

A Market Landscape and
Strategic Approach to Increasing
Access to Hearing Aids and
Related Services in Low and
Middle Income Countries

PRODUCT NARRATIVE:

HEARING AIDS



ATscale

GLOBAL PARTNERSHIP FOR
ASSISTIVE TECHNOLOGY

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The views and opinions expressed within this report are those of the authors and do not necessarily reflect the official policies or position of members of the ATscale Forming Committee, partners of the AT2030 programme, or funders.

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ACRONYMS

APS	Assistive Product Specifications
AT	Assistive Technology
BTE	Behind the Ear (Hearing Aid)
CHAI	Clinton Health Access Initiative, Inc.
CHW	Community Health Workers
CSR	Corporate Social Responsibility
dB	Decibels
DPO	Disabled Persons' Organisation
EHC	Ear and Hearing Care
ENT	Ear, Nose and Throat
FDA	Food and Drug Administration (USD)
GBP	Pound Sterling
HIC	High-Income Country
IHHAPP	International Humanitarian Hearing Aid Purchasing Program
LMIC	Low- and Middle-Income Country
LRS	Low Resource Setting
NGO	Non-Governmental Organisation
NHS	National Health Service (UK)
OTC	Over the Counter
PPP	Preferred Product Profile
SFHA	Self-fitting Hearing Aid
SO	Strategic Objective
TB	Tuberculosis
WHO	World Health Organization
WWH	World Wide Hearing

EXECUTIVE SUMMARY

GLOBALLY, AROUND 466 MILLION PEOPLE HAVE DISABLING HEARING LOSS, and this number is expected to double by 2050 due to ageing populations, and new cases of hearing loss caused by untreated ear infections, ototoxicity, and noise exposure. The World Health Organization (WHO) estimates that unaddressed hearing loss poses an annual global cost of US\$750 billion with negative impact on education, social life and employability of those with hearing loss.

A hearing aid is a rehabilitative device that amplifies sound for those with hearing impairment that cannot be resolved medically. Currently, WHO estimates that 72 million people worldwide need hearing aids, but only 10% that need at least one have them, with coverage less than 3% in low- and middle-income countries (LMICs). Hearing aids should be delivered in the context of a Ear and Hearing Care (EHC) programme within the health system, which is capable of screening for, diagnosing, and resolving the causes of hearing loss, as well as providing aural rehabilitation, other assistive listening devices and aids, and peer support.

Five suppliers control more than 90% of the hearing aid market and focus primarily on high-income countries (HIC) and high-value market segments in LMICs, such as wealthier, often urban populations. Market entry barriers and acquisitions have kept the market consolidated.

Key barriers that perpetuate the current situation of low interest from global suppliers in LMIC markets and low access to hearing aids include: limited investment by governments; high cost of product and services to the end users; lack of quality standards; and a service delivery model that requires high levels of resources in terms of personnel and infrastructure. Innovations in service delivery, diagnostic devices, and hearing aids themselves may provide opportunities to address these barriers.

Developing a market for hearing aids in LMICs will require affordability and availability of optimal hearing aids and services. Products and services can be defined as “optimal” if they meet a target/preferred product profile, meet the needs of the end user and are of suitable quality (i.e. compliant with high engineering and clinical standards). To achieve this, we propose five strategic objectives (SO) that can strengthen the market in both the near and longer-term:

- **SO#1:** Strengthen global policy guidance around service delivery standards, product selection and product quality;
- **SO#2:** Support LMIC governments to strengthen hearing aid provision including demand generation and investment in service delivery capacity, government purchasing and procurement support;
- **SO#3:** Engage the private sector to expand delivery of affordable, quality hearing aids and related services;
- **SO#4:** Work with suppliers to enter LMIC markets with affordable, quality hearing aids;
- **SO#5:** Spur innovation to support simplified provision models and introduction of optimal products.

A healthy market, defined as sustainable where demand meets supply, requires consensus around service delivery norms and product selection (SO #1). This consensus would serve as the foundation to build service delivery infrastructure via the public and private sector and rationalise procurement mechanisms (SO #2 & #3). More predictable and growing demand will enable economies of scale and support market shaping interventions proposed in SO #4 to support suppliers and distributors entering LMIC markets. Game-changing technologies that can help increase coverage are emerging and would benefit from investments now.

