

PATIENT CARE & POSITIVE OUTCOMES: THE FOCUS OF HEARING HEALTH

The Hearing Industries Association (HIA) is providing this paper to the Institute of Medicine (IoM) in support of efforts by its Committee on Accessible and Affordable Hearing Health Care for Adults as well as to the President’s Council of Advisors on Science and Technology (PCAST) in support of its review of hearing technologies. HIA’s objective is to assist both groups in their decision-making by consolidating and amplifying information that has been presented in previous meetings, as well as to provide different data to address information and views provided during this process. We applaud both IoM and PCAST for their focus on hearing loss and hearing care in America and appreciate the opportunity to contribute to their efforts to increase access to care and affordability of treatment.

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EXECUTIVE SUMMARY

Hearing health is a critical aspect of overall public health that has a major impact on many other elements of a person’s physical and psychological well-being. Failure to adequately address hearing loss can have profound negative consequences including an increase in dementia risk and a tripling of the risk for falling. Also, it has been demonstrated that the symptoms of depression are reduced, and quality of life improved for people with hearing loss who use hearing aids. In addition, hearing loss is also more likely to affect people with other chronic conditions such as diabetes and kidney disease, and the failure to hear also impacts on a person’s ability to comprehend and follow instructions given by doctors, pharmacists and others regarding medications.

Of critical importance, while hearing loss is often related to the aging process, a significant percentage of hearing loss is caused by other conditions, which cannot be self-diagnosed. Some of these, which are referred to as “red flag” conditions by the FDA, require timely intervention and treatment by a physician. These red flag conditions are not rare. Reports from two major national hearing aid retail chains covering more than 250,000 individual visits around the country indicate that approximately 4-5% of people who visited their stores for a hearing screening required a medical referral for a red flag condition.

Hearing aids, cochlear implants, and Auditory Osseointegrated Implants (AOIs) are the only medical devices recognized by the Food and Drug Administration (FDA) to treat hearing loss. The hearing aid industry invests over \$600 million in research and development each year in addition to money spent to insure product quality, robustness, biocompatibility and recallability. As a part of these R&D investments, more than 6,000 engineers and scientists work to develop sophisticated devices and algorithms—in comparison to sound amplifiers—to process sound instantaneously, classify these sounds, and produce the highest level of audibility, sound quality, and spatial perception (*i.e.* localizing sound) that resembles natural hearing—all with minimal power consumption. These modern devices must perform in difficult environments since they are worn on or inserted into the human body. Modern hearing aids also connect to an array of Bluetooth enabled devices such as smartphones, TVs, iPods, laptops, and car audio systems.

The hearing aid distribution network has also evolved dramatically in recent years, which has increased access for people with hearing loss. Major box-store chains, insurance networks, and on-line dispensing operations now provide access, while also offering the necessary elements of professional hearing evaluation and safe and efficacious devices ranging from basic to extremely sophisticated technology. These ongoing market developments provide multiple options for people with hearing loss to access hearing healthcare without resorting to self-diagnosis and treatment.

These evolving professional service and delivery structures provide for a wide range of hearing aid technologies and services that meet the needs of most budgets (\$500 - \$3,000 per hearing aid including testing, fitting and follow-up), while ensuring that proper safeguards and referrals for “red flag” conditions that preclude hearing aid use have been followed. Hearing aid manufacturers provide hearing aids for all markets including those that are considered “disruptive” of traditional distribution channels, without forcing the person with hearing loss to forego evaluation and fitting by a hearing professional.

The future promises ever greater technological innovation, increased access, and positive outcomes for people with hearing loss. However, this promise can only be realized if hearing healthcare is not trivialized to the level of a condition where people are erroneously encouraged to believe that they can self-diagnose the causes of their hearing loss and purchase a consumer electronic product (*i.e.* Personal Sound Amplification Product, or “PSAP”) to address that loss.

Given that 4-5% of people who access hearing care must be referred by a hearing professional for further medical evaluation based on the identification of a “red flag” condition, it is critical that policy changes should not be implemented to encourage people with hearing loss to diagnose and treat themselves. A policy to encourage PSAP marketers to make claims that their products address hearing loss will result in two types of errors: (1) the non-diagnosis of red flag conditions, and (2) unnecessary purchases of a non-medical device when a simple medical solution might solve the problem. Such a policy would be akin to urging individuals to postpone diagnosis and forgo appropriate treatment.

