

Opening the Market for Lower Cost Hearing Aids: Regulatory Change Can Improve the Health of Older Americans

Hearing loss is a leading cause of disability among older people. Yet only one in seven US adults who could benefit from a hearing aid uses one. This fraction has not increased over the past 30 years, nor have hearing aid prices dropped, despite trends of steady improvements and price reductions in the consumer electronics industry.

The President's Council on Science and Technology has proposed changes in the regulation of hearing aids, including the creation of a "basic" low-cost over-the-counter category of devices.

We discuss the potential to reduce disability as well as to improve public health, stakeholder responses to the president's council's proposal, and public health efforts to further mitigate the burden of disability stemming from age-related hearing loss. (*Am J Public Health*. 2016;106:1032–1035. doi:10.2105/AJPH.2016.303176)

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Hearing loss impairs communication, an essential human function.¹ The most common cause is age-related hearing loss (ARHL), characterized by progressive hearing loss and degraded speech comprehension in both ears.

In the United States, one quarter of adults aged 60 to 69 years have a bilateral disabling hearing loss; this climbs to nearly 80% among those aged 80 years and older.² ARHL reduces quality of life³ and is associated with social isolation⁴ and depression⁵—problems that are important in their own right and are risks for medical conditions such as cardiovascular disease. Hearing loss is also associated with falls, fractures, and faster cognitive decline.

Hearing loss disrupts health care. Compared with adults with normal hearing, those with hearing loss report worse communication with their physicians.⁶ They also report overall poorer health care quality.⁶ Because many older people have complex medical problems, these disruptions pose a serious challenge.

In this commentary, we contrast the high population burden of disability with the low prevalence of hearing aid ownership among older Americans. We describe cost as a barrier to ownership and discuss a recent high-profile call for regulatory change that could substantially lower costs.

We note factors beyond cost that need to be addressed to improve hearing health and functioning.

COST AS A BARRIER TO HEARING AID OWNERSHIP

Hearing aids improve communication,¹ and clinical trials show that they enhance overall quality of life.⁷ Despite emerging evidence regarding their value, only one in seven US adults with hearing loss wears a hearing aid.⁸ Use increases with age and degree of loss.⁹ Ownership is lowest among socioeconomically disadvantaged groups, including minorities and those with the lowest income and education.¹⁰

Hearing aids are expensive. Medicare and most insurance plans don't cover them, and so consumers typically pay for aids and fittings out of pocket. ARHL affects both ears, and a pair of aids typically costs on the order of \$6000, a sum beyond the reach of many seniors. In a recent population-based prospective study, a majority of participants

cited cost as a major deterrent to buying a hearing aid.⁹

WHY ARE COSTS SO HIGH?

In fall 2015, the President's Council of Advisors on Science and Technology (PCAST)—a panel of 19 academic scientists and industry leaders who act as an advisory to President Obama—reviewed issues of hearing aids and ARHL as part of a wider study of how technology might improve and enhance life for older people.¹¹ Noting the high prevalence and low ownership rates, PCAST identified cost as the key barrier to ownership and linked high cost to two interrelated institutional factors: (1) the noncompetitive hearing aid market and (2) inefficient hearing aid distribution channels.

The past two decades brought dramatic price reductions in consumer electronics, along with the development of ever better digital devices. But this hasn't happened in the hearing aid market. PCAST attributed this failure to market concentration:

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This article was accepted March 2, 2016.
doi: 10.2105/AJPH.2016.303176

innovative entrants are unlikely in a market in which six companies produce 98% of devices worldwide. Although information is tightly held about costs and margins within the supply chain, the components of a hearing aid cost about \$100.¹²

Audiologists and hearing instrument specialists are the primary distributors, often selling through private offices (although increasingly they compete with big box stores and online vendors). But private audiologists face manufacturers' pricing protocols, and dominant manufacturers often hold exclusive or close relationships with practitioners. This makes it hard for new firms to enter the market. It also means that consumers are often unable to compare a full range of products before making a purchase. Consumer choice is further blocked by opaque pricing practices: under the prevalent bundled service model, patients pay a lump sum that covers the initial evaluation, fitting, and purchase of the device as well as follow-up visits for adjustments and oftentimes batteries. Many consumers do not use follow-up services, and those services comprise the bulk of the bundled fee. In sum, the cost of hearing aids is out of reach for many, and current arrangements do not support competition, innovation, or consumer choice.

