


# Disruptions to the hearing health sector

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Technological innovation and changes to regulation are disrupting the hearing health sector, with implications for data privacy, product safety and accessibility, and provide challenges and opportunities for equitable hearing health.

It is estimated that over 1.5 billion people worldwide have hearing loss<sup>1</sup>. Beyond its direct effect on communication, hearing loss often coexists with poorer physical and mental health<sup>2</sup>. Disparities in access to hearing healthcare can be experienced by minority ethnic groups and exacerbated by socioeconomic factors<sup>2</sup>. Advanced digital capabilities and new ear-worn devices, alongside radical changes to regulation that enable over-the-counter (OTC) purchasing of hearing aids in the USA, are expected to increase access to hearing devices. To ensure consumer safety and equity of access to hearing healthcare, it is necessary to understand emerging technologies and consumer needs. It is also important to balance the interests of established and new stakeholders, including developers, providers and consumers of products and services and manage the power relationships between them.

## Access and affordability

Two major developments are currently disrupting the hearing healthcare sector. First, the technological developments of within-ear wearable devices (known as hearables) have created opportunities for direct-to-consumer models of hearing healthcare<sup>3,4</sup>. An example is the Apple AirPods Pro ear buds, which incorporate advanced sound technology similar to what could previously be found only in hearing aids. Second, a strategic call for action by the World Health Organization (WHO) has urged governments worldwide to review their hearing healthcare policies and practices<sup>1</sup>. Both developments aim to provide increased access to hearing-related interventions that can alleviate the pervasive effect of hearing loss on communication, social connection, education, employment, quality of life and health<sup>1</sup>.

The recently published OTC Hearing Aid Rule in the USA (announced as effective from 17 October 2022)<sup>5</sup> is an example of a regulatory change that was made possible because of new technological capabilities, and which aims to remove what is perceived as an unnecessary barrier to access hearing devices. This rule supports the OTC sale of safe and effective hearing aids for mild to moderate hearing loss, without requiring the involvement of a hearing health professional<sup>5</sup>.

Market competition can also improve the accessibility and affordability of technologies. Consumer-focused hearing-related product-development initiatives can now be found in companies such as Nuheara, Google, Apple and Meta (Facebook), with at least the latter two having recruited research audiologists within their teams. This suggests that several companies plan to expand their hearing-related products within a direct-to-consumer market.



## Hearing health disruptions

The response to the WHO's call for action to address hearing loss, rapid technological advances in hearing technologies, and the OTC Hearing Aid Rule in the USA are all expected to transform hearing health services internationally. Those manufacturers, organizations and clinicians who currently benefit financially from the provision of traditional hearing aids are likely to see their market share for such products decrease as consumers with the most common severity of hearing loss (mild to moderate) bring their attention to OTC alternatives.

In response, companies may develop new strategies to influence existing and developing markets. For example, although adults with more severe hearing loss are not targeted by OTC products, this population may become the main consumer target group for existing hearing aid developers. Alternatively, existing hearing aid developers may shift their developments toward OTC products, with limited product development targeted at more severe hearing loss. These commercial decisions of hearing aid developers will take place in parallel to commercial decisions made by developers of cochlear implants that are used by individuals who obtain limited benefits from hearing aids. Market changes may therefore lead to both a decrease in options and more aggressive advertising campaigns for consumers with more severe hearing loss. As with any disruptive technology, regulatory bodies may expect tensions, conflicts and increased lobbying approaches as existing markets are disrupted and new ones develop.

In addition to regulating new forms of advertising and competition, regulatory bodies will need to address the growing risks related to consumer data privacy, data usage and data integrity (meaning the accuracy, completeness and consistency of data) that may come with the integration of further digital health technology within hearing devices<sup>6-8</sup>. These innovations include: hearing aid biosensors and integrated software that can measure hearing, heart and brain activity; hearing aid microphones that can connect to smart home systems; and hearing aid systems that can track the direction of the users' gaze<sup>4,9,10</sup>, providing unprecedented data gathering and knowledge potential for the technology developers, which now include big tech companies such as Facebook and Google.

These technological advances are expected to attract large consumer markets, supporting improved communication and connectivity

## BOX 1

### Domains of policy and regulation that influence the hearing health sector

Markets and competition

Product safety and efficacy

Data integrity and privacy

Research practices

Professional practices

Health and disability financing

for people with and without hearing loss<sup>4</sup>. These advances will also facilitate already tested means of linking everyday activities to general medical care, which may further blur the distinction between health and non-health data.

#### Conflicts of interest

Traditional hearing devices such as hearing aids and cochlear implants already incorporate complex digital technologies for speech enhancement, noise cancellation, data-logging and wireless connectivity, and can be linked to electronic health records and rehabilitation support apps. To facilitate the provision of such advanced technologies within clinical services, close relationships have formed and various sale and support agreements exist between hearing device developers and hearing health providers<sup>11,12</sup>. These close relationships create an environment in which conflicts of interest can influence the quality and affordability of clinical services and products<sup>13</sup>. This may contribute to long-standing issues around trust in hearing care services<sup>14</sup>. Conflicts of interest related to the sales of hearing devices are of particular concern, as studies show a placebo effect when consumers are deceived to believe that they are trying a new hearing aid<sup>15</sup>.

