification if the technology was similar to the Class II hearing aid devices. These OTC wearable hearing devices would be subject to labeling requirements tailored to OTC selection, purchase, and use.

This regulatory approach would be similar to the FDA's regulatory approach of creating separate device classification regulations for "prescription eyeglasses" and "magnifying spectacles."[48] Magnifying spectacles are "convex lenses intended to be worn by a patient who has impaired vision to enlarge images." In contrast, prescription spectacle lenses "provide refractive corrections in accordance with a prescription for the patient." Similarly, a category of OTC wearable hearing devices could provide a simpler technological approach to improving hearing (e.g., amplification) than would a more complicated technology. (The parallel drawn with eyeglass regulation is specific to the regulatory approach and is not meant to draw parallels between the use and performance of the devices.) FDA has moved a variety of monitoring and therapeutic technologies to OTC status (such as noninvasive blood pressure monitoring systems, stethoscopes, burn dressings, medications) to enable consumers and patients to take more control of their own health and medical conditions.

In implementing an OTC wearable hearing device category, FDA should preempt state laws that could pose an obstacle to implementation. For example, FDA should preempt any state laws or regulations that would purport to prohibit OTC sale and distribution of these hearing devices, or purport to require dispensing, fitting, or evaluation by a licensed audiologist, hearing instrument specialist, or other professional occupation prior to purchase of these OTC wearable hearing devices. Various approaches to preemption could be considered by FDA. For example, preemption might be accomplished by making the OTC wearable hearing devices a new category of "restricted devices" (apart from the current regulations in 21 C.F.R. §§ 801.420 and 801.421) such that the FDA regulations would be requirements specifically applicable to the safety and

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[48] 21 C.F.R. §§ 886.5840, 886.5844.

effectiveness of this category of OTC wearable hearing device. In addition, the "OTC wearable hearing devices" would not be called "hearing aids," with the intention of avoiding application of state laws that already refer to and govern "hearing aids."

An alternative option that the committee considered was to retain the category of PSAP as a nondevice product that would be permitted to include claims to compensate for "normal" hearing loss as a result of aging. In essence, age-related hearing loss would not be considered a "disease," and thus the products would not be considered as within the statutory definition of "device." To keep PSAPs outside the device definition, FDA would also have to conclude that PSAPs are not intended to affect a structure or function of the body. This approach would not preempt state laws, however, and many state laws define "hearing aids" as instruments compensating for hearing loss and subject them to dispensing requirements. If the PSAPs claim to compensate for hearing loss, they might be swept into these state laws. Furthermore, this approach would not establish a framework for regulating the quality of PSAPs, the performance claims made for them, or the adequacy of labeling information provided to users—all of which are important considerations.

As medical devices, the OTC wearable hearing devices would be subject to regulatory requirements such as establishment registration (including payment of an annual user fee by the manufacturer), device listing, good manufacturing practices, labeling, and reporting. Compliance with FDA requirements would add to the costs of manufacturing and distribution of these devices. Nonetheless, compliance with these requirements would also provide safety and effectiveness benefits for users. FDA could apply the types of consensus standards that would be applicable to the performance of the OTC wearable hearing devices and also tailor or exempt certain regulatory requirements, such as specific quality system regulations, good manufacturing practices, or reporting requirements, as appropriate to the OTC wearable hearing devices.

Consumer-focused information (e.g., consumer education programs, user instructional brochures, package inserts, as well as specific labeling) will be important for OTC wearable hearing devices. Some OTC devices could be accompanied by software or apps for self-fitting and adjustment of the devices. The sales of OTC wearable hearing devices are anticipated to be similar to other OTC product sales with many reputable products having warranties and return policies. FTC requirements would continue to apply to protect consumers from fraudulent practices. The committee's recommendations regarding the OTC wearable hearing device category are generally consistent with the PCAST recommendation regarding the need for OTC devices (PCAST, 2015) but differ in certain respects and are more specific.

The committee recognizes the need for an FDA guidance document regarding PSAPs to clarify that PSAPs are for specific purposes not related to hearing loss in contrast to hearing aids and OTC wearable hearing devices that are aimed at addressing hearing loss. The committee believes that this guidance could be accomplished by retaining the 2009 PSAP guidance or through revisions to the 2013 document including recognition that PSAPs are for specific hearing situations not related to hearing loss. As noted above, this distinction would be important to maintain in order to ensure that consumers with hearing loss receive the benefits relating to quality, performance, compatibility, and labeling envisioned under the OTC wearable hearing device category.

The committee notes that these changes would result in a wider range of options for adults with hearing loss, particularly mild to moderate hearing loss (see Table 4-2) and would clarify the purpose of PSAPs (see Table 4-3).

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.

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, and

TABLE 4-2
Proposed Range of Hearing-Related Devices and Products for Individuals with Hearing Loss

Devices and Products	Description	Federal Regulations, Standards, or Oversight	Availability
Hearing aids	Medical devices that meet FDA definitions and regulations; used across the range of hearing loss needs	• FDA Class I or Class II devices • Some exempt from premarket review by FDA • Restricted devices subject to FDA requirements in 21 C.F.R. 801.420 & 801.421 • Relevant ANSI standards and others • FCC oversight as relevant regarding compatibility and interoperability • FTC oversight as relevant regarding advertising	• Dispenser (audiologist, hearing instrument specialist) • Online (in some cases) • State law licensing requirements for hearing aids and dispensing • Remove regulatory requirement for medical evaluation or waiver
OTC “wearable hearing devices” (proposed new category of device)	Medical devices available OTC that focus on addressing mild to moderate hearing loss in adults and meet FDA safety and labeling requirements	• FDA Class 1 or Class II devices • Exempt from premarket review (unless fundamentally new technology) • Labeling requirements appropriate to self-selection; warnings regarding when to consult physician or audiologist • Relevant ANSI standards and others • FCC oversight as relevant regarding compatibility and interoperability • FTC oversight as relevant regarding advertising	• OTC • Online • State laws applicable to “hearing aids” and dispensing license would not apply • Apply federal preemption to assure availability over the counter
Other hearing assistive technologies	Consumer products that connect the user to other technologies and communication systems (e.g., phone, computer, hearing induction loop) or that provide the user with other hearing-related opportunities (e.g., self-testing, mobile apps)	• CPSC oversight • FCC and FTC regulations as applicable	• OTC • Online

NOTE: ANSI = American National Standards Institute; CPSC = Consumer Product Safety Commission; FCC = Federal Communications Commission; FDA = Food and Drug Administration; FTC = Federal Trade Commission; OTC = over the counter.

TABLE 4-3
Consumer Products for Amplifying Sound

Products	Description	Federal Regulations, Standards, or Oversight	Availability
PSAPs	Consumer products that amplify sound and that cannot be labeled, claimed, or advertised for hearing loss; do not meet the OTC hearing device requirements	• CTA standards are being developed • FDA regulation under electronic product provisions of the FDCA applicable to non-medical-device products • FDA guidance to assure non-medical-device status • CPSC oversight • FTC oversight regarding advertising	• OTC • Online

NOTE: CPSC = Consumer Product Safety Commission; CTA = Consumer Technology Association; FDA = Food and Drug Administration; FDCA = Federal Food, Drug, and Cosmetic Act; FTC = Federal Trade Commission; OTC = over the counter; PSAP = personal sound amplification product.

    - 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), and
    - 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 Transparency, Compatibility, and Interoperability of Hearing Technologies and Telecommunications Systems

Individuals with hearing loss frequently use hearing aids with telecoils or other hearing assistive technologies to couple with many other electronic communications products. These individuals benefit from compatibility between and among products and from interoperable systems such as emergency communication system connections, text-to-911, and captioning of alerts. Performance standards and policies can ensure the needed interoperability among products so that the products can easily and seamlessly connect and provide optimum sound transmission and performance (see also Chapter 6). For example, the standards relevant to hearing aid telecoils and hearing induction loop technology ensure that consumers can use the telecoil available across many brands of hearing aids to effectively connect to induction loop systems from a number of different manufacturers that are available in a variety of public spaces.[49] Similar efforts are needed to standardize the interfaces and connection points of hearing aids, hearing assistive technologies, and OTC wearable hearing devices with other types of technologies and communications systems.

As discussed earlier in the chapter, an open platform for programming hearing aid settings could also increase accessibility to the devices and related services. The committee encourages standards development related to open platforms. An open platform approach would provide consumers with greater portability in their hearing health care including increasing the options for choosing their hearing health care professional. Consumers should

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[49] The interoperability between telecoils in hearing aids and hearing induction loop technology is possible due to national and international standards that can be used by both technologies (e.g., International Electrotechnical Commission's standard, IEC 60118-4 [IEC, 2014]). It is the committee's understanding that efforts are under way to examine referencing the recently updated hearing induction loop standards in the International Building Code and the International Code Council/American National Standards Institute standard A117.1 regarding accessible buildings (Kirkwood, 2013).

be notified prior to sale regarding the portability of hearing aid programming. Greater public awareness and user-friendly instructions about the availability, portability, connectivity, and use of hearing aids and hearing assistive technologies, as well as comparable details on product features, are needed to enable informed decision making.

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, the Federal Trade Commission, the Food and Drug Administration, the 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.**

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5

Improving Affordability of Services and Technologies

For many people cost can be a key factor in making health care decisions; for some people cost can be the driving factor in such decisions, including whether to forego the care entirely. Among respondents to the 2014 Survey of Household Economics and Decision Making who had a household income of less than $40,000, 45 percent reported going without some form of medical treatment in the preceding 12 months (Federal Reserve, 2015). The cost of hearing health care includes the cost of services and technologies, and these costs may be incurred multiple times over a period of many years in order to maintain and replace hearing aids and other technologies, to continue to monitor hearing status, and to retain the benefits from auditory rehabilitation and other services. In an ideal world, high-quality hearing health care would be easily and immediately accessible, and the costs would be fully covered. Opportunities for note-worthy improvement in affordability do exist throughout the U.S. hearing health care system. Lessons learned from individual health care systems and other health care models in the United States and internationally can shed light on appropriate paths forward to improve the affordability of hearing health care in the United States.

CONSUMER COSTS FOR HEARING HEALTH CARE

A key challenge to understanding the costs associated with hearing health care and how to make that care more affordable is the need to make accurate price comparisons (comparing technologies with similar technologies or services with equivalent services). As discussed in Chapters 3 and

4, there are several types of hearing health care professionals, services, and technologies from which an individual may benefit. The variety of options and the interest in meeting the unique needs and specific preferences of each individual make it all the more important that consumers be able to make informed decisions about what their personal expenses for hearing health care will be. The committee recognized this challenge throughout its deliberations, and it urges changes to ensure that the public is able to accurately interpret and easily compare the costs for hearing technologies and services in order to make more informed decisions. It was with this concern in mind that the committee considered how to improve not only the affordability of the hearing health care system but also transparency in pricing. Where data were available, this chapter contains references to the prices of hearing health care. Every effort was made to include information about what hearing health care was included—or not included—in a given price.

Professional Services

When consumers are provided with the prices for hearing health care services, they are often presented as a set price for each type of hearing aid they are considering (basic to advanced). It may or may not be obvious that the price includes not only the price of the device (primarily hearing aids, but sometimes other assistive products as well) but also the price for professional fees for services, which may include all or some of the following: a comprehensive assessment of hearing loss and hearing aid candidacy, a functional communication assessment, hearing aid fitting and programming, and other associated services such as routine maintenance for a defined period of time and accessories (see Chapter 3). This is commonly referred to as a "bundled" pricing model. This package price may also include an unlimited number of visits to the dispenser for programming adjustments until the consumer is satisfied and has adjusted to the hearing aids or other technologies. Visits for auditory rehabilitation services may also be included. These services are often needed to achieve optimal fit and maximal benefit from the device and for the individual to learn strategies to maximize communication abilities. An alternative model, unbundled or itemized billing, lists the price of each test, device, and service individually. Results from a 2012 billing practices survey of audiologists showed that 67 percent of respondents used a bundled pricing model;[1] in a 2015 survey

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[1] Personal communication. Letter to staff for the Committee on Accessible and Affordable Hearing Health Care for Adults, from Kim Cavitt, President, Academy of Doctors of Audiology; Judith Page, President, American Speech-Language-Hearing Association; and Larry Eng, President, American Academy of Audiology. Received August 27, 2015. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

of hearing instrument specialists, approximately 52 percent responded that they used a bundled model.[2] Thus, the majority of hearing health care financial transactions are conducted using a bundled price; moreover, the consumer may not be aware that this price includes devices and professional services and may incorrectly attribute the price solely to the device. A subsequent section of this chapter focuses on transparency in billing.

Nature and Scope of the Hearing Technology Market

The market for hearing aids is often expensive and generally not transparent. The hearing aid industry has been characterized as having "considerable vertical integration, with manufacturers controlling the design, development, manufacturing, and distribution of their products, nearly to the point of sale" (Seelman and Werner, 2014, p. 401). Audiologists and hearing instrument specialists may sell one or several brands of hearing aids but may not sell the full range of products due to the associated costs for programming and other reasons. Additionally, the average hearing health care professional may sell only about 20 hearing aids per month, limiting access to volume discounts (Strom, 2014b), or sell only one brand of hearing aid. These marketing and sales strategies can restrict competition and the associated benefits that competition provides for consumers.

The average retail price for a pair of hearing aids in 2013 was $4,700 (bundled price which includes professional services) (range: $3,300–$6,000) (Strom, 2014b). According to an industry estimate, 2.9 million hearing aids were dispensed in the United States during 2013, with approximately 20 percent dispensed by the Department of Veterans Affairs (VA) (Strom, 2014a). This number was estimated to be an increase of 4.8 percent over the previous year (Strom, 2014b). Globally, hearing aid sales were estimated to be 10.8 million in 2012, with total sales of $5.4 billion on the wholesale market. Of these, 45 percent were sold in Europe, 29 percent in North America, and 26 percent in other regions (Kirkwood, 2013).

A 2013 survey of hearing health care professionals (179 responding from 42 states) found the total weighted average price to the consumer to be $1,657 per economy-level hearing aid, $2,196 for a mid-level hearing aid, and $2,898 for a premium-level hearing aid, resulting in an average price of $2,363 per hearing aid of any level (it was not specified whether services were included in these prices) (Strom, 2014b). The respondents

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[2] Personal communication. Letter to the Committee on Accessible and Affordable Hearing Health Care for Adults, from Kathleen Mennillo, Executive Director, International Hearing Society. Received January 15, 2016. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

indicated that 37 percent of hearing aids dispensed were in the premium level, 44 percent in the mid-level, and 19 percent in the economy level. Respondents reported that 84 percent of fittings were for binaural hearing aids—the consumer purchasing two devices—with some providers offering discounts on the second hearing aid (Strom, 2014b). The pricing of "high end" hearing aids so that they are much more expensive than "basic" hearing aids implies a substantial benefit to the consumer for using high-end devices; however, few studies have been conducted to examine the benefit to consumers, particularly regarding effectiveness in real-world listening environments (see Chapter 4). A study by Cox and colleagues (2014) found little functional benefit to justify the price disparity between these two levels of hearing aids, which can be as much as several thousand dollars. Additional consumer price data for hearing aids are presented in Table 5-1.

The VA procures hearing aids for its beneficiaries directly from hearing aid manufacturers as part of large-volume contracts. According to one report published in early 2014, the VA paid an average of $369 per hearing aid, while one vendor's retail price for a similar hearing aid in the open market was $1,400–$2,200 (VA Office of the Inspector General, 2014). The VA's negotiation power may be due to their bulk purchasing of large numbers of hearing aids. As noted earlier, the VA's hearing aid purchases made up approximately 20 percent of the U.S. hearing aid market in 2013 (Strom, 2014a); in fiscal year 2014, the VA issued nearly 800,000 hearing aids (Chandler, 2015). In addition to the effects of bulk purchasing on hearing aid prices, another key difference between the price paid by the VA and the price paid by the public lies in paying for professional services associated with the hearing aid purchase. As discussed above, the retail price for the general public is often bundled to include the prices for both the hearing aid(s) and the professional services. The VA, on the other hand, negotiates a price that is only for the hearing aid itself, with fitting and rehabilitative services provided by audiologists and other providers employed by or partnered with the VA; the expenses for these professional services are not part of the price the VA pays to manufacturers for hearing aids. The VA report referenced above did not specify whether additional services were included in the vendor's open market price of $1,400–$2,200. The VA purchasing system provides a glimpse into what may be wholesale or bulk-purchasing prices and demonstrates the potential for and feasibility of lower priced hearing aids.

As discussed in Chapter 4, technologies are rapidly changing and lower cost technologies (e.g., over-the-counter wearable hearing devices) are being explored that could potentially meet the demands of many adult consumers with mild to moderate hearing loss. Currently, there are consumer electronic products termed personal sound amplification products (PSAPs; see Chapter 4) that range in cost from less than $50 to more than $500 (see

TABLE 5-1
Examples of Retail Prices for Hearing Aids and PSAPs

Retail Price	Reference
$1,800 per aid (2004)[a]	Donahue et al., 2010
$1,601 per aid (2008)[b]	Kochkin, 2009
Range of $1,182 to $2,876 per aid[b]	Kirkwood, 2009
Range of $1,000 to $6,000 per pair[b]	*Consumer Reports*, 2015
Average price $1,986 (2007)[b] Prices include professional services such as evaluation, selection, fitting, training, and care: Behind-the-ear: $1,149 to $2,672[a] Completely in the canal: $1,364 to $2,860[a] In the canal: $1,309 to $2,744[a] In the ear: $1,204 to $2,686[a] (not specified if price is per aid or per pair of hearing aids)	Johnson, 2008
$299 per aid via direct mail[b]	Kochkin, 2014
$1,500 per aid with custom fitting, although exact services included were not specified (survey included individuals receiving hearing aids through the Department of Veterans Affairs)	Kochkin, 2014
Average retail price per aid (2013): $1,657 for economy level[b] $2,196 for mid-level[b] $2,898 for premium level[b] $2,363 average price[b] (total weighted average of five brands and types of aids)	Strom, 2014b
Examples of range of economy level prices per aid in retail stores: $399.00 to $499.99	Costco Wholesale, 2016b; Walmart, 2016
Less than $50 for PSAP[b]	Kochkin, 2010
$25 to $500 for a PSAP[b]	*Consumer Reports*, 2015

NOTES: Many of these prices are from studies funded by the hearing aid industry. Prices reported as per aid (i.e., for one ear) or per pair (i.e., for two ears) depending on the unit used in the referenced source.

[a] Price includes professional services and technologies.

[b] Not specified what price includes in terms of services.

Table 5-1) and may overlap in some or many of the technological features that hearing aids have. Food and Drug Administration guidelines note that these products cannot be marketed for the intended purpose of addressing hearing loss. Product standards are being developed for PSAPs that may facilitate comparisons for consumers (see Chapter 4).

TYPES OF COVERAGE AVAILABLE FOR TECHNOLOGIES AND SERVICES IN THE UNITED STATES

Medicare

Original Medicare

Services Original Medicare (also known as Medicare Part A and Part B) covers costs associated with hospital stays and outpatient services and supplies considered medically necessary to diagnose and treat a disease or condition. As part of the Patient Protection and Affordable Care Act (ACA), Medicare beneficiaries are eligible for an Initial Preventive Physical Exam when they turn 65 years old (CMS, 2015b) and an Annual Wellness Visit every year thereafter (CMS, 2015a) performed by a physician or other qualified health care provider. These visits can include screening for hearing impairment at no additional cost to the beneficiary (Koh and Sebelius, 2010). Medicare also covers hearing testing only if it is ordered by a physician or nonphysician medical practitioner for the purpose of diagnosing a hearing or balance disorder (CMS, 2016e). Audiologists can be reimbursed for conducting this testing if ordered by a physician or nonphysician medical practitioner (see Chapter 3). However, beyond this hearing test, Medicare does not pay for any other services provided by audiologists to beneficiaries, such as counseling about hearing test results, conducting a functional communication assessment, management planning, or auditory rehabilitation, even though these services are within the scope of practice of audiologists.

Medicare does cover rehabilitation services related to hearing when the services are provided by a speech-language pathologist, however (ASHA, 2016a). Services provided by a speech-language pathologist generally include evaluation and treatment to regain and strengthen speech and language skills, including cognitive and swallowing skills. In the case of patients with hearing loss (but not balance disorders), evaluation for and treatment with auditory rehabilitation can be performed by a speech-language pathologist and be covered by Medicare. Medicare payment for these services provided by a speech-language pathologist must be billed using a general speech-language pathology Current Procedural Terminology (CPT®) code, not a code that is specifically for rehabilitating these particular functions. Extending Medicare coverage of auditory rehabilitation to provide reimbursement to audiologists, whom many consumers and patients are already seeking out for other elements of hearing health care, would make this treatment more affordable for Medicare beneficiaries.

Technologies As stipulated in the Social Security Amendments of 1965, Medicare does not provide coverage for hearing aids. Section 1862(a)(7) of the Act states, "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services . . . where such expenses are for . . . hearing aids or examinations therefor." This policy is codified in the regulation at 42 C.F.R. 411.15(d), which states that hearing aids or examination for the purpose of prescribing, fitting, or changing hearing aids are excluded from Medicare coverage. The question of whether Medicare should cover hearing aids has been raised (Whitson and Lin, 2014); however, some hearing health care and hearing industry professional associations discourage this measure for many reasons, including the projected loss of revenue from private and out-of-pocket payers (Wallhagen, 2014).

