



## Challenges and opportunities in direct-to-consumer hearing healthcare service delivery: a scoping review

Harini Madhu, Millie R. Kirkwood , Amir Hussain, Alison Porter-Armstrong & Adele M. Goman

**To cite this article:** Harini Madhu, Millie R. Kirkwood , Amir Hussain, Alison Porter-Armstrong & Adele M. Goman (2026) Challenges and opportunities in direct-to-consumer hearing healthcare service delivery: a scoping review, *Disability and Rehabilitation: Assistive Technology*, 21:1, 49-65, DOI: [10.1080/17483107.2025.2543032](https://doi.org/10.1080/17483107.2025.2543032)

**To link to this article:** <https://doi.org/10.1080/17483107.2025.2543032>



© 2025 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group



Published online: 29 Aug 2025.



Submit your article to this journal [↗](#)



Article views: 1548







View related articles [↗](#)



View Crossmark data [↗](#)

## Challenges and opportunities in direct-to-consumer hearing healthcare service delivery: a scoping review

Harini Madhu<sup>a</sup> , Millie R. Kirkwood<sup>a</sup>, Amir Hussain<sup>b</sup> , Alison Porter-Armstrong<sup>a</sup>  and Adele M. Goman<sup>a</sup> 

<sup>a</sup>School of Health and Social Care, Edinburgh Napier University, Edinburgh, UK; <sup>b</sup>School of Computing, Engineering and the Built Environment, Edinburgh Napier University, Edinburgh, UK

### ABSTRACT

Despite the rising prevalence of hearing loss worldwide, underutilization of hearing aids persists. Direct-to-consumer (DTC) hearing services have emerged as a potential solution to address barriers in conventional audiology services. This scoping review investigates the challenges and opportunities associated with direct-to-consumer service delivery in audiology. This review followed the Arksey and O'Malley and PRISMA-ScR guidelines. A systematic search of four databases and gray literature identified 12,034 records. Studies published in English between January 2015 and October 2024 were included if they explored challenges or opportunities in DTC hearing care service delivery from the perspectives of users aged 18 years or older with hearing loss or healthcare providers. After the screening and full-text review, 24 studies were included. The identified barriers included lack of professional guidance, safety concerns, limited user awareness and trust issues. Opportunities included improved accessibility, cost-effectiveness, integration of DTC into audiological practice, interprofessional collaboration, patient education and research comparing DTC and traditional service models. While DTC models can enhance access to hearing healthcare, overcoming challenges such as user education, trust, and professional involvement is crucial. Task shifting to other healthcare providers has emerged as a crucial strategy for enhancing service efficiency. The findings emphasise the need for a collaborative, multi-disciplinary approach to optimize DTC service delivery and inform future policy and practice.

### ARTICLE HISTORY

Received 2 March 2025  
Revised 10 July 2025  
Accepted 28 July 2025

### KEYWORDS

Direct-to-consumer; hearing healthcare models; patient-centred care; challenges; opportunities

### ► IMPLICATIONS FOR REHABILITATION

- Direct-to-consumer hearing service delivery can help to address the current barriers in traditional hearing care
- The involvement of audiologists and other healthcare professionals in this service delivery is important to ensure an effective and safe use of the devices
- Understanding the perspectives of both patients and providers can help design a user-centred and accessible hearing services

## Introduction

Over 5% of the world's population is affected by hearing loss [1], yet adults delay seeking help for hearing loss by on average about nine years after first noticing symptoms [2]. A global study estimates that 401.4 million individuals with hearing loss could benefit from hearing aids; however, despite the clear benefits of amplification devices [3], 83% do not use them [4]. These numbers highlight the gaps in hearing uptake, which can be linked to barriers in the existing service delivery models.

Hearing care has been delivered by clinician-led services, where patients receive assessment and treatment from qualified healthcare providers. However, multiple factors influence hearing aid uptake, including audiological and non-audiological barriers [5], such as accessibility of healthcare [6], unmanageable costs of hearing devices [7], and shortage of suitably qualified healthcare providers [8]. A longitudinal study of older individuals with hearing loss reported that the second most common

**CONTACT** Harini Madhu  [harini.madhu@napier.ac.uk](mailto:harini.madhu@napier.ac.uk)  School of Health and Social Care Edinburgh Napier University, Edinburgh, UK.

© 2025 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives License (<http://creativecommons.org/licenses/by-nc-nd/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited, and is not altered, transformed, or built upon in any way. The terms on which this article has been published allow the posting of the Accepted Manuscript in a repository by the author(s) or with their consent.

problem during the COVID-19 pandemic was inadequate or delayed services from hearing aid companies [9]. A National hearing loss charity in the United Kingdom, RNID- Royal National Institute of Deaf People stated that people from their community reported a waiting time of two years to receive their hearing aids [10]. Such delays can lead to late detection and intervention, ultimately affecting the quality of life of those in need [11]. These limitations emphasise the need for alternative service delivery models to improve access to hearing care.

Technological progress in the past decade has created new solutions to make hearing care more accessible and affordable. These developments include mobile applications for education, screening, and rehabilitation for hearing disorders [12], tele-audiology services [13], and direct-to-consumer (DTC) or over-the-counter (OTC) hearing devices [14]. The DTC model bypasses traditional clinician-led pathways and is intended to address critical barriers such as excessive costs and long waiting times [14]. This model is well-established in the United States (US) by the Food and Drug Administration (FDA) approving a new category of medical devices for individuals with mild-to-moderate age-related hearing loss in 2022 opening the market for other manufacturers to enter [15]. Recently Apple, a multinational consumer electronic company released “AirPods Pro 2” with an integrated, scientifically validated hearing test and an innovative Over-the-counter hearing aid capability for users with mild to moderate hearing loss [16]. In January 2025, the UK published a policy statement, to improve access to innovative technologies, including self-administered hearing tests and hearing aid use without professional involvement, provided that the device met medical regulations [17].

As the field of DTC hearing care expands, a comprehensive evaluation of its challenges and opportunities is required. The available literature on DTC can be grouped into three main areas [18]: 1. Acoustic quality of the device, where studies report mixed findings, with some indicating poor acoustic quality [19], while others have reported devices to meet appropriate standards [20]; 2. User-focused surveys that documented user-reported benefits and satisfaction. One such study analysed over 11,000 Amazon customer reviews and reported users frequently discussed the sound quality, cost and fit of the devices [21], and 3. clinical trials which evaluate the outcomes of these devices [14,22]. Existing research has often focused on isolated aspects such as technical features of the devices, individual user satisfaction, or healthcare provider perspectives leaving a lack of integrated understanding of the broader challenges and opportunities in DTC hearing care. This gap limits the ability to evaluate the practical implications of implementing DTC models, particularly within publicly funded systems like the UK National Health Service (NHS). This review addresses this gap by consolidating evidence across users, healthcare providers and healthcare systems offering a holistic view of the challenges and opportunities associated with DTC hearing care delivery. The review is guided by the question: “What is the current state of evidence on the challenges and opportunities associated with service delivery of direct-to-consumer hearing care?”

## Method

This review protocol was registered in the Open Science Framework (DOI 10.17605/OSF.IO/EMKVY) and adhered to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.

*Eligibility criteria:* Given the evolving nature of DTC hearing care, publications from all sources were considered, regardless of the research method, if they met the inclusion criteria.

