



Speech-Language & Audiology Canada
Orthophonie et Audiologie Canada
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SAC Position Paper on **Over the Counter Hearing Aids in Canada**

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A position paper represents the direction SAC has taken on a particular topic or provides guidelines for particular areas of practice. These positions are time-bound, representing the thinking at a particular point in time.

Position

With increased consumer access to hearing technologies, ensuring the well-being, safety, and satisfaction of users is a top priority for audiologists. As over the counter (OTC) hearing aids continue to gain traction as a means to improving access to hearing healthcare across Canada, Speech-Language & Audiology Canada (SAC) holds the position that its members and associates play a crucial role in developing and implementing comprehensive guidelines, standards, evaluation metrics, and public education for OTC hearing devices.

It is important to note that while the introduction of OTC hearing aids in Canada represents a step toward improving access to hearing technology, they do not address all hearing health gaps such as the need for professional assessment and tailored interventions for individuals with more complex needs.

SAC commits to:

- advocating to **government** for proper regulatory measures to ensure the quality and safety of OTC hearing aids;
- encouraging **hearing healthcare professionals** to offer patient-centered services to optimize the benefits of over-the-counter hearing aids; and
- providing educational resources to the **public** on when and how to use OTC devices effectively and safely.

Background

Hearing aids are amplifying devices currently prescribed for clinical management of individuals with hearing loss. They consist of a microphone, speaker, amplifier, microchip, processor, and battery. Sounds are picked up by the microphone and then amplified by an amplifier and delivered through a speaker. A considerable amount of literature has shown the benefits of hearing aids to improve audibility, hearing-specific health-related quality of life, and general health-related quality of life (Ferguson & al., 2017). Despite the evidence highlighting the benefits of hearing aids, research suggests only 38% of adults with hearing loss use hearing aids (Carr and Kihm, 2022). There are several factors that can explain the low adoption rate of hearing aids (McCormack and Fortnum, 2013; Knudsen & al., 2010; Pacala and Yueh, 2012), which include:

- lack of perceived effectiveness of hearing aids;
- stigma around hearing loss;
- complicated hearing aid delivery systems; and
- affordability.

Numerous types of technologies have become commercially available in the last decade, offering more affordable and accessible approaches to address hearing loss. Several terms are used interchangeably in the literature and there is no consensus concerning terminology of these technologies. Examples of such terminology include alternative listening devices

(i.e., devices that are not hearing aids) (Maidment et al., 2018; Pinsonnault-Skvarenina et al., 2023), connected hearing health technologies (i.e., amplification devices that connect wirelessly to smartphone technologies) (Olson et al., 2022), and direct-to-consumer hearing devices (i.e., technologies that can be purchased directly by consumers without requiring a hearing health professional) (Almufarrij et al., 2019). All these types of technologies typically are used to describe hearing-related electronic devices that can be used to improve hearing, excluding hearing aids that are only available from licensed hearing healthcare providers (hereafter referred to as “prescription hearing aids”). They include personal sound amplification products (PSAPs), hearables, and over the counter (OTC) hearing aids.

OTC hearing aids are intended for adults with perceived mild-to-moderate hearing loss, regulated by the Food and Drug Administration (FDA) to meet safety and performance standards, and designed to improve hearing and communication. PSAPs, on the other hand, are intended for individuals with normal hearing who want to amplify certain environmental sounds; they are not regulated as medical devices. Lastly, hearables refer to a broad category of in-ear or wearable devices that may include amplification features along with other functionalities like music streaming and fitness tracking, but they are generally not regulated as hearing devices unless explicitly marketed to address hearing loss.

In the United States, the OTC Hearing Aid Act, part of the US Food and Drug Administration (FDA) Reauthorization Act of 2017, aims to improve the accessibility and affordability of hearing aids. This legislation enables adults with mild to moderate hearing loss to purchase OTC hearing aids without consulting a hearing health professional. Because of this Act, OTC hearing aids are currently available direct-to-consumer on store shelves and online in the United States. These OTC hearing aids must meet specific criteria to ensure a baseline level of safety. It is important to note that other direct-to-consumer hearing devices remain unregulated and do not fall under this legislation.

OTC hearing aids can be classified into two categories: (1) self-fitting and (2) pre-set. Self-fitting OTC hearing aids allow users to customize their settings using a smartphone, often through in-app hearing tests or by importing an audiogram. Pre-set OTC hearing aids, on the other hand, come with multiple preprogrammed settings designed for different levels of mild to moderate hearing loss.