Medicare Reimbursement in Other Health Care Fields

Evaluating options for expanding Medicare coverage of hearing health care can build on other areas of health care where coverage is already provided.

Habilitative and rehabilitative services by occupational therapists, physical therapists, and speech-language pathologists Medicare provides coverage for evaluation and treatment related to habilitative and rehabilitative services and related technologies including for physical therapy, occupational therapy, and speech-language pathology. These services may be provided as outpatient, inpatient, in-home when the person is homebound, or in a skilled nursing facility. There is an annual therapy cap limit to reimbursement (see Table 5-2), which means that Medicare may not always cover all rehabilitation services needed by an individual beneficiary before the therapy limit is reached.

Prostheses Medicare covers programming and follow-up after cochlear implantation. This is based on the classification of a cochlear implant as a prosthetic device and the surgical placement as a medical necessity. Medicare defines a prosthetic device as one that replaces a body part or function. Prosthetic devices covered by Medicare include cochlear implants, corrective eyeglasses or contact lenses provided after a cataract operation (coverage is 80 percent), breast prostheses, and ostomy bags (CMS, 2016g).

Medicare Advantage

Medicare Advantage (also known as Medicare Part C) is a program that allows those eligible for Original Medicare to opt out of Medicare itself and choose their own private insurance plan. For each beneficiary who opts out of original Medicare and opts into a Medicare Advantage program, the

TABLE 5-2
Reimbursement for Outpatient Auditory Rehabilitation and Other Related Therapies Under Medicare Part B

	Audiologist	Occupational Therapist	Physical Therapist	Speech-Language Pathologist
Type of Therapy	Auditory Rehabilitation	Occupational Therapy	Physical Therapy	Speech-Language Pathology
Reimbursed?	No[a]	Yes	Yes	Yes
Therapy cap limit per patient in calendar year 2016 (deductible may apply)	Not applicable	$1,960	$1,960 (maximum allowed shared with speech-language pathology)	$1,960 (maximum allowed shared with physical therapy)

[a] See above discussion about speech-language pathology reimbursement for auditory rehabilitation.

SOURCE: CMS, 2016f.

federal government diverts the money it would have paid into Medicare to that enrollee's Medicare Advantage plan; depending on the plan, the beneficiary may have to pay an additional premium. Medicare Advantage allows the beneficiary to choose a plan that offers specific benefits that meet his or her needs. Some Medicare Advantage plans include coverage for hearing health care services and technologies, or they may offer the option to purchase extra coverage for hearing health care. As such, Medicare Advantage plans can serve as a source of hearing health care coverage for Medicare beneficiaries. Medicare Advantage plans are becoming increasingly popular, with approximately 31 percent of Medicare beneficiaries enrolled in a Medicare Advantage plan in 2015, a number that has increased steadily since 2004 (Kaiser Family Foundation, 2015).

Medicaid

Medicaid Coverage for Adults

As of early 2015, only 28 states covered hearing aid purchases for adult Medicaid beneficiaries, and the extent of coverage varied widely between states, with it being very limited in some states (HLAA, 2015). Many states that provide Medicaid coverage for hearing aids for adult beneficiaries require that an individual obtain a medical exam and an audiological evaluation to determine if a hearing aid is appropriate. Many states also have an established minimum hearing loss requirement for an individual to be eligible for hearing aids. Some states only cover certain types of hearing aids, and many have a limit on the number of hearing aids and accessories, such as batteries, that beneficiaries can receive within a given period of time. Some states set an annual cap on payments. Even when a state offers Medicaid coverage for hearing health care, finding a provider who will accept Medicaid can present another hurdle to overcome.

The Early and Periodic Screening, Diagnostic, and Treatment Program

The Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program is the child health component of Medicaid in which services are provided for children until they turn age 21 years (CMS, 2016a). As part of this program, each state must provide minimum hearing health care services to Medicaid beneficiaries under age 21 years, such as diagnosis and treatment, including hearing aids. When young adults covered by EPSDT turn 21 years old, they transition to the adult Medicaid program, if eligible, and receive the Medicaid hearing health care benefits provided by the state in which they reside. Thus, young adults may receive hearing health care benefits through the EPSDT program and then lose the benefits on their 21st birthday if their state Medicaid program does not provide hearing health care benefits to adults, which can make the transition to adulthood more challenging. It is important to note that states are not required to extend their EPSDT program to those who are covered by their Children's Health Insurance Program, which supports uninsured children and young adults up to 19 years of age if their families have an income that is too high for them to qualify for Medicaid.

Affordable Care Act

The ACA established state-level health benefit exchanges that provide access to a marketplace of affordable health insurance coverage for people who were previously uninsured and did not qualify for Medicaid. The ACA also offers states the option to expand their Medicaid programs to cover more people—anyone whose family income is up to 138 percent of the federal poverty line (CMS, 2016d).

While the ACA has improved access to medical services for many people, it has not substantially improved access to affordable hearing health care for adults. Under the ACA, individual state marketplace health insurance plans and expanded Medicaid programs are required to cover 10 "essential health benefits," including "rehabilitative and habilitative services and devices (services and devices to help people with injuries, disabilities, or chronic conditions gain or recover mental and physical skills)" (CMS, 2016b). The specific interpretation of what constitutes the benefit varies by state. Many states have chosen benchmark insurance plans that do not include hearing health care services or hearing aids for adults; if the benchmark plan does not include hearing health care coverage, then the expanded Medicaid program (if the state chose to expand) and the plans offered in that state's marketplace are not required to offer hearing health care coverage. Out of 50 states and the District of Columbia, only 7 states (Arizona, Hawaii, Nevada, New York, Rhode Island, Texas, and Wisconsin) have chosen benchmark plans that offer hearing aid coverage for adults, with the amount of the benefit and coverage for hearing aid–related services varying by state (CMS, 2016c). Other states have chosen benchmark plans that include hearing aid coverage for children defined in a variety of ways ranging from newborns to individuals under age 24 years.

Employer-Sponsored and Private Health Insurance

Third-party payment for hearing health care is limited; only a small number of private insurance companies cover hearing health care for adults (Andrews, 2012; *Consumer Reports*, 2015). Employer-based coverage for hearing health care tends to be modest at best. Of those insurance plans that provide some coverage of hearing health care, some cover diagnostic and evaluation services, while others cover part or all of the costs for hearing aids, and some employers offer their employees the option to purchase hearing health care insurance similar to optional dental or vision insurance (ASHA, 2016b).

Many adult Americans under the age of 65 years (i.e., the age to qualify for Medicare) are covered by employer-sponsored health plans, which are regulated under the federal Employee Retirement Income Security Act of 1974[3] (ERISA). There are two distinct types of ERISA plans: (1) those in which employers purchase health insurance coverage for their employees from a private health insurer or health maintenance organization (HMO), with the latter parties bearing the "insurance risk" of plan insolvency; and (2) employer "self-funded" plans in which the employer in effect "self-insures" the health care costs for its employees and bears the insurance risk itself but possibly engages an insurer to assist with claims administration or other non-risk-bearing functions for an agreed-upon fee. This distinction is important because it affects the degree to which state legislators and regulators can impose requirements—such as that employers must offer hearing health care insurance—on employer-sponsored health plans. States can

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[3] Employee Retirement Income Security Act of 1974, Public Law 93-406, 93rd Cong. (September 2, 1974).

legislate benefits mandates that apply to commercially sold health insurance or HMO plans, and these mandates will affect employer-sponsored plans to the extent that employers purchase such policies for their employees. However, because of a legal doctrine known as “ERISA preemption,” states cannot impose benefits mandates on ERISA self-funded plans. Thus, employers that offer self-funded health plans are not subject to state-imposed benefits mandates. Large employers may elect to use self-funded plans because their large workforces may be diversified enough to make the insurance risk financially manageable.

As of 2014, only three states—Arkansas, New Hampshire, and Rhode Island—mandated that health insurance plans include coverage for hearing aids (with some specifically stating that related services were included) for adults (ASHA, 2016c). In addition, self-insured plans are exempt, meaning that large companies that have their own insurance programs and that may hire thousands of employees do not have to provide coverage to their employees even if they are in a state with mandated coverage.

Employees who have access to a flexible spending arrangement, regardless of hearing health care insurance coverage, can contribute pretax income (up to a prespecified amount, the maximum being $2,550 in 2015) to their flexible spending arrangement to cover the costs of hearing aids, hearing exams, and other audiological services—in addition to all other medical costs—during the year (IRS, 2016). With this type of arrangement, the employee bears some risk because he or she must use the funds during the calendar year, and if the employee does not incur medical expenditures during the year, he or she will lose the funds (although some employers give their employees a grace period of up to 2.5 months into the following year to use the money in the account or they may allow their employees to carry over up to $500 per year to use in the following year).

Some Federal Employee Health Benefits plans—which cover many federal employees and members of the U.S. Congress—other fee-for-services plans, and HMO plans provide coverage for hearing aids and other services for adults (HLAA, 2008). The comprehensiveness of the benefits depends on the individual plan.

TRICARE, which provides health care for members of the military, military retirees, and their families, covers hearing aids and hearing aid services for beneficiaries with hearing loss that meets specific parameters (TRICARE, 2015). Military retirees may be able to access VA services for hearing health care (see next section on benefits for veterans) or access the Retiree-At-Cost Hearing Aid Program, which is available at certain military hospitals and clinics (MAA, 2016; TRICARE, 2015).

Benefits for Veterans

Audiology is one of the highest demand services in the VA; hearing loss and tinnitus are the two most prevalent causes of service-connected disability for U.S. military veterans (Chandler, 2015; VA Office of the Inspector General, 2014). These conditions affect veterans of all ages and may not be apparent until years after military service has ended. The VA provides diagnostic audiology services for all veterans enrolled in the VA's health care system, and hearing aids are provided at little or no cost to veterans who have a predefined minimum hearing loss that is determined to be the result of active military service (Beck, 2015) (38 C.F.R. 3.385). In some cases, veterans can receive hearing aids if their hearing loss is not directly related to their military service (38 C.F.R. § 17.149).

The VA's audiology services include the assessment, evaluation, treatment, and management of hearing loss and tinnitus; the fitting and programming of hearing aids and hearing assistive technologies and rehabilitation with cochlear implants and other bioelectric auditory implants; hearing screening and prevention services; and auditory rehabilitation services to optimize residual hearing.

Vocational Rehabilitation Programs

The Rehabilitation Act of 1973[4] authorizes and funds state vocational rehabilitation programs to assist individuals with a physical or mental disability that is a barrier to gaining part- or full-time employment or engaging in post-secondary education. Furthermore, it must be determined that vocational rehabilitation will help the individual with gaining employment or post-secondary education. Eligible individuals work with a counselor to create an Individualized Plan for Employment.

The program provides services, such as counseling, and devices to assist eligible individuals of all ages with disabilities. In 2014 the Workforce Innovation and Opportunity Act[5] amended the Rehabilitation Act of 1973 to require that all state vocational rehabilitation agencies dedicate at least 15 percent of their federal funds to services for young adults transitioning from secondary education to post-secondary education or employment. Efforts to aid young adults include summer programs for students with hearing loss transitioning to college (see Chapter 6).

For individuals with hearing loss or deafness, vocational rehabilitation services can include the provision of hearing aids and other hearing health

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[4] Rehabilitation Act of 1973, Public Law 93-112, 93rd Cong. (September 26, 1973).

[5] Workforce Innovation and Opportunity Act, Public Law 113-128, 113th Cong. (July 22, 2014).

care services if needed for obtaining employment. Vocational rehabilitation services are administered by state programs with funding primarily through the Department of Education's Rehabilitation Services Administration (RSA, 2016). State vocational rehabilitation agencies can and do differ in the way they operate, including how they operate when they have insufficient funds to support all eligible individuals. During these times, by law a state vocational rehabilitation agency determines priority for clients by a process called Order of Selection for Services. Under this process, individuals determined to have the most significant functional limitations are given the highest priority for benefits, while others who are determined to have less severe disabilities may be placed on a waiting list to receive services. The determination of which functional limitations should be given the highest priority is left to the state. Order of Selection for Services may reduce access to vocational rehabilitation services for people with hearing loss as they may not be seen as having as significant a functional limitation as other individuals (University of Arkansas Rehabilitation Research and Training Center, 2008).

One of the challenges identified by state vocational rehabilitation agency staff is raising awareness in the general public, particularly among individuals with hearing loss, that vocational rehabilitation programs exist and may be able to provide them with needed hearing technologies and services.[6] Opportunities to disseminate this information more widely include collaborations among state and local disability agencies and through hearing health care professionals, as well as through advocacy organizations.

LESSONS LEARNED FROM HEARING HEALTH CARE BENEFITS PROVIDED IN OTHER COUNTRIES

Several countries with comparable development and resources to the United States provide some form of public hearing health care funding, which offers a number of funding models from which the U.S. hearing health care system can learn (see Table 5-3). The extent of coverage for technologies and services varies widely, including the extent to which maintenance, batteries, and repair are covered. Wait times to see a professional for the purpose of accessing hearing health care can be several months in some public health systems, which may lead some individuals with hearing loss to choose self-pay options to avoid long wait times.

In some countries that subsidize the cost of hearing aids or provide them free of charge, use of the devices is greater than in the United States (see Chapter 4), but market survey data indicate that the rates of use are still

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[6] Personal communication, B. Bell, Alabama Department of Rehabilitation Services, February 16, 2016.

TABLE 5-3
Examples of Countries with Publicly Funded Hearing Health Care for Adults

	Australia	Denmark	Finland	Germany	Switzerland	United Kingdom
Who is eligible for public coverage?	Adults with a pension, disability, veteran, or under age 26 years	All	All	All	Working adults with disability insurance or retired adults	All
Public coverage for basic hearing aid and related services	100%	100%	100%	Fixed subsidy	Fixed subsidy; covers ~75% for retirees	100%
Public coverage for batteries, repair, maintenance	Yearly fee	Batteries: covered Repair and maintenance: covered	Batteries: usually not covered Repair and maintenance: usually covered	Batteries: not covered Repair: usually covered	Batteries: subsidized Repair: subsidized	Batteries: covered Repair and maintenance: covered
Wait times to receive care	Public: 4–8 weeks Private: minimal	Public: 10–84 weeks Private: none	Public: 8–24 weeks Private: shorter wait time	None	None	Public: ~18 weeks Private: minimal
Uptake of hearing aids by those with hearing loss	39%	47.8% (50.0% of people 18+ years)	< 15%	34.9% (35.0% of people 18+ years)	41.4% (41.9% of people 18+ years)	42.4% (42.7% of people 18+ years)

SOURCES: Anovum, 2016a,b,c,d; Australian Government Office of Hearing Services, 2016a,b; Bisgaard, 2009; Egbert et al., 2012; Hear-it.org, 2016a,b,c,d,e; National Health Service, 2015.

low even in these countries (see Table 5-3). Population-based epidemiological studies of hearing loss have similar findings: In the Age, Gene/Environment Susceptibility–Reykjavik study (Iceland), hearing aids were found to be used by 21.9 percent of the participants with hearing loss (Fisher et al., 2015). Use was strongly related to the severity of hearing loss and ranged from less than 10 percent usage among those with mild loss to more than 90 percent of those with severe hearing loss (≥ 65 decibel hearing level). In addition to the severity of hearing loss, another, independent predictor of whether an individual used a hearing aid was self-reported hearing loss.

A similar effect was seen in the Blue Mountains Hearing Study (Australia), where the cost of hearing aids was subsidized for older adults with limited means. The 5-year incidence of hearing aid use was 18 percent and 48 percent, respectively, among participants with mild and moderate/severe bilateral hearing loss, was 6 percent among those with unilateral hearing loss, and was 23 percent overall. This was slightly higher than the 15 percent utilization rate reported in the Epidemiology of Hearing Loss Study (Wisconsin, USA) (Fischer et al., 2011; Gopinath et al., 2011). As in the study by Fischer and colleagues (2011), self-reported hearing loss was an independent predictor of the incidence of hearing aid use (Gopinath et al., 2011). Uptake rates in non-U.S. countries that provide subsidized or free hearing health care indicate that the cost of hearing aids is one of a complex combination of factors that contribute to an individual's decision of whether to seek help for hearing loss and is not necessarily the sole reason that some of those who could benefit from hearing aids do not get them (see Chapter 4 for other contributing factors).

INNOVATIVE APPROACHES TO IMPROVING AFFORDABILITY

Improving Transparency in Hearing Health Care Billing Practices

Over the past several years, questions have been raised about the use of a bundled model for hearing health care billing (described earlier in this chapter). First, there is a lack of transparency for the consumer regarding the itemized costs of professional services and technologies. Fees for services are included in the purchase price of the device, which raises the (apparent) cost of hearing aids to the consumer. Second, in the bundled model, prices include a package of services that the individual consumer may or may not use. In the bundled model, prices for services are generally set by computing the average number of appointments across a large number of patients for a specific time period (typically within the manufacturer's warranty period for the hearing aid or other technology or for a certain number of months after fitting). This calculation estimates the fee for providing services and running the business for the average patient in the practice, and this fee is then added to the retail price of the hearing aids. Third, bundled models may include services that are advertised as "free," such as hearing tests to determine candidacy for hearing aids and follow-up appointments. The advertised "free" hearing test may not include a comprehensive audiologic evaluation and functional communication assessment (see Chapter 3 for detailed description) but rather a screening-type evaluation, with a comprehensive exam included in the bundled cost presented to the consumer (if this exam is not covered by the consumer's insurance or Medicare as being a medically necessary evaluation). Thus, in a bundled billing system, individuals may be paying for services that they do not need (or may need but do not use), while not paying for or receiving additional services that they do need.

There is some evidence that improved transparency in health care services pricing can lead to substantial reductions in the prices paid by consumers (Reinhardt, 2014). For example, employers with self-funded health plans have used reference pricing to reduce health care costs; if an employee chooses a health care provider that charges more than a given price limit (i.e., the reference price), the employee then pays the difference in price for obtaining the device or service. Reference pricing has proven effective in lowering the price of orthopedic surgery, imaging, and laboratory tests (Robinson and MacPherson, 2012), and it proved to be an effective mechanism for lowering health care expenditures per capita for hearing aids in Germany (Baumler et al., 2008; Schreyogg et al., 2009).

Transparency in hearing health care billing could help to differentiate the cost of the technologies from professional fees for hearing tests, professional services to fit the device, and services to provide follow-up care as needed. This type of "fee-for-service" model is familiar to patients in other areas of health care where they are accustomed to paying for visits to health care professionals, including those providing a combination of devices and services, such as in the cases of physical therapy and dental care, or the separate costs associated with a procedure versus professional services, such as often occurs when billed for visiting a primary care provider and receiving a vaccination or laboratory test.

Separating out the price of the technologies from the price of associated professional services educates the consumer about the retail prices of hearing aids and facilitates a direct comparison of similar devices across manufacturers. A better understanding of the retail prices of hearing aids also makes it easier to make an educated evaluation of the added costs of special features and technologies, such as directional microphones, noise reduction, and multiple programs. In addition, transparent pricing allows consumers to distinguish among the many components of hearing health care services, and it can promote informed decision making by allowing individuals to make informed comparisons and choose the care appropriate and affordable for them. Itemized and transparent lists of prices for technologies and professional services may help consumers understand all of the facets of services that may be helpful in addressing their hearing loss, including assessing the individual's functional communication abilities and the need for intervention, selecting and fitting of the hearing aid or other technologies as needed, auditory rehabilitation services to enhance communication, and ongoing care and support. Price transparency for hearing aids and hearing assistive technologies, professional services, and follow-up care is particularly relevant under new health insurance and health care financing models that are increasing consumer exposure to health care costs (HFMA, 2014).

With transparent pricing options available, consumers can choose to itemize and pay using a "fee-for-service" model. Alternatively, consumers may opt to pay for a separate "service plan" over a fixed period of time, but this package can be billed separately from the fees for pre-fit evaluations and the cost of the devices. Because in an unbundled model individuals are paying only for the services they need and use, unbundling has the potential to reduce the total cost of services for the individual. To further enhance transparency, individuals purchasing technologies should be notified by the seller that additional visits for more services may be necessary and whether the cost of any of those visits is included in the initial purchase price. This model may also lessen the need for a large upfront investment by the consumer because the fees are collected as services are used, which occurs over an extended period of time.

Increased transparency and itemized billing may also be of benefit to consumers who use a direct-to-consumer model of delivery (e.g., online ordering), who are traveling and may want assistance with their hearing aids, or who may want to seek assistance in learning how to use the devices to their full potential, to acquire needed accessories, or to obtain assistance with ongoing maintenance and repairs. Itemized billing provides a means for dispensers to establish a unique fee schedule for these services to provide care for individuals who already own their devices but still require assistance, thus reaching more people and increasing the likelihood that those who have hearing technologies will have opportunities to learn how to get maximal benefit from those technologies. It also provides the means for individuals who purchased technologies from one dispenser to obtain service from another dispenser should the individual move, become dissatisfied with the original dispenser, or have some other reason for wanting to see a different dispenser (see Chapters 3 and 4). Although increasing transparency in pricing can help consumers make more informed decisions, some consumers and their family members still might not know exactly what services they need and will require additional help. Consumer education that accounts for an individual's health literacy level will be needed to complement transparent pricing and itemized billing (see Chapter 6).

