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Editorial Open Access

Over the Counter Hearing Aids

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Editorial

Audiology resides in an ever changing landscape; we see it on a daily basis. In regards to hearing aids and other amplification devices, we've seen changes in size, shape, and function. Today, along with the common ear-level, air conduction hearing aids, personal sound amplification devices (PSAPs) are gaining popularity. Many modern PSAPs may also be referred to as "wearables" to be consistent with the popular devices such as wearable fitness trackers, smart watches, etc. If the term "wearable" is not appealing, maybe the term "hearable" is. The term "hearable" modified from "wearable" has been coined to provide consumers a more accurate and specific image. There are many similarities between modern hearing aids and PSAPs that allow for easy comparison. Both hearing aids and PSAPs are programmable to change user settings appropriate for different listening environments. Both types of devices have wireless capabilities, such as Bluetooth, to allow for communication between multiple types of devices. So, it is reasonable to compare hearing aids with PSAPs. However, the difference between PSAPs and hearing aids is rooted in their intended function and the agencies by which they are regulated. Although hearing aids are regulated by the Federal and Drug Administration (FDA) as a medical device, PSAPs, wearables, or hearables are not. Hearing aids are intended for use to facilitate better hearing for those with hearing loss; PSAPs amplify sound and assist in hearing, but for reasons such as listening to music, telephone use, or hunting.

This changing landscape has not been overlooked by the federal government. In fact, in October of 2015, the President's Council of Advisors on Science and Technology or PCAST, provided a status report with recommendations regarding hearing loss treatment. So, what is the PCAST? And why should we care? The PCAST is an advisory group consisting of scientists and engineers with the sole charge of providing the President and the Executive Office of the President with counsel on contemporary topics, like hearing aids and amplification devices. Historically, the PCAST, in one form or another and with varying names, has been in existence for over eighty years, dating back to Franklin Roosevelt's administration.

PCAST reported a commonly discussed observation, that the hearing aid adoption rate or market penetration is low. The PCAST also stated that the hearing aid industry had been stifled by factors that include high product cost, low innovation in technology, dispenser as a hindrance to access, and the classification of hearing aids as Class I medical devices. The degree of validity for each of these factors can be debated. One area of consideration stated in the report suggests that the counsel approached the task from a perspective that equated hearing aids to other consumer electronics, but failed to compare them to other medical prosthetic devices. Although a comparison of hearing aid costs to the cost of other prosthetic devices would not likely improve accessibility, it might contribute to future observations. Another area of consideration addresses the hindrance of access via the dispenser model. The fitting of hearing aids should be thought of as more than a simple purchase. Individuals with hearing loss, even mild-to-moderate hearing loss, can benefit from verification, rehabilitative procedures, and counseling. Presently, any self-fit procedure would likely lead to equipment calibration problems and user error. Such errors have the potential to further damage the user's residual hearing. Verification of proper fit by a qualified dispenser, on the other hand, has been shown to lead to improved patient loyalty toward the clinician, which could translate into an easier transition into more powerful amplification, when and if needed. An additional consideration are the data indicating that PSAP users are not likely to transition from PSAPs to hearing aids easily. It may be presumed that those using the proposed OTC hearing aids, as elaborated upon in subsequent discussion, may also be challenged in the transition to prescribed hearing aids, resulting in low hearing aid adoption rates.

In addition to identification of factors limiting accessibility, the PCAST report provided recommendations to overcome these factors. Their first recommendation is for the FDA to re-classify a portion of the hearing aids on the market; those identified as helping individuals with "bilateral, gradual onset, mild-to-moderate age-related hearing loss" would be designated as over-the-counter (OTC) hearing aids. OTC hearing aids would be purchased on-line or in stores without the consultation of a dispenser. The final recommendations assign the patient the right to any and all test results to be used by other vendors and across state lines. Decisions about the application of these recommendations are forthcoming; but the discussion they generate is valuable. Research indicates that consumers and their families prefer to have more control over the process of acquiring hearing aids, and that those dispensing or in the industry prefer to keep the dispenser model as is today.

As of April of this year, the FDA held a workshop discussing these and other topics, in which representatives from clinics and industry were provided an opportunity to address ideas, issues, and concerns. The PCAST is scheduled to publish a report in June with more information about hearing aids, OTC hearing aids, and PSAPs. This and future reports are definitely worthy of our attention as they may influence this influential component of our scope of practice.