INTRODUCTION

1. Assistive Technology and Market Shaping

Assistive technology (AT) is an umbrella term covering the systems and services related to the delivery of assistive products such as wheelchairs, eyeglasses, hearing aids, prosthetics, and personal communication devices. Today, over 1 billion people require AT to achieve their full potential, but 90% do not have access to the AT that they need.¹ This unmet need for AT is driven by a lack of awareness of this need, discrimination and stigma, a weak enabling environment, lack of political prioritisation, limited investment and market barriers on the demand and supply side. Narrowing in on the market shortcomings that limit the availability of assistive products, market shaping is proposed to address the root causes that limit availability, affordability and access of appropriate AT with the wider aim of ensuring improved social, health and economic outcomes for people who require AT. To accelerate access to AT, the global community needs to leverage the capabilities and resources of the public, private, and non-profit sectors to harness innovation and break down market barriers.

Whether by reducing the cost of antiretroviral drugs for HIV by 99% in 10 years, increasing the number of people receiving malaria treatment from 11 million in 2005 to 331 million in 2011,² or doubling the number of women receiving contraceptive implants in 4 years while saving donors and governments US\$240 million,³ market shaping has addressed market barriers at scale. Market shaping interventions can play a role in enhancing market efficiencies, improving information transparency, and coordinating and incentivising the numerous stakeholders involved in both demand and supply-side activities. Examples of market shaping interventions include: pooled procurement, de-risking demand, bringing lower cost and high-quality manufacturers into global markets, developing demand forecasts and market intelligence reports, standardising specifications across markets, establishing differential pricing agreements, and improving service delivery and supply chains.

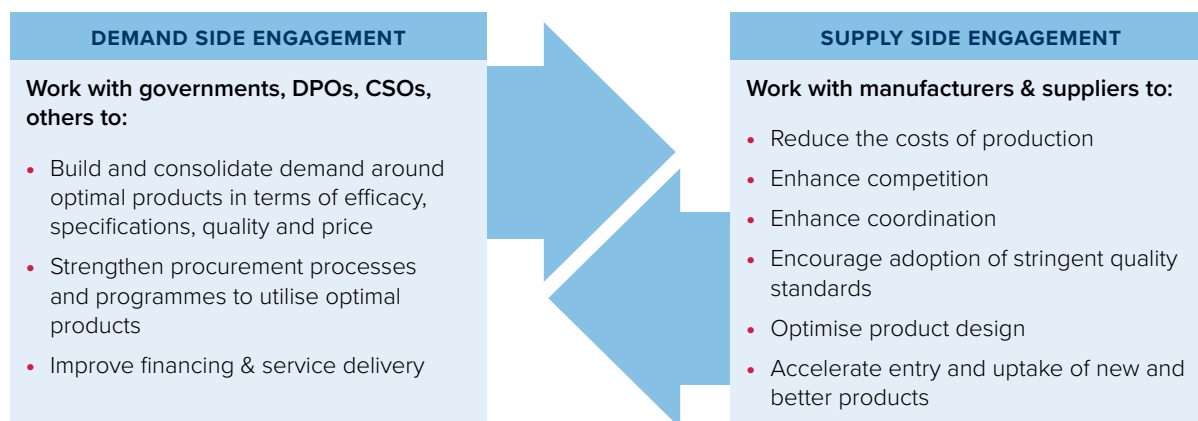
Market shaping interventions often require coordinated engagement on the demand and supply side (refer to Figure 1). Successful interventions are tailored to specific markets after robust analysis of barriers and look to coordinate action on both the demand- and supply-side. These interventions are catalytic and time-bound, with a focus on sustainability, and are implemented by a coalition of aligned partners providing support where each has comparative advantages.

¹ World Health Organization, 'Assistive Technology', accessed 12 June 2019, <https://www.who.int/news-room/fact-sheets/detail/assistive-technology/>.

² UNITAID and World Health Organization, 'UNITAID 2013 Annual Report: Transforming Markets Saving Lives' (UNITAID, 2013), http://unitaid.org/assets/UNITAID_Annual_Report_2013.pdf.

³ Mark Suzman, 'Using Financial Guarantees to Provide Women Access to the Modern Contraceptive Products They Want to Plan Their Families' (Bill & Melinda Gates Foundation & World Economic Forum, May 2016), http://www3.weforum.org/docs/GACSD_Knowledge%20Hub_Using_Financial_Guarantees_To_Provide_Women_Access_To_Modern_Contraceptives.pdf.

FIGURE 1: ENGAGING BOTH DEMAND- AND SUPPLY-SIDE FOR MARKET SHAPING



Historically, AT has been an under-resourced and fragmented sector and initial analysis indicated that a new approach was required. ATscale, the Global Partnership for AT, was launched in 2018 with an ambitious goal to provide 500 million people with the AT that they need by 2030. To achieve this goal, ATscale aims to mobilise global stakeholders to develop an enabling environment for access to AT and to shape markets to overcome supply- and demand-side barriers, in line with a unified strategy (<https://atscale2030.org/strategy>). While the scope of AT is broad, ATscale has prioritised to identify interventions needed to overcome supply- and demand-side barriers for five priority products.

