Over-The-Counter Hearing Aids

NZAS POSITION STATEMENT
SEPTEMBER 2024

NZ AUDIOLOGICAL SOCIETY PO BOX 36-067, NORTHCOTE, AUCKLAND 0748

Summary

The New Zealand Audiological Society (NZAS) recognizes the growing interest and accessibility of over-the-counter (OTC) hearing aids as an alternative means for individuals seeking solutions for hearing loss. The Society acknowledges the potential benefits of OTC hearing aids in terms of affordability and convenience, which may contribute to improved access to hearing assistance for a greater part of the population. While acknowledging these potential advantages, the NZAS emphasises the importance of maintaining high standards of hearing healthcare to ensure the best outcomes for individuals with hearing loss. This position statement defines an OTC hearing aid with respect to international regulations and ongoing research, and in doing so identifies the considerations that have arisen as a result of this new regulatory category internationally and within New Zealand. NZAS - as a Society and individual members - is called to consider the opportunities offered by OTC hearing aids for individuals with hearing loss to improve their quality of life, as well as for different health providers to work together to maximise these benefits. In summary,

- NZAS supports OTC hearing aids as an option for certain individuals with hearing loss and encourages members of the public to talk to their audiologist or audiometrist about the options available to them.
- NZAS advocates for education, regulatory oversight, professional involvement, and continued research, to ensure that individuals have access to safe and effective hearing solutions that enhance their overall quality of life.
- NZAS recommends that all audiologists and audiometrists improve their understanding of OTC hearing aids so that they can most appropriately support members of the public who come into their clinic seeking information or assistance.

Context

In August 2022, the Food and Drug Administration (FDA) in the United States of America (USA) established a regulatory category for over-the-counter (OTC) hearing aids, specifically for adults aged 18 years and older with perceived mild to moderate hearing loss. This ruling was brought about by the FDA Reauthorisation Act of 2017 which mandated the FDA to establish such a category and specify certain requirements for this category (FDA, 2022). The OTC hearing aid category supersedes the previous direct-to-consumer (DTC) hearing aid category (based on devices sold online).

Definition of an OTC Hearing aid?

The FDA (2023) defines an OTC hearing aid as:

- An air-conduction hearing aid that does not require implantation or other surgical intervention.
- Approved for adults aged 18 years and older.
- Intended for individuals with perceived mild to moderate hearing loss.
- May use self-assessment tests or wireless technology to assess the user's hearing loss. (Note, it is not required that the OTC hearing aid is self-fitting (AA0-HNS, 2023)[1]).
- Users can customise the device and control the device settings using tools, tests or software.
- Devices must be able to make changes in pitch (ie. bass versus treble) and volume (ie. louder or quieter), so that the user can control and customise to their needs the frequency-dependent output profile and the output volume for safety and effectiveness.
- May be purchased in-person, by mail, or online without the involvement of a hearing healthcare professional.
- A health care professional (such as an Ear, Nose and Throat specialist, audiologist or audiometrist) is not required to undertake a medical exam, prescribe and fit the OTC, or oversee its use.

The FDA regulations specify the mandatory information to be displayed on the outside packaging for a consumer to read and review prior to buying the device. The FDA also provides ways for potential consumers to check if a device has been FDA-cleared and / or if the medical device manufacturer is registered with FDA (Hearing Industries Association, 2023). Note, the FDA does not approve or endorse any product; a device is cleared by the FDA based on claims and intended use (Akbari, 2024).

Of the OTC hearing aids on the market, many of the manufacturers are affiliated with producers of prescription hearing aids (Carr, October 2023):

[1] The FDA has three letter "product codes" which distinguish between non-self-fitting and self-fitting, wireless and non-wireless, OTC and prescription hearing aids. The product codes can be searched on this publicly-available database - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

The FDA clears products based on their safety and effectiveness. In the absence of a qualified professional to fit the device, the impetus for safety and effectiveness is greater. As such, clinical data, robust labelling, claims and the intended use have to be provided for an OTC hearing aid to be evaluated by the FDA and each summary is publicly available on a searchable database (Akbari, 2024). The clinical data includes, at least the following for each OTC hearing aid (Akbari, 2024):

- Evidence of equivalence to recognised consensus electro-acoustic standards (ie. ANSI/ASA S3.22)
- The 'self-fitting rationale' - typically NAL-NL2
- The 'endpoint' - typically the Abbreviated Profile of Hearing Aid Benefit (APHAB) or similar self-reported outcome measure

A number of wireless tests are required by the FDA, including assessment of wireless co-existence (ANSI/IEEE C63.27) and wireless radiated immunity (ANSI/IEEE C63.19). It is imperative for the FDA that consumers are provided with safe and effective OTC products.

