



Hearing Devices

The Possibilities and Limitations

Various task forces have been assembled over the past few years to examine the affordability of, and access to, hearing health care. These efforts have resulted in reports from the President's Council of Advisors on Science and Technology (PCAST) in October 2015 and the National Academies of Sciences, Engineering, and Medicine (NAS) in June 2016. Both task forces proposed that low-cost, over-the-counter (OTC) hearing devices be made available to consumers who have mild to moderate hearing loss.

By Larry Medwetsky

In reviewing the reports and considering comments from various individuals and organizations, I felt the need to write an article on this topic. My goal is to encapsulate the key aspects and issues involving the sale of low-cost OTC amplification devices, even though I know much of what I write will likely be outdated within a year.

Unlike eyeglasses, which are fairly simple to mass produce and relatively easy to fit, hearing aids are mini-computers that often require a number of visits to get the fitting just right. The audiologist or hearing instrument specialist must tailor the amplification to the client's needs across a wide range of frequencies and input levels and for a variety of listening situations and environments (such as a library versus a noisy restaurant). This is to ensure that incoming sounds will not only be audible but never exceed a person's loudness discomfort.

Depending on the dispensing practice, the cost of the office visits might be "bundled" with the purchase price of the hearing aid or paid separately (unbundled) for each office visit. Hearing aids range greatly in price, depending on the features included with the hearing aid.

As many of you know, hearing aids are not covered by Medicare or most private insurers. This is because hearing aids have not been deemed a medical necessity. However, I do not agree with this determination. Several recent studies have shown the possible connection between hearing loss and such medically significant health issues as depression, dementia and falls.

Because hearing aids are not covered by Medicare, their cost must be borne by consumers (unless partially covered by a third-party insurer). If they were, as are such things as motorized wheelchairs and pacemakers, we would not even be having a discussion concerning hearing aid affordability.

Personal Sound Amplification Products (PSAPs)

Over the past ten years we have seen a proliferation of low-cost hearing amplification products come into the marketplace. Many of these are advertised as being able to address various hearing-related needs. Yet, most of them have not been approved for sale as hearing aids by the Food and Drug Administration (FDA).

In 2009, the FDA defined hearing aids as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for impaired hearing." On the other hand, PSAPs are "intended to amplify environmental sound for non-hearing impaired consumers. They are not intended to compensate for hearing impairment." But it is apparent

that many manufacturers of PSAPs are intending to sell these devices to individuals with hearing loss, but with a disclaimer, typically buried in the fine print.

You might be wondering why a manufacturer would choose to sell a device as a PSAP rather than as a hearing aid. Hearing aids are regulated by the FDA as Class 1 medical devices. As such, they must adhere to stringent manufacturing and design guidelines. In addition, a manufacturer might have to pay a significant amount of money to register their device and have it classified as a hearing aid with the FDA. On the other hand, PSAPs are not regulated, and thus are not subject to the strict manufacturing guidelines or registration fees.

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It should be noted that while PSAPs cannot be marketed as a hearing aid for people with hearing loss, it is probable that there are devices sold on the internet that are labeled as such. It might be unclear in reviewing the advertised material if they have gone through the regulatory process and thus can legally be called a hearing aid, or are simply breaking the law and don't care. Consequently, "buyer beware."

Going forward, should a new FDA-regulated category of OTC hearing aids become a reality, it is possible that both PSAPs and OTC hearing aids would be available without seeing a hearing health care professional. The distinguishing feature is whether they have gone through the FDA process. Again, it is important that the consumer do their research and pay close attention to the labeling of the product.

One issue audiologists have concerning PSAPs is that they could deliver sound output levels intense enough to cause hearing damage. Conversely, as mentioned earlier, when hearing aids are fitted by an audiologist they are programmed to ensure the maximum output does not exceed an individual's tolerance at any frequency.

Research conducted by the European Association of Hearing Aid Professionals and the European Federation of Hard of Hearing People found in the testing of 27 PSAPs that all of the devices produced output levels unsafe for

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individuals with normal hearing to those with moderate to severe hearing loss. In addition, the amplification for most of them was limited to the lower frequencies, with little amplification above 2,000 Hz (i.e., little or no amplification in the region which most individuals with mild to moderate hearing loss have the greatest need). The European groups' recommendation was that "PSAPs need to be designed and manufactured in a manner... that ensures that they are inherently safe and do not cause hearing damage."

I do not want to make it seem as if all PSAPs are necessarily of bad quality. A recent study by Smith, Wilbur and Cavitt (2016) compared the performance of a number of low- and high-end PSAPs to hearing aids. They found that low-end devices tended to have high levels of low-frequency amplification with little high-frequency amplification, and also significant internal noise. The models in this category were thus generally deemed to be of very poor quality. However, there was one high-end PSAP that did provide appropriate levels of amplification and even included directional microphones that improved performance in the presence of background noise.