Clinton Health Access Initiative (CHAI) is delivering a detailed analysis of the market for each of the priority products under the AT2030 programme (<https://www.at2030.org>), funded by UK aid from the UK government, in support of the ATscale Strategy. What follows is a detailed analysis of hearing aids, one of five priority products identified by ATscale to be evaluated.

2. Product Narrative

The product narrative defines the approach, identified by CHAI, to sustainably increase access to high-quality, low cost AT in LMICs. The goals of this narrative are to: 1) propose the long-term strategic objectives for a market shaping approach; and 2) identify immediate opportunities for investments to influence accessibility, availability and affordability of hearing aids.

This report has been informed by desk research, market analysis, key informant interviews, and site visits with relevant partners, representatives of users and governments to develop a robust understanding of the market landscape and the viability of the proposed interventions. A list of all individuals interviewed or consulted during the development process can be found in Appendix A. This document is divided into two chapters:

- **CHAPTER 1: MARKET LANDSCAPE**, including market context, the current product landscape, state of access and provision, supply chain analysis, stakeholders' current engagement, as well as key market challenges and barriers to access on both the demand and supply side;
- **CHAPTER 2: STRATEGIC APPROACH TO MARKET SHAPING** including strategic objectives highlighting the long-term outcomes required to shape the market. A series of immediate next steps or actions to support achieving each strategic objective are proposed. For any given objective, the interventions are discrete, testable opportunities that support the development of longer-term, scalable interventions and investments.

CHAPTER 1:

MARKET LANDSCAPE

3. Market Context

3.1 Globally 466 million people have disabling hearing loss; this number is expected to double by 2050 due to ageing populations, and new cases of hearing loss caused by untreated ear infections, ototoxicity, and noise exposure.

Hearing loss that prevents hearing at thresholds lower than 40 decibels (dB) in the better hearing ear in adults and lower than 30 dB in the better hearing ear in children is known as disabling hearing loss.⁴ More than 5% of the global population—or 466 million people—have disabling hearing loss, with 34 million of these being children.⁵ It is the fourth leading cause of disability globally.⁶ Approximately 90% of people with hearing loss live in low- and middle-income countries (LMICs) with prevalence rates almost four times that of high-income regions.⁷

Multiple causes for hearing loss exist, but they can primarily be placed into two categories: congenital and acquired factors. Congenital causes include genetic causes and complications due to pregnancy or childbirth such as maternal infections (especially congenital syphilis), birth asphyxia, exposure to certain drugs during pregnancy, and low birth weight or jaundice. It is estimated that five out of every 1,000 babies are born with hearing loss or acquire it soon after birth in one or both ears. Acquired causes can occur at any age and include infectious diseases, such as mumps, measles or rubella, chronic ear infections, use of ototoxic medicines (i.e. medicines known to damage cells in the ear), injury, noise exposure, and blockages in the ear canal.⁸ Untreated infections, ototoxicity and ear blockages are the primary factors for hearing loss in LMICs.

The number of people with disabling hearing loss is expected to double to 900 million people by 2050,⁹ driven by:

- **POPULATION GROWTH AND AGEING.** Disabling hearing loss is associated with ageing; approximately one-third of people over 65 years of age are affected by disabling hearing loss¹⁰ and as the population increases from 7.5 billion people¹¹ in 2017 to 10 billion in 2050,¹² the world's population over 65 years of age is expected to double to 1.5 billion.¹³
- **NOISE EXPOSURE.** Noise exposure can come from occupational environments, entertainment venues, and personal listening devices. The WHO estimates that 1 billion young people are at risk of hearing loss due to listening practices.

⁴ World Health Organization, 'Deafness', accessed 13 June 2019, <https://www.who.int/news-room/facts-in-pictures/detail/deafness>.

⁵ World Health Organization, 'Deafness and Hearing Loss', accessed 12 June 2019, <https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss>.

⁶ World Health Organization, 'Addressing the Rising Prevalence of Hearing Loss', February 2018, <https://apps.who.int/iris/bitstream/handle/10665/260336/9789241550260-eng.pdf?sequence=1&ua=1>.

⁷ World Health Organization.

⁸ World Health Organization, 'Deafness and Hearing Loss'.

⁹ World Health Organization, 'Addressing the Rising Prevalence of Hearing Loss'.