Surveys suggest that hearing health professionals and consumers disagree on what they consider to be unethical practices<sup>16</sup>, and a correspondingly wide variety of professional practices and regulations have developed across countries to manage potential conflicts of interest related to sales of hearing devices<sup>17</sup>. This spectrum includes hearing health services that are fully covered by public insurances<sup>17</sup>, regulations that prevent hearing health professionals who recommend hearing devices from financially benefitting from the sale of these devices<sup>18</sup>, and practices that permit ownership of hearing health services by device manufacturers and allow sales targets to be set within clinics<sup>19</sup>. These varying regulations have differentially affected the power relationships between consumers, device developers, health professionals who recommend hearing devices and those who benefit financially from device sales<sup>18,19</sup>. A direct-to-consumer hearing health market raises further questions about the potential effect of conflicts of interest on individuals with hearing loss.

Another aspect of device sales that influences current clinical practices is that, in many jurisdictions, the cost of hearing devices

## BOX 2

### Stakeholders who influence hearing health information, services and products

Deaf, hard-of-hearing, and other consumer groups

Hearing, communication and health researchers

Hearing, communication and health professional educators

Hearing and communication service providers

Hearing and communication product providers

Hearing and communication technology developers

Digital health and information system developers

Public policy makers

has been bundled with the costs of the professional services offered by hearing health clinicians<sup>20</sup>. This not only increased the expected cost of hearing devices but also concealed the costs and benefits of hearing health services, as well as the sources of income for hearing health professionals<sup>21</sup>. The ongoing development of hearables and the OTC hearing aid market will affect the way the different healthcare systems and clinicians offer hearing health information and services.

The increased opportunities to collect data from ear-worn devices exacerbate concerns about the interests that determine what data are collected, who has access to these data and for what purposes. For example, user data can be monetized because of its usefulness in advertising and further product development. Therefore, product providers may offer more affordable devices to users in exchange for the data that the devices collect. In such transactions it is important to be mindful of the potential conflicts of interest and power imbalances between users and product providers<sup>7</sup>. Furthermore, exclusive control over what is collected and ownership of the resulting data by the product developers may prevent independent clinicians and researchers from effectively appraising the validity of commercial claims or conducting independent clinical research on intervention benefits. Such exclusive control could therefore stymie the development of algorithms used in hearing health informatics and automation systems<sup>8</sup>.

#### Equitable hearing care

A range of policies and regulations (Box 1) can affect how different stakeholder groups collaborate within the hearing health sector (Box 2) to provide information, services and interventions for consumers with hearing loss. Access to innovations should be promoted alongside the strengthening of existing systems and establishment of new independent systems to assess and protect the integrity of data<sup>8,22</sup>, as well as launching initiatives on transparency of research and education that can be used to inform clinical recommendations, and allocate funding for hearing services and products.

Hearing devices are currently regulated primarily in terms of professional practices, product safety and efficacy, and within the

context of competition law. Because of the data collection capabilities of new digital hearing products, regulation should also consider data collection, integrity, access and user privacy<sup>8,22</sup>. Device developers, providers and healthcare professionals should focus on furthering health and health equity, which will require attention to power imbalances and structural inequities. Longitudinal studies will be needed to assess the effects of the changes in the hearing health sector on consumer experience, professional roles and clinical service availability across countries with different structural regulations.

Consumer education and support to access hearing services and products will be especially important for people who may be more vulnerable to misleading marketing claims<sup>15,23</sup> because of limited digital, health or research literacy. More than 65% of adults aged over 60 have hearing loss, with clear increases in prevalence with every decade of age<sup>1</sup>. Hearing loss is associated with higher risks of dementia and cognitive impairment<sup>1</sup> and deaf and hard-of-hearing people are more likely to experience communication challenges that limit their access to information<sup>24</sup>. Vulnerable groups, including poorer populations, are less likely to access new technologies than less vulnerable groups, and this may contribute to decreased health equity<sup>25</sup>. Hearing loss is also associated with common illnesses such as hypertension and diabetes<sup>1</sup>, and with an increased risk of hospitalization and mortality<sup>26</sup>. Adults with hearing loss are therefore overly represented among patients who receive other health and disability services.

Professional education is required across health and disability sectors to support the communication and safety needs of patients with hearing loss<sup>24</sup>. This will particularly benefit patients who do not receive any hearing care and those who may access direct-to-consumer hearing devices without the services of a hearing health professional such as an audiologist or an otologist. Empowering a broad range of professionals to better support the needs of people with hearing loss could improve engagement and satisfaction with healthcare in general<sup>24</sup>. This could also increase opportunities for adults with hearing loss to receive information and advice that is independent from product sales.

Everyone with hearing loss should have access to reliable and complete information and to independent professional advice when selecting safe, evidence-based and cost-effective hearing and communication support<sup>1</sup>. Tectonic shifts in the landscape of the hearing device and hearing service industries may pose a critical threat to achieving this goal, as well as providing fresh opportunities. Further research is needed on conflicts of interest, gaps in regulation, and the rapid expansion of emerging technologies if the benefits of these innovations are to be realized by all.

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## Author contributions

I.B., A.D., E.L., J.S.M. and W.L. conceived and developed the main ideas for this article. I.B. led the writing with substantial contributions from A.D., E.L. and M.C. All authors provided critical input, and approved the final version. M.N. provided a critical review from the perspective of a person with lived experience of hearing loss.

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