This study demonstrates the importance of involving a hearing health care professional in the selection of a device that is safe, effective and of good quality. It is interesting to note that in reviewing the literature about PSAPs I found that the cost of some higher-end models were actually in the price range of lower-cost, unbundled hearing aids.

Downloadable Apps

In the September/October and November/December 2015 issues of *Hearing Loss Magazine*, I discussed amplification apps that can be downloaded from the internet at a very low cost. These apps vary in the manner in which they amplify sound and the degree to which the user can manipulate the amplification characteristics. Some of these apps offer only the ability to increase the overall volume, while others include features found in some hearing aids, such as programming options (listening in quiet, in a restaurant, to music, etc.). Thus, depending on one's listening needs, finances, or readiness to purchase hearing aids, a downloadable amplifier app could be a viable option for some.

The Over-the-Counter Hearing Aid Act of 2017 would make certain types of hearing aids available over the counter and remove or modify some of the requirements currently in place that might prevent people from seeking hearing health care.

Over-the-Counter Hearing Aids

In response to the recommendations contained in the PCAST and NAS reports, bipartisan legislation was recently introduced that would require the FDA to create a new class of over-the-counter hearing aids for people with mild to moderate hearing loss. The Over-the-Counter Hearing Aid Act of 2017 would make certain types of hearing aids available over the counter and remove or modify some of the requirements currently in place that might prevent people from seeking hearing health care.

This category of devices would require the FDA to issue regulations concerning safety and labeling, thus ensuring manufacturing quality. It is not clear at this time what would constitute an OTC hearing aid or how they would differ from prescribed hearing aids.

Sifting Through the Information

One assumption that was made in the PCAST and NAS reports was that it is easier to address the hearing needs for individuals with mild to moderate hearing loss than for individuals with more severe hearing loss. It is indeed more difficult to enhance the hearing performance for people with more severe hearing loss. However, this does not mean that providing lower-cost OTC hearing aids will easily address the needs of the mild to moderate hearing loss population.

First, individuals with milder hearing loss tend to be younger and the most resistant to wearing hearing aids (Taylor, 2015). Second, in countries where hearing aids are provided at little or no cost through government plans, the utilization rates are not much higher than in the United States (Smriga, DJ, 2016). This suggests that other factors—such as self-esteem and stigma—also contribute to the low usage rate.

Another factor to consider is that the problem most often reported by individuals with mild to moderate hearing loss is the ability to hear in the presence of background noise. These individuals tend to not report much difficulty in quiet settings but do when they are in settings with



background noise, reverberation, or when there are multiple talkers. At the present time, these situations are best addressed through the use of higher-end digital hearing aids and/or remote mic systems (such as FM systems). Because of the higher costs of these devices, a significant percentage of those who could possibly benefit from such technology (assuming they are even aware it exists) have deemed that the benefits are not worth the costs. In addition, remote mic systems require the individual with hearing loss to place a microphone close to the talker. This action publicly exposes one's hearing loss, requiring the individual to have a sufficient confidence level to use the system.

Comparing OTC Hearing Aids to Reading Glasses

PCAST also suggested that the purchase of OTC hearing aids could be similar to that of non-prescription reading glasses and that an audiological evaluation would not be required before purchasing. They noted that there was a very low risk of the presence of medical issues impacting hearing, and that such issues have not prevented the sale of OTC glasses.

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However, there is a major difference when it comes to this comparison. In the case of middle-aged individuals who are beginning to experience difficulty reading, simple magnification is often an adequate solution. Such vision problems usually involve the iris (which could be analogous to the middle ear bones) and do not involve the retina or optic nerve.

On the other hand, most hearing loss is permanent, involving the inner ear and auditory nervous system. In most cases, simply amplifying the auditory signal would not adequately address an individual's hearing loss. This is more akin to vision conditions such as retinitis pigmentosa or macular degeneration. The magnification of reading glasses would still leave these individuals being unable to easily distinguish visual stimuli. Note that OTC eyeglasses are intended only to address reading-related issues where the focal point is close to the individual. However, if seeing at a distance is the problem the individual would have to see an eye specialist to address it.

One other difference between the two scenarios is that reading glasses are relatively inexpensive, ranging in price

from about \$10-\$30. If the glasses did not help correct the problem the consumer could then schedule an appointment with an eye specialist and be out only a small amount of money. Similarly, if an individual were to purchase OTC hearing aids and they did not work, the consumer could schedule an appointment with a hearing specialist.