OTC Hearing Aids vs. Other Devices

OTC hearing aids need to be differentiated from other alternative amplification systems.

	Over-the-Counter (OTC) Hearing Aids	Prescription Hearing Aids (Any hearing aids that do not meet OTC requirements)	Personal Sound Amplification Products
Type of Product	Medical device Electronic product	Medical device Electronic product	Electronic product
Intended Users	• People 18 years and older • For those with perceived mild to moderate hearing loss	• People of any age, including those younger than 18 years • For people with any degree of hearing loss, including severe	• People of any age with normal hearing to amplify sounds in certain environments
Conditions for Sale	• Purchaser must be 18 years or older • No medical exam • No prescription • No fitting by audiologist • No need for licensed seller	• Prescription needed • Must purchase from licensed seller in some states	No applicable FDA requirements regarding conditions for sale

Source: US. Food & Drug Administration, 2023, Hearing Aids and Personal Sound Amplification Products: What to Know, https://www.fda.gov/consumers/consumer-updates/hearing-aids-and-personal-sound-amplification-products-what-know

The terms 'personal sound amplification products' (PSAPs) and Hearables are often used interchangeably. PSAPs and Hearables are meant for individuals with normal hearing who want to amplify sounds in certain environments, whilst hearing aids are intended to manage hearing loss (Manchaiah, 2023). The FDA prohibits PSAPs from being marketed as hearing aids to people with hearing loss (Hearing Loss Association of America, 2023). The FDA does not regulate the safety and effectiveness of PSAPs or Hearables as they are not regulated as medical devices, but rather as consumer electronics, so the packaging of PSAPs may use the terms "hearing amplifier", "sound amplifier" or "sound enhancer". Hearables wirelessly receive a sound signal from another device (ie. phone, television) and are intended to provide a listening solution for a specific situation (AAA, 2023). Some Hearables may allow the user to adjust the pitch or loudness of the sound but do not provide custom amplification for the user based on their hearing levels and the sound signal (AAA, 2023).

Given the overlap in features between devices, a recent review suggested that more specific classification is warranted than the broad categories of "PSAPs" and "hearing aids". Maidment and colleagues (2024) in a meta-analysis of 10 studies, found that premium PSAPs provided improved speech intelligibility in noise for people with mild-to-moderate hearing loss, due to the technological features of the premium devices. However, given that all devices in these studies were fitted by a trained individual, the benefit reported for the PSAPs may not translate to the real-world "out-of-the-box" PSAPs which the user must fit themselves.

Considerations – Opportunities and Concerns related to OTC hearing aids

OTC hearing aids have been promoted as improving access and affordability. The affordability (or lower cost) of OTC hearing aids is attributed to (1) technology differences and (2) buying only the device, not any professional services.

1. **Technology Differences:** Most OTC hearing aids have the same components as prescription hearing aids but differ with respect to software (Akbari, 2024). Research arising from specifically a cost-effectiveness analysis of OTC hearing aids remains absent. Some research suggests that OTC hearing aids that yield similar benefit to prescription hearing aids will have comparable pricing (Borre, 2023), but it is still too early for valid comparisons particularly in NZ where the funding structure differs to the USA (where the previous research has been conducted).
2. **No Professional Services:** Research is also limited with regards to OTC hearing aids as a device-only purchase. Given the recency of the FDA regulations, there are limited published clinical research trials comparing the effectiveness of self-fitting OTC hearing aids and audiologist-fitted prescriptive hearing aids using products that are on the market, but the few available studies support similar

self-reported benefit (De Sousa et al., 2023; Swanepoel et al., 2023). Research undertaken prior to the establishment of the new OTC hearing aid regulatory category had demonstrated feasibility and provided validation for specific steps of the self-fitting process, including measuring pure-tone thresholds (O'Brien, 2010; Convery, 2015; Keidser, 2011); the consumer choosing their hearing aid based on preset fitting parameters (Humes, 2019); assembling the hearing aid and inserting in their ear (Convery, 2013; Convery, 2011); suitability of pre-configured gain-frequency responses (Urbanski, 2021); and the user self-selecting effective amplification parameters (Sabin, 2020).