Alternative Care Delivery Systems

As described in Chapter 3, a number of alternative and innovative systems for delivering hearing health care exist and continue to be tested. For example, telehealth models of care have been tested as ways to expand access to various types of health care services, including audiology, and can be particularly useful for patients living in rural areas (see Chapter 3). The use of community health workers is also being tested as a potentially cost-effective mechanism for expanding access, and it may be especially beneficial in bridging access gaps caused by health professional shortages and in providing culturally sensitive care in underserved communities. Additionally, retail clinics are being used to improve access and reduce the growing demands on primary care providers. These alternative approaches to care delivery have the potential to increase access, reduce disparities, promote efficiency and value, and reduce costs for consumers, insurers, and health care as a whole. This section will focus on the potential costs and reimbursement factors related to the provision of care under these models, as Chapter 3 already described these innovative models and considered how they could affect access to care while reducing disparities.

Community Health Workers

The World Health Organization—which supports the use of community health workers in low-income countries as a cost-effective approach to greatly expanding access, maximizing finite resources, and improving health outcomes—describes how community health worker programs can be integrated into larger health care systems (Global Health Workforce Alliance and WHO, 2010; McCord et al., 2013). As noted by McCord and colleagues (2013), the resulting close connections between the community health worker programs and the health care system can lead to such benefits as timely referrals, sufficient supervision, and evidence-based information and processes. Although the specific costs associated with community health worker programs (e.g., HIV and tuberculosis screening, nutrition, pneumonia care) in low-income countries are not relevant to this discussion (McCord et al., 2013), the types of operating costs for a community health worker–delivered program for hearing-related services are likely to be similar. For example, costs might include training, salary, and benefits for the community health workers; equipment for basic screening and education; consultation time for community health workers with health care professionals (e.g., audiologists); and other overhead costs (e.g., transportation, community engagement and outreach).

In the United States, information on the costs and cost effectiveness of community health worker–provided services is limited. A systematic review of evidence related to community health worker programs concluded that the available evidence was insufficient to assess and compare the cost effectiveness of the services provided (Viswanathan et al., 2010). Of the 53 studies identified for the review, only six featured data relevant to the cost or cost effectiveness of community health worker programs. The studies—which included interventions related to children's health, cancer screening, and the management of chronic health conditions (e.g., asthma and mental health)—found a large range of annual costs per patient ($52–$6,200) depending, in large part, on the intensity and follow-up requirements of the program (Viswanathan et al., 2010).

Using community health workers to extend access to hearing health care services is still in the very early phases of testing and implementation. In terms of cost, researchers affiliated with the Access HEARS program[7] in Baltimore, Maryland, have reported affordable preliminary outcomes, with the complete cost of the service provided plus the hearing product averaging approximately $200 per person served (Leaderman, 2015). If proven effective, this approach to basic care and treatment options could offer a significant reduction in costs for individuals with mild hearing loss when compared to the much higher cost (discussed earlier in this chapter) that might be required for clinical hearing health care services, which may be a barrier for some individuals. In Arizona, a partnership between academia, a local community, and a private, nonprofit Federally Qualified Health Center serving a mostly rural, low-income population employs Promotoras de Salud (i.e., community health workers) to deliver a hearing health education program in Spanish (Colina et al., 2016). Researchers from the University of Arizona are currently conducting a randomized controlled trial to evaluate the efficacy of this community health worker program to expand access to culturally and linguistically relevant hearing health care education and support. It is important to note that within each of the above-cited examples under research and development, mechanisms for referral and access to clinical care are embedded within the program. There is an ethical responsibility to provide underserved populations with equitable access to quality health care from well-trained professionals. Community health worker programs present novel ways to facilitate this access and make pathways to care more efficient. Currently, coverage and reimbursement for community health worker–provided services through

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[7] The Access HEARS program (http://accesshears.com) was launched from the Johns Hopkins University and initially funded through a grant from the AARP Foundation. The program recently completed the proof-of-concept trial and hopes to achieve sustainability through fund raising and employ two full-time community health workers (Leaderman, 2015).

Medicare, Medicaid, and other insurers are limited. However, the ACA has expanded reimbursement and funding opportunities for community health worker–provided services. For example, the ACA authorized the Centers for Disease Control and Prevention (CDC) to administer grants for various types of evidence-based interventions, including efforts to "educate, guide, and provide outreach in community settings regarding health problems prevalent in medically underserved communities," (CDC, 2015, pp. 4–5), which may represent an opportunity for hearing health care. The legislation also led to an amendment to the Centers for Medicare & Medicaid Services' rules regarding who may be paid for preventive services under the Medicaid program; although this ruling was not directly relevant to audiology, it may open a door for other types of services to be added in the future. Effective October 2013, nonlicensed care providers, including community health workers, may be eligible to receive payment under Medicaid, as long as these services are recommended by a licensed health professional (CDC, 2015; CMS, 2013). States are also establishing a more defined place for community health workers within the health care system through Medicaid. A policy brief from the CDC describes how individual states are authorizing Medicaid reimbursement for community health workers that goes beyond preventive services to integrate community health workers into team-based approaches to health care (CDC, 2015), which could lead to improved access and outcomes for individuals in underserved communities. Leveraging existing models of community health worker–provided services across the United States may provide opportunities for the hearing health care field.

Telehealth and Tele-Audiology

The use of telehealth has been promoted as a mechanism to expand access, improve care continuity and coordination, ensure quality, and increase value and efficiency (AMA, 2016; Klink et al., 2015). Telehealth can also save patients time and money on travel and transportation. For example, the Alaska Federal Health Care Access Network, which provides telehealth services in a state where approximately one-third of the population lives in a rural area, estimated a savings of $8.5 million in travel costs for Medicaid beneficiaries in 2012 (AHRQ, 2013; U.S. Census Bureau, 2012). However, the overall potential for costs saving and the cost effectiveness of telehealth is less certain and will depend on the type of care being provided, the health professionals providing the care, and the types of equipment and other resources needed to provide the care. A systematic review of literature concluded that telehealth services appear to be no more cost effective than conventional health care delivery mechanisms (Mistry, 2012). Despite these findings, telehealth, like retail clinics (described below), holds the potential to reduce expenditures on more expensive forms of care (e.g., emergency department visits), which would result in a net savings for payers and the health care system.

Inconsistencies and limitations related to reimbursement regulations have been cited as barriers to the wider adoption of telehealth (e.g., AMA, 2016; Klink et al., 2015). For example, Medicare coverage of telehealth services is currently limited to beneficiaries who live in rural areas; a defined set of services provided by specific providers;[8] and live, synchronous interactions between the patient and provider (CMS, 2015c). Legislation has been introduced in Congress to update Medicare's coverage of telehealth services: the Medicare Telehealth Parity Acts of 2014 and 2015 (H.R. 5380 and H.R. 2948), if enacted, would have expanded coverage beyond rural areas; included reimbursement for audiologists, speech-language pathologists, and other types of health professionals; and allowed remote patient monitoring for some chronic health conditions (Lacktman, 2015).

Many states have also enacted laws which provide for reimbursement through Medicaid and private insurances (Bachrach et al., 2015). Almost every state allows some form of reimbursement for telehealth services through Medicaid (48 total), and almost half have parity laws covering private insurances (24 total). However, the legal frameworks in many states set limits on the provisions of telehealth. For example, nine states have reimbursement restrictions related to distance or population density (e.g., distance between patient and provider, use in rural areas), and four states forbid the use of cell phone videos for the purposes of telehealth. Additionally, many states limit reimbursement to only cover live, synchronous interactions, prohibiting the use of remote patient monitoring, store-and-forward interactions, or transfer of saved images (Thomas and Capistrant, 2015). In its most recent gap analysis, the American Telemedicine Association, an advocacy organization that supports the broad implementation of telehealth in the United States, ranked Alaska as the most telehealth-friendly state in numerous categories (e.g., Medicaid reimbursement, the use of eligible technologies) (Thomas and Capistrant, 2015).

With regard to hearing health care in the United States, the use of telehealth services is currently limited due, in part, to reimbursement restrictions. As noted above, Medicare regulations do not include audiologists and speech-language pathologists as eligible providers of telehealth services (AAA, 2016; CMS, 2015c). However, Medicaid programs in some states do allow reimbursement for audiology services that can realistically be provided remotely. For example, earmold impressions cannot be taken

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[8] I.e., physicians, physician assistants, specific types of nurses, registered dieticians and nutritionists, and clinical psychologists and sociologists.

remotely, but teleprogramming of hearing aids could be covered in some states (AAA, 2016; ASHA, 2012). Beyond expanding access to care and reducing travel costs for patients, other possible cost savings associated with tele-audiology remain unclear. Given the uncertainties about time requirements, administrative and technical costs and requirements, and reimbursement coverage and rates, some hearing health care professionals may be reluctant to offer telehealth to their patients. Further investigation and policy changes will be required to ensure the widespread adoption of tele-audiology services that satisfy the needs and preferences of both patients and providers.

Retail Clinics

The number of retail clinics in the United States has increased by more than 9-fold in the past 10 years (from 200 in 2006 to more than 1,800), and estimates suggest that the number of visits to these clinics increased between 4- and 7-fold during roughly the same timeframe (Bachrach et al., 2015; Mehrotra and Lave, 2012). As described in Chapter 3 and in previous reports from the Institute of Medicine, these clinics offer a convenient and efficient alternative to some primary care services, which may also result in savings to patients, payers, and the health care system as a whole (IOM, 2010, 2011). For example, a 2010 study by Weinick and colleagues (2010) estimated that approximately 13 to 27 percent of emergency department visits could be managed safely and effectively in retail and urgent care clinics, representing a possible overall savings of approximately $4.4 billion dollars per year. However, questions remain about whether the increased availability of retail clinics in the last decade is reducing unnecessary emergency department visits or driving an increased utilization of health care services overall and thus increasing cost (Mehrotra, 2015).

In setting costs for patients, the retail clinic model uses a transparent, fixed pricing scheme in which prices for services are readily available or clearly posted in stores and online. The costs for most services range from $30 to $75, representing a significant savings to patients and insurers when compared with the cost of a visit to a physician's office or an emergency department (IOM, 2010; Mehrotra, 2015). For example, the cost of care in physicians' offices or emergency departments for the three most commonly treated conditions in retail clinics (i.e., otitis media, pharyngitis, and urinary tract infections) ranges from approximately $160 to more than $550, whereas care for those conditions in a retail clinic cost approximately $100[9] (IOM, 2010; Mehrotra, 2015; Mehrotra et al., 2009). Although

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[9] These estimates include the cost of the consultation with the health care professional(s), pharmacy/prescription services, and laboratory expenses (Mehrotra et al., 2009).

most retail clinics accept health care insurance—Medicare, Medicaid, and private insurance—and some insurance companies encourage the use of retail clinics by reducing or waiving copay fees, approximately 35 percent of patients choose to pay for services out of pocket (IOM, 2010; Rudavsky et al., 2009). The lower costs for these services can be attributed to the use of less costly health care professionals (e.g., nurse practitioners, physician assistants); efficient models of care that implement clearly defined care protocols, algorithms, and clinical practice guidelines; and new technology.

The services offered through retail clinics are evolving to include management for some chronic health conditions, and more retail clinics are being integrated into health care systems as a way of ensuring timely referrals, improving care coordination, and possibly lowering costs for payers (Bachrach et al., 2015), further opening the possibility of including hearing health care services. Just as community health workers can be trained to administer basic audiometry services and technologies in underserved communities, so too can health care professionals in retail clinics, as is currently being considered by the partnership between the Walgreens Boots Alliance and Connect Hearing (Sonova) (see Chapter 3). Costco Wholesale warehouses offer another retail example with approximately 500 hearing aid centers located in Costco Wholesale warehouses across the United States. These hearing aid centers offer hearing tests and sell hearing aids from four of the six largest hearing aid manufacturers at prices lower than average retail prices (from $499.99 per hearing aid) (Costco Wholesale, 2016b; Kirkwood, 2014; Stock, 2013) (see Table 5-1). Costco Hearing Aid Centers also provide free follow-up care and assistance with cleaning (Costco Wholesale, 2016a). Although this model offers more affordable options to those who have a Costco membership, there are concerns about the lack of training some Costco Hearing Aid Center employees have (e.g., Kasewurm, 2014). In conjunction with companies that operate retail clinics, researchers, health care professionals, health care systems, and regulators, the hearing health care field needs to determine which services and treatments can be provided in retail clinic settings and still ensure high-quality, cost-effective care that is integrated with other hearing health care professionals and services.

NEXT STEPS AND RECOMMENDATIONS

In the hearing health care system that serves adults, nearly all costs are out of pocket and the costs are relatively high. The vast majority of employers do not provide hearing health care insurance. Few state Medicaid programs offer hearing health care benefits without strict limitations. Vocational rehabilitation programs offer a tremendous benefit for those with hearing loss who are seeking employment, but wait times can be long, and those with hearing loss who are seeking assistance can be skipped over in order to help those who have disabilities considered to be more prohibitive for gaining employment. Given the high number of Americans who have hearing loss and the high cost of hearing health care, changes to the cost of hearing health care are needed.

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;**
- **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.

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.

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6

Engaging a Wider Community: Awareness, Education, and Support

Hearing plays a vital role in how individuals experience, interact with, and relate to the people and environment around them. Hearing is sometimes referred to as the “social sense” because of its function in developing and maintaining intimate relationships and social connections with family, friends, coworkers, and acquaintances. As described in Chapter 1, the social-ecological model depicts the complex network that encompasses the interplay among individuals and their families, the social networks and relationships in their lives, the organizations and institutions that provide services and support to the individuals, the communities in which the individuals work and live, and society at large. Supporting individuals with hearing loss requires adaptable solutions that span society—not just solutions geared toward individuals with hearing loss or solutions within the context of a medical model that revolves around the delivery of care and services in a health care setting. Components at all levels of the social-ecological model can contribute to hearing health and overall well-being.

This chapter focuses on education, support, and awareness for individuals with hearing loss, their families, their communities, and society as a whole. Attitudes and beliefs about hearing loss and the use of hearing health care services and technologies are explored from the perspectives of individuals and family members, employers and coworkers, and the general public, including the media. The chapter provides insights on the role of health literacy, the Internet, community-based support, and the built environment, such as public and private spaces that can be designed or altered to enhance acoustics and accessibility, and it also describes how these factors can empower individuals with hearing loss. The chapter also examines the role of the community, organizations, and the public in supporting individuals with hearing loss and considers whether attitudes about hearing loss have improved with the increasing use of technology, specifically mobile technologies. Finally, the chapter highlights areas of focus for next steps as well as research priorities that are essential for optimizing support and access for individuals with hearing loss.

Although the knowledge, attitudes, education initiatives, and community support associated with other health conditions, such as HIV/AIDS, epilepsy, cancer, and substance use and mental health, have been well studied and are thoroughly described in published, peer-reviewed literature and in previous Institute of Medicine (IOM) reports (e.g., IOM, 2006, 2012; IOM and NRC, 2005), the literature about hearing loss is considerably more limited and is often based on relatively small samples (frequently less than 100 individuals) and anecdotal evidence. In conducting its literature searches and reviews for this chapter, when possible the committee focused on articles that were relatively recent—less than 15 years old—because of the natural evolution in attitudes and beliefs that are often associated with advances in technology, changes in education, and shifts in societal norms.

INDIVIDUALS AND FAMILIES

Living with hearing loss or having a loved one with hearing loss, especially when the loss is severe or untreated, has the potential to affect many aspects of everyday life and can be associated with a diminished quality of life (see Chapter 2). 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, falls, and mortality (see Chapter 2). As described in earlier chapters, both the severity of hearing loss and the impact that hearing loss has on individuals' lives vary. These variations combined with numerous individual-specific factors (e.g., environment, available support, attitudes, preferences, or socioeconomic status) create unique circumstances for each person with hearing loss. Recognizing these individual circumstances and empowering individuals and their families to take action and to become familiar with the full range of options for managing hearing loss is fundamental to maximizing quality of life and ensuring that individuals with hearing loss and members of their families have every opportunity to thrive. Individual empowerment should be built on a foundation of awareness, education, and support, where individuals and families play a central role within a constellation of other entities across the social-ecological model (see Chapter 1), including health care providers, employers, advocacy organizations, communities, and the public—all of which can contribute to empowerment.

Attitudes and Beliefs

People with hearing loss may perceive and experience a range of feelings and emotions about hearing loss, seeking care, and using such technologies as hearing aids. Negative attitudes and beliefs about hearing loss can originate both internally—arising from the beliefs and attitudes of the individual experiencing the hearing loss—and externally—produced by the beliefs and attitudes held by various social connections, including family members, friends, health care professionals, employers and coworkers, the general public, and the media. When considering how hearing loss may affect self-perception and social identity, many individuals cite fears of feeling or being perceived as old, frail, less capable, vulnerable, uninteresting, unattractive, or less desirable or as having a disability or cognitive impairment (Habanec and Kelly-Campbell, 2015; Kochkin, 2007b; Munro et al., 2013; Southall et al., 2010; Wallhagen, 2010). Because of these perceptions, people may hide their hearing loss or deny that it affects their lives, may opt not to seek treatment, or may choose not to use hearing aids after they have been purchased.

Similar to many other health conditions, attitudes and beliefs about hearing loss are directly linked to behavior (Glanz et al., 2008; van den Brink et al., 1996). Studies of older adults have demonstrated that hearing loss is often accepted as a natural part of aging that does not require intervention and that individuals often believe that hearing aids are not effective or that they only marginally benefit the user (Kochkin, 2000; McCormack and Fortnum, 2013; Ng and Loke, 2015; Oberg et al., 2012; van den Brink et al., 1996). As discussed in Chapter 4, there are numerous reasons why individuals choose not to adopt or use hearing aids or choose not to seek hearing health care. One notable factor is attitude. In a market survey, Kochkin (2007b) found that attitudes and stigma played a sizable role in decisions about hearing aid adoption. Two-thirds of survey respondents reported negative attitudes that resulted from problems with hearing aid performance, and almost half chose not to use a hearing aid due to some form of perceived stigma; respondents specifically noted embarrassment, pride, and fear of being viewed by others as old or frail or as having a physical or mental disability (Kochkin, 2007b).

In a longitudinal study of experienced and reinforced stigma among older adults with hearing loss and their communication partners,[1] Wallhagen (2010) developed a model of the interaction between three primary areas

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[1] A communication partner can be a spouse, partner, family member, or friend who frequently converses with the individual who has hearing loss.

of experienced stigma—self-perception, ageism, and vanity—and reinforced stigma (see Figure 6-1). The specific attitudes and beliefs that are described converge and affect decisions about whether to be evaluated for hearing loss, to seek treatment, and to use hearing aids and hearing assistive technologies. These types of beliefs, misperceptions, and stigmas, in combination with other barriers described earlier in the report (e.g., affordability, accessibility), can directly hinder action and timely access to the kinds of high-quality care and community-based services that can help greatly to optimize quality of life and overall well-being.

The attitudes and beliefs of spouses, partners, family members, and friends are also highly influential in decision making and can either help to overcome or reinforce the perceived stigma associated with hearing loss and the use of hearing aids and other technologies. Positive attitudes and beliefs of partners and family members, along with greater levels of family support, have been associated with seeking help for hearing loss, the successful adoption and use of hearing aids, and increased self-efficacy in the use of hearing aids (Dawes et al., 2014; Hickson et al., 2014; Meyer and Hickson, 2012; Meyer et al., 2014; Ng and Loke, 2015). In fact, Hickson and colleagues (2014) concluded that the strongest indicator of positive outcomes for hearing aid use was having the support of family, friends, and significant others. Conversely, negative attitudes of family members—such as perceptions of old age, disability, and poor aesthetics—contribute to delays in disclosing

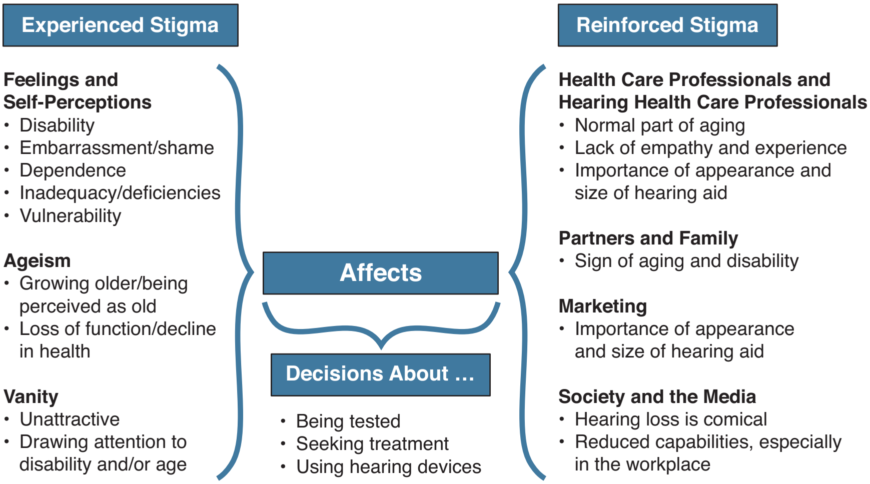

FIGURE 6-1 The interrelationship between experienced and reinforced stigma and how stigma can affect decision making for people with hearing loss.
SOURCE: Adapted from Wallhagen, 2010. Reprinted with permission of Oxford University Press.

hearing loss, seeking help, and using hearing aids (Kochkin, 2007b; Meyer and Hickson, 2012; van den Brink et al., 1996; Wallhagen, 2010). The attitudes and support of others, especially loved ones, do matter and can have a meaningful effect on the attitudes and beliefs of the individual with hearing loss, which in turn can promote action.