CHAPTER ONE: COMPLEXITY OF HEARING LOSS

A common misconception is that simply increasing the volume of sound will enable a person with hearing loss to hear and understand fully. Although one of the hallmarks of hearing impairment is a loss of sensitivity to certain sounds which must be amplified to be made audible, hearing impairment is also defined by the distortions experienced for incoming sounds that are above threshold.¹ Simply amplifying sounds to adjust a patient’s sensitivity to softer and moderate sounds can also create a condition in which incoming sound is not properly encoded by the peripheral auditory system making it more difficult to understand speech or other sounds.² Therefore, simple amplification is not enough to overcome the full effect of hearing impairment.

It is important to recognize that hearing impairment is not fully reflected by the hearing test. Most patients who use amplification suffer from changes to the complex physiology of the peripheral auditory system, and only a part of these changes are captured by the audiogram. The cochlea and associated mechanical and neural structures turn a complex acoustic waveform into a neural code. In order to perceive sound, an intact population of inner hair cells must be stimulated in a way that properly reflects the frequency, intensity and timing of incoming sound. The inner hair cell activation is then transmitted to the central auditory system. But in order for that inner hair cell activation to occur in a proper way, many other structures and functions must work properly.³ Simply providing increased amplification cannot replicate the complex interactions between the auditory system and the brain, so the provision of OTC hearing aids (or PSAPs sold to people with hearing loss) will not adequately address the needs of a person with hearing loss.

A range of physical conditions can create hearing impairment: exposure to noise, genetic effects, infections, aging and accidents, among others. Some of the underlying causes of hearing loss are related to serious medical conditions that must be addressed by a physician, and which can only be detected during a physical exam of a person's ear. When one of these etiologies creates the changes that lead to hearing loss, there will also be changes in the complex interactions between structures and functions within the cochlea and associated neural structures.²

One of the hallmarks of hearing loss is that significant variability exists from patient to patient and how these structures and functions change. Among other complex factors, this variability can stem from differences in:

1. *Frequency resolution* (the ability to tell two pitches apart);
2. *Temporal resolution* (the ability to properly perceive the timing of auditory events); or
3. *Loudness perception* (how much range is available between the softest sound that can be heard and the loudest sound that can be tolerated).

A combination of deficiencies in any of these factors can result in complex acoustic input that is not properly represented in the central auditory system, particularly when a patient is trying to communicate in a complex listening environment. The cognitive system is capable of suppressing unwanted competition to allow the listener to focus on the primary signal. However, in the presence of hearing loss in which the signal coming from the periphery is incomplete or distorted, these natural squelching abilities are compromised. For most patients, the effects of background noise are significantly more exaggerated, and the range of the effect of speech understanding in noise from patient to patient is great and not well predicted by the audiogram.¹ This makes intervention by a hearing professional who can program the hearing aids to the person's specific hearing loss essential.

Amplification is Only Part of the Solution to Address Hearing Loss

In the process of evaluating a person's hearing loss and fitting hearing aids, all of these distortional effects are taken into consideration by the professional. The need for more advanced signal processing, the adjustment of those systems, and proper patient counseling are all driven by the professional's interpretation of the individual impact of hearing impairment on the particular patient. Simply measuring the audiogram and using those measurements as a complete description of the patient's perceptual issues is inadequate.

In addition to variability in the effects of peripheral hearing impairment, it must be recognized that speech understanding is a cognitive process. The peripheral auditory system encodes acoustic information, but the interpretation of that information, particularly when considering speech, happens in the brain. One finding that is well recognized is that normal age-related changes in neural activity can lead to a loss of

efficiency in the processing of cognitive information.⁴ Long before conditions such as dementia or Alzheimer's emerge, normal age-related slowing of neural activity can lead to communication difficulties.

Hearing Professionals Must Consider Impaired Cognition and Hearing Loss

When the signal being encoded by the peripheral auditory system is inaccurate or less than complete because of the effects of hearing impairment, the central cognitive system must work that much harder to interpret this incomplete or distorted signal. However, if the cognitive system is beginning to show age-related changes, then communication, especially in difficult listening environments, becomes compromised to an even greater degree. Thus, the loss of efficient cognitive processing is another area where the skill of the professional is essential to understanding how to properly select and adjust technology and how to properly educate and counsel the patient and loved ones.