*Population and setting:* Studies or other data sources reporting the challenges and opportunities in DTC hearing care service delivery from the perspectives of users aged 18 years or older with hearing loss or healthcare providers

*Context:* This review included studies or other data sources in the global hearing healthcare and audiology sector.

*Study design:* Any study design was included

*Timescale:* The initial search was conducted in October 2023, collecting studies published between January 1<sup>st</sup>, 2015, and October 31<sup>st</sup>, 2023. The search was subsequently updated in October 2024 to include studies published from October 31<sup>st</sup>, 2023, through October 31<sup>st</sup>, 2024.

*Language:* Studies published only in English were included

## Literature search

The primary reviewer (HM) conducted an initial literature search across multiple databases, including PubMed, CINAHL, Scopus, Web of Science, and gray literature, to identify relevant studies and sources published in English. This search included peer-reviewed literature, gray literature, and conference proceedings. Before conducting the database search, the team formulated the search terms (Appendix A) and the inclusion and exclusion criteria (HM and AG). The search strategy employed a three-group structure, utilising the “OR” operator within each group and the “AND” operator between groups. The first group referred to hearing technology, the second group referred to stakeholders, and the third group referred to service delivery.

## Data management

After searching the database, the primary reviewer (HM) removed the duplicates. Later, the two independent reviewers (HM and MRK) screened the titles and abstracts of all reports identified from databases and gray literature, using the Rayyan software. Later, the primary reviewer (HM) retrieved full-text copies of all the relevant articles and assessed them for inclusion. The selection process is illustrated in the flow chart (Figure 1).

## Data extraction

Data extraction was conducted by the primary reviewer (HM) using a pre-defined Excel extraction template. The extracted data included: (i) bibliographic data of the study (e.g. title, author(s), year of publication, country), (ii) study design, (iii) objective, (iv) results/outcomes, and (v) challenges/opportunities reported (Tables 1 and 2). To enhance reliability and reduce risk of bias, a second reviewer (MRK) independently cross-checked a random sample of six studies (20% of the included studies). Minor interpretation differences were discussed and resolved through consensus.

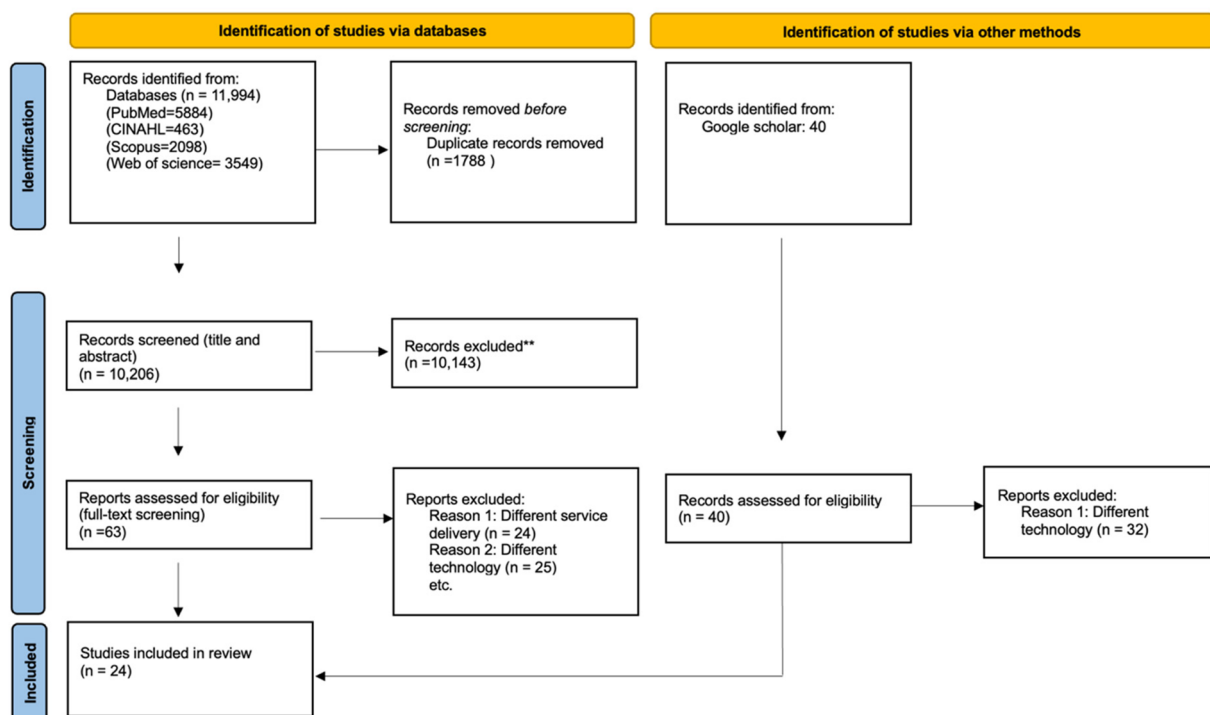


Figure 1. PRISMA-ScR diagram of included studies.

Table 1. Data charting of included peer-reviewed studies.

Author	Location	Study design	Participants	Study Outcomes	Challenges	Opportunities
Bothe et al. [32]	Australia	Explorative qualitative study using three focus groups with adults with hearing difficulties, one focus group with audiologists and one online focus group for each participant group the rest were in-person	12 adult-users of a commission-free hearing care provider with self-reported hearing difficulties who have not been fitted with hearing aids and 6 audiologists from the same hearing care provider	This exploratory qualitative study reported four main themes from the focus group: desire for trustworthy sources of advice and information about hearables, desire for help and support when considering and using hearables, balancing cost and performance when considering hearables and evaluating hearables based on individual lifestyle and needs. Six themes from audiologist focus groups were identified including viewing hearables as both an opportunity to reach a wider client base and a potential challenge to traditional audiology practice, uncertainty about their professional roles and responsibilities with hearables, and concerns about the potential impact of hearables on their current business models.	Limited understanding and awareness of technology Trust	Accessibility Cost Integration of DTC hearing service delivery into audiological practice Interprofessional practice Patient Education
Chandra & Searchfield [23]	New Zealand	Qualitative interview	18- experienced hearing aid users	This article explores the perceptions of older individuals (65 years and older) who use hearing aids towards receiving their devices through internet-based delivery. The findings identified both potential benefits and concerns regarding online hearing aid purchases. Benefits included lower costs and increased accessibility, while concerns involved lack of professional guidance, trustworthiness of online retailers and unfamiliarity with internet use.	Lack of professional support Limited understanding and awareness of technology Trust	Accessibility Cost Integration of DTC hearing service delivery into audiological practice Patient Education
Davis et al. [24]	US	Cross-sectional survey study	111 primary care physicians across the US	This study assessed primary care physicians' familiarity and attitudes towards over-the-counter hearing aids. The key outcomes were most physicians viewed OTC hearing aids positively and desired involvement with them. The majority reported being unfamiliar with OTC hearing aids and lacked confidence in managing and counselling patients about them.	Lack of professional support Limited understanding and awareness of technology	Interprofessional practice Patient Education
Hay-McCutcheon et al. [25]	US	Randomized controlled trial	51 adults with perceived mild-to-moderate hearing loss	The clinical trial assessed the impact of varying levels of support on over-the-counter hearing aid benefits and use. The study measure includes word understanding, communication in natural settings and hearing aid use and care habits. The study's findings suggest that while some participants could successfully set up and use their OTC HAs independently, others required varying levels of assistance. The study also identifies the potential for pharmacy and audiology collaborations to improve hearing healthcare access in rural areas	Lack of professional support	-

(Continued)

Table 1. Continued.