During the development of the FDA regulations for the new OTC hearing aid category – specifically the consultation phase – the following points of concern were taken into consideration and relevant authorities provided their expertise to ameliorate the concerns. The points are discussed here to assure readers that NZAS has considered their importance.

- **Excessive noise exposure:** FDA-cleared OTCs have an output limit of 111 dB SPL, or 117 dB SPL if the device is equipped with activated input-controlled compression (this will automatically reduce the device's output and maximise the dynamic range). This output limit is supported by the American Academy of Otolaryngology-Head and Neck Surgery as an appropriate balance of safety and effectiveness (AA0-HNS, 2023). Given that research studies of "self-fitting" aids (prior to the OTC hearing aid regulation) showed that users tended to prefer less gain than that prescribed by an audiologist (Sabin, 2020), and OTC hearing aids are required to have a user-adjustable volume control, it is unlikely that a consumer will wear a device that is uncomfortably loud. So, the risk of hearing loss from an OTC hearing aid is likely low.
- **Risk of damage to eardrum:** FDA-cleared OTC hearing aids must be 10 mm or greater from the tympanic membrane. Given there is anatomical variability, a fixed length design requirement was not specified by the FDA, instead this minimum distance from the eardrum is deemed to be conservative enough to ensure safety (AA0-HNS, 2023).
- **Minimum User Age:** OTCs cannot be sold to anyone under the age of 18 years old and this is included within the labelling requirements. But the FDA does not require age verification with purchase (AA0-HNS, 2023), and it does not prevent an adult from purchasing for a child (Educational Audiology Association, 2021). Good public understanding is required to understand the risks associated with children being fitted with an OTC hearing aid; although, this potential risk is likely reduced in New Zealand by the funding available for children's prescription hearing aids.
- **User literacy:** OTC hearing aids are typically chosen and fitted by the individual with little or no support from an audiologist, audiometrist or hearing instrument specialist. Consequently, the consumer needs to be able to self-identify their hearing loss, research the different OTC options, select the one best suited to his/her needs, appropriately position the device in the ear for threshold testing, follow instructions to fit and tune the device, learn how to handle the device, and

troubleshoot any ongoing issues (Manchaiah, 2023). How well an individual understands each of these steps may differ depending on their health literacy, cultural differences and/or cognitive function, and will affect the perceived benefit of the device (Manchaiah, 2023). Based on feedback received, the final FDA ruling included specifications regarding the language level of warnings and other important information that must appear on the outside and inside of the packaging to increase understandability for users (AA0-HNS, 2023). However, there is still concern that if an individual has difficulty fitting and adjusting the OTC hearing aid to themself then their experience of the device may be less than optimal and as such the device may be put away and be the reason the person cites for not seeking hearing aids for their hearing difficulties in the future.

- **Audiological support:** The regulations do not specify any requirement to seek consultation with a hearing care professional prior to wearing an OTC hearing aid, and in the absence of this, concerns have been raised related to the diagnostic assessment and device-related aspects of a hearing aid fitting process:
    - **Medical Clearance:** An OTC hearing aid does not require a prior medical exam or audiological assessment. In the absence of a medical exam, ear conditions which require medical attention may be missed (AAA, 2023). ASHA (2023) has provided a list on their publicly available webpage of medical conditions which should have a medical consultation prior to purchasing an OTC hearing aid.
    - **Assessment:** In the absence of an audiological assessment, an individual will not have an accurate diagnosis of their degree and type of hearing loss, and their candidacy for an OTC hearing aid relies on their own evaluation of having symptoms concordant with a mild to moderate hearing loss. Self-perceived hearing loss has been seen to differ depending on the assessment tool (ie. questionnaire, self-test) (Urbanski, 2021), and more research is being sought for how self-perceived hearing loss differs depending on an individual's audiometrically-defined configuration of hearing thresholds (Urbanski, 2021).
    - **Device:** By the virtue of how OTC hearing aids are sold, verification and validation of the hearing aid output and benefit is not typically possible nor required. Many unknowns remain pertaining to the predictors of success of OTC hearing aids, such as the effectiveness of different self-fitting algorithms, pre-set versus self-fit OTC hearing aids, the role of user-specific variables (biographical, demographic and audiological), when and where users access the OTC HAs and then choose to wear the aid (Manchaiah, 2023). The ecological validity, or relevance, of such research findings will be improved when the published studies include OTC hearing aids that are currently on the market or soon to come onto the market. Currently there are a number of ongoing randomised controlled trials, which utilise self-reported and/or behavioural outcome measures, for which results have yet to be published (Manchaiah, 2023).