The mistaken belief that simple amplification alone will be sufficient to overcome the full impact of hearing loss leads to misunderstanding and frustration among patients and family members. However, with proper counseling from a hearing care professional, the true nature of the condition can be better explained to patients who are being fitted with hearing aids. The hearing care professional must understand the full impact of hearing loss on the patient and then find the right solutions (hearing aids and appropriately selected accessories as necessary) and combination of settings within those solutions to address the specific nature and impact of that person's hearing loss.

CHAPTER TWO: SOPHISTICATION OF TECHNOLOGY

Research and Development for a new hearing aid platform incorporates many areas of expertise including software, hardware, programming interfaces, tooling, and quality and regulatory activities. Hearing aid and component manufacturers spent almost \$600 million on Research and Development in 2014 as part of ongoing efforts to develop the technological breakthroughs in digital processing, wireless programming, and other areas that have enhanced the performance of hearing aids. This also represents the activity of over 6,000 employees working in these areas. In addition to resources spent on Research and Development, hearing aid manufacturers are also involved in significant regulatory activities, including compliance with FDA's quality system regulation (QSR), and environmental and biocompatibility considerations and other FDA regulations.

These efforts have enabled hearing aid manufacturers to make tremendous progress in developing hearing aids as sophisticated devices with powerful processing that can be programmed by a hearing professional to address the individual needs of each person with hearing loss. The major components of a modern hearing aid include a microphone, loudspeaker (also referred to as a receiver), the amplifier or signal processing chip, and a power supply (battery). A major challenge for hearing aid engineers is ensuring that all of these components are miniaturized so they can fit within or behind the ear and work on very low battery current. Almost all hearing aids manufactured today use digital signal processing that is considerably more powerful than the analog devices of the early 1990s. Use of a processing chip inside the hearing aid provides tremendous opportunities for the development of advanced algorithms.

Hearing Aids are Programmed to Adapt to Specific Listening Situations

The algorithms, or mathematical models that drive the hearing aid, are responsible for a multitude of tasks that provide the wearer of the hearing aid with reliable operation. These include the following:

1. Automatic adjustment of the loudness of the amplified signal,
2. Classification of the input signal with automatic adjustments to the hearing aid,

3. Steering of directional microphones,
4. Identification and reduction of environmental background noise,
5. Calculation of any potential feedback (or whistling),
6. Binaural signal processing tasks, and
7. Streaming of audio signals such as television or cell phones.

To determine the appropriate amount of amplification (or gain), the processor must first determine the overall loudness of the input signal to the hearing aid. The appropriate amount of amplification is added to the input signal to allow for speech understanding. Another feature of modern hearing aids is the ability to classify the signal to engage necessary algorithms to automatically provide audibility and sound comfort. These classification categories include standard listening environments such as speech in quiet, speech in noise, music, and riding in a car. Once the signal is classified, each unique listening environment has properties that are addressed by one or more of the special algorithms in the amplifier or chip. These complex algorithms enable a person with hearing loss to function in a more “normal” listening atmosphere, whereby background noise that is normally filtered through the complex interaction of the brain and auditory system (*i.e.* exhaust fans) is filtered by the hearing aid.

Hearing in background noise is typically the most difficult situation for individuals with hearing loss, such as during a large reception when background noise is comprised of other speakers. Modern hearing aids using directional microphone technology incorporate two microphones that will receive the signal at slightly different times due to the spacing between them. This difference influences the signal processing scheme to focus on either the primary signals in front of the wearer (in a conversation) or the loudest signal even if it is behind them, such as from a passenger in the rear seat of a car. This can play a critical safety role, such as when a person yells “danger” behind the person with hearing loss. Directional microphones can also be programmed to follow a sound that may be moving somewhere around the wearer (*i.e.* an auto passing on the street) and reduce the negative effects of that signal – allowing the wearer to focus on the conversation in front of them.

One of the most beneficial algorithms is digital feedback reduction. While older hearing aids often produced significant whistling feedback, today’s hearing aids have all but eliminated unwanted feedback by using noise cancelling techniques to identify true feedback conditions and introducing phase inverted signals to cancel the feedback. Feedback elimination is accomplished without perception by the wearer, and has no impact on speech understanding while eliminating the embarrassment that hearing aid users experienced routinely in the past, and which was given by some as a reason for non-adoption.