Author	Location	Study design	Participants	Study Outcomes	Challenges	Opportunities
Humes et al. [30]	US	Single-site, prospective, double-blinded clinical trial	40- adults with mild-moderate hearing loss aged 54–78 years	The main objective of this follow-up clinical trial was to replicate the findings of the previous trial while using less screening of participants to mimic the real-world DTC service delivery approach; hence they did not include a pre-intervention hearing screening test battery. The trial demonstrated positive outcomes of the direct-to-consumer model identical to the previous trial, where they compared the direct-to-consumer model with the conventional hearing delivery model including an audiologist. Additionally, it highlighted that some participants opted for placebo devices, highlighting the importance of proper guidance in device selection.	Lack of professional support Safety	–
Manchaiah et al. [26]	US	Retrospective survey	653 – hearing health providers, 54 hearing aid business owners, 18 hearing instrument specialists, 5 audiology doctoral students	The survey results revealed that HHPs have concerns related to safety, counselling, device-handling and self-adjustment, service delivery models and optimal benefits and adverse events. Despite these concerns, nearly half of the HHPs reported willingness to support patients with OTC hearing aids purchased elsewhere, while a quarter stated they would sell OTC hearing aids in their clinics or websites. Additionally, many hearing care providers are considering implementing unbundled pricing (differentiating prices for services vs. hearing aids) instead of bundled pricing (bundling the audiologist service cost with the cost of the hearing aid).	Lack of professional support Safety	Integration of DTC hearing service delivery into audiological practice
Midey et al. [27]	US	Cross-sectional descriptive study using an online survey	524 licensed pharmacists in the United States	The study assessed pharmacist awareness, interest and readiness for the OTC hearing aids. The study identified that while most pharmacists had positive attitudes towards OTC hearing aids and recognized their potential benefits, their knowledge and preparedness to counsel patients on these devices were limited. The study also identified a need for increased education and training for pharmacists regarding OTC hearing aids and related hearing healthcare services.	Lack of professional support Limited understanding and awareness of technology	Integration of DTC hearing service delivery into audiological practice
Singh & Dhar [34]	US	Mixed methods survey	1037- US residents older than 50 years with no previous hearing aid experience	This study assessed attitudes towards direct-to-consumer hearing healthcare. The majority expressed a preference for in-person healthcare and hesitancy about purchasing online without prior hearing testing. Some participants indicated a willingness to engage with online hearing healthcare options. Additionally, the study revealed that individuals with lower incomes and those without insurance coverage for hearing aids were more likely to consider online HHC options	–	Cost Integration of DTC hearing service delivery into audiological practice

(Continued)

Table 1. Continued.

Author	Location	Study design	Participants	Study Outcomes	Challenges	Opportunities
Swanepoel et al. [29]	US	Ecological, cross-sectional survey design	406- hearing aid users through conventional hearing care professional services, 250 through a direct-to-consumer model	The study compared the hearing aid outcomes of individuals who received their aids through different service deliveries using an open-ended questionnaire about hearing aid experiences, and the International Outcome Inventory for Hearing Aids (IOI-HA) with 7 domains and general health, well-being, and social network items. No significant overall difference in self-reported hearing aid outcomes was found between the two groups. However, some variations were observed in the daily use and residual activity domain of IOI-HA where direct-to-consumer service users reported less difficulty than conventional users in certain situations.	Lack of professional support	Research to compare traditional practice with DTC services
Olson et al. [31]	UK	Delphi review	34 Hearing healthcare providers (22- National Health Service, 12- independent clinical practice)	This study aimed at achieving consensus among UK hearing healthcare providers on several facets of connected hearing health technologies (CHHT). CHHT includes personal sound amplification devices, direct-to-consumer hearing aids, and smartphone-connected hearing aids. Audiologists who participated in the review agreed that CHHT was suitable for adults over 18 years old with communicational issues and no medical contradictions. Additionally, the authors reported the participants expressed their concerns over self-fitting and adequate user support and their support for incorporating CHHT into clinical practice. The experts agreed that involving staff with lower skill sets could lead to cost savings and increased accessibility.	-	Accessibility Cost Integration of DTC hearing service delivery into audiological practice Patient Education
Nieman et al. [33]	US	Randomized controlled trial	128 adults aged 60 years or older with acquired hearing loss across speech frequencies	The trial evaluated the effectiveness of a community health worker-delivered personal sound amplification device intervention on self-perceived communication function in older adults with hearing loss. They found that the intervention group showed significant improvement in self-perceived communication function at 3 months compared to the wait-list control group. They also reported improvements were sustained at 12 months suggesting the intervention had a lasting impact. They also reported the intervention group demonstrated improvement in physical health-related quality of life and listening self-efficacy.	-	Accessibility, Integration of DTC hearing service delivery into audiological practice
Knoetze et al. [35]	US	Secondary data analysis of retrospective, cross-sectional study	Secondary analysis of a cross-sectional survey	The key themes from this study are mostly related to cost and uptake. Prescription hearing aid users reported excessive costs as the major barrier, leading some to delay purchases or seek alternatives. OTC hearing aid users reported being more satisfied with the cost but still some found them to be expensive.	-	Cost Patient Education

(Continued)

Table 1. Continued.

Author	Location	Study design	Participants	Study Outcomes	Challenges	Opportunities
Mothemela et al. [36]	US	Cross-sectional survey study	398 hearing aid users residing in the United States	The study explored factors associated with hearing aid outcomes, including social networks, self-reported mental health, and service delivery models. They found that larger social networks and better self-reported mental health were associated with more positive hearing aid outcomes. No significant differences in outcomes were observed between different service delivery models.	-	Cost Integration of DTC hearing service delivery into audiological practice
De Sousa et al. [37]	South Africa	Randomized controlled trial	64 adults with bilateral, symmetrical, mild to moderate sensorineural hearing loss	This clinical trial compared the effectiveness of an over-the-counter self-fitting hearing aid to an audiologist-fitted hearing aid. By the end of the 6-week trial, there were no clinically meaningful differences between the groups in objective measures of hearing aid benefit. Both groups showed significant improvement from baseline in self-reported hearing aid benefit and satisfaction.	-	Integration of DTC hearing service delivery into audiological practice Research to compare traditional practice with DTC services
Humes et al. [38]	US	Single-site, prospective, double-blinded clinical trial	40- adults with mild-moderate hearing loss aged 54-78 years	The clinical trial aimed to compare the audiology best practices (hearing aids opted through professional guidance) and the direct-to-consumer model. The direct-to-consumer group significantly outperformed the placebo in terms of speech recognition benefits in noise and hearing handicap inventory for the elderly. However, participants who received professional guidance reported higher satisfaction with hearing aid features and were more likely to keep the hearing aids compared to the DTC model.	Lack of professional support Safety	-
Berenbrok et al. [44]	US	Delphi review	12 healthcare providers (3- professional pharmacy organization, 2- community pharmacy practice, 4- professional audiology organization, 1- private audiology practice, 2- hearing aid manufacturers), 2 - representing persons with hearing loss	This study established 26 consensus-based competencies for pharmacists regarding direct-to-consumer hearing services. The competencies comprise various aspects of patient care, including identification of hearing loss, device selection and patient education. While two statements were rejected, 11 statements did not reach a consensus, highlighting areas for future research. A unique insight from this study is the potential for pharmacists to play a crucial role in expanding access to hearing health care. This study highlights interprofessional opportunities for pharmacists to work alongside audiologists.	-	Interprofessional practice
Berenbrok et al. [45]	US	Case report	One adult: male patient with self-reported untreated hearing loss	The case report highlights several insights. It demonstrates the potential role of pharmacists in supporting OTC hearing aid adoption, including identifying appropriate candidates, assisting with device selection and supporting setup processes. It also emphasized the importance of technical support for users, particularly older adults who may struggle with app-based self-fitting processes.	-	Interprofessional practice

Table 2. Data charting of reports/viewpoints.