- **Post-sale Requirements:** Hearing aids typically have a return policy; yet this is not required by the FDA for OTC hearing aids, and instead is determined by the manufacturer and country or state of sale. Furthermore, the FDA OTC hearing aid regulations do not require manufacturers to provide a warranty (FDA, 2023), on the basis that these post-sale requirements are not deemed to impact the safety and effectiveness of the OTC hearing aids. If a consumer does have an adverse event related to an OTC hearing aid (such as injury from the device or increased hearing loss with device use), the FDA website provides an online form to complete or a phone number to call to report the injury, malfunction or adverse event (FDA, 2023).

NZAS recognises the possible opportunities provided by the introduction of a regulatory category of OTC hearing aids but also acknowledges that there is limited published research from currently available FDA-cleared OTC hearing aids.

New Zealand Context

With respect to New Zealand, it is prudent to note that to date there has been no specific regulation regarding hearing aids. Within the Database of Medical Devices Regulations 2003, hearing technology is not specifically listed as a medical device (Medicines (Database of Medical Devices) Regulations 2003 (SR 2003/325) (as at 07 August 2020) – New Zealand Legislation); although in fairness the regulations appear to be more focused on the risk classification of medical devices, and given that hearing aids are non-invasive and do not store any biological material, they would be considered low risk. The Web Assisted Notification of Devices (WAND) database, which arose as a result of 2003 regulations, houses information about all medical devices supplied in New Zealand and is used by Medsafe to respond to any safety concerns (Manatū Hauora, 2014). Yet this database is not an approval system, and there is no requirement for medical devices to be approved by a regulator prior to being supplied in New Zealand. In the absence of any government ruling regarding OTC hearing aids, the New Zealand population does not have the protection of FDA-regulated products as in the United States of America.

New Zealanders typically access some funding for their hearing aids through Whaikaha (Ministry of Disabled People). In order to obtain funding, the device being fitted must be on the Whaikaha list of hearing aids and be fitted by a MNZAS Audiologist or MNZAS Audiometrist.

1. To be on the Whaikaha hearing aid list, the hearing aid must meet the definition of a hearing aid, be registered on the WAND database and meet the European and US standards.
2. Whaikaha manages quality by requiring a MNZAS audiologist or MNZAS audiometrist to fit and provide follow-up care. When a MNZAS audiologist or MNZAS audiometrist sells a hearing aid, they are required to adhere to the NZAS Professional Standards and are recommended to follow NZAS

best practice guidelines. The Guidelines advise that real-ear measurements should be utilised to verify that the hearing aid's output is in accordance with the individual's hearing loss at different frequencies. Furthermore, objective validation, such as aided speech testing, is recommended to ensure that the individual is optimally fit, with no risk of auditory damage arising from the hearing aid being under- or over-prescribed.

Currently there are two OTC hearing aids on the Whaikaha list. An individual can opt to purchase an alternative hearing aid which is not on the list, but they will not be able to access Whaikaha funding.

NZAS has been discussing the opportunities and risks associated with online and OTC hearing aids for more than 10 years. Graduates of the two New Zealand-based Masters of Audiology programmes have been receiving teaching regarding OTC hearing aids for over ten years (before they were labelled OTCs in the USA). OTC hearing aids are discussed as part of the teaching in the context of different devices, future trends, service delivery models, clinical ethics, and person-centred care. This teaching enables graduating audiologists to be aware of the opportunities and caveats to OTC hearing aids.

NZAS Actions

While there are unknowns that continue to be researched, NZAS acknowledges the concerns that have been raised by hearing healthcare professionals (Manchaiah, 2023) and wishes to advocate for the following actions in accordance with the NZAS Constitution (adopted 2022):

1. Consumer Education:
    - NZAS will advocate for comprehensive consumer education to ensure individuals are well-informed about:
        - Identifying hearing loss
        - Medical red flags
        - Different habilitation options for hearing loss and the importance of choosing the option best suited to an individual's needs and values.
        - Realistic expectations of the capabilities, limitations, appropriate use and servicing requirements of different hearing devices, including an OTC hearing aid.
        - Communication strategies
        - Hearing protection
    - NZAS will explicitly state that OTC HAs are not suitable for children or adolescents, individuals with ongoing middle or outer ear pathology, individuals with large conductive hearing losses, or individuals with Auditory Neuropathy Spectrum Disorder.