However, the difference lies in the potential cost of an OTC hearing aid versus the cost of reading glasses. While we don't yet know what will ultimately constitute an OTC hearing aid, it is still likely their price will be significantly greater than that of OTC reading glasses. Further, and more importantly, because of the subtle nature of some underlying medical conditions that can cause hearing loss, the extended time it would take to try an OTC hearing aid as a possible solution could result in a significant worsening of the condition before one saw a medical specialist.

Again, although it is unknown what will define an OTC hearing aid, it is likely that such devices will not provide many of the technological capabilities of hearing aids obtained through a professional, such as:

Compression—The ability to provide greater amplification for softer sounds and a decreasing amount of amplification as the input level increases. Thus, compression makes softer sounds audible, moderate-intensity sounds are heard at a comfortable level, and loud sounds at a level as to not hurt someone's ears.

Feedback canceling—Prevents the annoying whistle-like sound from occurring.

Speech enhancement—Amplifies only those sounds identified as speech.

Noise suppression—Decreases the intensity of background noise, especially useful when only a single loud background noise is present, such as a bathroom shower.

Adaptive directionality—Adjusts the hearing aids to focus or amplify the identified speech source, while decreasing background noise coming from different directions.

Telecoil (or t-coil)—Blocks out background noise by providing a direct input to the hearing aid from the sound source when used in conjunction with hearing assistive technology such as a hearing aid compatible phone or hearing loop.

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In the absence of such features, amplification devices function similarly to the linear hearing aids that were prevalent before the incorporation of digital technology.

Involvement of a Hearing Health Care Professional

I highly recommend a thorough, professional hearing evaluation prior to the purchase of hearing aids in order to make an educated, informed decision about a possible solution. It is my observation that the public perception of a hearing test is that it only entails presenting some beeps to determine if an individual has a hearing loss. However, a hearing assessment is so much more than that.

Initially, the audiologist poses questions to determine the nature of the client's hearing difficulties. The audiologist will determine the client's goals and subsequently conduct a comprehensive assessment to a) determine the individual's hearing acuity and tolerance levels for loud sounds as well as the ability to process speech in both quiet and noise; and b) assess if there is any possible underlying medical issue that would require referring the client to a medical professional.

If a permanent hearing loss appears to be present, the audiologist, in collaboration with their client, will determine the solution that will best address his or her needs. For someone who has some higher-frequency hearing loss the recommendation might consist of communication strategies. For individuals with a greater hearing loss that is impacting their quality of life, the audiologist's recommendations will be based on factors such as lifestyle and the degree of difficulty experienced.

The audiologist will seek to balance the technological recommendations with the client's listening lifestyle needs. Individuals who are fairly sedentary and rarely in noisy settings might get sufficient benefit from a low-end hearing aid, or possibly from a PSAP or downloadable app. The latter solutions might also be recommended for those who are not ready to wear hearing aids in public but are willing to try them in the privacy of their home. An audiologist who is willing to incorporate such products into their practice should be involved in fitting the devices to ensure they meet the client's needs, with the caveat that the products are of good quality and reliability.

On the other hand, most low-cost amplification devices that are currently readily available will likely not meet the needs of someone who has an active lifestyle and is often in difficult listening settings. In these instances, an audiologist would probably recommend a higher-end hearing aid with the features suited to meet the client's

individual listening needs. The client could then determine the best solution based on the information presented.

It is also important for the client to factor the cost of the hearing aid in the decision and whether or not he or she can afford what has been recommended (and what would be lost in terms of hearing capability if a less expensive option was chosen). They could also ask if a financing plan was available.

Concluding Remarks

Low-cost amplification devices such as PSAPs are here to stay. They can be of benefit to a certain segment of the population, including individuals whose primary listening needs or goals are restricted to activities in quiet settings. If cosmetics are not an issue but price is, such a device or even a downloadable amplifier app might be sufficient.

In addition, these products would also allow those who are not sure if a hearing aid would be of help to determine if they could benefit from some form of amplification. At some point they might decide to purchase higher-end hearing aids if their lifestyle necessitated a more encompassing technological solution. Many hearing health care professionals offer lower-cost hearing aids that are comparable in price to currently available higher-quality PSAPs and which also have features not found in most PSAPs. Benefits of purchasing a lower-cost hearing aid from an audiologist include the knowledge that the hearing aids will be appropriately fitted and programmed and the assurance they will have met manufacturing quality standards.

Whatever a consumer ultimately decides, it should be based on obtaining as much information as possible. Consumers need to recognize that the solutions which will best meet their listening needs will not only be based on the degree of their hearing loss, but also on their lifestyle. Individuals should not make the decision to purchase a device based solely on price but on what will ultimately be the most cost-effective solution to address their hearing needs. **HLM**

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