PROPOSALS FOR REGULATORY CHANGE

In PCAST's estimation, a small set of regulatory changes could help overcome much of this inefficiency and under-treatment and bring prices down (see the box on the next page). Foremost is a proposed change in the Food and Drug

Administration (FDA) regulation to create a new class of over-the-counter (OTC) "basic" hearing aids to be targeted at people with early (mild to moderate) ARHL. These would be sold in much the same way as OTC reading glasses. Creating an OTC market would foster competition, broaden consumer choice, and drive down prices. It could also normalize hearing loss and wearing in-ear devices by bringing device purchase into the consumer mainstream. Finally, vigorous competition might spur the development of more appealing, less prosthetic-looking devices—an innovation that has largely eluded the hearing aid industry to date.

A second recommendation concerns the FDA stance on so-called personal sound amplification products (PSAPs; sometimes called "hearables"). These electronic devices are worn in or over the ear, amplify and process sound signals, and at the high end (approximately \$350–\$500) share many features with hearing aids. There is no question that PSAPs can be helpful for people with hearing loss and may even assist people with normal hearing when they are in noisy environments. But to date, the FDA has distinguished between hearing aids and PSAPs on the basis of their intended uses rather than their performance.

According to FDA guidance, hearing aids are intended for people with hearing loss, and PSAPs are intended for people without hearing impairment who want hearing assistance in certain difficult listening situations. Although the FDA has declined to regulate PSAPs, it has warned PSAP manufacturers against making claims that their products are suitable for people with hearing loss. According to PCAST, this has led to an

"unproductive and escalating exchange between PSAP vendors and the FDA regarding the wording of product labels and advertisements for PSAPs"^{11(p7)} that does not serve the interests of consumers. The FDA should allow PSAP vendors to market their devices to people with mild to moderate ARHL.

The third and fourth recommendations, which were made to the Federal Trade Commission, have to do with transparency and enhancing consumer choice. The first states that consumers should have the right to a free copy of their hearing health-related data (audiogram and programmable audio profile) so that they can take their medical data and purchase a hearing aid from whomever they wish. This is analogous to the rule that allows a no-cost copy of an eyeglasses prescription. The other says that patients should be able to authorize hearing aid vendors (in state or out of state) to get a copy of patients' medical data to allow purchase from any vendor. This is analogous to the rule that governs the sale of contact lenses from low-cost vendors. Both recommendations would likely bolster online sales.

All four of the recommendations could be implemented by the federal agencies without legislative action.

MIXED RESPONSES FROM STAKEHOLDERS

PCAST's recommendations offer a plausible path to increased device ownership in a population with a high disease burden and high need. The PCAST report has been hailed by the Hearing Loss Association of America, the premier advocacy group for Americans with hearing loss,

as well as the Consumer Technology Association, which represents the interests of PSAP manufacturers. The Academy of Doctors of Audiology, the voice for doctoral-level clinical audiologists, has also expressed qualified enthusiasm.

Others have been more critical, citing concerns about patient safety and quality of care. These include the American Speech-Language-Hearing Association and the American Academy of Audiology, which represent audiologists practicing in a variety of settings, as well as the Hearing Industries Association, which speaks for hearing aid manufacturers. Although these groups have varying concerns, perhaps the most prominent is that the shift to OTC devices would come at the cost of missed opportunities to screen for serious underlying disease. For example, hearing loss can be caused by underlying medical conditions such as acoustic neuroma (tumor of the hearing nerve), chronic otitis media, or impacted ear wax. Since 1976 the agency has required a medical examination before having a hearing aid dispensed to rule out these and other significant medical conditions. However, the agency allows informed adult consumers to sign a waiver of the requirement and purchase aids directly from audiologists or dispensers.