- NZAS will advocate for accessibility of OTC HAs for Māori communities, in honour of our obligations under the Te Tiriti o Waitangi, including bilingual packaging and instructions, and support services that are culturally relevant and sensitive to the needs of Māori.

2. Regulatory Oversight and Quality Assurance:
    - NZAS will advocate for regulatory oversight to establish and maintain quality standards for OTC hearing devices, ensuring their safety, efficacy, and reliability.
    - NZAS and its members will advocate for the relevant regulatory bodies to promote evidence-based practices and to protect consumers from potential risks associated with improperly designed or manufactured devices.
3. Professional Involvement
    - NZAS aims to increase awareness of the breadth of services and expertise available by audiologists and audiometrists. Audiologists and audiometrists are trained as healthcare providers to specialise in the diagnostic and non-medical treatment of hearing and balance-associated disorders.
    - NZAS advocates that an individual with hearing difficulties partners with an audiologist or audiometrist, with the shared aim of improving the individual's quality of life. This requires that the individual's needs and values underpin the audiologist's or audiometrist's recommendations, and that any decision regarding habilitation for the hearing loss arises from collaboration.
    - If an individual chooses to use an OTC hearing aid, NZAS recommends that they involve a qualified audiologist or audiometrist in the process of selecting, fitting and/or adjusting the device.
        - Some OTC HAs may not be adjustable using software that a NZAS member has available. NZAS will clearly state this in any educational resources for the public and expects that a NZAS member will provide an honest indication of their ability to assist a consumer with their OTC HA.
        - NZAS acknowledges that there are many hearing aid options available and it can be impractical for an individual audiologist or audiometrist to be familiar with all devices on offer. It is expected that a NZAS member will assist a consumer in a fair and transparent manner.
    - NZAS will facilitate communication and collaboration with other professionals (ie. pharmacists) who may in the future, based on international trends, be expected to assist with an OTC hearing aid.
4. Continued Research and Innovation
    - NZAS supports ongoing research and innovation in the field of hearing healthcare, including the development of OTC devices, to enhance their performance, accessibility, and user satisfaction.

- Collaboration between researchers, manufacturers, and healthcare professionals is encouraged to drive advancements in OTC hearing device technology.

In summary, NZAS will aim to improve public understanding of the importance of hearing loss treatment, which is safe and effective, and where OTC hearing aids may be appropriate. In concert, members of NZAS will be better equipped to respond to such enquiries and see the opportunity to expand their role as a collaborator working in partnership with a person (and any support people) to ensure client-centered hearing healthcare is provided.

With respect to the future beyond New Zealand, it is expected that the FDA regulations will continue to prompt innovation of OTC hearing aids. As part of this innovation, different styles of hearing devices may be produced. Newer styles, ie. earbuds or spectacle frames, may make it more appealing to some individuals who have previously been hesitant for reasons such as cosmetics or having too many things on/behind the pinna. Thus, improving the accessibility of these hearing aids for those who need them. Furthermore, it is expected that as consumer trust and comfort grows for direct-to-consumer healthcare, so should the uptake of OTC hearing aids. This improved accessibility is favorable for many reasons, including employment opportunities and social connectedness. Conversely, untreated hearing loss due to inaccessibility of a treatment can significantly affect an individual's quality of life and wellbeing.

Conclusion

The NZAS believes in striking a balance between the accessibility of OTC hearing devices and the need for maintaining high standards of hearing healthcare. By promoting education, regulatory oversight, professional involvement and continued research, NZAS aims to ensure that individuals have access to safe and effective hearing solutions that enhance their overall quality of life. NZAS, like other international audiology professional bodies, recommends that all audiologists and audiometrists upskill in their understanding of OTC hearing aids so that they can most appropriately support members of the public who come into their clinic seeking information or assistance.