Hearing Aids with Wireless Features Create New Options for People with Hearing Loss

It is becoming increasingly important for modern hearing aids to have the capability to connect wirelessly to a wide range of consumer products—including mobile phones, MP3 players, and televisions. Signals from these can be streamed to hearing aids using direct signal input or through an intermediary device. In addition, patients have access to a wide variety of applications that allow them to control such features as loudness, change of listening programs, and focus of the directional microphones for greater understanding and listening comfort. The apps are available on both Apple and Android platforms, and can be used with almost any smart phone.

In summary, the modern hearing aid is an advanced medical device that must operate efficiently in a wide variety of settings, as it is crucial to enhancing the overall quality of life for the person with hearing loss.

CHAPTER THREE: ACCESSIBILITY & AFFORDABILITY

Given that untreated hearing loss increases the risk of dementia, depression, falls, and other adverse health conditions, it is critical that people act to address their hearing loss. A wide range of hearing aids, at a variety of price points that include professional evaluation, fitting and follow-up, are available nationwide. In addition, numerous hearing aid distribution models exist and continue to evolve to provide access to care by hearing health professionals without forcing the patient to accept the risks inherent in self-diagnosis and treatment.

As discussed above, sound amplification alone is not enough to overcome the full effect of hearing loss, and it is critical for an individual with suspected hearing loss to seek care from an appropriately qualified hearing professional (*i.e.* an audiologist, hearing aid dispenser or a medical doctor with expertise in otology). The failure to do so may result in the person with hearing loss selecting a product to improve hearing without considering – or even being aware of – other factors that may be contributing to or causing the hearing loss. This could include other medical conditions that require treatment beyond the use of a hearing aid. Consultation with a hearing professional prior to selecting a hearing aid is critical to ensure that: (1) patients are fitted with devices that are appropriate for their particular needs, and (2) potentially significant medical conditions are not overlooked. Given the importance of patient-specific adjustments to hearing aids, access to hearing professionals is of paramount importance.

The Evolving Market for Hearing Aids and Professional Services

There are approximately 22,000 licensed hearing professionals⁵ in the United States available to dispense hearing aids. In fact, there is one hearing professional for every 1,500 of the 33 million people with hearing loss in the U.S.⁶ Of critical importance, the ratio of hearing professionals to current hearing aid users is one for every 500 people who use hearing aids. If the American hearing aid usage rate were to climb to 50%, there would still be one hearing professional for every 750 people with hearing loss. These hearing professionals provide diagnostic, fitting and follow-up care to prospective hearing aid users through a variety of different distribution channels, including the following:

1. Public sector (24%), including the Veterans Administration, Government Services, Medicaid;
2. Private sector (39%), including clinical, retail, and private practice affiliates;
3. Third-party contract affiliate programs (16%), including Medicare Advantage, health care insurance affinity programs;
4. Manufacturer-owned retail stores/clinics (11%);
5. “Big Box” stores (10%), including Costco, Sam’s Club, etc.

The pricing options available through these professional service and delivery structures provide for a wide range of hearing aid technologies and services that meet the needs of most budgets (\$500 - \$3,000 per hearing aid including testing, fitting and follow-up), while ensuring that proper safeguards and referrals for “red flag” conditions that preclude hearing aid use have been followed. Hearing aid manufacturers provide hearing aids for all of the markets listed above including those that are considered “disruptive” of traditional distribution channels, without forcing the person with hearing loss to forego evaluation and fitting by a hearing professional.

Furthermore, there are a number of companies that offer financing plans and loss/damage insurance in the event that the device is damaged or broken. Such ancillary financial services and the increasingly diverse channels through which people can access hearing aids ensure hearing aid affordability without

eliminating the crucial participation of hearing professionals to ensure that important health conditions are not ignored. This combination of new technologies, varying prices, and multiple distribution channels allows consumers to receive precision medicine.