Underlying PCAST's recommendation is a public health calculation that balances risks of foregoing medical examinations for a small number of patients with currently unrealized benefits to millions of Americans with untreated hearing loss. PCAST acknowledges that medical exams can uncover occult disease but argues that the "frequency and severity of the conditions that are likely to be detected" should be weighed

SUMMARY OF REGULATORY CHANGES RECOMMENDED BY THE PRESIDENT’S COUNCIL ON SCIENCE AND TECHNOLOGY

To the FDA Regarding OTC Device Sales

The FDA should designate a new, distinct class of “basic” hearing aids intended to address mild to moderate ARHL to be sold OTC.

For “basic” aids, consultation with a credentialed dispenser should not be required, and federal regulation should preempt any state laws requiring such consultation.

OTC devices could be labeled with appropriate warnings about red flag symptoms of serious underlying conditions.

The FDA should approve OTC tests that allow consumers to self-fit and adjust devices.

The FDA should withdraw its draft guidance on PSAPs.

PSAPs should be understood as devices for discretionary consumer use, which may be helpful to people with hearing loss as well as those with normal hearing who have difficulty understanding speech in some situations.

To the FTC Regarding Non-OTC Device Sales

Analogous to the “eyeglass rule,” audiologists and hearing aid dispensers must provide consumers with copies of hearing tests and programmable audio profiles at no additional cost.

Clinicians must provide medical information that the consumer can take to other dispensers or vendors to configure a hearing aid for the consumer.

Clinicians must provide tests and fittings without requiring consumers to purchase additional goods and services.

Analogous to the “contact lens rule,” the FTC should define a process whereby (in-state and out-of-state) hearing aid and PSAP vendors can get a copy of the consumer’s hearing test and programmable audio file from the clinician who performed the test at no additional cost.

Clinicians must provide medical information that will allow other vendors to configure a hearing aid for the consumer.

Note. FDA=Food and Drug Administration; FTC=Federal Trade Commission; OTC=over-the-counter; PSAP=personal sound amplification product.
Source. President’s Council of Advisors on Science and Technology.¹¹

against “the greater barriers to obtaining assistance for mild-to-moderate hearing loss among the tens of millions of aging Americans”^{11(p5)} resulting from current regulations. They argue for informing consumers: hearing aids can be safely sold OTC if labeled with appropriate warnings about red flag symptoms that could signal serious occult disease (e.g., sudden hearing loss or unilateral loss, which is typical of acoustic neuroma).

Other criticisms revolve around the self-service model implied by PCAST. Some audiologists and members of the hearing aid industry argue that professional guidance is essential to diagnosis, device fitting, and device adaptation, even for those

with early hearing loss (the group targeted by PCAST). To our knowledge, there is little evidence to support or refute this claim for those with early ARHL.¹³ Nor is there strong evidence to support claims that OTC devices are effective in reducing disability for the same group.

In response to PCAST’s call, the FDA has reopened the comment period on its previously issued draft guidance on PSAPs and will convene stakeholders for a public workshop in spring 2016¹⁴ on regulations surrounding the manufacture of hearing aids—rules that now make it difficult for manufacturers to innovate

quickly and serve as barriers to market entry.

BEYOND THE COST BARRIER

PCAST’s proposals have the potential to significantly improve public health by lowering financial barriers for patients, which would stimulate innovation by manufacturers and bring hearing loss into the consumer mainstream. However, there are many barriers to better hearing.