Author	Location	Study design	Outcomes	Challenges	Opportunities
Sheffield et al. [28]	US	Viewpoint	This viewpoint provides recommendations for clinicians and users regarding the service delivery of DTC hearing care. This highlights the importance of user education and personalized instruction from manufacturers for the effective use of direct-to-consumer devices. They also emphasised the valuable role of hearing health providers in educating both users and other healthcare providers.	Lack of professional support	Cost
Emily Francisco & Frank [39]	US	Commentary	This commentary is a guideline based on the project conducted in their clinic on how to incorporate DTC services in their practice. The authors mentioned that to better serve their patients, they started using the term "communication needs assessment" rather than hearing aid selection as shifting towards a more tailored patient-centric approach. They also mentioned that their clinic offers unbundled services, which means the patients can choose the services they want and pay only for the specific services.	-	Integration of DTC hearing service delivery into audiological practice
Perez-Heydrich et al. [40]	US	Perspective	This proposed workflow outlines multiple entry points for OTC hearing aid users seeking care. They suggested incorporating professional evaluation and support to avoid the risk of inappropriate self-fitting and troubleshooting issues. They also emphasise the continued role of audiologists in assisting patients who may have difficulty obtaining or using OTC hearing aids.	-	Integration of DTC hearing service delivery into audiological practice
Smith [41]	US	Editorial	This editorial discusses the potential impact of direct-to-consumer devices on clinical practice. It outlines three possible perspectives and provides strategies for audiologists based on their stance. He suggests ways to integrate DTC devices into clinical practice for those who accept them, offers a middle-ground approach for those who see a limited role for DTCs and advises on emphasising professional care for those who don't believe DTCs will affect the market.	-	Integration of DTC hearing service delivery into audiological practice
Bennett et al. [42]	Australia	Commentary	This commentary presents findings from four research studies, including a workshop conducted to explore users' and audiologists' needs for the adoption of hearables. The workshop is the focus of the commentary, aimed at developing a service delivery framework for incorporating hearables into existing audiology clinics. One of the unique insights is the potential for selling hearables via clinic websites. Another interesting finding is the need for a clinical tool to assist in discussion and shared decision-making to hearable selection, which could empower patients to actively participate in their treatment.	-	Integration of DTC hearing service delivery into audiological practice
Berenbrok et al. [43]	US	Commentary	This commentary outlines new opportunities for interprofessional collaboration between audiologists and pharmacists. The key outcomes include recognition of potential barriers to pharmacist-audiologist collaboration, such as lack of trust and distance between practice sites, and suggestions for overcoming these barriers. The author suggests a call to action between the healthcare providers to embrace this opportunity for collaboration to positive impact on hearing health	-	Interprofessional practice
Coco [46]	US	Viewpoint	This viewpoint summarizes the progress made in the first year after the introduction of OTC hearing aids in the U.S. It highlights the positive impact on the availability and accessibility of hearing aids and new opportunities for collaboration with pharmacists and other health care providers. It emphasizes the role of audiologists in improving public awareness and addressing misconceptions about the devices.	-	Patient Education

## Results

The literature search identified 11,994 articles from four databases (PubMed, CINAHL, Scopus, Web of Science, and Medline) and 40 references from gray literature. After removing duplicate entries, 10,206 studies remained. These studies were screened based on their titles and abstracts, resulting in the exclusion of 10,143 studies. Ultimately, 63 studies were selected for full-text screening, of which 24 were considered relevant for reporting the current state of evidence on the service delivery of direct hearing healthcare. The included studies were published between 2016 and 2024.

### *Study characteristics*

The review identified a mix of quantitative and qualitative studies, reports, and guidelines reporting challenges and opportunities in the service delivery of direct-to-consumer hearing care. Of the 24 studies examined, 11 were Survey/Delphi reviews (quantitative/qualitative), 5 were clinical trials, one was a case report (Table 1), and the remaining 7 comprised reports guidelines or commentaries (Table 2) focusing on various elements of direct-to-consumer hearing care service delivery. Of the included studies, 11 focused on user perspectives, five on healthcare providers and one study included perspectives from both groups. Most studies were conducted in the United States ( $n=19$ ), with others originating from Australia ( $n=2$ ), the United Kingdom ( $n=1$ ), New Zealand ( $n=1$ ), and South Africa ( $n=1$ ).

## Challenges

### *Lack of professional support*

The lack of professional support was frequently identified across studies as a key barrier to the implementation of DTC hearing services by both users and healthcare providers [23–29]. In a semi-structured interview study [23] older adults using hearing aids expressed concerns regarding the lack of professional guidance in online device purchasing, with many preferring expert consultations for hearing tests and personalized counselling. These participants emphasized the importance of face-to-face consultations, which they reported were not feasible in DTC hearing service delivery [23]. Similarly, a randomized controlled trial reported that users of DTC hearing service delivery required assistance with hearing aid use, emphasising the need for continued professional support [25]. A cross-sectional survey revealed that participants using OTC hearing aids reported fewer hours of device usage compared to those using professionally fitted hearing aids [29]. Audiologists [26] and primary care physicians [24] indicated in survey responses a shared concern that DTC hearing service delivery may be potentially less effective than professional fitting due to a lack of professional assessments, guidance, patient education on device usage, hearing protection and individualised adjustment tailored to the patient needs. A survey of pharmacists [27] revealed that time and workflow constraints, and a lack of training in hearing care hindered their engagement in DTC hearing service delivery. A viewpoint suggested that hearing healthcare providers (HHPs) and physicians should assess patient candidacy for DTC hearing aids [28] and manufacturers should educate patients about hearing loss and device suitability [28].

### *Safety*

Safety concerns were identified as a key barrier across three studies [26,30,31]. A retrospective survey of HHPs revealed that more than three-quarters expressed concerns about the potential for missing medical “red flag” conditions [26]. A clinical trial [30] comparing audiologist-delivered care with DTC hearing service delivery further highlighted this issue, that the lack of professional evaluations could increase the risk of undiagnosed medical conditions [30]. Similarly, a Delphi review involving HHPs reached unanimous consensus on barriers associated with connected hearing health technologies (CHHT) (a term used in the Delphi review to refer to smartphone-connected hearing aids, OTC hearing aids, personal sound amplification products (PSAPs), hearables, and smartphone applications) [31]. These included the potential delay in diagnosing treatable medical conditions, the risk of incorrect results from self-administered

hearing assessments, the possibility of poor physical fit leading to user discomfort, and the potential to miss other relevant medical conditions [31].