Although experienced and perceived stigma can prompt delays in disclosing hearing loss and seeking assessment and treatment (Clements, 2015; Southall et al., 2010; Wallhagen, 2010) (see Figure 6-1), not everyone manages stigma and negative attitudes in the same way. Some individuals tend to have more positive attitudes and to be more resilient and are able to overcome the effects of stigma by pursuing positive opportunities, learning new skills to manage the hearing loss, and seeking out interactions with others who have hearing loss (Shih, 2004; Southall et al., 2010; Wallhagen, 2010). Some individuals look within their social circles for support or focus on the possible benefits that treatment can offer. Studies demonstrate that, among other factors, people with more positive attitudes and expectations are more likely to be empowered to take action and experience success with treatment options such as hearing aids and communication programs (Laplante-Lévesque et al., 2012b; Ng and Loke, 2015; van den Brink et al., 1996). This ability for some to thrive in spite of perceived stigma presents an opportunity for educating others and fostering resilience among individuals with hearing loss. Resilience and educational interventions, for both individuals with hearing loss and their families, should be studied in greater depth in order to develop and evaluate techniques and adaptable programs that can encourage resilience and enable individuals to overcome barriers and take action in communities across the country.

Health Literacy and Understanding Hearing Loss

Health literacy is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (Ratzan and Parker, 2000, p. vi). It was elevated to a national public health priority following the 2000 release of the goals and objectives for the Healthy People 2010 initiative and the release of the IOM report *Health Literacy: A Prescription to End Confusion* in 2004 (HHS, 2000; IOM, 2004). Adults more than 65 years old; racially and ethnically diverse populations, especially Hispanic adults; people with lower socioeconomic status (i.e., lower levels of education and income); and people with disabilities all tend to have lower levels of health literacy, as do more men when compared with women (Kutner et al., 2006; NCHS, 2012). In recent years, health literacy researchers have uncovered various serious consequences of low health literacy, such as poor health outcomes and overall health status, declines in physical function among older adults, decreased access to and use of health care services, and increased health disparities among racially and ethnically diverse populations (e.g., Bennett et al., 2009; Berkman et al., 2011; Smith et al., 2015b). The IOM's 2004 report concluded that increasing health literacy is a shared responsibility, "based on the interaction of individuals' skills with health contexts, the health-care system, the education system, and broad social and cultural factors at home, at work, and in the community" (IOM, 2004, p. 35).

Despite the national focus on increasing health literacy, few studies have examined the role of health literacy on hearing health care or the impact it may have on the uptake of and adherence to various treatments. Nair and Cienkowski (2010) identified a clear mismatch between the literacy levels of individuals with hearing loss and the language that audiologists used during consultations and also the language used in written hearing aid user instructional brochures produced by manufacturers and given to individuals purchasing hearing aids, as mandated by the Food and Drug Administration (FDA). Caposecco and colleagues (2014) conducted a review of 36 hearing aid user instructional brochures and determined that 25 of them (69 percent) were not suitable for older adults because of the terminology, technical vocabulary, and jargon used. The authors also identified deficiencies with the scope of the content and the layout/typography. Another recent review of a modified hearing aid user instructional brochure, which was developed using best practices in health literacy (e.g., the use of graphics, lower-level vocabulary, and increased font size), found that people who were given the modified brochure performed better on a test of hearing aid management and were able to complete more hearing aid operation tasks without assistance than those who were given the manufacturer's brochure (Caposecco et al., 2016). In addition to the FDA-mandated provision of user instructional brochures, some manufacturers and hearing health care professionals provide customized information on specific hearing aids and other technologies in order to better guide and educate consumers. However, the written information provided during consultations may vary widely in content, depth, and health literacy scores.

Atcherson and colleagues (2013) found that audiologists may not be aware of the extent of low levels of literacy and health literacy in the United States and that they may also be unaware of the discrepancies between literacy rates and the written materials that are often presented to patients (e.g., consent forms, privacy forms). The American Academy of Audiology's *Standards of Practice* calls for audiologists to develop and use language and written materials that are at appropriate heath literacy levels (AAA, 2012). When communicating with individuals with hearing loss and their families, there are numerous other communication factors that audiologists and other health care professionals need to be aware of if they are to ensure effective communication and comprehension. For example, self-efficacy and the comprehension of hearing terminology and hearing aid jargon may increase over time with experience. Therefore, an individual diagnosed with hearing loss or using a hearing aid for the first time may require a more simplified explanation than an individual who has been managing hearing loss and using hearing aids for many years.

An individual's hearing loss in and of itself may create unique communication challenges for patients, regardless of the health care setting. The possibility that some individuals with hearing loss may not accurately hear some explanations and instructions may compound underlying barriers related to health literacy, further complicating the individual's ability to understand and process information provided during hearing assessments and consultations, as well as during other interactions with the health care system (see Chapter 3). Furthermore, possible language barriers need to be considered when consulting with patients and their families. Appropriate and comprehensible communication, both written and verbal, is crucial to further empower people with hearing loss, increasing the likelihood of successful self-management of hearing loss and uptake of appropriate treatments.

Improving Consumer Measures

In considering how to improve health literacy and understanding about hearing loss for individuals and their families, the committee suggests that researchers explore the possibility of developing an easy-to-understand measure of hearing and hearing loss for patients. There is currently no simple, consumer-friendly measure in wide use, and the results of standard hearing evaluations, in the form of audiograms and other measures of hearing and communication, may be too complicated for some individuals with hearing loss to understand or retain. Although audiometric results are complex, the committee recognizes the importance of the pure-tone thresholds recorded on an audiogram as an important, basic measure of hearing acuity and urges efforts to determine ways to better convey this important information. One such example of a counseling tool in audiology is the familiar sounds audiogram, although there is potential for further simplification into a tracking metric.

Physicians and researchers have identified and developed numerous measures to assess, quantify, and improve health. Table 6-1 provides examples of commonly used health measures and indicators. Although some consumers may not fully understand the underlying principles and physiological mechanisms of these measures, the measures provide individuals with a discrete number, usually associated with a range of outcomes (e.g., normal, at risk, high), that can be used to better understand risk factors and

TABLE 6-1
Examples of Health Measures That Are Available for Individuals to Easily Track and Monitor Changes in Their Health Status

Measure/Test	Testing Methods and Use
A1C	A1C levels are determined through a blood test and offer an average measure of blood glucose levels during the prior 3 months. A1C can be used to help identify and diagnose diabetes and pre-diabetes. Levels can be measured periodically to identify changes in blood glucose and to determine whether treatments and lifestyle changes are effective for individuals with diabetes (NIDDK, 2014).
Blood pressure	Blood pressure can be measured using an automated blood pressure cuff or with a cuff and a stethoscope. It is reported with two numbers: systolic, the pressure in the vessels when the heart beats, and diastolic, the pressure when the heart is at rest. Blood pressure measures are divided into three categories—normal, at risk (prehypertension), and high—and can be used to determine risk for heart disease, stroke, and kidney disease (CDC, 2014).
BMI	Body mass index (BMI) is an estimated measure of body fat, which is calculated by dividing a person's weight by his or her height and squaring that number. The BMI scale is usually divided into four categories—underweight, normal, overweight, and obese—and it can be used to assess risk for health conditions such as diabetes, hypertension, some types of cancer, and other conditions associated with obesity (CDC, 2015a).
Visual acuity	Visual acuity tests are administered using standardized vision charts. Visual acuity is frequently expressed as a fraction: The top number is the distance of the patient from the eye chart (usually 20 feet) and the bottom number is the distance away from the chart that a person with normal vision would need to stand in order to read the same line correctly as the person being tested. The test can be used to measure changes in vision over time and identify possible eye conditions that may need further treatment (NLM, 2016).

more easily track changes in their health over time. These specific measures also provide a simplified starting point for discussions between individuals and health care professionals about opportunities to improve health and well-being and may contribute to improved hearing health literacy.

The American Heart Association and health care systems across the United States have leveraged specific health metrics through Know Your Numbers campaigns in order to educate individuals about diabetes and about risk factors for cardiovascular disease, such as obesity, high cholesterol, and high blood pressure. These education initiatives encourage individuals with pre-diabetes and diabetes to track their weight and body mass index, blood sugar levels, cholesterol, and blood pressure (AHA, 2015; BCBS of Nebraska, 2016; Johns Hopkins University, 2016). In Australia, researchers developed a community-based Know Your Numbers intervention that focused on educating consumers in pharmacies about high blood pressure and other risk factors for stroke. Three months after measuring the participants' blood pressure and providing educational resources, knowledge about hypertension and its risk factors improved across the study population (Cadilhac et al., 2015). A similar consumer measure is needed for hearing.

An easy-to-remember consumer measure could be generated from the results of pure-tone audiometry, but a simplified, real-world measure of communication abilities could also be beneficial in providing consumers with understandable and realistic results. For many years, researchers have suggested that measuring speech recognition in noisy backgrounds has substantial benefits over the traditional assessment, which involves measuring speech recognition using lists of simple words that are presented at relatively high volumes in a quiet background (e.g., McArdle and Wilson, 2008; Smeds et al., 2015; Wilson, 2011). McArdle and Wilson (2008) argued that testing speech recognition in the presence of noise offers four primary advantages, including

- better alignment with the most common concern of people with hearing loss—understanding speech in noisy or complex acoustic environments;
- a more accurate assessment of the impact of hearing loss in real-world settings;
- informing the selection of the most appropriate hearing technology given individual needs; and
- helping set expectations regarding hearing aids and their performance in real-life situations.

Box 6-1 provides examples of hearing tests that were designed to measure speech recognition in noise by presenting the listener with sentences or words in the presence of various types and levels of background noise. Primarily, there are two types of tests that measure speech recognition in noise. The first uses fixed levels of speech and noise, with the outcomes reported as a percentage of words or sentences repeated correctly (i.e., 0–100 percent). In the second type, known as an adaptive procedure, the speech or noise levels, or both, are adjusted depending on the response of the listener, and the outcomes are reported in terms of signal-to-noise ratio in decibels (dB SNR). This ratio represents the difference between the level of speech and noise that is required for an individual to understand 50 percent of the words or sentences presented during the test. Evidence-based reference standards for dB SNR results have been established through tests of large numbers of people with normal hearing.

Box 6-1 EXAMPLES OF TESTS DESIGNED TO ASSESS SPEECH RECOGNITION IN NOISE

- **Bamford-Kowal-Bench Speech-in-Noise Test**—(Bench et al., 1979, 2006)
- **Connected Speech Test**—(Cox et al., 1987)
- **Digit Triplet Test/Digits-in-Noise Test**—(Jansen et al., 2010; Smits et al., 2013; Watson et al., 2012)
- **Hearing in Noise Test**—(Nilsson et al., 1994)
- **Listening in Spatialized Noise-Sentences Test**—(Brown et al., 2010; Cameron and Dillon, 2007; Cameron et al., 2011; Glyde et al., 2013)
- **Matrix Sentence Test**—(Kollmeier et al., 2015; Zokoll et al., 2013)
- **Quick Speech-in-Noise Test**—(Killion et al., 2004)
- **Speech-in-Noise Test**—(Killion and Villchur, 1993)
- **Speech Perception in Noise Test**—(Bilger, 1984; Kalikow et al., 1977)
- **Words-in-Noise Test**—(Wilson, 2003, 2011; Wilson and Strouse, 2002; Wilson et al., 2007)

These standards serve as a point of comparison for dB SNR measures for people with hearing loss, and they can provide an assessment of the ability to understand speech in noisy environments.[2] As part of a consultation with a hearing health care professional, these results—along with the pure-tone audiogram, which is a measure of hearing acuity—could provide a more comprehensive assessment of how individuals might function in real-life settings, which are frequently filled with background noise (e.g., restaurants, classrooms, offices with an open design, public transportation, sports arenas, gatherings of friends and family), and how hearing technologies and auditory rehabilitation may be used to improve communication. Although these tests do exist and have been validated in some cases, little is known about how frequently they are employed during hearing assessments and consultations.

The exploration, development, and widespread application of easy-to-understand and real-world tests of hearing loss could provide a basis for moving beyond the current focus on the audiogram. Additionally, a consumer-friendly measure, particularly if it were tied to outcomes of real-world tests, could be used to promote regular hearing assessments for those who have questions about changes in their hearing and would enable

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[2] For example, a result of –5 dB SNR indicates that the speech level was 5 dB lower than the noise level in order to correctly identify the words or sentences 50 percent of the time, which is a standard result for an individual with normal hearing. A +5 dB SNR indicates that the speech level had to be 5 dB higher than the noise level in order to achieve the same 50 percent correct score. This dB SNR outcome is considered poorer compared to someone with normal hearing and may be typical of some individuals with hearing loss.

individuals to more easily monitor changes in their hearing over time, potentially reducing confusion about hearing loss measures and empowering individuals to seek treatment. These types of easy-to-understand tests and measures could also be used to realistically set expectations and demonstrate the effectiveness of hearing aids in more realistic listening environments to individuals and their families so that they can compare them to un-aided hearing in those environments.

Improving Information for Consumer Comparisons

In order for consumers to obtain, process, and understand information relevant to hearing loss treatment options, easy-to-understand, evidence-based information needs to be readily available and presented by health care professionals following a diagnosis of hearing loss. Given the assortment of hearing aids and assistive technologies on the market, the decisions that individuals must make regarding which type of services or product will best meet their needs, preferences, and budgets can be overwhelming, and they are further complicated by marketing materials that do not meet health literacy standards. Currently, there are few independent information sources available to consumers that would allow easy comparisons across hearing aids and hearing assistive technologies. Furthermore, the lack of standardized terminology between manufacturers about the features and capabilities of these technologies makes comparisons even more challenging (see Chapter 4).

Consumer Reports recently issued a consumer's guide to buying hearing aids that offers advice on factors to consider when purchasing a hearing aid. However, the guide does not feature a head-to-head quality comparison across brands, as has been done with other consumer products (*Consumer Reports*, 2015). In an effort to better guide consumer decision making, the Hearing Loss Association of America (HLAA) developed a consumer checklist that provides individuals and their families with questions to ask when purchasing hearing aids (HLAA, 2016c). However, additional efforts are necessary in order to provide consumers with information that is easy to understand, fulfills health literacy requirements, and uses standardized terminology to describe hearing aid features. Consumer information on hearing aids and hearing assistive technologies should be made available through independent websites and other media. To ensure that consumers have the necessary tools to make informed decisions, websites with this information should include the following:

- comprehensive descriptions of the full range of hearing aids and hearing assistive technologies available and their features, including connectivity options and requirements; and

- comparative data on technical traits and differences, clinical traits and performance variations, and practical traits, such as variations in features, connectivity, and costs.

Empowering Individuals and Families through Education and Support

The path toward the recognition of hearing loss and the seeking of treatment can be influenced by numerous factors and will vary from one person to the next. Still, that path will often follow the transtheoretical model, also known as the stages-of-change model (see Figure 6-2). Since its development in the 1980s, the transtheoretical model has been applied to numerous public health concerns including smoking cessation, substance use, weight loss and obesity, cancer screening, HIV/AIDs testing, and medication compliance, and it has also been applied in the hearing loss literature (e.g., Laplante-Lévesque et al., 2012b, 2013, 2015; Ng and Loke, 2015; Saunders et al., 2012). Ng and Loke (2015) hypothesized that factors such

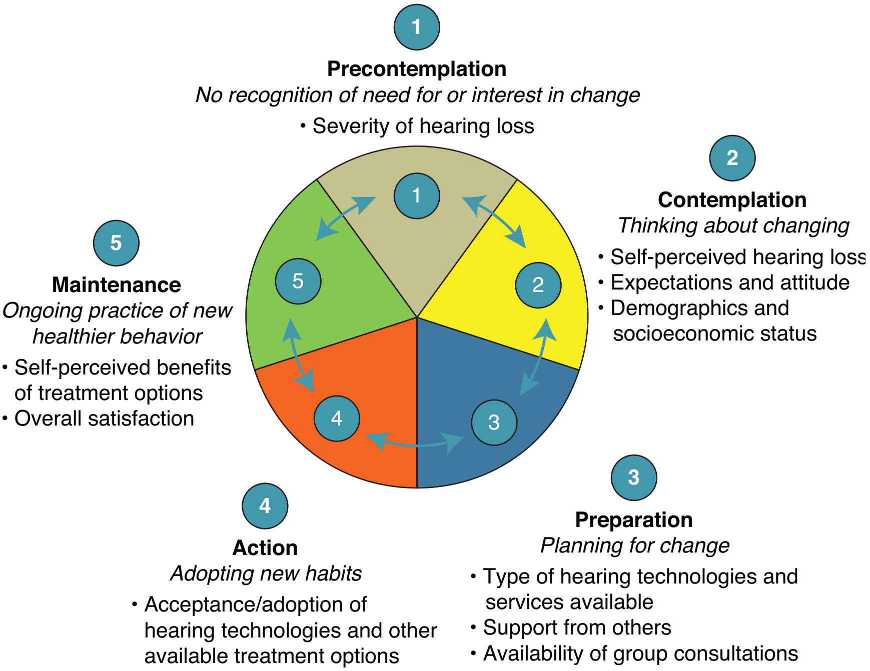

FIGURE 6-2 Transtheoretical model of behavior change.
SOURCES: Adapted from Ng and Loke, 2015, and Prochaska and Di Clemente, 1982. Reprinted with permission from Taylor and Francis, Ltd. Copyright British Society of Audiology; International Society of Audiology; Nordic Audiological Society.

as self-perception of severity of hearing loss, expectations about hearing aid efficacy, the types of hearing aids that are available, support from others, and the availability of group consultations may all contribute to how an individual advances through the stages of the transtheoretical model.

During the first stage, which can last up to approximately a decade, an individual begins to recognize and may admit to age-related hearing loss (precontemplation stage) (Davis et al., 2007). Even after a hearing loss is first recognized, it may take another period of time for that individual to seek assessment, diagnosis, and treatment (contemplation and preparation stages). Although the stages are somewhat fluid, the contemplation stage typically entails the individual confirming that the hearing loss exists, that it has an impact on everyday life, and that some action needs to be taken. It is also the phase in which the individual begins to consider possible actions and treatments options. During the preparation phase, the individual becomes poised to take action (e.g., talking more openly about the hearing loss with others, researching assessment and treatment options, making the first appointment). Active steps toward seeking assessment and diagnosis, as well as adopting a treatment option, represent the action phase. Following a diagnosis, some individuals may begin to wear hearing aids, use other assistive technologies, or participate in peer-support groups (maintenance phase), while others may choose not to take action (returning to the precontemplation and contemplation stages). Still others may decide not to use or maintain a hearing aid after it has been purchased (a breakdown in the action and maintenance stages).

The transtheroetical model exists within the broader social-ecological model that is described above and in Chapter 1. Numerous factors, external and internal, can influence an individual's progression or regression through the five stages of the transtheoretical model. As described above, the attitudes and beliefs of the individuals and the support of family and friends play a role in an individual's ability to recognize the problem, seek professional assistance, and use hearing aids and other technologies and services. Additionally, health care professionals, advocacy organizations, and the availability of community-based resources can also affect progress, both directly and indirectly. The specific individual needs, environment (e.g., living or working in a noisy environment rather than a quiet one), and preferences of the person will also affect progression through the model. There are times when an individual may be ready to take action but cannot because of a lack of resources or support at the health care system or community levels—challenges that are directly related to accessibility and affordability. Therefore, the committee reiterates the need for solutions at all levels of the social-ecological model that will in turn empower individuals to progress through the stages of change represented by the transtheoretical model and will ensure that care and support are readily available.

The committee believes that awareness, education, and community-based support are central factors in overcoming barriers that prevent people with hearing loss from getting the care and services that they need. The following sections explore the role of community-based education and support programs, advocacy organizations, and the Internet in educating, supporting, and empowering people with hearing loss as they move through the stages of the transtheoretical model. A subsequent section in this chapter will describe other aspects of community—work environments and the built environment—that can benefit and support people with hearing loss. (See below and Chapter 3 for the role of the health care community.) Chapter 4 and other sections throughout the report have described other mechanisms for empowering individuals to take a more active role in identifying and managing their hearing loss (e.g., mobile applications; over-the-counter wearable hearing devices; self-fitting hearing aids) with innovations developing in multiple areas.

Community-Based Education and Support

Studies suggest that portions of medical information presented at the time of diagnosis can be misunderstood or quickly forgotten (Kessels, 2003; Martin et al., 1990; Reese and Hnath-Chisolm, 2005). Although written information presented at the time of a diagnosis can be helpful in many ways, information provided in that form may not be sufficient to address the personal adjustment and psychosocial elements of living with hearing loss. In order to effectively meet the needs and preferences of people with hearing loss and their families, education and support should not terminate in the professional office setting; it needs to extend into homes and communities, where it can be available when individuals are ready to absorb and operationalize it. Educational and support resources can take numerous shapes, from formal auditory rehabilitation programs in audiology clinics (see Chapter 3) to informal community-based support groups and self-guided resources provided by advocacy organizations. It is essential that health care professionals, particularly hearing health care professionals, are fully aware of what resources are available in their communities and reliably connect individuals with hearing loss and their families with those resources.