Clinical Uncertainty & Long-Term Risks Are Inherent in the “PSAP Alternative”

There are a number of entities that propose allowing people with hearing loss to select what are known as “personal sound amplification products,” or PSAPs, to treat their hearing loss. FDA has repeatedly stated that PSAPs are not medical devices and that PSAP marketers may not make claims that their product is intended to treat hearing loss. FDA has also made it clear that if a product is intended to treat hearing loss, then it is a medical device. Instead, PSAPs are for people with normal hearing who have a desire or need to amplify sounds in certain situations, such as for hunting or bird-watching.⁷

One of the reasons provided by FDA for not allowing PSAPs to be marketed to consumers essentially as over-the-counter hearing aids, without first visiting a hearing professional, is that “[d]oing so could delay the diagnosis of a treatable or serious ear condition and lead to further hearing loss or other complications.”⁸ Therefore, in considering accessibility and affordability, it is also important to address patient well-being. Having an off-the-shelf option is of no benefit if that option is not appropriate for the user, and its use may, in fact, negatively impact the care and treatment of the user.

Hearing Aid Regulation Protects People with Hearing Loss

As noted above, PSAPs are not regulated by FDA as they are not medical devices. As a result, PSAPs can be sold legally without any FDA oversight, let alone the basic safeguards and special controls required of hearing aids, which are either Class I or Class II medical devices. These controls go well beyond the requirement for a medical examination.

As medical devices, hearing aids must be manufactured in compliance with the Quality System Regulation found at 21 C.F.R. Part 820, which regulates the design, manufacture, packaging, and labeling of medical devices. Compliance with the QSR is one way to ensure that hearing aids will be safe and effective for their intended use. Additionally, hearing aid manufacturers must track, investigate and evaluate complaints for reporting to FDA, and implement recalls if they learn of a potential defect or other issue requiring remediation. Moreover, hearing aids are required to comply with certain testing standards that would not be required of a consumer product such as a PSAP. All of these controls serve as a safeguard against defective or fraudulent products, or products that do not perform as intended.

PSAPs are subject to none of these safeguards. Treating PSAPs interchangeably with hearing aids means that consumer protections will be lowered, and products may be marketed to treat hearing loss without requiring the testing necessary to confirm that the products achieve their intended purpose. Indeed, reports show that PSAPs can generate very high amplification, potentially harming the consumer’s hearing. For hearing aids, FDA recommends that special care be taken by hearing professionals when selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user.⁹

Moreover, adequate hearing can play a key role in protecting individuals. Not hearing auditory cues can put patients at risk. A PSAP that does not enable a consumer to perceive a safety signal can put that individual at risk. The well-known understanding of self-perceived hearing loss compared to actual hearing loss further illustrates the challenges in considering PSAPs to be an appropriate solution for hearing impairment.

FDA regulation is critical to establishing the safety and efficacy of medical devices meant to address a specific condition such as hearing loss. To promote a consumer product instead of a medical device to people with hearing loss violates FDA's statutory authority and puts consumers at increased risk.

Identifying “Red Flag” Conditions is Crucial to Patient Safety & Effective Treatment of Hearing Loss

Of critical importance, a patient acting independently would not be able to determine the cause of his or her hearing loss or evaluate his or her own condition. FDA has long recognized the potential risks that could accompany the sale of OTC hearing aids without examination by a clinician. FDA has referred to these conditions as “red flag” conditions including:

1. Visible congenital or traumatic deformity of the ear,
2. History of active drainage or bleeding from the ear within the previous six months,
3. Air-bone gaps of certain proportions,
4. Asymmetric hearing loss,
5. Acute or chronic dizziness,
6. Visible evidence of excessive ear wax,
7. Ongoing pain or discomfort.¹⁰

Even if a self-selected hearing product resulted in some improvement in the hearing impairment related to these conditions, the serious underlying condition would go unnoticed and untreated.

Reports from two major national hearing aid retail chains covering more than 250,000 customer visits around the country indicate that approximately 4-5% of individuals who visited their stores for a hearing screening required referral for additional medical care because the hearing professional determined that the cause of the hearing impairment may be related to a medical or “red flag” condition requiring treatment in addition to, or instead of, a hearing aid. With approximately 33,000,000 people with hearing loss in the United States, counting both hearing aid users and non-adopters,⁶ this 4-5% rate would equate to approximately 1,320,000 to 1,650,000 people with possible red flag conditions. Applying this 4-5% red flag referral rate to the estimated 2.3 million people who purchased a hearing aid in 2014,¹¹ an estimated 92,000 to 115,000 people who visited a hearing health professional in 2014 might have been referred for red flag conditions. In some of these cases, a simple procedure such as the removal of cerumen buildup would have addressed the problem, and no further intervention would have been necessary. And in other cases, more serious conditions would have required intervention by a physician.