### ***Limited understanding and awareness of technology***

Lack of awareness and understanding of DTC hearing service delivery has been identified as a challenge for both users and healthcare providers [23,24,27,32]. A New Zealand-based survey study found that, despite older adult participants awareness of online hearing aid purchase, some participants expressed concerns regarding their ability to independently manage the purchase process, suggesting a likelihood of seeking support from a younger family member [23]. Among healthcare providers, a survey of pharmacists revealed that more than half of the participants were unfamiliar with DTC hearing care services [27]. Similarly, a survey of primary care physicians reported a general lack of awareness and familiarity with DTC hearing service delivery [24]. Additionally, a qualitative focus group study reported that some audiologists expressed uncertainty about hearables (personal sound amplification products) because they had limited education about hearables and perceived a lack of evidence or effectiveness [32].

### ***Trust***

Two studies have highlighted users' lack of trust in online retailers [23,32]. A qualitative focus group study found that adult hearing aid users emphasised the importance of trust when engaging with HHPs and highlighted the need for reliable information about hearables [32]. Similarly, a qualitative semi-structured interview study reported that older adult participants expressed concerns about potential scams when purchasing hearing aids online [23]. Additionally, some participants indicated that they had previously interacted directly with the manufacturers of their hearing aids and would consider purchasing the same brand if available through an online platform [23].

## **Opportunities**

### ***Accessibility***

The reviewed studies suggested that DTC hearing service delivery has the potential to enhance accessibility. A qualitative interview reported that most participants in their study indicated that the ability to purchase hearing aids online is convenient, particularly for those with mobility issues or those living in rural and remote areas [23]. In an exploratory qualitative study, audiologists expressed that the availability of alternate devices, such as personal sound amplification devices or other assistive listening technologies, could be beneficial for two groups of clients: those who are unwilling to use traditional hearing aids, and those whose level of hearing has not yet reached the threshold where hearing aids are medically recommended [32]. A Delphi review by Olsen et al. found that remote assistance, such as fine-tuning hearing aids *via* the Internet, improves accessibility by reducing the need for travel and in-person clinic visits [31]. A randomized clinical trial found that a hearing care intervention delivered by community health workers using over-the-counter hearing aids improved self-perceived communication function among older adults with hearing loss while also enhancing accessibility for those facing geographical barriers [33].

### ***Cost***

Multiple studies identified cost as a key opportunity of DTC hearing service delivery [23,28,31,32,34–36] with evidence from the U.S. ( $n=5$ ), New Zealand ( $n=1$ ), and Australia ( $n=1$ ). A survey reported participants with lower household income and no hearing aid insurance were more inclined to purchase hearing devices online [34]. An interview study reported participants perceived online purchases as a cost-effective option, avoiding the costs associated with clinic-based purchases [23]. A focus group [32] and a survey study [35] of hearing aid users reported lower cost as an important motivator for adults

considering hearables or DTC devices. A hearing aid user focus group reported cost as the primary factor in choosing between hearing aids and hearables [32]. A Delphi review suggested that offering CHHT through the NHS in the UK, could lead to cost savings by utilising staff with lower skills sets [31]. A survey identified that those who obtained hearing aids through big-box stores and third-party payers reported better hearing aid outcomes on the International Outcome Inventory for Hearing Aids, a self-reported scale of hearing aid outcomes, compared to those who acquired them from private practices or university clinics [36]. A viewpoint suggested that since these devices span a wide range of prices, price-conscious users may choose one that fits their budget, even if performance varies [28].

### ***Integration of DTC hearing service delivery into audiological practice***

The reviewed literature highlights a strong opportunity to integrate DTC hearing service delivery into traditional audiological practices [23,26,31,32,34,36–42]. In a focus group, audiologists proposed providing supported set-up sessions, maintaining demonstration stock for trials, and offering brief appointments for hearables as assistive listening devices to incorporate DTC hearing service delivery into existing clinical practice [32]. A US-based survey study revealed that while 85% HHPs reported providing support to adults with hearing loss with externally purchased DTC hearing aids, only 26% directly retail these products, with 42% of HHPs offering unbundled service pricing [26]. A user reported survey revealed a strong preference for professional hearing assessments before buying a device [34] and post device purchase adjustments by a local audiologist [23]. Some participants indicated willingness to consider online purchases if guided by an audiologist's prescription and if cost savings were substantial [23]. UK-based Delphi study reinforced clinician-mediated approach, suggesting that CHHT should ideally be distributed through clinically qualified HHPs, while acknowledging potential cost efficiencies by dispensing through staffs with lower skills sets within the NHS pathway [31]. Clinical trial evidence indicates that while DTC models improved accessibility, professional oversight correlated with higher user satisfaction and improved hearing aid outcomes in self-reported standardised measures such as the Profile of Hearing Aid Benefit (PHAB) and the International Outcome Inventory for Hearing Aids IOI-HA [37,38]. Proposed implementation frameworks involve collaborative workflows where primary care physicians conduct initial medical evaluation, with an audiologist providing technical support [40]. Implementation strategies from viewpoints and commentaries included establishing in-clinic product displays, developing staff training protocols [41], offering unbundled services (pay -as-you-go) in clinics [39] and creating customised practice workflows to accommodate both online and in-person service delivery [42]. A survey study that reported improved self-reported mental health associated with improved hearing aid outcomes suggested incorporating mental health screenings into hearing care [36].

### ***Interprofessional practice***

The reviewed literature highlights the critical role of interprofessional collaboration among healthcare providers including pharmacists, primary care physicians, and community health workers, to support DTC hearing service delivery [24,27,32,33,36,43–45]. Evidence highlights distinct yet complementary roles for these healthcare providers. A randomized clinical trial in which community healthcare workers assisted with hearing aid fitting and training, reported significant improvement in self-perceived communication function as measured by Hearing Handicap Inventory for Elderly-Screening (HHIE-S) [33]. A survey study reported 94% of pharmacists expressed interest in further DTC related training [27]. A Delphi study reported consensus that pharmacists can support self-fitting of hearing devices by recognizing hearing loss symptoms, identifying medical conditions, explaining screening results, helping users select devices and collaborating with hearing healthcare providers for referrals [44]. Similarly, a commentary outlines new opportunities for collaboration between pharmacists and audiologists [43]. A survey of primary care physicians reported strong interest in DTC involvement [24]. Three studies recommended incorporating hearing care into medical education and emphasised the potential collaboration between mental health providers and audiologists to provide a more holistic approach to patient care [32,36,45]. These findings collectively underscore the opportunity for an integrated, team-based approach to improve DTC hearing service delivery.

### **Patient education**

The importance of patient education to support DTC hearing service delivery has been reported in several included studies [23,24,31,32,40,44,46]. A Delphi study [31] and a viewpoint [40] recommended the use of risk assessment, such as the Consumer Ear Disease Risk Assessment (CEDRA) to guide adults in identifying ear conditions and determining the appropriate care pathway. Three studies emphasized the responsibility of various healthcare providers, primary care physician [24], hearing care providers [32], and pharmacists [44] in educating patients about hearing loss, OTC devices and ear health. An interview study reported that participants with hearing loss expressed a willingness to learn about hearing aids available online and evaluate new technologies themselves [23]. Broader public education strategies, such as community-led awareness programs guided by local healthcare systems were recommended to ensure equitable and informed use of OTC hearing aids [32,46]. Collectively, these findings support the need for accessible and customized educational initiatives to enhance DTC hearing service delivery [32,46].