Community-based support resources and peer-support groups dedicated to hearing loss can promote resilience and provide resources for individuals with hearing loss. In recent years, the United Kingdom has increased its emphasis on community-based support services, some of which are specifically designed for hearing loss and may provide good models for supporting individuals and families. In order to respond to some of the growing demands on primary care providers and hospitals, the government of Scotland has set up community-based "sensory support centres" to deliver support services to individuals with hearing or vision loss (Smith et al., 2015a). Services provided include hearing aid fittings, mobility training, the installation of smoke alarm systems and doorbells designed for individuals with hearing loss, the provision of other assistive technologies such as telephones and alarm clocks, and instruction on how to use hearing aids and hearing assistive technologies. A review of one of the support centers in rural Scotland concluded that clients were satisfied with the services and levels of empathy shown in the providers. Additionally, individuals who used the services cited reductions in feelings of isolation and increases in self-confidence, self-esteem, and sense of safety.

In another study from the United Kingdom, Pryce and colleagues (2015) examined the role of volunteers in providing community-based peer support for people with hearing loss. The researchers found that volunteers can be used to bridge the gaps between audiology services and the community. However, the interactions were mostly limited to hearing aid maintenance and troubleshooting (e.g., cleaning, battery changes, re-tubing) and did not extend to psychosocial support and adjustment (Pryce et al., 2015). Despite the limited focus of the interactions described in this study, volunteers could be trained to provide greater support in psychosocial areas. For example, in previous studies (e.g., Brooks and Johnson, 1981; Norman et al., 1994) volunteers were trained to provide pre- and post-fitting counseling in an effort to set expectations, improve satisfaction, and increase the use of hearing aids among first-time hearing aid users. In addition to the use of volunteers for the provision of community-based support, ongoing studies are also investigating the possible role of community health workers in identifying and screening for hearing loss, as well as implementing community-based rehabilitation programs (see Chapters 3 and 5).

Peer-support groups can provide opportunities for individuals to connect with others who have hearing loss in order to share concerns, experiences, and strategies for coping with challenges in daily life, and these groups can foster resilience and restore social identity. The possible benefits and limitations of peer-support groups, including Internet- and phone-based groups, for other health conditions (e.g., cancer, diabetes, mental health) have been widely discussed in the literature, with mixed results (e.g., Campbell et al., 2004; Dale et al., 2012; Galinsky and Schopler, 2013; Griffiths et al., 2012). However, few studies have focused on peer-support groups designed for individuals with hearing loss and their families, and little is known about how prevalent or active such groups are throughout the United States. Many local chapters of HLAA (described below) offer peer-support groups led by trained volunteer leaders. Additionally, some state universities with speech and hearing centers and academic medical centers (e.g., Indiana University, 2016; University of Arizona, 2016) have established counseling or support groups, usually led by audiologists, where participants can share experiences and discuss the challenges of living with hearing loss. Cummings and colleagues (2002) reviewed a Web-based peer-support group for individuals and families. The researchers found that participants with less real-world support and less hearing loss were more active within the group, and those who were most active derived the most personal gains. The use of peer-support groups may offer a valuable mechanism for community-based education and support, but further research is needed to establish efficacy and determine best practices.

Advocacy organizations at the national and local levels can also play an important role in supporting those affected by hearing loss. In the United States, HLAA is a national membership and advocacy organization dedicated to improving communication access for people with hearing loss through education, support, and public policy and advocacy work. In addition to working at the national level, the organization has a network of approximately 200 state and local chapters. These chapters organize meetings, provide psychosocial support, make connections among people who have hearing loss, and offer education related to living with hearing loss and assistive services and technologies. Although most states have multiple local chapters, there are 13 states without a state or local chapter,[3] leaving large geographic regions without access to these resources and supports (HLAA, 2016a).

In addition to HLAA, which covers a broad constituency of types of hearing loss, there are organizations that provide support to individuals with more severe hearing loss and deafness, such as the Association of Late-Deafened Adults, the National Association of the Deaf, the American Cochlear Implant Alliance, and TDI (formerly the Telecommunications for the Deaf and Hard of Hearing, Inc.) (ACI Alliance, 2016; ALDA, 2016; NAD, 2016; TDI, 2016). A number of international organizations also are geared toward maximizing independence for people with hearing loss, such as Action on Hearing Loss and Hearing Link in the United Kingdom, Better Hearing Australia, and the Canadian Hard of Hearing Association (Action on Hearing Loss, 2016b; Better Hearing Australia, 2016; CHHA, 2016; Hearing Link, 2016). Although the resources and services offered through advocacy organizations certainly provide value, the reach and efficacy of available resources have not been studied.

As young adults with hearing loss transition from adolescence to adulthood, they may require focused community-based education and support. When they leave secondary school systems, where the Individuals with Disabilities Education Act ensures that they receive an education tailored

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[3] Alabama, Alaska, Hawaii, Louisiana, Maine, Mississippi, Montana, Nevada, New Hampshire, North Dakota, South Dakota, West Virginia, and Wyoming.

to meet their needs, they must advocate for themselves and clearly express their needs, preferences, and rights. For youth with disabilities, including those with hearing loss, reviews of available literature and meta-analysis of data have identified small, but positive associations between specialized education and support (e.g., the development of self-advocacy skills, vocational education, and transition programs) and positive outcomes in employment and higher levels of educational attainment (Haber et al., 2016; Schoffstall et al., 2015; Test et al., 2009). In communities across the United States, vocational rehabilitation counselors can offer a blend of educational and support services for young adults to help them build the skills and knowledge needed to maximize success in workplaces, colleges, and universities (Schoffstall et al., 2015). Some communities and states offer summer programs to assist college-bound students with hearing loss in their transition (e.g., Marion Downs, 2016; RIT, 2016). Additionally, peer-support groups and advocacy organizations can provide community-based resources and play a supportive role to better prepare young adults for managing real-world challenges.

At the other end of the age spectrum, older adults may also need specialized education and support. Beyond the community-based education and support resources that are specific to hearing loss, Schneider and colleagues (2010) found that older adults with hearing loss, especially untreated hearing loss or more severe hearing loss, are more likely than those without hearing loss to use community support services, such as Meals on Wheels programs, community-based nursing services, and home care services. This study also found that these individuals had an increased reliance on nonspouse family members and friends for assistance with daily activities, including grocery shopping and household chores. In a 5-year follow-up, individuals with hearing loss—both hearing aid users and those with untreated hearing loss—relied more heavily on community services and nonspouse family or friend support, with increasing use seen by those with greater severity of hearing loss. The participants with hearing loss were more likely to report having low health status, having experienced a fall in the last year and having an impairment related to walking, vision, or cognition (Schneider et al., 2010). These comorbid health concerns combined with the hearing loss may contribute to the increase in demands for the services described in this study. Understanding the community services and support needs of older adults with hearing loss will be beneficial as communities prepare for aging populations that will include large proportions of individuals with hearing loss and other health concerns that could affect independence.

The Role of the Internet in Educating Individuals and Their Families

When faced with a health concern or a new diagnosis—including hearing loss—many individuals and their families turn to the Internet for information and support (e.g., Bundorf et al., 2006; Couper et al., 2010; Medlock et al., 2015; Purcell and Rainie, 2014). Additionally, health care systems are now employing the Internet as a means to facilitate patient education and self-management of chronic conditions. In the United States, Internet access has increased rapidly since the 1990s, with more than 87 percent of the population using the Internet as of 2014 and almost 75 percent of households having high-speed Internet as of 2013 (File and Ryan, 2014; World Bank, 2016). Despite high rates of overall access, there are still groups with lower levels of access, including older populations, people with lower levels of education and income, those who live in rural areas, and ethnic and racial minority populations, especially black and Hispanic populations (File and Ryan, 2014; Pew Research Center, 2014).

The methodologies used to study Internet and computer use among individuals with hearing loss vary, as do the findings. For the most part, studies have found that those with hearing loss use the Internet at a rate similar to that of the general public. However, some studies have found higher rates of Internet use among those with hearing loss compared to their age-matched peers without hearing loss or the general public (Barak and Sadovsky, 2008; Henshaw et al., 2012; Thoren et al., 2013). Despite these findings, Henshaw and colleagues (2012) found that Internet use among adults between the ages of 50 and 74 years was reduced among individuals with more severe hearing loss compared with those with mild to moderate loss. In another study of older adults with hearing loss ages 55 to 95 years, Moore and colleagues (2015) concluded that increasing age is often associated with lower computer literacy and self-efficacy, a finding that is also reflected in the older adult population in general, which tends to have lower rates of technology adoption and Internet use (Pew Research Center, 2014). All of these findings may change in the coming decades as baby boomers, who tend to be more tech savvy, grow older.

Individuals searching for information on hearing loss on the Internet can get tens of millions of results within fractions of a second. These results have varying degrees of relevance and reliability, and the sheer number can present a challenge in terms of identifying which Web-based resources can be trusted to provide evidence-based information. Health information from government agencies, national advocacy organizations, and health care systems offer a wealth of helpful information. However, reviews of the readability of hearing and hearing loss information on the Internet suggest that consumers would need between 9 and 14 years of education to comprehend the available information, representing a sizable mismatch when compared to average health literacy rates in the United States[4] (Laplante-Lévesque and Thoren, 2015; Laplante-Lévesque et al., 2012a). Although readability is a fundamental factor in the comprehension of the information, Laplante-Lévesque and colleagues (2015) noted, "Readability is only one of the many prerequisites for successful . . . understanding, comprehending, and making good use of health information" (p. 287). Additional factors in the comprehension of information include usability, visual design, ease of navigation, searchability, reliability, compatibility with multiple Web browsers and devices, and accessibility. Box 6-2 presents examples of Internet resources on hearing loss.

Regardless of the type of information and the mechanism by which that information is provided, Internet-based resources must be written and presented at appropriate levels of literacy and usability to maximize comprehension by the target audiences. Health literacy and usability are imperative design factors, especially when the target audiences are older adults with hearing loss and other populations that may have limited Internet access and computer literacy. Since an emphasis on health communications was announced as part of Healthy People 2010, the Department of Health and Human Services (HHS) and its agencies have released numerous freely available resources to encourage and facilitate public and private entities, such as advocacy organizations, nonprofit organizations, and health care systems, to simplify Internet-based health information. For example,

- Usability.gov is an HHS-sponsored website that provides resources and best practices for Web developers to make websites more accessible and user friendly (HHS, 2016b).
- HHS has published an online guide to health literacy and simplifying content to better meet the needs of the public (HHS, 2016a).
- The National Institutes of Health (NIH) Office of Communications & Public Liaison has a webpage devoted to clear communication that features information on health literacy and cultural respect (NIH, 2016).
- The Centers for Disease Control and Prevention (CDC) has a webpage and numerous resources devoted to health literacy and has created the Clear Communications Index, which is a tool to help plan and assess materials and resources that will be used for public communication purposes (CDC, 2015b).

The hearing loss community and advocacy organizations need to evaluate Internet-based resources, take advantage of available government resources,

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[4] Studies suggest that approximately one-third of the U.S. population has low levels of health literacy defined as basic and below basic (e.g., the ability to read and comprehend basic medical instructions) (HHS, 2008; NCES, 2006).

Box 6-2 EXAMPLES OF INTERNET RESOURCES FOR ADULTS WITH HEARING LOSS

Consumer and Patient Organizations:

- Action on Hearing Loss (www.actiononhearingloss.org.uk)
- American Cochlear Implant Alliance (www.acialliance.org)
- Association of Late-Deafened Adults (www.alda.org)
- Better Hearing Australia (www.betterhearingaustralia.org.au)
- Canadian Hard of Hearing Association (www.chha.ca/chha)
- Hearing Link (www.hearinglink.org)
- Hearing Loss Association of America (www.hearingloss.org)
- National Association of the Deaf (www.nad.org)
- TDI (formerly Telecommunications for the Deaf and Hard of Hearing) (www.tdiforaccess.org)

U.S. Federal Government Agencies:

- Americans with Disabilities Act information (www.ada.gov)
- Centers for Disease Control and Prevention (resources about noise-induced hearing loss) (www.cdc.gov/niosh/topics/noise)
- Department of Defense Hearing Center of Excellence (www.hearing.health.mil)
- Department of Education Rehabilitation Services Administration (www.rsa.ed.gov)
- Department of Veterans Affairs (www.research.va.gov/topics/hearing.cfm)
- Disability.gov (www.disability.gov)—multiple agencies
- Federal Communications Commission (www.fcc.gov/consumer-and-governmental-affairs/about-bureau/disability-rights-office/general/disabilities)
- Federal Trade Commission (www.consumer.ftc.gov/articles/0168-buying-hearing-aid)

and implement strategies to optimize the information and educational materials on hearing and hearing loss for individuals and their families. Additionally, health care professionals need to be aware of the available online information sources and resources, and they should discuss the wide range of resources with their patients to ensure that people with hearing loss and their families are directed to reliable, evidenced-based information.

THE ROLE OF COMMUNITIES

Individuals and families are intrinsically woven into their communities, as is indicated in the social-ecological model. Communities are complex social structures where all people live, work, socialize, learn, and play. Most of the topics discussed throughout this chapter touch on community

- Food and Drug Administration (www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/HearingAids/default.htm)
- National Institute on Aging (www.nia.nih.gov/health/publication/hearing-loss)
- National Institute on Deafness and Other Communication Disorders (www.nidcd.nih.gov)
- National Institute on Disability, Independent Living, and Rehabilitation Research (www.acl.gov/programs/NIDILRR)

Professional Associations:

- Academy of Doctors of Audiology (www.audiologist.org/patient-resources)
- American Academy of Audiology (www.howsyourhearing.org)
- American Academy of Otolaryngology-Head & Neck Surgery (www.entnet.org/content/patient-health)
- American Speech–Language–Hearing Association (www.asha.org/public/hearing/hearing-loss)
- International Hearing Society (www.ihsinfo.org/IhsV2/Hearing_Health_Info/Index.cfm)

Additional Resources:

- AARP (www.aarp.org/health/conditions-treatments/hearing-resource-center)
- Consumer Reports Hearing Aids Guide (www.consumerreports.org/cro/hearing-aids/buying-guide.htm)
- Mayo Clinic (www.mayoclinic.org/diseases-conditions/hearing-loss/basics/definition/con-20027684)
- World Health Organization (www.who.int/mediacentre/factsheets/fs300/en)

in one way or another. This section focuses on workplace environments and the built environment. Although these factors are vital to supporting and encouraging participation for people with hearing loss, these environments are not always designed specifically for people with hearing loss and may require some form of modification or education to fully support people with hearing loss. This section also provides a high-level overview of the protections and opportunities that are offered by the Americans with Disabilities Act (ADA), which was signed into law in 1990 and revised in 2009.

Employers and the Workplace

Communication is necessary in the vast majority of jobs and career paths, whether it involves communication with a client or a coworker in a conference room or it ensures an employee's safety in a factory or industrial setting. In recent decades the profile of workplaces and workers has changed; more jobs than ever are found in office settings, and individuals are remaining in the workforce longer, increasing the likelihood that hearing loss could affect interactions and relationships with coworkers, job performance, promotion potential, and overall employment opportunities at some point in workers' careers (Munro et al., 2013). Despite the enactment and revision of the ADA, which provides a series of protections for employees (see Box 6-3), individuals with hearing loss may continue to experience stigma, unfavorable attitudes, employment disadvantages, and overt or perceived discrimination in the workplace. For example, among 174,610 allegations of discrimination filed with the U.S. Equal Employment Opportunity Commission under Title I of the ADA between 1992 and 2003, Bowe and colleagues (2005) found that almost 9,000 complaints had been filed by individuals with some degree of hearing loss. Additionally, a study by McMahon and colleagues (2008) concluded that of the discrimination claims they studied, hearing was the second most cited reason—after back problems—for claims related to hiring decisions.

Box 6-3 HIGHLIGHTS OF TITLE I OF THE AMERICANS WITH DISABILITIES ACT[a]

- Employers with 15 or more employees may not discriminate against individuals with actual or perceived disabilities with regard to the following:
    - job applications (e.g., qualification standards, selection criteria);
    - hiring procedures (e.g., testing, screening);
    - promotion or advancement;
    - compensation (e.g., pay, benefits);
    - training opportunities;
    - discharge or dismissal; or
    - other employment terms, conditions, or privileges.

- Employers with 15 or more employees are required to make reasonable accommodations for employees with disabilities, which may include the following:
    - job restructuring;
    - modified work schedules;
    - reassignment;
    - acquisition or modification of equipment or devices;
    - adjustment or modifications of examinations, training materials or policies;
    - availability of readers or interpreters; and
    - other similar accommodations.

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[a] Americans with Disabilities Act of 1990, Public Law 101-336, 101st Cong. (July 26, 1990).

People with hearing loss can experience a variety of challenges in terms of employment and the workplace, including obstacles related to finding employment, career development, promotion and career advancement, equitable compensation, and the balance between job demands and a sense of control or confidence in managing work-related situations (Southall et al., 2010, 2011; Tye-Murray et al., 2009). When they occur, these challenges may reflect the presence of stigma in the workplace. In interviews conducted by Southall and colleagues (2010), participants described instances of being compelled to give up responsibilities or duties; being demoted, terminated, or forced to seek disability payments through Social Security; and being pressured or bullied by coworkers and supervisors. For many individuals, these experiences created stress and isolation, reinforced stigma, and undermined self-confidence (Southall et al., 2010).

The perceived attitudes and beliefs of coworkers, supervisors, and employers have been cited as reasons for employees not disclosing their hearing loss, not seeking accommodations in the workplace, and delaying assessment and treatment for hearing loss (Clements, 2015; Kochkin, 2007a; Southall et al., 2011). However, as described earlier, not everyone perceives or responds to stigma in the same way. The majority of participants (70 percent) in focus groups[5] conducted by Tye-Murray and colleagues (2009) had disclosed their hearing loss in the workplace, and many described positive interactions with and support from coworkers, supervisors, and employers. The participants in this study maintained positive, "can-do" attitudes; had used effective coping mechanisms; developed the resolve and stamina to overcome barriers; and noted that hearing loss was becoming more commonplace in professional employment settings because of the aging baby boomer generation (Tye-Murray et al., 2009). In part, these employment experiences can be attributed to supportive relationships and environments—beneficial factors that are often associated with positive outcomes and resilience. These positive experiences are encouraging and lead to the question of how to ensure these types of experiences become the norm in workplaces across the United States.

Although Tye-Murray and colleagues (2009) suggest that stigma associated with hearing loss in the workplace has declined, perceived stigma is still a concern. Further reducing stigma, fostering a supportive environment in the workplace, and developing coping mechanisms and resilience among employees with hearing loss are crucial steps to eliminating discrimination, promoting broader support in the workplace, and enabling employees to remain in the workforce longer, if they so choose. These steps are also necessary to encourage and empower employees to see the value in seeking

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[5] Focus groups included 48 individuals with confirmed hearing loss—27 men and 21 women, ages 29–79 years (average 61).

assessment and treatment for possible hearing loss rather than hiding it and possibly allowing it to interfere with performance, employment, and career opportunities. Some auditory rehabilitation programs (see Chapter 3) include instruction on assertiveness and communication strategies, which can be beneficially applied in the workplace. A group-based rehabilitation program evaluated by Habanec and Kelly-Campbell (2015) encouraged people with hearing loss to be assertive in the workplace in order to ensure that their communication needs were being met, that effective communication strategies with the employer were being used, and that employees were aware of their rights and employer obligations under the ADA.

Additionally, people with hearing loss need to receive information from health care and hearing health care professionals as well as from employers about the accommodations that are available, the protections that are afforded by the ADA, and the resources that are available through the U.S. Equal Employment Opportunity Commission in the event that workplace discrimination does occur (e.g., EEOC, 2015). This type of information is also important for young adults as they transition from an academic setting to join the workforce and begin to navigate various workplaces and career paths for the first time. On the employer side, human resources professionals and hiring supervisors need to have information on what are reasonable accommodations for hearing loss and how to acquire them; and tools for interviewing, hiring, working with, and supporting people who have hearing loss.

Built Environment and Universal Design

The acoustic profile of community and personal spaces in which people live, work, learn, and gather determines the atmosphere and functionality of those locations just as much as other aspects of structure and design. For people with hearing loss, the availability of hearing aids and hearing assistive technologies, acoustics, and the connections to other communications systems (see Chapter 4) may mean the difference between participating in conversations and engaging with their surroundings and feeling isolated. For the purposes of this report, the built environment refers to public and private spaces within a community that can be designed or altered to improve the experience for people with hearing loss through enhanced acoustics and accessibility. The committee believes that the built environment is an intrinsic part of addressing hearing loss and one that represents a major opportunity where solutions at many levels of the social-ecological model can be used to further empower people with hearing loss and enhance listening conditions for everyone. This is a broad topic with a number of ongoing efforts.

In addition to providing individuals with hearing loss meaningful protections and accommodations within the workplace, the ADA also includes provisions for the built environment. Title II (local, state, and federal government facilities) and Title III (places of public accommodation and commercial facilities[6]) of the ADA were designed to make public spaces more accessible for people with disabilities, including individuals with hearing loss. Additionally, section 504 of the Rehabilitation Act of 1973, and its subsequent amendments, requires that programs that receive federal funding provide accommodations in order to ensure effective communication. These laws emphasize that communication with individuals who have a disability must be equivalent to those without a disability, and thus auxiliary aids or services should be provided whenever requested and feasible. Examples of communication services and technologies for individuals with hearing loss may include the following:

- written materials, exchange of written notes, or the availability of note takers;
- real-time, computer-aided transcription;
- amplifiers and hearing aid–compatible telephones;
- open and closed captioning, as well as closed captioning decoders;
- various telecommunication systems (e.g., captioned telephones, video phones);
- videotext screens and displays;
- secondary auditory programs; and
- other assistive technologies or systems.