However, allowing PSAPs to be sold as OTC products for patients with hearing loss could result in failure to identify the underlying medical condition that is causing the hearing loss. This failure could result in either the person with hearing loss incurring unnecessary expenses for a hearing product that is not needed, or not receiving timely medical attention for the underlying condition.

Some OTC medical devices, such as reading glasses, are appropriate to address conditions such as presbyopia, a relatively common form of vision loss associated with aging. As noted by Eric Mann, Clinical Deputy Director, Division of Ophthalmic and Ear, Nose and Throat Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA, reading glasses do not provide any benefit for more serious vision problems, and the successful use of reading glasses cannot mask any other more serious vision problems. Dr. Mann distinguished this lack of “masking” capabilities for reading glasses from the clear long-term detrimental “masking” effects that PSAPs could have. A PSAP might result in apparent improvement in hearing, causing the consumer to skip or delay the intervention necessary to address the underlying condition.¹² Furthermore, OTC reading glasses continue to be regulated as medical

devices, whereas individuals supporting use of PSAPs for hearing loss propose doing so entirely outside the FDA's framework.

Comparison of Hearing Aid Adoption in Europe vs. US

While some private insurance companies partially (and in some rare cases fully) cover the cost of hearing aids, the largest US healthcare insurer, Medicare, specifically prohibits reimbursement for any services associated with the evaluation for or delivery of hearing aids, including the costs of the devices themselves. This policy is in contrast to those of many European nations where the national healthcare program covers some or all of the cost of hearing aids and services. Despite these policy differences, hearing aid adoption rates across Europe are not very different than they are in the US, as revealed in the latest MarkeTrak (MT9) and EuroTak studies.^{13,14} For example, the hearing aid adoption rate in the US is estimated at 30.2%, as compared to 24.6% and 30.4%, in Italy and France which offer relatively low reimbursement. In Germany, with substantial reimbursement, the adoption rate is 34%, while the rate is 41.1% and 42.5% in the United Kingdom and Norway respectively, both of which provide full reimbursement for hearing aids and services.

Hearing aid utilization rates do not exceed 50% in these countries, even when hearing aids and services are provided at little or no charge to the patient. This demonstrates that even the offer of “free” hearing aids to every American will not be a “silver bullet” that solves the patient hearing aid adoption issue.

Given the complexity of hearing loss and the variety of conditions that may contribute to such loss, selecting an appropriate hearing aid is critical to successfully remediating the problem. The simplistic belief that amplifying sound is sufficient to overcome the complex nature of hearing loss leads to misunderstanding and frustration among patients and family members. However, with proper counseling from a hearing professional, the true nature of the condition can be better explained, and an appropriate intervention can be selected. Understanding the full impact of the hearing impairment on the patient and then finding the right solutions – including identifying red flag conditions – is a task that requires professional education, training, and experience.

CHAPTER FOUR: NON-AUDITORY IMPLICATIONS

Although hearing loss has often been considered by many to be of lesser consequence than other medical conditions, an expanding body of research demonstrates the clear connection between untreated hearing loss and other serious conditions. It is, therefore, critical that a person with hearing loss seek help from a hearing health professional both to rule out red flag conditions and to increase the chance that their decision to seek assistance will address the problem.

Hearing Loss and Cognitive Decline

Evidence has recently emerged associating age-related hearing loss with cognitive decline.^{15,16,17,18,19} The question remains whether one causes the other or if the two share some common causal factor. Researchers prospectively studied the relationship between hearing loss and all-cause dementia among 639 individuals participating in the Baltimore Longitudinal Study of Aging.¹⁵ Following a median follow-up period of 11.9 years, the results revealed that the risk of incident all-cause dementia increased with the severity of hearing loss, suggesting that hearing loss is independently associated with incident all-cause dementia. Similar findings were reported in a prospective investigation of 1984 participants enrolled in the Health ABC Study.¹⁷ Again, severity of hearing loss at baseline appeared to be independently associated with later cognitive decline. Overall, those with hearing loss had a 24% increased risk of cognitive decline compared to those with normal hearing at baseline. A recent review of existing literature examining the relationship between hearing loss and cognition¹⁹ concluded that the evidence is

convincing for such a link. There is a clear need, however, to prospectively examine whether audiologic intervention (*i.e.* hearing aids and accessories) has a mediating effect on the time course and/or severity of cognitive decline among older individuals with hearing loss.