### **Research to compare traditional practice with DTC services**

A survey found that adults using DTC and clinician-led service delivery reported similar levels of satisfaction, perceived benefits, and quality of life among participants [29]. A clinical trial by Humes et al. demonstrated that both audiologist-led best practices and DTC hearing service delivery improved self-perceived speech communication in older adults, who obtained hearing devices through healthcare providers reported higher daily usage, while those using the DTC hearing service delivery faced fewer challenges in specific listening situations [38]. Another randomised control trial found no differences in speech perception in noise, sound quality, or perceived hearing handicap between self-fitting hearing aids with remote support and audiologist-fitted devices [37].

### **Discussion**

This review highlights several key barriers and opportunities associated with DTC hearing service delivery. The key challenges identified include lack of professional support, limited user knowledge and understanding, and potential safety risks of missing treatable ear conditions. The identified opportunities include incorporating professional guidance into direct-to-consumer services, interdisciplinary collaborations with other healthcare providers, and using innovative approaches such as unbundled pricing and online platforms to improve accessibility and adoption. The findings from this review highlight the challenges in effectively implementing DTC hearing service delivery and the need for adaptable strategies to meet the needs of users and healthcare providers.

A key challenge identified by users and healthcare providers is the lack of professional support [23–29]. Clinical trials in the review reported that traditional clinical practice and DTC hearing service delivery had similar benefits, but individuals who received professional support reported longer hearing aid use [30,37,38]. One possible explanation is that professional counselling and guidance have been demonstrated to play a crucial role in helping individuals derive meaningful benefits from hearing aids [38]. Owning a hearing aid alone does not contribute to a successful use. Effective adoption and usage of hearing care services involve continuous interaction between the user and hearing healthcare providers [47]. Hence, the role of a hearing health professional may be crucial for any service delivery to succeed. An opportunity to address this challenge is to integrate professional support and guidance into DTC hearing service delivery [23,26,30,31,34,39,41]. Few studies have identified potential entry points within clinical practice where individuals who obtain direct-to-consumer hearing devices could access professional guidance for device maintenance or hearing evaluation [40,42,43] or consult a local audiologist or clinic for any hearing services [23,31,40,42]. Innovative ideas such as building websites for these types of devices and providing unbundled prices were also mentioned as opportunities to integrate service delivery into traditional clinical practice [42].

According to Perez-Heydrich et al. DTC hearing service delivery can improve accessibility and reduce the number of required clinical visits required [40]. By eliminating the need for multiple appointments [48,49], these services can help reduce long waiting times, which has been a challenge in countries such

as the UK [50]. This increased accessibility allows individuals who may benefit from these devices to try them more conveniently [15]. A UK-based study reported that the devices offered through DTC service delivery can act as “gateway products” [31]. The concept of gateway products originates from public health and behavioural research, where it refers to the use of an initial, often lower-risk product that increases the potential to progress to more usage [51]. This has been previously discussed in the context of tobacco cessation [52]. In the context of hearing healthcare, DTC hearing aids may bridge the gap between neglecting hearing loss and seeking intervention through a hearing care professional [53]. Given their accessibility and affordability, these devices may serve as an initial, less intensive option, encouraging earlier adoption of hearing care and gradually increasing the likelihood of formal hearing aid adoption.

In January 2025, the UK government issued a new policy statement on businesses selling innovative hearing devices directly to users [18]. DTC hearing technology availability is expected to raise awareness of hearing loss, encourage earlier adoption of hearing aids, and make self-managed hearing care more convenient [54].

Findings from this review suggest that DTC hearing service delivery has the potential to enhance convenience and accessibility, particularly for people with hearing loss living in rural areas [34]. However, a key concern is the risk of missing treatable ear conditions [26,31,38]. To address this, some studies have highlighted the use of risk assessment questionnaires such as CEDRA that patients can use to identify any ear conditions before opting for these devices [31,40]. In the U.S., the OTC hearing aid regulated by the FDA includes red flag conditions in their labelling to help users assess the suitability of the device and recognise when a professional consultation may be necessary [55]. Beyond these regulatory measures, various online hearing tests and mobile applications, such as the Hearing Number developed by the Johns Hopkins Bloomberg School of Public Health provide accessible ways for individuals to assess their hearing status [56]. Various resources are available to support users who opt for DTC hearing care; however, increasing the visibility and awareness of these tools among users is crucial. Healthcare providers can play a key role in creating awareness among users towards these resources and supporting informed decision-making towards hearing healthcare.

Some studies have reported the involvement of other healthcare providers, such as pharmacists in educating users about ear conditions and hearing devices, presenting a valuable opportunity for inter-professional collaboration and comprehensive patient care [31,41,44]. Pharmacists often recommend over-the-counter medical devices to patients, like blood glucose monitors [57]. This example demonstrates how pharmacists can collaborate with hearing healthcare providers and play a key role in patient education and care. Another important theme that emerged from the literature was patients’ understanding of direct-to-consumer hearing services. The review highlighted studies that reported the knowledge of patients regarding these services to be limited [23]. A key finding of these studies was the increased willingness to gain further knowledge about these services, which has the potential to eliminate barriers [23]. This challenge could be addressed by healthcare providers by educating the users, advertising on clinical websites, and allocating separate timings for patients who opt for direct-to-consumer services.

The current study only included literature published and available in English; therefore, any relevant work published in other languages may have been missed due to the absence of translation. Many studies included in the review were conducted in the United States; however, the application of this model may differ in countries with varying healthcare systems. This type of service delivery has not yet been established in some countries. In the UK, the NHS offers hearing aids to users at no cost [58]. However, a recent policy statement [17] highlights a shift towards improving accessibility, which also raises concerns about the need for a regulatory framework to ensure the safe use of these devices. Contrastingly, in the U.S., OTC hearing aids are regulated as a distinct category by the FDA, with specific requirements for labelling, safety, and performance [55]. However, such regulations may be lacking in other countries where DTC hearing care is emerging.

Future research should focus on examining the perspectives of healthcare providers and patients in regions where service delivery is not yet available. This global approach will provide a more holistic understanding of the barriers and opportunities, leading to better implementation strategies and improved patient outcomes. Furthermore, integrating suggestions from both users and healthcare

providers in developing a workflow for these services is crucial for ensuring their effectiveness. Exploring the role of other healthcare providers in DTC hearing care service delivery should be considered as a future research opportunity, as it could enhance the overall accessibility of care. Importantly, creating a patient education program that increases awareness of existing hearing technology may empower patients to make informed decisions and actively participate in their hearing healthcare. Future policies should prioritise establishing regulations that balance accessibility with user safety, ensuring that users receive reliable products with adequate support.

In conclusion, the findings of the scoping review highlight both the existing challenges and innovative opportunities in DTC hearing care service delivery. Key challenges include a lack of professional guidance, safe use of the devices, and limited patient understanding and awareness of the technology. However, opportunities exist to integrate DTC hearing care into existing clinical pathways, collaborate with other healthcare providers to guide individuals who choose this pathway and implement patient education initiatives to improve informed decision-making. Implementing stronger regulations, improving access to risk assessment resources, and using unbundled services in clinics could optimise DTC hearing care service delivery.