The current body of research is limited in terms of scope as the focus is primarily on a small number of OTC hearing aids, each with unique adjustment programs and procedures, and on young adult users with mild hearing loss. Although limited, the body of research supports the safety of FDA approved OTC devices for the population studied (Almufarrij et al., 2019; Kim et al., 2022; Pinsonnault-Skvarenina et al., 2023; Shah et al., 2024) and highlights positive long-term outcomes for self-fitting and customizable OTC hearing aids, with results comparable to those achieved with professionally fit hearing aids (DeSousa et al., 2023; DeSousa et al., 2024). Additionally, studies indicate that other direct-to-consumer hearing technologies can improve speech intelligibility (Maidment et al., 2024). It should be noted that research looking at PSAPs and hearables demonstrates highly variable performances as these devices lack regulatory oversight, raising concerns about their suitability for individuals with hearing loss.

Rationale

Since the passing of the OTC Hearing Aid Act in the United States, many Canadian audiologists have been receiving questions from patients and treating patients who have purchased these devices. As a result, Canadian audiologists have been seeking guidance on how these devices may impact their practice.

This Position Paper will:

- provide guidance on recommended approaches to the servicing of OTC hearing aids;
- promote the role of audiologists in supporting patients who have purchased OTC hearing aids;
- educate governments, policy makers, the public and other professions about evidenced-informed audiology services related to OTC hearing aids; and
- support SAC in advocacy messaging to federal, provincial and territorial decision-makers regarding OTC hearing aids.

Recommendations

The recommendations that follow are supported by the highest level of evidence available and are intended to inform decision-making at the government level, hearing healthcare level, and the Canadian public level.

1. Advocate to government for proper regulatory measures to ensure the quality and safety of OTC hearing aids.

1.1: Strengthen Health Canada regulations for direct-to-consumer hearing devices to ensure public safety.

The Canadian Federal government has a role in the approval of hearing aids as Health Canada (Federal Ministry) is directly responsible for testing and approving all “medical” devices that can be sold in Canada. Approval by Health Canada is not, however, determinative of whether a medical device will be sold in Canada as the sale of medical devices is controlled at the provincial and territorial level. Provincial and territorial governments are responsible for the management, organization and delivery of health care services and devices for their residents. Classifying hearing aids as Class II medical devices, in theory, ensures that they meet national safety and efficacy standards before entering the Canadian market. Up until this point in time, applications for hearing aid licences have been with the intent for “professional” consumption, versus “consumer” consumption. As more OTC hearing devices seek Health Canada approval, it is crucial to reinforce Health Canada’s obligation to protect the public. Direct-to-consumer devices must be subject to stricter regulations to uphold safety standards. This includes implementing clear guidelines on labeling (e.g., detailing who may or may not use an OTC hearing aid and when to consult with a health professional), mandatory adverse event

reporting, and enforceable safe output limits. If these stricter regulations for OTC hearing aids are not upheld, there is a significant risk to the public which includes (but is not limited to) damage to the cochlea caused by the hearing aids being too loud. Specific recommendations for these stricter regulations will be developed, with a Canadian context, as a follow-up to this paper.

1.2: Ensure that consumers and professionals are informed about federal classifications and provincial/territorial regulations to support compliance and access to appropriate hearing care services.

The provinces and territories have the constitutional jurisdiction to “deliver” healthcare and regulate the standard of care for those who provide care to patients. In Canada, all provinces have statutory regulation of audiology and speech-language pathology, including five provinces that have also instituted statutory regulation (or quasi regulation) of hearing instrument dispensing (British Columbia, Newfoundland & Labrador, Saskatchewan, Ontario, and Quebec). Each province and territory has their own regulatory framework governing the practice of audiology, including the dispensing of hearing aids. Commonly, only licensed and regulated professionals, such as audiologists, are authorized to dispense these devices, and a prescription is often required. To support compliance and ensure access to appropriate hearing care services, it is essential that both consumers and professionals are well informed about federal classifications and provincial/territorial regulations.

2. Encourage hearing healthcare professionals to offer patient-centered services to optimize the benefits of over-the-counter hearing aids.

2.1. When patients seek assistance with their OTC hearing aids, audiologists are encouraged to provide people-centered services to maximize the benefits of their devices.

As part of our scope of practice, audiologists are responsible for providing comprehensive services related to hearing aid fitting, including the assessment, selection, prescription/recommendation, dispensing, validation, verification, servicing, and development of hearing aids, as well as other appropriate hearing assistive and (re) habilitative strategies for individuals with hearing impairment (Speech-Language & Audiology Canada, 2016). As audiologists working with patients who are struggling with hearing loss, we strive to reduce activity limitations caused by hearing loss and restore functional abilities in real-life situations. In this person-centered care approach, we must focus on and be respectful of people’s needs and preferences (WHO, 2021). When a patient visits the clinic seeking assistance with their hearing aids—whether prescribed or over-the-counter—audiologists should offer person-centered services to optimize the benefits of their devices. Audiologists must always demonstrate professionalism and respect in their interactions with patients (Speech-Language & Audiology Canada, 2024).