¹⁰ World Health Organization, 'WHO Global Estimates of Hearing Loss', (2018), <http://www.who.int/deafness/estimates/en/>.

¹¹ The World Bank, 'The World Bank 2017 Population Data', accessed 21 May 2019, <https://data.worldbank.org/indicator/SP.POPTOTL>.

¹² United Nations, 'World Population Projected to Reach 9.8 Billion in 2050, and 11.2 Billion in 2100 | UN DESA | United Nations Department of Economic and Social Affairs', accessed 13 June 2019, <https://www.un.org/development/desa/en/news/population/world-population-prospects-2017.html>.

¹³ World Health Organization, 'Facts about Ageing', WHO, accessed 30 May 2019, <http://www.who.int/ageing/about/facts/en/>.

- **UNTREATED EAR INFECTIONS.** Inability of health systems to identify and treat incident and chronic ear infections will result in an additional 16.5 million people developing hearing loss each year.¹⁴
- **OTOTOXICITY.** Certain classes of drugs, such as some used in the treatment of neonatal infections, malaria, drug-resistant tuberculosis (TB) and cancers, have ototoxic side effects that can result in hearing loss (refer to Case Study 1).

CASE STUDY 1: MANAGING OTOTOXICITY IN THE TB TREATMENT PROGRAMME

Drug-resistant TB requires the use of second-line injectable anti-TB drugs, such as aminoglycosides and polypeptides, which are associated with hearing loss. Studies demonstrate that the frequency of ototoxicity in patients on treatment has ranged from 10 – 50%.¹⁵

To address this issue, the National Department of Health in South Africa implemented an ototoxicity management programme in 2001 with the aim to prevent ototoxicity among people taking medication for TB by implementing hearing screening to identify patients who need hearing aids. In 2019, the eMoyo Foundation, in collaboration with Entheos (a US-based NGO) and Ndlovu Group (a South Africa based NGO), set up a hearing health care pop-up clinic at a local TB hospital to provide hearing health services. These include: ear and hearing assessment, ear impression taking, hearing aid fitting (including free hearing aids with earmoulds), and post-hearing aid fitting and maintenance support.

3.2. WHO estimates that 72 million people worldwide need hearing aids, but current coverage of hearing aids meets less than 3% of need in LMICs.¹⁶

A hearing aid is a rehabilitative device that amplifies sound frequencies for those with hearing impairment. Not all people with hearing loss will require or benefit from a hearing aid. Appropriateness of hearing aid use for an individual is dependent on the type (conductive or sensorineural; Table 1)¹⁷ and severity¹⁸ (mild to profound; Table 2) of hearing loss.¹⁹ Hearing aids support improvement for varying degrees of hearing loss from mild to severe sensorineural hearing loss, which is caused by damage to the small sensory cells in the inner ear.

TABLE 1: HEARING LOSS BY TYPE

	CONDUCTIVE	SENSORINEURAL	MIXED (CONDUCTIVE AND SENSORINEURAL)
Description	Sound is prevented from reaching the inner ear/ cochlea. Can be caused by acute problems such as ear infections or ear wax, or by malformations of the outer or middle ear	Caused when the hair cells of the inner ear and/ or cochlear nerve are damaged	Combination of conductive and sensorineural hearing loss
Treatment Protocol	Medical or surgical	May be managed using hearing technology (i.e. hearing aids)	Resolve conductive component medically and manage sensorineural component with hearing technology

¹⁴ World Health Organization, 'Deafness and Hearing Loss'.

¹⁵ Hearing Loss in Patients on Treatment for Drug-Resistant Tuberculosis | European Respiratory Society', accessed 14 August 2019, <https://erj.ersjournals.com/content/40/5/1277>.

¹⁶ World Health Organization, 'Assistive Technology', Fact Sheet, Assistive technology, 18 May 2018, <https://www.who.int/news-room/fact-sheets/detail/assistive-technology>.

¹⁷ Melissa Auchter, 'The Basics of Hearing' (University Presentation, n.d.).

¹⁸ The Boston Consulting Group, 'Hearing Aid Compendium', (27 April 2018).

¹⁹ Individuals with hearing loss and their families may also utilise other skills to support language development and communication in place of or in combination with hearing aids. This could include the use of sign language, such as American or British, Australian and New Zealand Sign Language, International Sign or Manually Coded English, natural gestures, speech reading, finger spelling, listening or auditory training, and spoken speech.