### Author contributions

CRedit: **Harini Madhu**: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing; **Amir Hussain**: Writing – review & editing; **Alison Porter-Armstrong**: Writing – review & editing; **Adele M. Goman**: Conceptualization, Supervision, Writing – review & editing.

### Disclosure statement

No potential conflict of interest was declared by the authors.

### Ethical approval

Ethical approval was not required for this research.

### Funding

The author(s) reported there is no funding associated with the work featured in this article.

### ORCID

Harini Madhu  <http://orcid.org/0000-0002-9410-143X>  
Amir Hussain  <http://orcid.org/0000-0002-8080-082X>  
Alison Porter-Armstrong  <http://orcid.org/0000-0002-3186-9599>  
Adele M. Goman  <http://orcid.org/0000-0002-5084-0185>

### References

- [1] World Health Organization. Deafness and hearing loss; 2025.
- [2] Simpson AN, Matthews LJ, Cassarly C, et al. Time from hearing-aid candidacy to hearing-aid adoption: a longitudinal cohort study hhs public access. *Ear Hear*. 2019;40(3):468–476. doi:10.1097/AUD.0000000000000641.
- [3] Ferguson MC, Shan L. Survey evaluation of pharmacy practice involving deaf patients. *J Pharm Pract*. 2016; 29(5):461–466. doi:10.1177/0897190014568379.
- [4] Orji A, Kamenov K, Dirac M, et al. Global and regional needs, unmet needs and access to hearing aids. *Int J Audiol*. 2020;59(3):166–172. doi:10.1080/14992027.2020.1721577.
- [5] Knoetze M, Manchaiah V, Mothemela B, et al. Factors influencing hearing help-seeking and hearing aid uptake in adults: a systematic review of the past decade. *Trends Hear*. Thousand Oaks, CA: SAGE Publications Inc; 2023.
- [6] Hay-McCutcheon MJ, Yuk · MC, Yang · X. Accessibility to hearing healthcare in rural and urban populations of alabama: perspectives and a preliminary roadmap for addressing inequalities. *J Community Health*. 2021;46(4):719–727. doi:10.1007/s10900-020-00943-4.

- [7] Blazer DG, Domnitz S, Liverman CT. Hearing health care for adults: priorities for improving access and affordability. Washington, DC: National Academies Press; 2016.
- [8] Independent Review of Audiology Services in Scotland. Independent Review of Audiology Services in Scotland Review report and recommendations. 2022.
- [9] Rahimi V, Tavanai E, Taghavi SMR, et al. Uncovering the effects of pandemic conditions on hearing aid experiences: a dual perspective from audiologists and hearing aid users. *Disabil Rehabil Assist Technol*. 2025;20(3):652–662. doi:10.1080/17483107.2024.2405557.
- [10] The British Irish Hearing Instrument Manufacturers Association. Audiologist Survey Report. 2024.
- [11] Johnson JCS, Marshall CR, Weil RS, et al. Hearing and dementia: from ears to brain. *Brain*. 2021;144(2):391–401. doi:10.1093/brain/awaa429.
- [12] Frisby C, Eikelboom R, Mahomed-Asmail F, et al. M-health applications for hearing loss: a scoping review. *Telemed J E Health*. 2022;28(8):1090–1099. doi:10.1089/tmj.2021.0460.
- [13] D'Onofrio KL, Zeng F-G. Tele-audiology: current state and future directions. *Front Digit Health*. 2021;3:788103. doi:10.3389/FGTH.2021.788103/BIBTEX.
- [14] Tran NR, Manchaiah V. Outcomes of direct-to-consumer hearing devices for people with hearing loss: a review. *J Audiol Otol*. 2018;22(4):178–188. doi:10.7874/jao.2018.00248.
- [15] Chung K, Zeng F-G. Over-the-counter hearing aids: implementations and opportunities. *Front Audiol Otol*. 2024;2:1347437. doi:10.3389/fauot.2024.1347437.
- [16] Apple. introduces AirPods 4 and the world's first all-in-one hearing health experience with AirPods Pro 2; 2024.
- [17] Department of Health and Social Care. Hearing aid in the UK. Policy Statement. 2025.
- [18] Manchaiah V, Swanepoel DW, Sharma A. Prioritizing research on over-the-counter (OTC) hearing aids for age-related hearing loss. *Front Aging*. 2023;4:1105879. doi:10.3389/fragi.2023.1105879.
- [19] Chan ZYT, McPherson B. Over-the-counter hearing AIDs: a lost decade for change. *Biomed Res Int*. 2015;2015:827463–15. doi:10.1155/2015/827463.
- [20] Reed NS, Garcia-Morales E, Willink A. Trends in hearing aid ownership among older adults in the united states from 2011 to 2018. *JAMA Intern Med*. 2021;181(3):383–385. doi:10.1001/jamainternmed.2020.5682.
- [21] Manchaiah V, Amlani AM, Bricker CM, et al. Benefits and shortcomings of direct-to-consumer hearing devices: analysis of large secondary data generated from amazon customer reviews. *J Speech Lang Hear Res*. 2019;62(5):1506–1516. doi:10.1044/2018\_JSLHR-H-18-0370.
- [22] Manchaiah V, Taylor B, Dockens AL, et al. Applications of direct-to-consumer hearing devices for adults with hearing loss: a review. *Clin Interv Aging*. 2017;12:859–871.
- [23] Chandra N, Searchfield GD. Perceptions toward internet-based delivery of hearing aids among older hearing-impaired adults. *J Am Acad Audiol*. 2016;27(6):441–457. doi:10.3766/jaaa.15058.
- [24] Davis RJ, Lin M, Ayo-Ajibola O, et al. Over-the-counter hearing aids: a nationwide survey study to understand perspectives in primary care. *Laryngoscope*. 2025;135(1):299–307. doi:10.1002/LARY.31689.
- [25] Hay-McCutcheon MJ, Hubbard AF, Brothers EB, et al. An over-the-counter hearing aid clinical trial in rural Alabama: project design and potential implications for pharmacy and audiology interprofessional collaborations. *Pharmacy (Basel)*. 2024;12(3):76–76. doi:10.3390/PHARMACY12030076.
- [26] Manchaiah V, Sharma A, Rodrigo H, et al. Hearing healthcare professionals' views about over-the-counter (OTC) hearing aids: analysis of retrospective survey data. *Audiol Res*. 2023;13(2):185–195. doi:10.3390/audiolres13020018.
- [27] Midey ES, Gaggini A, Mormer E, et al. National survey of pharmacist awareness, interest, and readiness for over-the-counter hearing aids. *Pharmacy*. 2022;10(6):150–150. doi:10.3390/pharmacy10060150.
- [28] Sheffield SW, Jacobs M, Ellis C. Considerations for the over-the-counter hearing aid delivery model. *Perspect ASHA Sigs*. 2022;7(6):1802–1805. doi:10.1044/2022\_PERSP-22-00058.
- [29] Swanepoel DW, Oosthuizen I, Graham MA, et al. Comparing hearing aid outcomes in adults using over-the-counter and hearing care professional service delivery models. *Am J Audiol*. 2023;32(2):314–322. doi:10.1044/2022\_AJA-22-00130.
- [30] Humes LE, Kinney DL, Main AK, et al. A follow-up clinical trial evaluating the consumer-decides service delivery model. *Am J Audiol*. 2019;28(1):69–84. doi:10.23641/Asha.
- [31] Olson A, Maidment DW, Ferguson MA. Consensus on connected hearing health technologies and service delivery models in the UK: a Delphi review. *Int J Audiol*. 2022;61(4):344–351. doi:10.1080/14992027.2021.1936223.
- [32] Bothe E, Bennett RJ, Ferguson MA. Consumer and audiologist perspectives on hearables: a qualitative study. *Int J Audiol*. 2025;64(4):374–383. doi:10.1080/14992027.2024.2341973.
- [33] Nieman CL, Betz J, Garcia Morales EE, et al. Effect of a community health worker-delivered personal sound amplification device on self-perceived communication function in older adults with hearing loss: a randomized clinical trial. *JAMA*. 2022;328(23):2324–2333. doi:10.1001/JAMA.2022.21820.
- [34] Singh J, Dhar S. Assessment of consumer attitudes following recent changes in the us hearing health care market. *JAMA Otolaryngol Head Neck Surg*. 2023;149(3):247–252. doi:10.1001/jamaoto.2022.4344.
- [35] Knoetze M, Manchaiah V, Oosthuizen I, et al. Perspectives on hearing aid cost and uptake for prescription and over-the-counter hearing aid users. *Am J Audiol*. 2024;33(3):942–952. doi:10.1044/2024\_AJA-23-00116.