2.2: Audiologists should apply the same established hearing aid fitting guidelines used for prescribed devices when fitting and servicing OTC hearing aids.

When fitting and servicing OTC hearing aids, audiologists are encouraged to follow the same evidence-based guidelines used for prescribed devices (e.g., APSO, 2021), as the

general recommendations included in these guidelines remain applicable. As always, audiological intervention should be patient-centered and grounded in a comprehensive assessment, including a thorough needs evaluation and pre-fitting tests. Real-ear verification is possible with OTC hearing aids. The fit-to-target should be assessed for low, medium, and high-level speech signals using a validated prescriptive method, the patient's measured hearing thresholds, and their individual real-ear-to-coupler difference (RECD). Additionally, the maximum power output of the device must be measured to ensure it does not exceed the patient's frequency-specific loudness discomfort levels. Orientation should cover proper use, care, and maintenance of the device, while counseling should focus on optimizing the patient's adaptation to amplification and addressing their specific listening and communication needs. To validate the effectiveness of the intervention, outcome measures such as standardized questionnaires and aided speech-in-noise testing should be utilized. Additionally, follow-up care should be provided to ensure ongoing support and optimal device use. Audiologists may bill for OTC-related services using an hourly rate or an unbundled service fee specific to OTC care.

2.3: Quality control assessments should be conducted with the ANSI/CTA-2051-2017 testing protocol used when possible.

When verifying and fitting OTC hearing aids, some level of customization is required, as these devices typically offer limited options for professional adjustments. For example, many OTC hearing aids lack a "test mode" that would deactivate adaptive features (e.g., noise reduction, directional microphones, feedback cancellation) for standard electroacoustic assessment. In such cases, other quality control assessments should still be performed, including visual inspections, listening checks, and electroacoustic performance evaluations using a hearing aid analyzer. As suggested by the FDA OTC hearing aid rule (FDA, 2022), the ANSI/CTA-2051-2017 testing protocol should be used instead of the ANSI S3.22-2024 standard when appropriate. Interpretation of the pass/fail criteria with these measurements of OTC devices should be approached with caution and the audiologist is encouraged to use their clinical judgement when coming to any conclusions.

It is important to note that some OTC hearing aids are equipped with sensors—such as heat, pressure, or motion sensors—that are designed to deactivate the device if it is not placed in a real human ear. These sensors may interfere with coupler-based measures, so verification should ideally be conducted in the ear whenever possible. While coupler-based electroacoustic performance assessments are feasible, they can be challenging depending on the specific OTC hearing aid being tested. To ensure activation while the device is placed on a coupler, certain OTC hearing aids may require special adaptations, such as using putty, a rubber band, or a silicone sleeve to cover the sensors. Additionally, using monitor headphones connected to the hearing aid analyzer can help the audiologist confirm that the device remains active during the electroacoustic assessment.

2.4: Audiologists should assist their patients in testing and selecting settings that optimize fit-to-target and listening comfort.

If adjustments to gain or frequency response are needed after verification, the audiologist may work with the patient to explore the fitting options available through

the OTC device. Since most OTC hearing aids do not support professional fitting software, customization must be done using the device's end-user controls, such as the volume knob, preset program selection switch, or a connected phone/tablet app. OTC hearing aids with an app often include an equalizer feature, allowing for frequency-specific gain adjustments. Some models also offer manual or automatic adjustments for noise reduction, directivity, and other amplification parameters based on preset listening environments. In these cases, the audiologist can guide the patient in testing and selecting the settings that optimize fit-to-target and listening comfort, even without professional fitting software.

However, it may not always be possible to fully meet the patient's amplification needs with certain devices. In such cases, audiologists should inform their patient of the device's limitations and suggest a more suitable alternative. At the time that this paper was written, it should be noted that some OTC hearing aid apps may not be available for download in Canada.

3. Provide educational resources to the public on when and how to use OTC devices effectively and safely.

In the U.S., despite OTC hearing aids being available now for some time, a 2023 ASHA survey found that consumers still had misconceptions about OTC hearing aids, with 19% of respondents reporting that they thought OTC hearing aids were intended for both adults and children (ASHA, 2023). As OTC hearing aids become more readily available across Canada, it is imperative that there is a robust public awareness campaign to accompany this change in access to hearing devices that includes the recommendations below.