Uptake of hearing aids is low, even in nations where aids are available for free. In the United Kingdom, for instance, aids are provided by the National Health

Service, but uptake and use are not substantially higher there than are uptake and use reported in the United States.¹⁵ Typically, people wait close to 10 years from the time that they notice hearing loss to the time that they acquire an aid, and by this time, their loss has often progressed to a moderate to severe level.¹⁵ In the United States, a longitudinal study of people with hearing loss who did not own a hearing aid at baseline found that after 10 years only one third had acquired aids.⁹ Three key barriers to acquisition were seen: the perception that an aid was not needed, acquaintance with someone who had a negative experience with an aid, and cost.

ARHL comes on slowly, recognition of disability is often

gradual, and many consider hearing loss to be an inconsequential part of aging.¹ Stigma profoundly influences acceptance of hearing loss, readiness to have hearing tested, and the decision to use an aid.¹⁶ Half of people with hearing loss who do not use hearing aids cite some form of stigma as a major reason for their decision.¹⁷ Factors include the perception that wearing hearing aids makes one look disabled, weak, or old; the fact that hearing aids are noticeable; and the perception that people treat wearers differently. Hence ageism and vanity are significant factors, as well.

Many people who own hearing aids do not use them, perhaps because of the incorrect expectation that hearing aids will restore hearing or communication to normal levels. Adaptation takes patience and requires skilled help for those with substantial losses. Indeed, this is part of PCAST's rationale in recommending "starter" OTC devices for those with early loss. Such open canal devices can be relatively easy to fit and adapt to, and early treatment may prevent the atrophy and degradation of auditory systems that accompany loss—although again, evidence for this is scant. Continued use and success also requires social and professional support: like all electronic devices, hearing aids can malfunction and need repair. Changes in hearing loss over time mean that aids must be monitored and adjusted during regular visits to an audiologist or hearing instrument specialist.

A variety of adjunctive technologies (hearing assistive technologies) and rehabilitative practices can extend the effectiveness of hearing aids. Environmental accommodations benefit individuals and whole communities. Hearing loops (thin wires installed

around a room's perimeter that allow the wireless streaming of sound via magnetic induction to hearing aids that contain electromagnetic sensors or T-coils) are not commonly used in the United States. But in some European nations, looping systems allow people with hearing loss to function well in train stations, airports, churches and cathedrals, and theaters.¹⁸ Other personal devices accept sound transmitted via FM (frequency modulation) signal, Bluetooth, or other proprietary protocols and can extend communication in the home or office. User-controlled technology, including iPhone-based systems, offer promise for the future.

People with hearing loss beyond the early stages typically need more than just hearing aids. Aural rehabilitation includes training on use of hearing aids and hearing assistive technologies as well as education on strategies to improve comprehension in challenging listening environments. Rehabilitation can be delivered to individuals or groups, either in person or online; it has proved effective in some studies.¹⁹ However most audiologists do not offer rehabilitation services, and Medicare and most third-party payers do not cover them. This is an area where stronger evidence on effectiveness could drive changes in training, practice, and reimbursement.

MOVING FORWARD

Stakeholders will converge on the FDA this spring. Expectations run high for an Institute of Medicine consensus document scheduled for release this summer. The Institute of Medicine report will cover issues well beyond access to devices, including

prevention, screening, innovative models for delivery of hearing health care, and matters relating to access to care for specific vulnerable populations.

Older adults have long struggled with disability from hearing loss. Baby boomers—health conscious, tech savvy, and consumer aware—are unlikely to accept the hearing loss status quo. Regulatory change, innovation, research, and new approaches to clinical practice could all contribute to better population health in the future. **AJPH**

CONTRIBUTORS

Both authors contributed to the conceptualization, writing, and editing of this commentary.

ACKNOWLEDGMENTS

We thank Shari Eberts, Richard Einhorn, Carrie Nieman, Sara Mamo, Ashley Predith, Mark Schwartz, Leonardo Trasande, and Beth Weitzman for their thoughtful comments on prior drafts.

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