Hearing Loss and Depression

The association between hearing loss and depression (or sense of well-being) is well-studied,^{20,21,22} as are the links between hearing loss, cognitive decline, and depression.^{20,23,24} The suspected mechanism for these interactions is that hearing difficulties lead to disengagement from previously enjoyable activities resulting in a cascade of negative consequences including decreased social interaction and integration, increased withdrawal, and, eventually, depression. It might be assumed that providing improved communication performance through the use of hearing aids may mediate this cascade of events; indeed, the evidence, going back several decades, appears to support the benefits of adequately programmed hearing aids in reducing depression.^{23,25,26}

Hearing Loss and Falls

Falls are the leading cause of fatal and non-fatal injuries among the elderly leading to significant health, social, economic, and emotional consequences.²⁷ There is growing evidence of an association between hearing loss and falls. While earlier studies failed to find an increased risk of falls among those with hearing loss based on hip bone mineral density,²⁸ other studies have supported such an association.^{29,30} In one study,³⁰ more than 2,000 individuals who participated in the National Health and Nutritional Examination Survey (NHANES) between 2001 and 2004 underwent hearing and fall history assessment. The results revealed that those with hearing loss were three times as likely to fall as those with normal hearing. It has been suggested that good hearing acuity is important for safe mobility,²⁹ as postural stability requires accurate and timely input from multiple sensory systems.

Hearing Loss and Income

Hearing loss has been shown to have significant societal costs related to identifying and managing the condition. A 2010 Survey by the Better Hearing Institute on “The Impact of Untreated Hearing Loss on Household Income” compared income levels of people who used hearing aids, people with untreated hearing loss and people with no hearing loss. The data shows that untreated hearing loss results in a loss of income per household of up to \$30,000 per year depending on the degree of hearing loss.³¹ A critical review of the literature on this issue also revealed that hearing loss impacts the social welfare system more than the medical care system.³² Hearing loss also has an adverse impact on earning potential—with those exhibiting severe-to-profound hearing loss aged 18-44 earning only 67% of their normal hearing counterparts, and those aged 45-64 earning 87% of those with normal hearing.³¹ An inverse association between all-severity hearing loss and income was identified as part of the Beaver Dam Study on the epidemiology of hearing loss.³³

CONCLUSION

Hearing loss is derived from a complex set of factors, for which sound amplification alone is not a solution. As outlined above, modern hearing aids incorporate many cutting edge technologies to improve the listening experience for people with hearing loss including interconnectivity with modern consumer products like smart phones. These technologies not only improve auditory function and reduce the frustrations associated with outdated technologies, but can also reduce risks of hearing loss-related adverse medical events and conditions.

Given that untreated hearing loss increases the risk of dementia, depression, falls, and other adverse health conditions, it is critical that companies continue to engineer ever-better hearing aids to help people address hearing loss, while hearing professionals continue to ensure the provision of appropriate treatment. A wide range of hearing aids at a variety of price points is already available, making it possible for most people to afford the treatment required; at the same time, “disruptive” hearing aid distribution models are already playing a significant role in the market while continuing to provide access to care by hearing health professionals.

Use of PSAPs, which are unregulated consumer products lacking any safety and effectiveness standards or scrutiny by FDA, to address hearing loss eliminates the crucial component of professional hearing care. Given that 4-5% of people who access hearing care must be referred by a hearing professional for further medical evaluation, it is critical that policy changes should not be implemented to encourage people with hearing loss to diagnose and treat themselves. A policy to encourage PSAP marketers to make claims that their product addresses hearing loss will result in patients buying a non-medical device when a simple medical solution might solve the problem, as well as patients foregoing the opportunity to receive the medical care they need.

We thank the IoM and PCAST for their consideration of this emerging issue and urge the Institute and Council to place appropriate emphasis on traditional hearing aid technologies and the critical role played by hearing professionals.

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