3.1: Educate the public on how to recognize the symptoms of hearing loss.

Education on how to recognize symptoms of hearing loss is crucial. This can be achieved by providing clear, accessible information on when OTC hearing aids are suitable and when a consultation with a health professional is necessary. Individuals who suspect they have hearing loss and are considering hearing devices should be encouraged to consult an audiologist. An audiologist will assess their hearing status, determine which hearing devices, if any, are appropriate, and decide if medical intervention is needed. A hearing test is essential to identify whether hearing loss is present and, if so, its degree. OTC hearing aids are intended for adults with self-perceived mild to moderate hearing loss only. They are not intended for children and individuals who have normal hearing. Potential consumers of OTC devices should also be informed about the costs associated with replacement parts (such as disposable earpieces that may need regular replacement), as well as repairs, warranties, and return/exchange policies.

3.2: Educate the public on the potential impact of OTC hearing aids on vulnerable populations.

Families, educators, healthcare providers, and others involved in the care of children and infants should be informed that OTC hearing aids are not suitable for this group due to small parts that pose choking hazards and the limited adjustability of these devices. Customizing hearing aids to meet the specific hearing needs and physical ear

structure of children is essential to optimize speech and language development during the critical period of brain plasticity and to prevent further hearing damage (McCreery et al., 2016). This process requires specialized equipment and expertise that hearing care professionals are trained, and in some jurisdictions (such as British Columbia), licensed, to use. Improperly fitted hearing aids that do not align with prescription targets can result in reduced speech perception performance (Amri et al., 2022; Wiseman et al., 2023). Additionally, the maximum power output levels considered safe for adults, as set by FDA regulations for OTC hearing aids, may pose a risk to children due to their smaller ear size, which can amplify sound intensity (Lewis, 1999).

3.3: Educate the public on the importance of transparency in product quality and performance.

Without consistent monitoring, consumers may be exposed to devices that do not meet high standards of reliability and effectiveness. It is essential that consumers receive clear guidance on proper device use to avoid misinformation and unrealistic expectations about their performance. Individuals who suspect that hearing devices may be sold illegally in their jurisdiction are encouraged to report the issue to Health Canada and the local regulatory body for hearing instrument practitioners and audiologists.

3.4: Educate other health professionals about the benefits and limitations of OTC hearing devices.

It is important to provide healthcare professionals, including general practitioners, pediatricians, and other specialists, with clear, accurate information about OTC hearing devices. Educating these professionals will enable them to better inform patients about the potential benefits and limitations of these devices to ensure that individuals seeking hearing solutions are guided appropriately. Healthcare providers should understand when OTC hearing aids may be appropriate and when a referral to an audiologist or other hearing care professional is necessary. By fostering this knowledge, healthcare professionals can play a key role in ensuring patients make informed decisions about their hearing health.

Summary Statement

To ensure the effective and safe use of OTC hearing aids, SAC recommends the following key actions:

- Advocate for stricter regulations to ensure the safety and quality of OTC hearing aids, especially for direct-to-consumer devices. Encourage hearing healthcare professionals to provide patient-centered services that optimize the benefits of OTC hearing aids, including comprehensive fitting and follow-up care.
- Provide public education on recognizing the symptoms of hearing loss, using OTC devices effectively, and understanding the limitations of these devices, particularly for vulnerable populations such as children.

- Foster transparency in product quality and performance, ensuring consumers are well-informed about the standards of OTC devices and the potential risks.
- Educate other healthcare professionals on the benefits and limitations of OTC hearing aids so they can better guide patients in making informed decisions.

These actions are essential to safeguard public health, ensure the optimal use of OTC hearing aids, and maintain high standards of care. SAC will lead efforts to collaborate with stakeholders, create educational resources, and advocate for the necessary policy changes to enhance the safety and effectiveness of OTC hearing aids. Through these initiatives, SAC aims to empower both professionals and the public to make informed decisions regarding hearing healthcare.

While the introduction of safe and effective OTC hearing aids in Canada represents a step toward improving access to hearing technology, it does not fully address the broader issue of equitable access to proper hearing care. Many Canadians continue to face significant barriers, including affordability, lack of public awareness, and limited access to professional hearing care services, particularly in rural and underserved communities. Without comprehensive support, including government policies that enhance affordability, expanded access to audiological care, and promotion of public education, OTC hearing aids alone will not resolve the hearing healthcare gap. Whichever pathway an individual chooses to take to address their hearing concerns, audiologists are hearing health professionals that are here to help.

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