TABLE 2: HEARING LOSS BY SEVERITY

	MILD	MODERATE	SEVERE	PROFOUND
Hearing Loss Threshold (can hear sounds louder than)	40dB	60dB	80dB	N/A
Relative distribution (%, million people)	/	77% (359 million)	20% (93 million)	3% (14 million)
Description	Difficulty hearing soft speech, speech from distance or against a background noise	Difficulty hearing regular speech, even at close distances	May only hear very loud speech or sounds (e.g, sirens), but no conversational speech	May perceive loud sounds only as vibrations
Use of hearing aids appropriate?	Yes, in some cases, and depending on the type	Yes, depending on the type	Yes, but some cases may require cochlear implants	

WHO estimates that more than 72 million people worldwide would benefit from the use of hearing aids, but only 10% of those that need it have it, with coverage at less than 3% in LMICs.²⁰ This estimate is based on limited data and is considered by many experts to be an underestimate. The forthcoming World Hearing Report, which is expected to be published in 2020 by the WHO, will provide updated estimates of need.

Not all individuals with severe to profound sensorineural hearing loss will benefit from a hearing aid. When hearing aids are insufficient or do not provide expected benefit and in select circumstances, cochlear implants may be recommended. A cochlear implant is a medical device that consists of an external portion that sits behind the ear and an internal portion that consists of an electrode array and receiver/stimulator that must be surgically implanted. A cochlear implant bypasses the damaged portions of the ear to deliver sound signals directly to the auditory nerve. Hearing via a cochlear implant takes time to learn or relearn. While an important assistive technology, cochlear implants will not be a focus of this product narrative as they only benefit a tiny fraction of the population (less than 50,000 cochlear implants are sold globally each year) and are currently prohibitively expensive for LMICs with costs for the device and surgery ranging from \$40,000 to \$100,000 per implant, require complex surgical and audiological care that is often not available in LMICs yet.

For people with conductive hearing loss, for which hearing aids are not appropriate, medical treatments, such as antibiotic therapy or earwax removal performed by primary care healthcare workers or primary care physicians, or surgical treatments performed by Ear, Nose and Throat (ENT) surgeons, may help resolve hearing issues. For example, WHO estimates that 330 million of the 466 million people with disabling hearing loss suffer from chronic ear infections or chronic otitis media,²¹ which can be resolved medically. Once the conductive hearing loss has been resolved, patients may require a hearing aid in case of sustained damage to the ear.

²⁰World Health Organization, 'Deafness'.

²¹World Health Organization, 'Deafness'.

3.3. Unaddressed hearing loss has a profound effect on individuals, and hearing aids can assist to counteract negative effects.

Studies show that quality of life is significantly lower among people with hearing loss, and people with hearing loss tend to secure lower rates of employment. Additionally, WHO estimates that unaddressed hearing loss poses an annual global cost of US\$750 billion with a negative impact on education, social life and employability of those with hearing loss.²² Negative outcomes associated with hearing loss can be attributed primarily to three factors:²³

- **LEARNING.** In children, hearing loss can adversely affect speech acquisition, learning, and academic performance. In LMICs, children with hearing loss may not receive schooling, which may contribute to unemployment later in life. It is important to identify children with hearing loss early and provide rehabilitative support. In most HICs, newborn hearing screening is the standard of care. In the UK, for example, newborn hearing screening has coverage rates as high as 99%. In many LMICs, newborn hearing screening is not routine. WHO recommends that newborns identified with hearing loss start using hearing aids, combined with rehabilitation services, from the age of 3 months to support speech and language development.
- **SOCIAL.** The inability to communicate with others can have an adverse social and emotional impact due to loneliness, isolation and frustration. A study in Nigeria concluded that elderly people with hearing loss have higher rates of depression, reducing their interest in daily activities, with 62% reporting depression symptoms as opposed to 17% for those without hearing loss.²⁴
- **HEALTH.** Loss of hearing can increase the incidence of dementia, among other comorbidities such as falls.²⁵ One study suggests that individuals with hearing loss have a two to five times higher risk of dementia, depending on severity, than those with normal hearing.²⁶ Hearing loss is also associated with accelerated cognitive decline among older adults.²⁷

Hearing aids can have a transformative impact on reducing the negative outcomes of hearing loss. A study conducted by World Wide Hearing (WWH) and Sonrisas que Eschuchan Foundation in Guatemala in 2016 assessed the positive impact of hearing aids among 180 people with moderate to profound hearing loss. In less than a year of usage, the study found that 56% reported improved ability to communicate with family and friends and 88% reported that hearing aids had positively changed their enjoyment of life.²⁸

CASE STUDY 2: A USER'S EXPERIENCE WITH HEARING AIDS²⁹

Shine, a 3-year-old girl, had her first hearing assessment in November 2017 in Lusaka, Zambia when her mother brought her to the clinic due to delayed speech but was not aware that this was the result of hearing loss. Shine was tested using play audiometry (a technique used to test the hearing of young children to respond to sounds as part of a game), which confirmed that she has severe sensorineural hearing loss in both ears. After impressions of her ears were taken to make a custom earmould, Shine was fitted with hearing aids. Shine's mother was taught how to use hearing aids. In a follow-up appointment, the audiologist noted that Shine had been wearing hearing aids for 11 hours per day and additional tests confirmed that she was benefitting from the hearing aids.