Bibliography

AA0-HNS, A. A.-H. (2023). *https://www.entnet.org/advocacy/regulatory-advocacy/over-the-counter-sale-of-hearing-aids/aao-hns-summary-fda-over-the-counter-hearing-aids-final-rule/.* Retrieved November 13, 2023

AAA, A. A. (2023). *https://www.audiology.org/consumers-and-patients/managing-hearing-loss/consumers-and-otc-hearing-aids/.* Retrieved November 10, 2023

Akbari, D. (2024). *Considerations in Over-the-Counter Hearing Aids: Past, Present, and Future*. Audiology Online.

ASHA. (2023). *Over-the-Counter Hearing Aid Toolkit (asha.org)*. Retrieved November 09, 2023

Borre, E. D. (2023). Potential clinical and economic outcomes of over-the-counter hearing aids in the US. *JAMA Otolaryngol Head Neck Surgery*, 149(7), 607-614.

Carr, K. (October 2023). *OTC Hearing Aids: One Year Later*. International EUHA Congress.

Convery E, K. G. (2011). Management of hearing aid assembly by urban-dwelling hearing-impaired adults in a developed country: implications for a self-fitting hearing aid. *Trends Amplif*, 15(4), 196-208.

Convery E, K. G. (2013). Hearing-aid assembly management among adults from culturally and linguistically diverse backgrounds: toward the feasibility of self-fitting hearing aids. *Int J Audiol*, 52(6), 385-393.

Convery E, K. G. (2015). Factors affecting reliability and validity of self-directed automatic in situ audiometry: implications for self-fitting hearing aids. *J Am Acad Audiol.*, 26(1), 5-18.

De Sousa, K. C., Manchaiah, V., Moore, D. R., Graham, M. A. & Swanepoel, D. W. (2023). Effectiveness of an Over-the-Counter Self-fitting hearing aid compared with an Audiologist-fitted hearing aid. *JAMA Otolaryngology-Head & Neck Surgery*, 149 (6), 522-530.

Educational Audiology Association. (2021). https://edaud.org/position-statements/.

FDA. (2022). *https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids#p-228*. Retrieved November 09, 2023

FDA. (2023). *https://www.fda.gov/medical-devices/hearing-aids/otc-hearing-aids-what-you-should-know*. Retrieved November 09, 2023

Hearing Industries Association. (2023). *https://betterhearing.org/policy-research/otc-hearing-aids/*. Retrieved November 10, 2023

Hearing Loss Association of America. (2023). *https://www.hearingloss.org/hearing-help/technology/otc-hearing-aids/*. Retrieved November 09, 2023

Humes LE, K. D. (2019). A follow-up clinical trial evaluating the consumer-decides service delivery model. *Am J Audiol*, 28(1), 69-84.

Keidser, G. D. (2011). Threshold measurements by self-fitting hearing aids: Feasibility and Challenges. *Trends in Amplification*, 15(4), 167-174.

Maidment, D., Nakano, K., Bennett, R., Goodwin, M., & Ferguson, M. (2024). What's in a name? A systematic review and meta-analysis to assess the effectiveness of non-medical amplification devices in adults with mild and moderate hearing loss. *International Journal of Audiology*, 1-10. doi:10.1080/14992027.2024.2321184

Manatu Hauora, M. o. (2014). *https://www.medsafe.govt.nz/regulatory/DevicesNew/3WAND.asp*. Retrieved December 4, 2023

Manchaiah, V. S. (2023). Hearing healthcare professionals' views about over-the-counter (OTC) hearing aids: Analysis of retrospective survey data. *Audiology Research*, 13(2), 185-195.

Manchaiah, V. S. (2023). Prioritizing research on over-the-counter (OTC) hearing aids for age-related hearing loss. *Frontiers in Aging*, 4, 1105879.

O'Brien A, K. G. (2010). Validity and reliability of in-situ air conduction thresholds measured through hearing aids coupled to closed and open instant-fit tips. *Int J Audiol*., 49(12), 868-876.

Sabin AT, V. T. (2020). Validation of a self-fitting method for over-the-counter hearing aids. *Trends Hear*., 24, 1-19.

Swanepoel, D. W., Oosthuizen, I., Graham, M. A. & Manchaiah, V. (2023). Comparing hearing aid outcomes in adults using Over-the-Counter and hearing care professional service delivery models. *Am J Audiol*, 32, 314-322.

Urbanski D, H. H. (2021). Toward a new evidence-based fitting paradigm for over-the-counter hearing aids. *Am J Audiol*, 30(1), 43-66.