When a government facility, school, or business is unable to provide a requested aid or service because of financial limitations, the law requires that other forms of assisted communication be offered to ensure that the person with hearing loss understands what is being said and can communicate effectively (ADA National Network, 2014). The committee emphasizes the importance of these laws in ensuring that all students with hearing loss (from kindergarten through post-doctoral programs) regardless of race/ethnicity, socioeconomic status, or geographic location have access to communication aids and assistive services in schools and universities, thus giving them an equal opportunity to learn; to actively engage with their peers, teachers, and professors; and to thrive.

In 2010 the Department of Justice released revisions to ADA regulations that included the ADA Standards for Accessible Design. The standards outline specific minimum requirements that are enforceable for newly designed

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[6] Examples of places of accommodation include any place where the public may conduct business or gather: restaurants, hotels, movie theaters, places of worship, bakeries, shopping malls, stores of all types, museums, libraries, public transportation hubs, zoos, health clubs, hospitals, schools, homeless shelters, senior citizen centers, etc.

or renovated public spaces as defined under titles II and III (DOJ, 2016). For example, sections 219 and 706 of the document provide standards and requirements for the implementation of assistive systems, and sections 215 and 702 describe requirements for fire alarm systems (DOJ, 2010). Acoustic design in the built environment has been a point of consideration for advocacy efforts and guideline development for decades with mixed results. For example, in 1993 the U.S. Architectural and Transportation Barriers Compliance Board—now called the U.S. Access Board—commissioned a report to provide guidelines for designated quiet areas in restaurants. The purpose of the quiet areas was to allow people with hearing loss to enjoy the experience of dining out while more easily interacting and communicating with other people around them.[7] However, these guidelines have not been endorsed or implemented broadly. The availability of design standards and guidelines is a valuable step to strengthening the built environment and ensuring equitable accessibility. However, it is the consistent prioritization, application, and enforcement of evidence-based standards and guidelines that is needed in order to make real differences in the coming decades. Box 6-4 provides additional examples of current design standards and guidelines that are relevant to creating favorable acoustic environments and greater accessibility for people with hearing loss.

As discussed in Chapter 4, hearing assistive technologies include systems that employ transmitters, receivers, and coupling technologies to connect listeners to the source of sound via technologies such as wired devices (e.g., receivers with headsets), induction loops, or infrared or radio technologies (DOJ, 2010). These systems may also include technologies such as Bluetooth and will likely encompass emerging technologies as they become available. The installation of induction loops (also referred to as hearing loops) are an example of one type of hearing assistive technology that can be integrated into the built environment and has been described in various news outlets recently (e.g., National Public Radio, *The New York Times*, and *Scientific American*) (Hearingloop.org, 2015). As described in Chapter 4, when installed within a public space, induction loops can be paired with hearing aids and cochlear implants that have embedded telecoil technology to directly receive the transmission from the sound system. While this pairing requirement may be a limiting factor for those without hearing aids, hearing loops have been installed in a variety of public spaces, including theaters, museums, airports, sports arenas, classrooms and audi-

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[7] Personal communication. Email to staff for the Committee on Accessible and Affordable Hearing Health Care for Adults from Daniel Fink, Quiet Areas in Restaurants. Final report to U.S. Architectural and Trasportation Barriers Compliance Board by R. Moulder, 1993. Received January 20, 2016. Available by request from the National Academies of Sciences, Engineering, and Medicine Public Access Records Office. For more information, email PARO@nas.edu.

Box 6-4 EXAMPLES OF DESIGN STANDARDS AND GUIDELINES FOR ENHANCING THE BUILT ENVIRONMENT

- Department of Justice's ***ADA Standards for Accessible Design*** "set[s] minimum requirements—both scoping and technical—for newly designed and constructed or altered State and local government facilities, public accommodations, and commercial facilities to be readily accessible to and usable by individuals with disabilities" (DOJ, 2010, p. 1).
- American National Standards Institute's ***American National Standard Acoustical Performance Criteria, Design Requirements, and Guidelines for Schools Part 1 and Part 2*** are available to guide the design of classroom settings, both permanent and temporary (part 1 and part 2, respectively), that ensure optimal speech comprehension for students.
- ASTM International's ***Standard Guide for Open Office Acoustics and Applicable ASTM Standards*** provides guidance for architects, engineers, and office managers who are interested in enhancing the acoustic environment and privacy in an open office setting.
- The Ceilings & Interior Systems Construction Association's ***Acoustics in Healthcare Environments*** is a white paper that provides design strategies and guidance to improve patient experience, privacy, and safety in health care settings.

toriums, places of worship, and other large venues. However, the use of this technology is not limited to large public venues, as it can also be installed in private homes and on other smaller scales (Shaw, 2012). Current efforts to further expand the use of hearing loops in public spaces include installation in subway booths by the New York City Metropolitan Transit Authority and in taxicabs, post offices, and banks in the United Kingdom (Myers, 2010; Shaw, 2012). Further efforts to provide hearing assistive technologies and ensure compatibility among assistive technologies and across other communications technologies (e.g., phone, emergency alert systems) are critical (see Chapter 4).

In addition to the availability of hearing assistive technologies and services, the built environment can also be augmented to permit an optimal acoustic environment that benefits all individuals, regardless of hearing ability. Universal design is a concept that calls for environments and products to be designed so that they are "usable by all people to the greatest extent possible" (Mace et al., 1991, p. 2). The researchers who conceived universal design believed that the solutions should be of little or no cost and should simplify everyone's lives. Sidewalk cutouts are a prime example of a universal design element: There is little or no additional cost associated with the cutouts, and they benefit people who use wheelchairs, scooters, walkers, and canes, as well as people pulling luggage, pushing strollers, riding bikes, or using wheeled dollies. In terms of improving the acoustic environment to benefit those with hearing loss and the general public, universal design elements could include installing noise-dampening panels, insulation, floor covering/carpet, and plush furnishings; diminishing excessive background noise whenever possible; optimizing reverberations; and configuring floor plans and workspaces to enhance acoustics (CHHA, 2008). The committee urges the development, evaluation, and implementation of design elements that can optimize acoustics in public spaces whenever possible, with an emphasis on universal design solutions. Additional work in the arena of universal design and the built environment in terms of ameliorating the effects of hearing loss is also needed.

PUBLIC EDUCATION AND AWARENESS

Society is the all-encompassing level of the social-ecological model within which all other activities occur. At this level, laws, regulations, policies, culture, and social norms shape solutions that are implemented at community and organizational levels, which then affect individuals with hearing loss, their families, and their social networks. The public, broadly speaking, also resides at this level. This section will explore public attitudes toward and understanding of hearing loss. It will consider how the media, public awareness campaigns, and advocacy efforts can be used to better educate the public, thus building a more supportive society and public experience for people with hearing loss. Although large-scale, nationwide initiatives that are designed to influence the public can be expensive; time consuming; requiring of multipoint stakeholder partnerships; and challenging to plan, execute, and measure, the solutions at this level arguably offer the potential for the largest impact and benefit to the most people.

Public Attitudes and Understanding

Changing public attitudes and understanding represents another opportunity to reduce the stigma that individuals with hearing loss experience. Although a few studies and targeted surveys have reported a positive evolution in public attitudes (described below), some literature suggests that individuals with hearing loss can be deemed by others as being old, socially inept, less friendly, cognitively impaired, or poor communication partners (Clements, 2015; Erler and Garstecki, 2002; Wallhagen, 2010). For example, when people respond inappropriately to verbal cues or do not respond at all, those people may be mistakenly perceived as being confused or being disengaged from or disinterested in their surroundings, when in fact the person did not hear the cue. Although negative public attitudes and stigma are serious concerns and can have a strong impact on the attitudes, beliefs, and decision making of people with hearing loss, interviews of people with hearing loss and targeted surveys suggest that public perceptions might be improving (AARP and ASHA, 2011; Rauterkus and Palmer, 2014; Wallhagen, 2010). This shift may be a result of an increased awareness and acceptance of disabilities in recent decades; the aging of the baby boomer generation, which is experiencing and openly discussing chronic, age-related health conditions and focusing on living well; younger generations that tend to have more tolerant views of individual differences; and advances in technology that provide individuals with new hearing and communication options.

Interviews of individuals with hearing loss suggest that there is an overall perceived lack of awareness and understanding about hearing loss among the general public (Southall et al., 2010). Surveys focused on noise-induced hearing loss shed some light on knowledge and understanding of this specific type of hearing loss. In a survey of university students and faculty, Shah and colleagues (2009) found that a large majority of participants (85 percent) expressed some concern about age-related hearing loss, and almost three-quarters (73 percent) were interested in learning about opportunities to prevent noise-induced hearing loss. However, participants cited a limited availability of information on hearing loss and prevention (Shah et al., 2009). Despite the possible gaps in available information, college students were generally knowledgeable about noise-induced hearing loss, with most participants correctly stating that this type of hearing loss could not be cured and was not reversible (Crandell et al., 2004; Shah et al., 2009). However, Crandell and colleagues (2004) found that young African American respondents were less likely to correctly answer questions about the reversibility of noise-induced hearing loss and symptoms related to excessively loud, potentially damaging noise. In considering these findings, the authors also noted that young African Americans were also less likely to report exposure to activities associated with risks for noise-induced hearing loss (e.g., motorcycle riding, racing cars, and listening to portable music devices).

The public also seems to be unaware of the difficulties and challenges that people living with hearing loss experience on a daily basis (Southall et al., 2010). Interviews focused on hearing loss in the workplace indicate that people do not necessarily know how to respond to or communicate with individuals who have hearing loss. Another commonly cited concern from these interviews was that colleagues tend to forget about an individual's hearing loss and need to be reminded by the person with hearing loss. Table 6-2 lists basic communication strategies that can be used by friends, family members, coworkers, and the public to enhance communication with individuals who have hearing loss. Although many of these strategies target general interpersonal communication skills, they also offer the possibility of increasing comprehension and reducing frustrations.

TABLE 6-2
Examples of Communication Strategies

Strategy	Rationale
Speak face-to-face	When the speaker's face is turned toward the listener, there is improved signal-to-noise ratio, and the listener uses facial cues to fill in the gaps that he/she may not have heard.
Reduce background noise	The ability to understand speech in the presence of background noise or distractors (e.g., television or restaurant noise) declines as a function of age, even for older adults without hearing loss.
Speak slower, instead of louder	When someone speaks loudly or shouts, it actually distorts the speech, often making it more difficult to understand. Also, shouting can make both the speaker and the listener more stressed.
State the topic	By making the topic of conversation clear at the beginning, the listener can more effectively use context cues to fill in the gaps.
Rephrase the statement	Repeating oneself becomes frustrating for the speaker and the listener. When the question or statement is rephrased, the listener has more context cues to fill in the gaps. In addition, some words are actually easier to hear, depending on the person's hearing loss and the frequencies of the sounds in the word.

SOURCES: Adapted from Mamo et al. (2016) and Marrone et al. (2012). Reprinted with permission from ASHA. Copyright 2012. Reprinted with permission from Elsevier. Copyright 2016.

During the committee's third workshop, Zina Jawadi and Patrick Holkins, speakers for the panel that focused on the young adult perspective, described hearing loss as an invisible disability that is often misunderstood, noting that moderate hearing loss is especially difficult for the public to understand in comparison to deafness (Holkins, 2015; Jawadi, 2015). A general lack of understanding by the public can contribute to negative attitudes and can lead to stigma, which highlights the importance of public education efforts and campaigns that can reach diverse audiences through a variety of mechanisms.

The Role of the Media

Very little academic research exists on how hearing loss is represented in the media. Anecdotal experience and indirect references in the literature suggest that hearing loss is often portrayed as something comical in entertainment media (Foss, 2014; Noble, 2009). Cartoons, comic strips, television shows, and movies have depicted hearing loss using images that commonly involve an older person cupping his or her hand around an ear or using an ear trumpet, a person who completely misunderstands a conversation and responds inappropriately, or a person shouting at someone with some degree of hearing loss. The media uses these types of images as a comedic tool, in part, because most people have experienced amusing miscommunications due to a misheard statement, regardless of hearing loss; therefore, the audience can relate to these images to some extent. However, this type of comedy is not only insensitive to people who live with hearing loss, but it also reinforces public misperceptions and stigma associated with hearing loss.

A review of 276 fictional television shows originally broadcast between 1987 and 2013 examined how hearing loss has been portrayed in the media and why stigma has been perpetuated (Foss, 2014). The review focused on complete, start-to-finish storylines that featured characters who experienced hearing loss, most of which was sudden and due to an acute cause (e.g., foreign object, explosion, infection, magic). Therefore, this review did not capture all scenes or all images of hearing loss. The review found instances of hearing loss in 11 television shows over a total of 47 episodes. The characters that experienced the hearing loss were typically young, attractive professionals, and in the majority of cases (8 out of 11) the hearing loss was short-term and remedied by the end of the episode. A total of three characters experienced permanent hearing loss, with the loss being age-related in only one case. In all three cases, the character with permanent hearing loss adopted hearing aids, but there were no challenges with using the devices, there were no other accommodations or support needed, and the individual's hearing was restored completely by the hearing aid—a combination of outcomes that is not very realistic. Despite many inaccuracies in the storylines studied, most characters denied the presence of their hearing loss and tried to hide it from their coworkers and friends—a reaction that is common in real life (Foss, 2014).

As discussed in the IOM report on the public health dimensions of epilepsy, a highly stigmatized health condition, the media portrayal of health concerns is an important tool for educating large audiences, increasing awareness, and possibly reducing stigma (IOM, 2012). In 2005 more than half of the respondents to the Porter Novelli HealthStyles survey reported that they learned new information about a health condition or disease through television dramas or comedies (CDC, 2005). Box 6-5 summarizes lessons that were highlighted in the IOM epilepsy report and the lack of storylines featuring hearing loss, especially age-related hearing loss, combined with the high prevalence of and overall misperceptions about hearing loss indicate that there is an opportunity for action. As concluded in the CDC's analysis of the HealthStyles survey, "TV dramas/comedies serve a critical health education function when they provide accurate, timely information about disease, injury and disability in storylines for the vast majority of U.S. residents who watch at least a few times a month, and especially for 64% of the population . . . who are regular viewers watching

Box 6-5
LESSONS TO PROMOTE THE DEVELOPMENT AND USE OF HEARING LOSS STORYLINES[a]

- Principles from social-cognitive theory, or social modeling, suggest that audiences learn from individuals with whom they identify and that they are likely to emulate behavior that has positive outcomes and avoid behavior with negative outcomes (Bandura, 1986).
- Careful evaluation and viewer surveys are required to measure the success of story lines and to identify best practices for future efforts.
- Clear, concise, accurate, and compelling information is necessary to inform writers and producers.
- A variety of resources, such as websites, social media, and toll-free numbers, offered in connection with the story lines provide viewers with multiple access points to valuable information, as well as a way to track audience response.
- Public–private partnerships facilitate and expand advocacy and outreach efforts and can play an important role in activities, such as expert consultations on story lines and development of informational resources.
- Existing initiatives, which include a variety of educational opportunities and awards that typically target journalists and entertainment media writers and producers, can be leveraged in order to inform and engage writers whose stories and interviews will inform and educate the public.

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[a] Text excerpted from the 2012 Institute of Medicine report *Epilepsy Across the Spectrum: Promoting Health and Understanding*, pp. 393–396.

two or more times a week" (CDC, 2005, p. 3). Furthermore, a national study of health literacy found that individuals with lower health literacy are more likely to obtain health-related information from radio and television programs than individuals with higher levels of health literacy, who tend to seek information from written sources such as the Internet, newspapers, and magazines (Kutner et al., 2006).

Such fictional portrayals of hearing loss are not the only media opportunity for educating the public about hearing loss; the news media can also play a role. One type of hearing loss that has been frequently discussed in the news media is noise-induced hearing loss (see Chapter 2). Concerns about the risks of hearing loss caused by loud noise became more prevalent with the widespread use of portable music devices starting in the 1980s (Peng et al., 2007; Punch et al., 2011). As researchers considered the effects of portable music devices on hearing, the news media began to highlight the risks of and prevention strategies for noise-induced hearing loss (NIDCD, 2015b). Although the available evidence regarding the link between portable music devices and noise-induced hearing loss is mixed and somewhat controversial, most experts agree that young adults should be educated on the topic and consider the intensity and duration of listening (Punch et al., 2011). In surveys of young adults through the MTV.com website, Quintanilla-Dieck and colleagues (2009) found that young people identified popular media as the most informative resource available for information on hearing loss and the prevention of noise-induced hearing loss, which highlights the opportunities for the media to reach various audiences. Social media efforts, often applied in association with public education campaigns (described below), may also contribute to educating the public, especially young adults, about hearing loss—both noise-induced and age-related hearing loss. The use and efficacy of social media to educate the public and increase awareness warrants additional investigation.

Marketing and Its Role in Educating the Public

Interviews and surveys of people with hearing loss suggest that many of them view hearing aids as a visual reminder of the stigma and negative attitudes and feelings about hearing loss that are described above (Dawes et al., 2014; Kochkin, 2007b; Laplante-Lévesque et al., 2010; Southall et al., 2011), and factors related to vanity and overall aesthetics are commonly cited as reasons why people choose not to adopt or use hearing aids (McCormack and Fortnum, 2013; Wallhagen, 2010). To combat these concerns, hearing aid manufacturers and marketers have focused on developing and advertising smaller, easy-to-hide hearing aids over the last three decades (Clements, 2015). Although advances in technology and size reductions may be credited for prompting individuals who are sensitive about the size and appearance of hearing aids to purchase and use them, the emphasis on these features in advertising—another form of media—may also be responsible for reinforcing negative public attitudes and stigma associated with hearing aids by implying that a small hearing aid is more desirable because it enables the wearer to hide his or her hearing loss (Wallhagen, 2010). This attitude can also magnify the perception of stigma for those for whom a small hearing aid may be challenging to use and thus a larger hearing aid is more appropriate (e.g., an individual who has trouble manipulating very small objects). Hearing aid advertisements commonly appear on television, in print media (e.g., magazines, newspapers), and in audiology clinics and physician offices, thus reaching—and possibly influencing—large segments of the population.

To better serve people with hearing loss, reduce stigma, and educate the public, the marketing for hearing aids and any hearing assistive technology should focus on individuals finding a solution that is effective, meets their needs, and helps them reconnect with family and friends, become more socially engaged, and continue to participate in their communities, rather than highlighting the ease with which an individual can hide his or her use of hearing aids or hearing assistive technologies. Kochkin and Rogin (2000) call for a shift in messaging that moves away from hiding the hearing aid and away from thinking of it as device to be sold and toward a message that technology can change people's lives, enhance relationships and intimacy, and reduce stress.

Public Education and Advocacy Efforts

Education is one of the most effective mechanisms available to combat misperceptions and stigma and should be used to help address these types of challenges with hearing loss. Public awareness campaigns and other public education efforts have been used successfully in the public health sphere for decades. In many cases, campaigns focus on educating the public and promoting behavior change (e.g., smoking cessation, exercise, and physical fitness), while others are developed to increase awareness and encourage a clearly defined, achievable action (e.g., taking part in cancer screening or HIV/AIDs testing, stopping drunk driving, using seat belts) or are designed to increase public awareness, correct misperceptions, encourage normalization, and reduce the stigma associated with a specific health condition (e.g., mental health conditions, disabilities, or epilepsy).

The most effective public awareness campaigns are usually large scale and multifaceted, have a specific goal, and involve a range of outreach activities, stakeholders and sponsors, educational materials, messaging, and media platforms. Public awareness campaigns may also include lobbying efforts to change laws, regulations, and policies at the local, state, and national levels. However, limitations in resources—for example, funding, time, and expertise—often hinder the development and implementation of large-scale public awareness campaigns. When a public awareness campaign is not feasible, advocacy organizations, government agencies, and other stakeholders often use smaller-scale efforts (e.g., videos, public service announcements, blogs) to educate the public about various public health topics and, in some cases, to reduce stigma.

WISE EARS! is an example of a nationwide public awareness campaign that was designed to educate the public about noise-induced hearing loss and strategies for prevention. The campaign ran from 1999 to 2006 and was jointly sponsored by the National Institute on Deafness and Other Communication Disorders (NIDCD) and the National Institute for Occupational Safety and Health. Nearly 90 public and private organizations were also involved in some capacity (NIDCD, 2015b). The far-reaching campaign was not targeted to a specific audience or age group, but it featured audience-specific materials and outreach activities. For example, the campaign included activity books for elementary school children (grades 3–6) and an interactive web curriculum for middle-school students (grades 7–8). To convey its messages, the campaign used bilingual (English and Spanish) multimedia educational materials including factsheets, a website, promotional items, presentations, and other tools. In 2006, NIDCD conducted a two-pronged evaluation of the campaign through an environmental scan of available information about noise-induced hearing loss and informal discussion with campaign collaborators. The evaluation pointed to the need to focus on a specific age range as the target group for the campaign as well as to expand partnerships for this effort (NIDCD, 2015b). The new campaign, It's a Noisy Planet, has a broad partnership (NIDCD, 2015a).

Box 6-6 describes other hearing loss campaigns that have been carried out over the last decade. Many of these efforts, such as WISE EARS! and those described below, have focused on the prevention of noise-induced hearing loss. Unfortunately, most of the campaigns identified by the committee for this report did not include a planned evaluation, or if they did, the results of the evaluations are not publicly available. The lack of an evaluation makes measuring success impossible at this time. It also limits the opportunities to identify lessons learned that could be used to inform plans for future public awareness efforts.