²²The WHO analysis suggests that annual cost of unaddressed hearing loss is in the range of \$750-790 billion (in 2015 international dollars) with \$67-107 billion attributed to costs in the health-care sector, \$3.9 billion estimated cost to the education sector of providing support for children with unaddressed hearing loss, \$105 billion due to loss productivity from unemployment and premature retirement and \$573 billion attributable to societal costs of social isolation, communication difficulties and stigma.

²³World Health Organization, 'Deafness and Hearing Loss'.

²⁴Olusola Ayodele Sogebi, Lateef Olutoyin Oluwole, and Taofeeq Oluwaninsola Mabifah, 'Functional Assessment of Elderly Patients with Hearing Impairment: A Preliminary Evaluation', *Journal of Clinical Gerontology and Geriatrics* 6, no. 1 (1 March 2015): 15-19, <https://doi.org/10.1016/j.jcgg.2014.08.004>.

²⁵Harvey Abrams, 'Hearing Loss and Associated Comorbidities: What Do We Know?', *Hearing Review*, accessed 3 August 2019, <http://www.hearingreview.com/2017/11/hearing-loss-associated-comorbidities-know/>.

²⁶Frank R. Lin et al., 'Hearing Loss and Incident Dementia', *Archives of Neurology* 68, no. 2 (February 2011): 214-20, <https://doi.org/10.1001/archneurol.2010.362>.

²⁷Frank R. Lin et al., 'Hearing Loss and Cognitive Decline Among Older Adults', *JAMA Internal Medicine* 173, no. 4 (25 February 2013), <https://doi.org/10.1001/jamainternmed.2013.1868>.

²⁸International Centre for Evidence in Disability, World Wide Hearing, and London School of Hygiene & Tropical Medicine, 'Do Hearing Aids Improve Lives? An Impact Study among a Low-Income Population in Guatemala' (Guatemala, December 2016).

²⁹Sound Seekers, 'World Hearing Day 2018: Shine's Story', *Sound Seekers* (blog), 3 March 2018, <https://www.sound-seekers.org.uk/world-hearing-day-2018-shines-story/>.

3.4. Experts recommend that hearing aids should be provided within the context of a broader Ear and Hearing Care programme, but multiple implementation challenges exist.

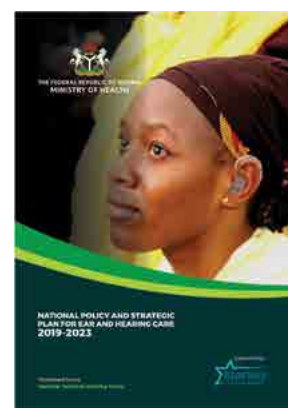
Hearing aids are only one component of a comprehensive service delivery and rehabilitation model, known as Ear and Hearing Care (EHC), which is required to effectively identify and address pathologies of the ear. The WHO promotes EHC programmes and strategies. Services are required across all levels of a health system, from the community to the hospital level. Each health level would involve activities from prevention and raising awareness to screening and detection to treatment and rehabilitation (refer to Appendix B for detailed activities to be provided at each level of the health system).

Beyond general health system constraints, multiple challenges associated with the implementation of EHC in LMICs exist, including:

- **LACK OF A NATIONAL OR SUB-NATIONAL EHC STRATEGY.** A WHO multi-country assessment published in 2013 reported that of the 46 LMICs that participated, 41% did not have a national or subnational strategy for EHC.³⁰
- **LACK OF PLANNING AND BUDGETING FOR SERVICES,** including required equipment, human resources and products. In the same WHO assessment, countries cited lack of financial resources and lack of human resources as the primary reason for not having developed a national program. Competing health priorities and insufficient political will were also noted.³¹
- **LACK OF TRAINED HEALTH WORKERS,** including audiologists and ENT surgeons at all levels. Many countries require that hearing loss diagnosis and hearing aid fitting only be conducted by audiologists or ENT surgeons. LMICs generally have a shortage of audiologists—who typically need two years of post-graduate coursework—which limits the ability to scale services. Only six out of 37 low and lower-middle-income countries had more than one audiologist per 1 million people compared to 17 out of 20 upper-middle- and high-income countries.³² The low availability of audiologists can partly be attributed to the migration of many audiologists to higher income countries. For example, approximately 50% of Indian audiologists are estimated to have relocated to other nations.³³
- **LACK OF TRAINING TO SUPPORT TASK SHIFTING.** While training models are available for EHC from the WHO, there are no training modules available specifically for hearing aid provision; therefore, NGOs have trained community health workers, nurses and audiology technicians by creating their own training modules to provide hearing care services.