- [36] Mothemela B, Manchaiah V, Mahomed-Asmail F, et al. Factors associated with hearing aid outcomes including social networks, self-reported mental health, and service delivery models. *Am J Audiol.* 2023;32(4):823–831. doi:10.1044/2023\_AJA-22-00206.
- [37] De Sousa KC, Manchaiah V, Moore DR, et al. Effectiveness of an over-the-counter self-fitting hearing aid compared with an audiologist-fitted hearing aid: a randomized clinical trial. *JAMA Otolaryngol Head Neck Surg.* 2023;149(6):522–530. doi:10.1001/jamaoto.2023.0376.
- [38] Humes LE, Rogers SE, Quigley TM, et al. The effects of service-delivery model and purchase price on hearing-aid outcomes in older adults: a randomized double-blind placebo-controlled clinical trial. *Am J Audiol.* 2017;26(1):53–79. doi:10.23641/Asha.
- [39] Emily Francisco BM, Frank DJ. Guidelines to Dispense PSAPs in Audiology Clinics. Boston; 2020.
- [40] Perez-Heydrich CA, Zenczak C, Roque L, et al. The role of hearing professionals for over-the-counter hearing aids. *Front Audiol Otol.* 2023;1:1167853. doi:10.3389/fauot.2023.1167853.
- [41] Smith K. OTCs and your clinical practice. California; 2018. <http://journals.lww.com/thehearingjournal>
- [42] Bennett B, Bothe E, Ferguson M. A new service delivery model for Hearables; 2023.
- [43] Berenbrok LA, DeRuiter M, Mormer E. OTC hearing aids: An opportunity for collaborative working relationships between pharmacists and audiologists. *J Am Pharm Assoc.* 2022;62(6):1765–8.
- [44] Berenbrok LA, Ciemniecki L, Cremeans AA, et al. Pharmacist competencies for over-the-counter hearing aids: A Delphi study. *J Am Pharm Assoc (2003).* 2021;61(4):e255–e262. doi:10.1016/j.japh.2021.01.039.
- [45] Berenbrok LA, Duchon A, Cyr T, et al. First experiences with over-the-counter hearing aids for mild-to-moderate hearing loss: a case report. *Pharmacy (Basel).* 2023;12(1):4–4. doi:10.3390/PHARMACY12010004.
- [46] Coco L. Amplifying access: progress after 1 year of over-the-counter hearing aids. *Perspect ASHA Sigs.* 2024;9(2):347–354. doi:10.1044/2024\_PERSP-23-00279.
- [47] Knudsen LV, Oberg M, Nielsen C, et al. Factors influencing help seeking, hearing aid uptake, hearing aid use and satisfaction with hearing aids: a review of the literature. *Trends Amplif.* 2010;14(3):127–154. doi:10.1177/1084713810385712.
- [48] Jorgensen L, Novak M. Factors influencing hearing aid adoption. *Semin Hear.* 2020;41(1):6–20. doi:10.1055/S-0040-1701242/ID/JR00818-27/BIB.
- [49] Powers TA, Bisgaard N. MarkeTrak and EuroTrak: what we can learn by looking beyond the U.S. market. *Semin Hear.* 2022;43(4):348–356. doi:10.1055/s-0042-1758361.
- [50] England NHS. Reforming elective care for patients; 2025.
- [51] Bell K, Keane H. All gates lead to smoking: the “gateway theory,” e-cigarettes and the remaking of nicotine. *Soc Sci Med.* 2014;119:45–52. doi:10.1016/j.socscimed.2014.08.016.
- [52] Etter JF. Gateway effects and electronic cigarettes. *Addiction.* 2018;113(10):1776–1783. doi:10.1111/ADD.13924.
- [53] Olson AD, Maidment D, Ferguson M. Consensus on the use of emerging hearing devices and service delivery models in the UK. *Hearing Review.* 2020;14.
- [54] Adshead V. UK audiology sector issues guidance on OTC hearing aids. *Br Acad Audiol.* 2025. Available from: <https://baaudiology.org/uk-audiology-sector-issues-guidance-on-otc-hearing-aids/>.
- [55] US Food & Drug Administration. OTC Hearing Aids: what You Should Know | FDA; 2023.
- [56] Johns Hopkins Bloomberg School of Public Health. Johns Hopkins Makes It Easy and Free to Know Your Hearing Numbers With New Hearing Test App. | Johns Hopkins | Bloomberg School of Public Health. 2025.
- [57] Food & Drug Administration. Home Use Devices Initiative. | FDA; 2023.
- [58] Aazh H, Prasher D, Nanchahal K, et al. Hearing-aid use and its determinants in the UK national health service: a cross-sectional study at the royal surrey county hospital. *Int J Audiol.* 2015;54(3):152–161. doi:10.3109/14992027.2014.967367.

## Appendix A. Database search strings

### *PubMed search string*

("Hearing aid" [All Fields] OR "Assistive listening device" [All Fields] OR "Hearing technology" [All Fields] OR "Hearing assistive technology" [All Fields] OR "Hearable" [All Fields])

AND

("Audiologist" [All Fields] OR "Consumer" [All Fields] OR "Providers" [All Fields] OR "Hearing health professional" [All Fields] OR "Patients" [All Fields])

AND

("Provision" [All Fields] OR "Hearing Care" [All Fields] OR "Service delivery" [All Fields] OR "Over-the-counter" [All Fields] OR "Direct-to-consumer" [All Fields] OR "Non-prescription" [All Fields])

### *Search strings for CINAHL, scopus, web of science*

((("Hearing aid" OR "Assistive listening device" OR "Hearing technology" OR "Hearing assistive technology" OR "hearable"))

AND

((("Audiologist" OR "Consumer" OR "Providers" OR "Hearing health professional" OR "Patient"))

AND

((("Provision" OR "Hearing care" OR "Service delivery" OR "Over-the-counter" OR "Direct-to-consumer" OR "Non-prescription"))