Advocacy organizations also play an important role in educating the public and supporting public education efforts. Action on Hearing Loss, a nonprofit organization started in 1911 in the United Kingdom, has developed and continues to operate several public campaigns covering a variety of topics, such as the need for screening, improving access to health and human services for people with hearing loss, the increased use of subtitles on television, and providing access to lip-reading classes and services. In its campaign efforts, Action on Hearing Loss lobbies the government, raises money, holds conferences, engages and activates people with hearing loss, provides educational materials, and provides guidance and support for local campaigns and awareness activities (Action on Hearing Loss, 2016a). HLAA also organizes public education and awareness events. Since 2006 it has supported walks across the United States in the spring and fall (HLAA, 2016b). Additionally, the American Academy of Audiology, NIDCD, the CDC, HLAA, and other organizations have supported October as National Protect Your Hearing Month and National Audiology Awareness Month, while May has been designated as Better Hearing Month (AAA, 2016; ASHA, 2016; CDC, 2015c; HLAA, 2013; NIDCD, 2014). In honor of these months, organizations may provide promotional tools, factsheets, posters, customizable press releases, and other materials that can be used to educate people with hearing loss and the public about healthy hearing. Other advocacy organizations, such as AARP and the National Council on Aging, have also dedicated resources to educating the public and their constituents about hearing loss, possible comorbidities associated with hearing loss, and resources that are available to assess and treat hearing loss (AARP, 2016; NCOA, 2016).

Box 6-6 EXAMPLES OF CAMPAIGNS RELATED TO HEARING LOSS

Get in the Hearing Loop was a year-long campaign (June 2010–June 2011) that was jointly sponsored by the Hearing Loss Association of America and the American Academy of Audiology. This marketing-based campaign was specifically targeted toward hearing aid users, audiologists, and hearing instrument specialists and technicians, and it focused on educating these audiences about the benefits of hearing loops, telecoils, and other assistive technologies and systems.

National Campaign for Better Hearing is an ongoing campaign in Canada to increase awareness of hearing loss and to ensure access to hearing assessments for Canadians over the age of 60 years. The campaign is sponsored by a number of hearing aid centers, and it hosts events across Canada which include free hearing tests, hearing aid check-ups, and educational sessions about available hearing technologies. The campaign website provides research findings and an active blog that features interviews with people with hearing loss.

Speak Up About Hearing Loss was a campaign led by the American Speech–Language–Hearing Association in 2012 that focused on television and radio public service announcements (PSAs). The goal of the PSAs was to encourage families to speak openly about hearing loss and to encourage loved ones to seek assessment and treatment. The PSAs were available in both English and Spanish and were featured on major media outlets nationwide. The campaign also featured a website that linked to research findings, podcasts, and additional information for individuals and families.

Turn it to the Left is a campaign that was launched by the American Academy of Audiology in 2008. The ongoing campaign is focused on increasing awareness about noise-induced hearing loss and raising money for research. The interactive website offers educational resources (e.g., posters, diagrams, a quiz), fact sheets, press releases, articles and stories that have appeared in the media, and a link to the academy's Find an Audiologist portal.

The availability of reliable, evidence-based information for consumers helps to reduce misperceptions and empower individuals with hearing loss to seek care and more openly discuss their hearing loss, the challenges it presents, and successful treatment stories with others. Given the current and expected number of individuals with hearing loss in the United States, advocacy organizations, government agencies, health care professionals, researchers, and industry need to collaborate in order to identify the best mechanisms for educating the public about hearing loss, the importance of hearing health, and what services and treatment options are available to people who live with hearing loss. To fully understand the impact of public awareness campaigns and advocacy efforts and to maximize the success of these initiatives, the following are needed:

Other campaigns have been tailored toward younger audiences with a goal of educating children, young adults, and their parents about noise-induced hearing loss. For example, the following multimedia campaigns have featured messages of risk reduction, prevention, the development of healthy listening practices, and overall healthy hearing:

- **Dangerous Decibels**—jointly supported by the Oregon Health & Science University, Portland State University, and the University of Northern Colorado.
- **It's a Noisy Planet**—sponsored by the National Institute on Deafness and Other Communication Disorders.
- **Listen to Your Buds**—sponsored by the American Speech–Language–Hearing Association.
- **It's How You Listen That Counts**—sponsored by the House Ear Institute.

SOURCES:

- Get in the Hearing Loop: http://www.hearingloss.org/content/get-hearing-loop
- National Campaign for Better Hearing: http://www.campaignforbetterhearing.org/#about-marquee
- Speak Up About Hearing Loss: http://www.asha.org/About/news/Speak-Up-About-Hearing-Loss
- Turn it to the Left: http://www.turnittotheleft.org
- Dangerous Decibels: http://www.dangerousdecibels.org
- It's a Noisy Planet: http://www.noisyplanet.nidcd.nih.gov
- Listen to Your Buds: http://www.asha.org/buds
- It's How You Listen That Counts: http://www.hearingreview.com/2010/12/to-teens-its-how-you-listen-that-counts

- clearly defined goals, target audiences, messaging, milestones, and successes;
- data and research to establish baselines of awareness and the misperceptions associated with hearing loss;
- participation and involvement of targeted audiences throughout the planning and implementation phases to ensure that the messaging and education efforts are reaching their intended audiences, are culturally sensitive, and are making a difference;
- coordination, collaboration, and partnerships to leverage limited resources, expand reach, and meet goals; and
- short- and long-term evaluation plans to measure success, adjust ongoing initiatives, and target future efforts.

New Technology and Shifting Public Perspectives

Over the past 30 years, high-tech mobile technologies (e.g., music players, smartphones, tablets) have changed the way people communicate, receive information, and interact with one another. Many of these technologies are paired with communication products such as headphones, earbuds, and Bluetooth headsets, vastly expanding the number of people who use some form of electronic technology in or near their ears. In a 2006 editorial, Jackler (2006) predicted that the public stigma associated with hearing aids would vanish with the pervasive use of earpieces among the general public, and preliminary data suggest that Jackler's prediction may be coming to fruition.

Since 1977, a series of studies have assessed the hearing aid effect, which is defined as "the assignment of negative attributes to individuals using hearing aids" (Rauterkus and Palmer, 2014, p. 894). More recently, Rauterkus and Palmer (2014) replicated study designs that were used in the 1970s and 1980s to determine whether, given the increasing use of personal listening devices by the public, the hearing aid effect has persisted over time. Study participants viewed images, each of which showed an individual wearing a different technology: three types of hearing aids (two behind-the-ear designs and one in-the-canal design), earbuds, and a Bluetooth headset. Participants were asked to rate the individual in each image based on eight attributes (e.g., from unattractive to attractive, from unintelligent to intelligent, from lazy to hard working). Rauterkus and Palmer had hypothesized that there would be an overall reduction in the hearing aid effect (i.e., reduction in negative attitudes). In fact, the images of individuals wearing hearing aids were not rated any more negatively than the images of individuals wearing earbuds or Bluetooth headsets, suggesting that the hearing aid effect was no longer present. Notable shortcomings of this study include the sample size and participant demographics; the study was conducted with 24 participants who were pursuing a masters of business administration degree in one city (Rauterkus and Palmer, 2014). Therefore, the findings show promise but are not generalizable to the U.S. population.

In a nationwide survey that was jointly conducted by AARP and the American Speech–Language–Hearing Association, stigma did not seem to be a major concern for participants. For example, most respondents, regardless of hearing status, indicated that they would not mind having others know about a hearing problem (66 percent), being seen wearing hearing aids (71 percent), or discussing difficulties with hearing (73 percent). Although attitudes may be shifting among older adults, the remnants of stigma may still be identifiable in these survey results. For example, few individuals with untreated hearing loss were willing to talk to family or friends about suspected hearing loss (25 and 15 percent, respectively), and more than half of respondents with untreated hearing loss (57 percent) found ways to "cover up" their hearing loss rather than seeking treatment (AARP and ASHA, 2011). The participants for this survey were carefully selected to reflect the demographics of AARP constituents; thus, like the Rauterkus and Palmer study, this survey is not representative of the U.S. population.

Companies within the consumer technologies market are beginning to work with hearing aid manufacturers in an effort to adapt micro hearing aid technologies (e.g., chips, batteries) for use in technologies that can stream audio and voice from a cell phone via Bluetooth. As these types of high-end technologies become available, the line between hearing aids and consumer technologies will blur and the negative perceptions about hearing aids may erode further (Hunn, 2015). Recent advances in hearing aids and hearing assistive technologies (described in Chapter 4)—including the pairing/controlling of hearing aids and hearables with apps for smartphones and watches—are bringing these technologies to younger and more tech savvy sectors of society. These new technologies are also putting an increased emphasis on user experience and visual design, offering colorfully patterned cases that draw attention to the device as a high-tech gadget rather than as something that should be hidden from view (Kosner, 2015). The continuing evolution and marketing of high-tech hearing technologies that are both functional and stylish is likely to promote additional shifts in public perceptions and attitudes about hearing aids and other technologies. However, some of these high-tech options may come with a higher price tag, something that is already a concern for many seeking hearing health care (see Chapter 5), and ensuring compatibility among assistive technologies will be important.

Although the studies and survey findings described in this section are encouraging, stigma is still cited in recent literature (described earlier in this chapter) as a concern among individuals with hearing loss, and additional efforts are required to ensure that stigma, negative attitudes, and misperceptions are not barriers that prevent individuals from seeking hearing assessments, treatments, and community-based support.

NEXT STEPS AND RECOMMENDATIONS

As discussed in previous chapters, hearing loss is about more than just the hearing loss itself. It is also associated with diminished physical and psychosocial well-being and overall quality of life, depression, anxiety, low self-esteem, social isolation, stress, mental fatigue, cognitive decline and dementia, reduced mobility, falls, and mortality (Dalton et al., 2003; Genther et al., 2015; Hornsby, 2013; Lin and Ferrucci, 2012; Lin et al., 2011, 2013; Mener et al., 2013; Mick et al., 2014; Munro et al., 2013). Although overall quality of life may be improved with the appropriate use of hearing aids and hearing assistive technologies (Chisolm et al., 2007; Kochkin and Rogin, 2000), many individuals delay seeking help and treatment or else do not regularly use their hearing aids or other technologies. Further, there has been limited research into positive experiences and adaptation to hearing loss as well as resilience factors among adults and their families (Hallam et al., 2008; Manchaiah et al., 2015; Stephens and Kerr, 2003). Multifaceted solutions are needed across the social-ecological model to improve support for individuals with hearing loss. Box 6-7 provides areas of focus and research priorities for improving attitudes and beliefs, fortifying education and community-based support, and enhancing public awareness.

Box 6-7 AREAS OF FOCUS AND RESEARCH PRIORITIES FOR IMPROVING SUPPORT FOR PEOPLE WITH HEARING LOSS

- The development of education and support programs along with other tools and techniques for individuals and families to foster resilience and empower them to overcome negative attitudes and perceptions
- The normalization of hearing health, screening, treatment, and management, as has been done with dentistry and eye/vision care
- The empowerment and education of individuals and their families to identify good hearing as a health priority, seek care, and pursue the services and technologies that meet their needs, with an emphasis on improving overall well-being
- The provision of high-quality community-based support to overcome misperceptions about hearing loss and the use of hearing technologies
- The development and evaluation of adaptable community-based education and support initiatives using multimedia platforms, the Internet, and peers with hearing loss to engage individuals and families together across the United States
- Education for employers and employees about the Americans with Disabilities Act (ADA) requirements, accommodations, and tools for successful interviews and hiring of people with hearing loss
- The widespread installation and use of hearing assistive technologies in public spaces, as stipulated in the ADA
- The development, evaluation, and implementation of design elements that can optimize acoustics in public spaces whenever possible, with an emphasis on universal design solutions
- A more positive portrayal of hearing loss and the use of hearing aids and hearing assistive technologies in the media
- The application and evaluation of social media to educate the public about hearing loss and the risks of noise-induced hearing loss
- Positive messaging and themes in hearing technology marketing, with an emphasis on topics such as connecting with family and friends rather than on aesthetics and hiding the hearing aid or hearing assistive technology

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.

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.

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.

- 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, and
    - Research and incorporate features into buildings and public spaces that improve hearing and communication (e.g., universal design, hearing assistive technologies).

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7

Opportunities for Action

Hearing is a vital human sense important to communications, health, function, and quality of life. Currently, hearing health care is simultaneously on the brink of and in the midst of innovation and change. Changes in technologies, changes in the delivery of hearing health care services, and changes in opportunities for consumer empowerment and public awareness are occurring at various rates and with various levels of research rigor and evidence. Thus, with the benefit of key institutional, technological, and regulatory changes to improve access and affordability, hearing health care is poised to undergo advances that will help individuals with hearing loss and their families find and fully utilize the appropriate, affordable, and high-quality services, technologies, and support they need. The committee's findings and recommendations for change are highlighted in Box 7-1 and discussed throughout this report. The recommended actions will require collaborative, determined, and sustained efforts to ensure that stakeholders from across the public and private sectors and across professions come together to provide accessible and affordable hearing health care. Fully developing the array of options for adults of all ages and with all levels of hearing loss (see Table 7-1) requires that hearing loss be recognized as a public health concern that demands multidisciplinary and collaborative efforts by all stakeholders working together with the common goal to improve hearing and communication abilities for individuals and across the population.

Box 7-1 KEY MESSAGES FOR IMPROVING ACCESSIBILITY AND AFFORDABILITY OF HEARING HEALTH CARE FOR ADULTS[a]

Findings:

- Hearing is 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.

Recommended Actions:

- Improve population-based information on hearing loss and hearing health care
- Develop and promote measures to assess and improve quality of hearing health care services
- Remove Food and Drug Administration (FDA) regulation for medical evaluation or waiver of that evaluation prior to hearing aid purchase
- Empower consumers and patients in their use of hearing health care
- Improve access to hearing health care for underserved and vulnerable populations
- Promote hearing health care in wellness and medical visits for those with concerns about their hearing
- Implement a new FDA device category for over-the-counter wearable hearing devices
- Improve the compatibility and interoperability of hearing technologies with communications systems and the transparency of hearing aid programming
- Improve affordability of hearing health care by actions across federal, state, and private sectors
- Evaluate and implement innovative models of hearing health care to improve access, quality, and affordability
- Improve publicly available information on hearing health
- Promote individual, employer, private-sector, and community-based actions to support and manage hearing health and effective communication

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[a] All findings and recommended actions are of equal importance and are not prioritized.

TABLE 7-1
Hearing Loss–Related Services and Technologies

Services	• Evaluation and assessment • Selection, fitting, adjustment, and maintenance of hearing aids and hearing assistive technologies • Auditory rehabilitation
Technologies	• Hearing aids • Over-the-counter wearable hearing devices (proposed) • Hearing assistive technologies, including products that connect with other communications technologies (e.g., phones, television)

A

Meeting Agendas

Committee on Accessible and Affordable Hearing Health Care for Adults

FIRST COMMITTEE MEETING
APRIL 27, 2015

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

Open Session – Room 100

10:30–10:35 a.m.	**Welcome and Introductions** *Dan Blazer, Committee Chair*
10:35 a.m.–12:30 p.m.	**Context for Study**
10:35–11:35 a.m.	**Panelist Presentations** • *Theresa H. Chisolm, University of South Florida* • *Dianne Van Tasell, Bose* • *Meg Wallhagen, University of California, San Francisco, School of Nursing*
11:35 a.m.–12:30 p.m.	**Committee Discussion with Panelists**

12:30–1:30 p.m.	**Lunch (Keck Atrium)**
1:30–4:45 p.m.	**Discussion of the Charge to the Committee**
1:30–3:30 p.m.	**Perspectives from Study Sponsors**
	National Institute on Deafness and Other Communication Disorders, *Amy Donahue* National Institute on Aging, *Molly Wagster* Hearing Loss Association of America, *Anna Gilmore Hall* Food and Drug Administration, *Eric Mann and Srinivas Nandkumar* Department of Defense, *Mark Packer and Lynn Henselman* Department of Veterans Affairs, *David Chandler* Centers for Disease Control and Prevention, *Marcus Gaffney*
3:30–3:45 p.m.	**Break**
3:45–4:45 p.m.	**Committee Discussion with Study Sponsors**
4:45–5:15 p.m.	**Public Comment**
5:15 p.m.	**Open Session Adjourns**

Committee on Accessible and Affordable Hearing Health Care for Adults

SECOND COMMITTEE MEETING
JUNE 30, 2015

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

Open Session – Keck 100

8:00–8:10 a.m.	**Welcome and Opening Remarks** *Dan Blazer, Committee Chair*
8:10–9:15 a.m.	**Panel 1: Impact of Hearing Impairment and Use of Services** *Facilitator: Karen Cruickshanks*
8:10–8:15 a.m.	Panel Introductions
8:15–8:55 a.m.	Presentations • *Karen Cruickshanks, University of Wisconsin, Committee Member* • *Carrie Nieman, Johns Hopkins University*
8:55–9:15 a.m.	Discussion with the Committee
9:15–10:40 a.m.	**Panel 2: Hearing Health Care Providers and Scope of Practice** *Facilitator: Deb Tucci*
9:15–9:20 a.m.	Panel Introductions
9:20–10:20 a.m.	Presentations • *Philip Zazove, University of Michigan* • *Gail Linn, Potomac Audiology* • *Michael Andreozzi, Beltone New England* • *Wade Chien, Johns Hopkins University*
10:20–10:40 a.m.	Discussion with the Committee
10:40–10:55 a.m.	**Break**

10:55 a.m.–12:05 p.m.	**Panel 3: Affordability and Coverage** *Facilitator: José Pagán*
10:55–11 a.m.	Panel Introductions
11:00–11:45 a.m.	Presentations • *Susan Miller, Centers for Medicare & Medicaid Services* • *Virginia Ramachandran, Henry Ford Health System* • *Stephanie Sjoblad, University of North Carolina at Chapel Hill*
11:45 a.m.–12:05 p.m.	Discussion with the Committee
12:05–1:05 p.m.	**Lunch** (Keck Atrium)
1:05–2:15 p.m.	**Panel 4: Hearing Health Care Service Delivery** *Facilitator: Judy Dubno*
1:05–1:10 p.m.	Panel Introductions
1:10–1:55 p.m.	Presentations • *Lu Beck, Department of Veterans Affairs* • *Marc Klau, Kaiser Permanente* • *Lisa Tseng, Optum, hi HealthInnovations*
1:55–2:15 p.m.	Discussion with the Committee
2:15–3:40 p.m.	**Panel 5: Devices** *Facilitator: Richard Ellenson*
2:15–2:20 p.m.	Panel Introductions
2:20–3:20 p.m.	Presentations • *Thomas Powers, Sivantos, Inc.* • *Holly Hosford-Dunn, Hearing Health and Technology Matters* • *Mead Killion, Etymotic Research, Inc.* • *Kinu Masaki, SmartEar, Inc.*
3:20–3:40 p.m.	Discussion with the Committee
3:40–3:55 p.m.	**Break**

3:55–5:20 p.m.	**Panel 6: Consumer Perspective** *Facilitator: Brenda Battat*
3:55–4:00 p.m.	Panel Introductions
4:00–5:00 p.m.	Presentations • *Julie Kearney, Consumer Electronics Association* • *Harvey Abrams, Hearing Industries Association* • *Richard Einhorn, Einhorn Consulting, LLC* • *Richard Uzuanis, Americans for Better Hearing Foundation*
5:00–5:20 p.m.	Discussion with the Committee
5:20–6:00 p.m.	**Public Comment** *Moderator: Dan Blazer*
6:00 p.m.	**Open Session Adjourns**

Committee on Accessible and Affordable Hearing Health Care for Adults

THIRD COMMITTEE MEETING
SEPTEMBER 10–11, 2015

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

Thursday, September 10, 2015

Open Session–Keck 100

8:30–8:40 a.m.	**Welcome and Opening Remarks** *Dan Blazer, Chair*
8:40–10:00 a.m.	**Panel 1: International Perspective** *Facilitator: Frank Lin*
8:40–8:45 a.m.	Panel Introductions
8:45–9:30 a.m.	Presentations • *Adrian Davis (via Webex)* • *Curtis Alcock, Audira (via Webex)* • *Mark Laureyns, AEA - European Association of Hearing Aid Professionals (via Webex)*
9:30–9:55 a.m.	Discussion with the Committee
9:55–10:05 a.m.	**Break**
10:05–10:55 a.m.	**Panel 2: Young Adult Perspective** *Facilitator: Kate Seelman*
10:05–10:10 a.m.	Panel Introductions
10:10–10:40 a.m.	Presentations • *Zina Jawadi, Stanford University (via Webex)* • *Patrick Holkins, Department of Justice*
10:40–10:55 a.m.	Discussion with the Committee

10:55 a.m.–12:30 p.m.	**Panel 3: Improving Accessibility and Affordability** *Facilitator: Darrell Gaskin*
10:55–11:00 a.m.	Panel Introductions
11:00 a.m.–12:00 p.m.	Presentations • *Ateev Mehrotra, Harvard Medical School* • *David Zapala, Mayo Clinic, Committee Member* • *Jani Johnson, University of Memphis* • *Gustav Chiarello, Federal Trade Commission*
12:00–12:30 p.m.	Discussion with the Committee
12:30–1:00 p.m.	**Public Comments**
1:00 p.m.	**Open Session Adjourns**

Committee on Accessible and Affordable Hearing Health Care for Adults

FOURTH COMMITTEE MEETING
NOVEMBER 13, 2015

Keck Center of the National Academies
Room 100
500 Fifth Street, NW
Washington, DC 20001

Open Session – Keck 201

11:00 a.m.–12:00 p.m. **Report of the President's Council of Advisors on Science and Technology**
Presentation
Christine Cassel, President's Council of Advisors on Science and Technology Member
Discussion with the Committee

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Committee Biographies

Dan G. Blazer, M.D., Ph.D., M.P.H. (*Chair*), is the J. P. Gibbons Professor of Psychiatry Emeritus at Duke University. He served 9 years as chair of the Department of Psychiatry and dean of medical education at Duke School of Medicine. Dr. Blazer's research interests include the epidemiology of late-life substance use disorders and depression, psychosocial predictors of adverse health outcomes, and trajectories of health outcomes. He has worked on the Established Populations for Epidemiologic Study of the Elderly (EPESE) and the National Comorbidity Study. He is the author or editor of 36 books, including *The Age of Melancholy: Depression and Its Social Origins* and a research methods textbook for clinical psychiatry research. He has produced a second edition of *Emotional Problems in Later Life* and authored or co-authored more than 200 published abstracts and more than 460 peer-reviewed articles. Dr. Blazer was president of the American Association of Geriatric Psychiatry and is a current member of the editorial board of *JAMA Psychiatry*. He has been a member of the National Academy of Medicine since 1995. Currently he is the chair of the National Academies of Sciences, Engineering, and Medicine's (the Academies') Board on the Health of Select Populations. He has served as a member or chair of many past Academies committees. He received the Walsh McDermott Award for Distinguished Service to the Institute of Medicine in 2014.