CASE STUDY 3: DEVELOPING EHC STRATEGIES IN AFRICA

As most countries in East and Central Africa lack financial resources to develop national EHC strategies, Starkey Hearing Foundation, the BMZ and CBM have funded the East and Central Africa EHC Forum, an advocacy group created by independent audiologists and ENT surgeons in 2016. The forum is advocating that all countries in the region develop national plans for EHC by end of 2019. These partners and the forum have advocated for and/or have supported the development of national plans for EHC in the following countries: Burundi, Democratic Republic of Congo, Ethiopia, Kenya, Madagascar, Malawi, Nigeria, Rwanda, Tanzania, Uganda, Zimbabwe, and Zambia.



³⁰World Health Organization, 'Multi-Country Assessment of National Capacity to Provide Hearing Care', 2012, https://www.who.int/pbd/publications/WHOReportHearingCare_Englishweb.pdf.

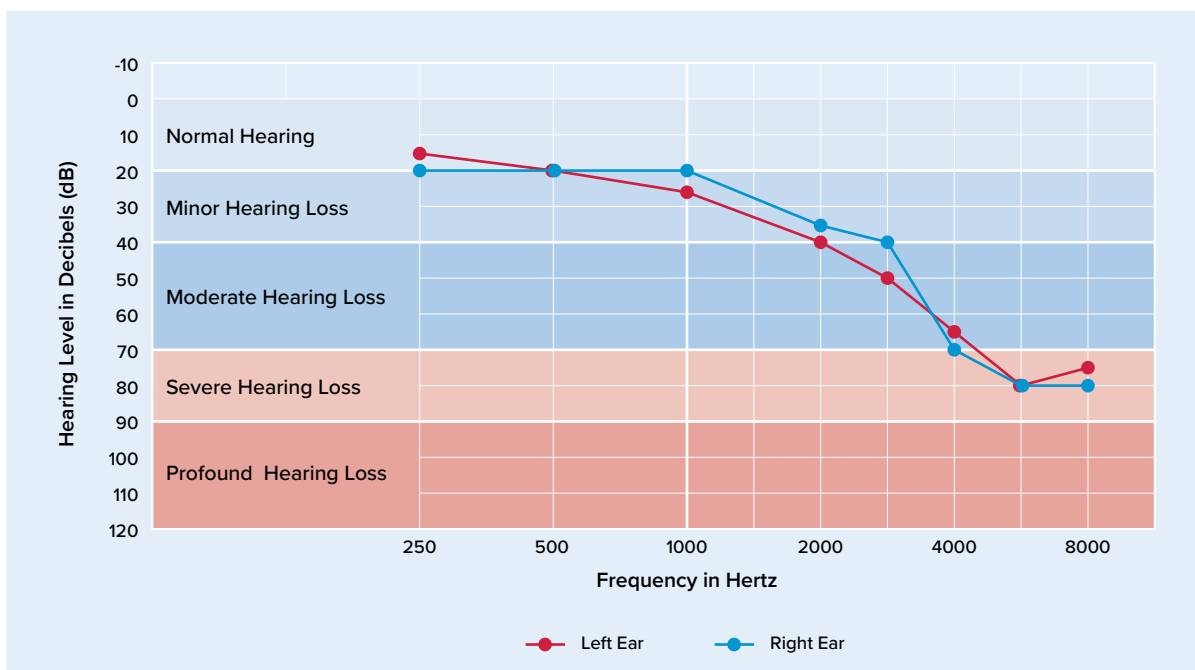
³¹World Health Organization.

³²World Health Organization.

³³Robert Tarynor, 'Status of Audiology in India—Robert Traynor', Hearing Health Matters, 18 April 2017, <https://hearinghealthmatters.org/hearinginternational/2017/status-audiology-india/>.

3.5. Provision of hearing aids generally includes the following steps: 1) screening for and diagnosing hearing loss; 2) selecting and fitting appropriate hearing aids; and 3) providing long-term follow-up and rehabilitation services to the user.