Brenda Battat, M.S., MCSP, is the retired executive director of the Hearing Loss Association of America (HLAA). During 24 years with the HLAA, 5 as executive director, she led nationwide advocacy efforts to change the way society views hearing loss, pushed for accessible and affordable hearing health care and consumer choice in the marketplace, promoted hearing-friendly environments through technology such as looping and captioning, and successfully advocated for hearing-aid-compatible mobile products. She upheld the philosophy of self-help and encouraged and taught consumers to self-advocate. Ms. Battat has served on government, professional, and business advisory boards, including the U.S. Access Board's Telecommunications Access Advisory Committee, the Federal Communications Commission's Consumer/Disability Advisory Committee, the AT&T Advisory Panel on Access and Aging, the National Advisory Group—National Technical Institute for the Deaf, the American and Northwest Airlines Consumer Advisory Committees, and the National Institute on Deafness and Other Communication Disorders Advisory Council of the National Institutes of Health. Ms. Battat received an M.S. in education from Indiana University and a B.Sc. in physical therapy from St. Mary's Hospital, London, England. For her work she received the Sheldon Williams Itzkoff Leadership Award (2010); Robert H. Weitbrecht Telecommunications Access Award (2007); Oticon Focus on People Advocacy Award (2005); and Self Help for Hard of Hearing People National Access Award (2002).

Karen J. Cruickshanks, Ph.D., is a professor of ophthalmology and visual sciences and population health sciences at the University of Wisconsin School of Medicine and Public Health. She received her Ph.D. in epidemiology from the University of Pittsburgh Graduate School of Public Health. Her research program is studying the health problems of aging through epidemiological cohort studies. The Epidemiology of Hearing Loss Study (EHLS) is funded by the National Institute on Aging (AG11099) to study hearing, olfactory, and cognitive impairments in a population-based cohort of 3,500 older residents of Beaver Dam, Wisconsin. The focus of this research is on the roles of inflammation and vascular factors on age-related disorders. The Beaver Dam Offspring Study funded by the National Institute on Aging follows the adult children of the EHLS to study generational differences in the risk of age-related sensorineural disorders. She is the director of the EpiSense Audiometry Reading Center which provides support for other cohort studies of hearing, including the Hispanic Community Health Study, a multicenter study of 16,000 Latinos, and the Epidemiology of Diabetes Interventions and Complications study of hearing impairment. A major theme of her research is the links between subclinical atherosclerosis, inflammation, and the sensory and neurological disorders of aging. Dr. Cruickshanks has served on a number of Institute of Medicine committees, including the Committee on Gulf War and Health: Long-Term Effects of Blast Exposure.

Jennifer E. DeVoe, M.D., D.Phil., is a practicing family physician and doctorally trained health services researcher who studies access to health care, disparities in care, and the impact of practice and policy interventions on vulnerable populations. Her research portfolio spans both Oregon Health & Science University (OHSU) Family Medicine and OCHIN, Inc., a health information technology network based in Portland, Oregon. Dr. DeVoe leads a multidisciplinary research team with expertise in informatics, sociology, epidemiology, biostatistics, economics, primary care, mental health, health-services research, clinical medicine, health care disparities, and anthropology. Using large health insurance claims, electronic health records (EHRs), and self-reported datasets, this OHSU/OCHIN team uses informatics and analytics to conduct policy-relevant and practice-relevant studies. Research findings inform community, practice, and policy interventions that help to improve the delivery of care for vulnerable populations and eliminate health disparities. Dr. DeVoe is chief research officer at OCHIN where she serves as executive director of the OCHIN practice-based research network of community health centers. Since 2004, Dr. DeVoe has led or supported more than 30 studies to conduct health services, primary care, and disparities research in primary care clinics in the OCHIN network. Dr. DeVoe is currently the principal investigator on six research studies funded by the Patient-Centered Outcomes Research Institute; the Agency for Healthcare Research and Quality; the National Cancer Institute; the National Heart, Lung, and Blood Institute; and the Centers for Disease Control and Prevention, with nearly $20 million in active grant funding. She also serves as the principal investigator of the ADVANCE Clinical Data Research Network, part of PCORnet, which is "horizontally" integrating outpatient EHR data, creating a unique community laboratory for including disadvantaged and vulnerable patients across the country. Dr. DeVoe earned her M.D. from Harvard Medical School in 1999. Selected as a Rhodes Scholar in 1996, she also earned an M.Phil. and D.Phil. from Oxford University in 1998 and 2001, respectively. She completed her family medicine residency at OHSU in 2004.

Judy R. Dubno, Ph.D., is a professor and the director of the Hearing Research Program in the Department of Otolaryngology–Head and Neck Surgery at the Medical University of South Carolina in Charleston. Her research, which is supported by grants from the National Institute on Deafness and Other Communication Disorders (NIDCD) at the National Institutes of Health (NIH), focuses on auditory perception and speech recognition in adverse listening conditions and how perception changes with age, hearing loss, hearing aids, and training. She previously served on the NIDCD Advisory Council of the NIH, three Institute of Medicine committees, as President and Secretary-Treasurer of the Association for Research in Otolaryngology, and as President and Vice President of the Acoustical Society of America. She is a fellow of the Acoustical Society of America and of the American Speech–Language–Hearing Association and the recipient of the James Jerger Career Award for Research in Audiology.

Richard Ellenson, M.B.A., is chief executive officer of the Cerebral Palsy International Research Foundation. He has spearheaded a major effort to transform basic health care for women with disabilities and developed a new initiative to use Kinect technology to provide an innovative gaming interface for people with disabilities. Prior to this, Mr. Ellenson was founder and chief executive officer of two assistive technology companies (Panther and Blink Twice) that helped transform the field of assistive technology for people with disabilities. He has worked tirelessly to create awareness about people with disabilities and to share stories about their vibrant lives. He and his son have been featured as ABC World News People of the Year, on CNBC's *Squawk Box*, in a *New York Times Sunday Magazine* cover story, and as a feature on ESPN's *E:60*. Prior to this work, he was an advertising executive who created campaigns for brands such as American Express and Remy Martin, and who penned the classic line, "It's Not TV. It's HBO." Mr. Ellenson has been honored with the 2012 Visionary Leadership Award from Resources for Children with Special Needs, as a Caregiver of the Year by United Cerebral Palsy of New York City, and by many other organizations within the world of disabilities. He has served on the Advisory Council of NIDCD and on the boards of the Center on Disabilities at California State University at Northridge, the United States Society for Alternative and Augmentative Communication, and the Assistive Technology Industry Association. He has also been the recipient of two NIH grants. He is a graduate of Cornell University and holds an M.B.A. from the Wharton School of the University of Pennsylvania.

Barbara J. Evans, J.D., Ph.D., LLM, joined the University of Houston Law Center (UHLC) in 2007. She is the George Butler Research Professor and the director of the Center for Biotechnology and Law at UHLC and is an affiliated member of the Center for Medical Ethics and Health Policy at Baylor College of Medicine. She was named a Greenwall Foundation Faculty Scholar in Bioethics for the period 2010–2013 and conducts an active research agenda including projects funded by the National Institutes of Health and the Food and Drug Administration (FDA). Her research interests include governance, privacy, and financing issues with large health information networks; the regulation of genomic testing under FDA's medical device regulatory framework and the Clinical Laboratory Improvement Amendments of 1988; and legal barriers to the introduction of new medical technologies and care-delivery concepts. Earlier in her career, she was a partner in the international regulatory practice of a large New York law firm and subsequently advised clients on U.S. privacy, research, and medical device regulatory matters. Prior to joining the University of Houston Law Center, she was a research professor of medicine and the director of the Program in Pharmacogenomics, Ethics, and Public Policy at the Indiana University School of Medicine/Center for Bioethics. She holds an electrical engineering degree from the University of Texas at Austin; M.S. and Ph.D. degrees from Stanford University; a J.D. from Yale Law School; and an LLM in health law from the University of Houston; and she completed a postdoctoral fellowship in clinical ethics at the MD Anderson Cancer Center.

Ellen J. Flannery, J.D., is a partner and past co-chair of Covington & Burling LLP's global food and drug law practice group. She advises clients on regulatory strategies and compliance for medical devices, pharmaceuticals, and biological products. She has significant experience in successfully helping clients navigate the regulatory process. Ms. Flannery's clients range from large multinational companies to development-stage companies, venture capital firms, clinical laboratories, and trade associations. She has experience with cutting-edge technologies, including, for example, companion diagnostics, software and mobile medical apps, imaging devices, combination products, and humanitarian use devices. She has successfully helped clients to develop strategic plans for obtaining FDA marketing clearance or approval; appeal from adverse determinations in investigational device exemption and 510(k) contexts; respond to FDA quality system inspections, including 483s and warning letters; and undertake product recalls. She has experience with Clinical Laboratory Improvement Amendments waiver applications and laboratory-developed tests. She advises clients on post-market reporting requirements and advertising and promotional issues. Ms. Flannery has served on Institute of Medicine committees that studied medical device and orphan drug matters, taught food and drug law seminars at three law schools, and regularly publishes and presents on regulatory developments. She is co-editor in chief of Covington's InsideMedicalDevices blog.

Darrell J. Gaskin, Ph.D., is an internationally known expert in health care disparities, access to health care for vulnerable populations, and safety net hospitals. He is the deputy director of the Johns Hopkins Center for Health Disparities Solutions. He seeks to identify and understand barriers to care for vulnerable populations and to develop and promote policies and practices that will improve access to care for the poor, minority, and other vulnerable populations and eliminate racial/ethnic and socioeconomic disparities in health care. His current projects explore the relationship between "place" and health care disparities and examine racial/ethnic and socioeconomic disparities in hospital care. Dr. Gaskin's research has been published in *Health Services Research* (*HSR*), *Health Affairs*, *Medical Care Research and Review*, *American Journal of Public Health*, *Medical Care*, and *Inquiry*. Currently, he serves on the editorial boards of *HSR*, *Medical Care Research and Review*, and *Medical Care*. He served on the Institute of Medicine's Committee on Valuing Community-Based, Non-Clinical Prevention Programs and the Committee on the Future of Emergency Care in the U.S. Health System. He is vice chair of the board of directors of AcademyHealth and a member of the Center for Health Policy Development Board, the board of directors for the National Academy of State Health Policy. He is involved in federal and state health policy. He was a member of the Congressional Black Caucus Commission on the Budget Deficit, Economic Crisis, and Wealth Creation. He is a former member of the board of directors of the Maryland Health Insurance Plan, the state's high-risk pool. He served as the vice chair of the board of directors of the Maryland Health Benefits Exchange Commission from 2011 to 2015.

William R. Hazzard, M.D., is a professor of internal medicine who has recently returned to the Wake Forest School of Medicine at the J. Paul Sticht Center on Aging in Winston-Salem, North Carolina. His focus on aging began approximately 40 years ago in Seattle when, following training in endocrinology and metabolism and initiating the Northwest Lipid Research Clinic, he was asked to develop the program on gerontology and geriatric medicine at the University of Washington. Following a sabbatical year in the United Kingdom learning the British approach to geriatrics, he successively initiated programs in geriatrics at three American academic health centers, in so doing moving progressively toward the center of the Department of Internal Medicine as a Division Head at Washington, vice chairman at Hopkins, and finally in 1986 as chairman at Wake Forest, where his negotiated recruitment goal was specifically to "gerontologize" the department and the institution, notably from a newly designed and constructed Sticht Center on Aging, which opened in 1997. Now in semi-retirement, his greatest satisfaction continues to derive from promoting career development with a focus on aging across the life span with students, fellows, and faculty at the Sticht Center and as a leading institutional priority to witness how deeply and broadly its program has continued to expand throughout the university and community. Through all of this he remains fascinated by the question that first drew him to this field: Why do women live longer than men?

Frank R. Lin, M.D., Ph.D., is an associate professor of otolaryngology, geriatric medicine, mental health, and epidemiology at the Johns Hopkins University School of Medicine and the Bloomberg School of Public Health. Dr. Lin completed his medical education, residency in otolaryngology, and

Ph.D. in clinical investigation, all at Johns Hopkins. He completed further otologic fellowship training in Lucerne, Switzerland. Dr. Lin's clinical practice is dedicated to otology and the medical and surgical management of hearing loss. His epidemiological research focuses on how hearing loss affects the health and functioning of older adults and the role of hearing rehabilitative strategies in potentially mitigating these effects. In particular, his research group has demonstrated that hearing loss in older adults is strongly and independently associated with the risk of cognitive decline, incident dementia, impairments in physical functioning and mobility, and greater health care resource utilization in multiple epidemiological studies. He collaborates extensively with researchers across multiple fields, including gerontology, cognitive neuroscience, audiology, and epidemiology, and he has collaborative working relationships with individuals in industry, government, and nonprofit advocacy organizations. In January 2014 he co-chaired for the Institute of Medicine and the National Research Council a 2-day workshop on hearing loss and healthy aging in Washington, DC.

Nicole Marrone, Ph.D., CCC-A, holds the James S. and Dyan Pignatelli/Unisource Clinical Chair in Audiologic Rehabilitation for Adults at the University of Arizona and is an assistant professor in the Department of Speech, Language, and Hearing Sciences. Her research investigates hearing loss and rehabilitation in adults, with a focus on reducing hearing health care disparities, maximizing communication access, and living well with hearing loss. Her laboratory-based research centers on understanding the effects of hearing loss and amplification on speech communication and memory; her community-based research efforts are focused on the implementation of group audiologic rehabilitation programs and rural health access. Dr. Marrone is the principal investigator of an interdisciplinary research project funded by NIDCD that is developing and testing the effectiveness of a community health worker program to increase access to hearing health care among older Spanish-speaking adults. Dr. Marrone earned her M.S. and Ph.D. degrees in audiology from Boston University and completed a postdoctoral fellowship at Northwestern University prior to joining the faculty at the University of Arizona in 2011. Dr. Marrone's research is currently funded by the University of Arizona Foundation, the University of Arizona ConfluenCenter for Creative Inquiry, the SERTOMA Community Foundation, and NIH.

José A. Pagán, Ph.D., is the director of the Center for Health Innovation at the New York Academy of Medicine and a professor in the Department of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai. He is a former Robert Wood Johnson Foundation (RWJF) Health & Society Scholar with expertise in health economics and health services research. Dr. Pagán received his Ph.D. in economics from the University of New Mexico, and he is also an adjunct senior fellow of the Leonard Davis Institute of Health Economics at the University of Pennsylvania. Dr. Pagán has served as a consultant on health insurance coverage for the Institute of Medicine and is a member of the National Advisory Committee of the RWJF Health & Society Scholars Program. He is also a member of the board of directors of the American Society of Health Economists. Dr. Pagán was the principal investigator of a 3-year, $7.3 million Health Care Innovation Award from the Centers for Medicare & Medicaid Services to develop and implement the Brookdale Senior Living Transitions of Care Program. He was also a professor and the chair of the Department of Health Management and Policy, School of Public Health, University of North Texas Health Science Center.

Thomas Pippin, BC-HIS, has worked in the hearing health field as a hearing instrument specialist since 1967. From 1973 to 2014 he owned his own practice with multiple offices. He retired in 2014. Mr. Pippin served on the Wisconsin state licensing board for hearing instrument specialists for 10 years, serving as chairman of the board for 9 years. While serving on the board he worked to promote interdisciplinary teamwork in hearing health care. He was active for more than 23 years in working with the Wisconsin licensing exam, including testing oversight and a rewriting of the exam. Mr. Pippin has served on numerous state and national committees related to hearing health, particularly regarding licensing and regulation. His work has focused on consumer service and ensuring quality hearing health care. Mr. Pippin has an extensive collection of antique hearing aids and has written several books on the topic.

Katherine D. Seelman, Ph.D., is the associate dean of disability programs and a professor of rehabilitation science and technology at the School of Health and Rehabilitation Sciences, University of Pittsburgh. She holds secondary appointments in the School of Public Health and the Center for Bioethics and an adjunct position at Xian Jiatong University, China. Formerly serving as co-research director, she became senior policy adviser for the National Science Foundation–supported Quality of Life Technology Engineering Research Center which is housed in the Robotics Institute at Carnegie Mellon University. Dr. Seelman has a lifetime interest in science, technology, public policy, and disability. She is a member of the National Council on Disability and has served as a consultant to the World Health Organization's (WHO's) blindness and deafness unit and to the World Bank. She was one of two from the United States serving on the WHO/World Bank's nine-member international editorial committee to guide the development of the first World Report on Disability and presented a chapter of the report, for which she was a principal section author, in 2011 at the United Nations. During the Clinton Administration, she served for 7 years as the director of the National Institute on Disability and Rehabilitation Research in Washington, DC. She was the recipient of the University of Pittsburgh Chancellor's Distinguished Service Award in 2007. Dr. Seelman, who is hard of hearing, serves as adviser to the University's Students for Disability Advocacy and is co-chair of the City of Pittsburgh-Allegheny County Task Force on Disability. She is widely published and the recipient of many awards.

Debara L. Tucci, M.D., M.S., M.B.A., is a professor of otolaryngology head and neck surgery, at Duke University. Dr. Tucci has a subspecialty practice in otology, neurotology, and skull base surgery, and she also conducts basic science and clinical research. Prior to medical school, she received an M.S. in audiology from the University of Michigan and worked as a clinical audiologist for 4 years at University of Virginia Hospital. She is co-principal investigator on an NIH–funded grant focused on establishing a network of academic and community-based research sites to conduct clinical research in hearing and balance disorders. In this effort she interfaces with the Duke Clinical Research Institute and has been able to access the resources of that institute for program development. She is also the principal investigator of a grant designed to develop a protocol for hearing screening of older adults in primary care practices and to investigate the need for medical evaluation of adults who are considering hearing aid purchase. Dr. Tucci's leadership roles in professional societies include president of the American Auditory Society, secretary-treasurer and president of the American Neurotology Society, president of the Association for Research in Otolaryngology, board of directors for the American Academy of Otolaryngology Head and Neck Surgery, and research fund trustee and current president of the American Otological Society. She completed a year-long leadership training program, Executive Leadership for Academic Medicine, and holds an M.B.A. degree with a certificate in health sector management from the Duke Fuqua School of Business.

David A. Zapala, Ph.D., is an associate professor of audiology in the College of Medicine, Mayo Clinic Foundation. He is also a senior consultant in otorhinolaryngology and the chair of the Audiology Section at the Mayo Clinic in Florida. He is active in direct patient care; resident, fellow, and postdoctoral mentorship; clinical research; and clinical information management. From a research perspective, he has focused on mathematical modeling methods to improve audiological and vestibular diagnostics and quantify the functional consequences of hearing impairment. He also studies the perceptual and functional consequences of vestibular and balance disorders. Dr. Zapala received a master of science degree from Utah State University in 1983 and a Ph.D. from the University of Memphis in 1993. Early in his career he developed the Mid-South Lions Infant Hearing Center and the Methodist/University of Tennessee Hearing and Balance Center at Methodist Healthcare in Memphis. He also served as a clinical professor in otolaryngology at the University of Tennessee. Dr. Zapala has published and taught in the areas of vestibular assessment and diagnostic audiology. He has served on the American Board of Audiology and the board of the American Academy of Audiology and the American Balance Society and is a past president of the Tennessee Academy of Audiology. He is the recipient of the Edward Dalstrom Distinguished Service Award by the Mid-South Lions Sight and Hearing Service (2001); Distinguished Service Award from the American Board of Audiology (2007); Jerger Mentor Award in Clinical Research (2009); Outstanding Alumnus of the Year by School of Communication Sciences and Disorders, University of Memphis (2013); and the Arnold D. Tuttle Award for co-authorship of the winning paper in Aviation, Space, and Environmental Medicine (2013). His research is supported by the Mayo Clinic, the Knowles Foundation, and NIH. He is currently funded by NIDCD to study how well consumers and audiologists can assess ear disease risk prior to hearing aid purchase.