FIGURE 2: SAMPLE AUDIOGRAM



The continuum of care includes the following high-level steps:

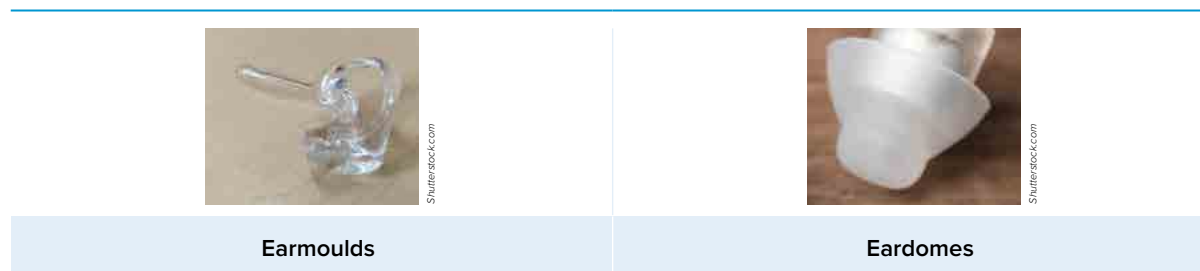
1. **SCREENING AND DIAGNOSIS.** Hearing aid provision begins with case finding and screening for hearing loss or an individual presenting for hearing evaluation. A provider then examines the ear with an otoscope to rule out conductive causes. This is followed by diagnostic testing using audiometry to determine the severity of the hearing loss and if a hearing aid is appropriate. Audiometry uses specialised equipment, called an audiometer, to develop an audiogram (Figure 2), which describes the hearing loss in terms of volumes (y-axis) across various frequencies (x-axis).
2. **FITTING OF HEARING AID.** Once a person has been determined to have hearing loss that can be addressed via a hearing aid and rehabilitation services, the appropriate hearing aid (one that is a good match for severity of hearing loss and takes into account a person's perceptual difficulties) is selected and fitted, whereby a trained professional uses a computer programme to match the audiogram to the appropriate amplification curve of the hearing aid and adjusts based on the user's feedback and potential additional testing. The fitting visit should include fitting, programming, verification, instructions on use, and counselling.
3. **REHABILITATION.** Rehabilitation services begin at the first fitting when the user is provided guidance and counselling on hearing aid usage. Additional adjustments are made over time to respond to the user's experience. Audiological rehabilitation or peer support may be used to instruct the user in hearing aid management and use as well as on how to adjust to the use of a hearing aid and increase skills related to hearing and speech. This counselling may be carried out in-person or via home-based exercises, e-mail and/or phone calls.
4. **AFTER-CARE.** Aftercare includes the maintenance and repairs of hearing aids, as well as battery and earmould management. Batteries must be available and replaced regularly, while earmoulds may be replaced every 6-12 months to 3 years depending on age.

Appendix C provides a more detailed description of the hearing aid continuum of care including screening, diagnosis, fitting, and rehabilitation and after-care.

Provision of hearing aids requires earmoulds and batteries over the life of the hearing aid:

- **EARMOULDS.** Usually made of medical-grade plastic or silicone, earmoulds are custom-made so that they sit comfortably within the user's ear canal, preventing feedback loop, a high-pitched whistling that is caused when the amplified sound leaks out and is re-amplified. The process to develop custom-made earmoulds requires specialised equipment and materials, adding to the supply chain complexity of hearing aids and time required for service provision and fitting. In most places, earmould impressions are sent to a lab where a trained technician develops the mould. This can add additional waiting time and requires follow-up visits to the clinic, which may limit access. Furthermore, earmoulds typically last 2-3 years for adults and 6-12 months among children and hence need to be made consistently available to ensure long-term usage. The medical-grade silicone or plastic is often unavailable locally and must be imported. Experts suggest that earmoulds in LMICs cost ~US\$5-8.
- **EARDOMES.** Many experts suggest the use of eardomes instead of earmoulds as a way to increase access, as they are factory made and do not require customisation (refer to Figure 3); however, they cannot be used for all users due to acoustic ventilation that can cause negative feedback loop or loss of amplification. Eardomes come in multiple sizes and the user can pick the one that is most comfortable. The cost of these eardomes is significantly lower than a custom earmould (< US\$0.10).³⁴

FIGURE 3: EARMOULDS AND EARDOMES



- **BATTERIES.** Access to a continuous supply of batteries is critical to ensure continued use as hearing aid batteries deplete on average every 5-10 days depending on the processing power and features of the hearing aid. Sizes of hearing aid batteries are developed for and unique to hearing aids; therefore, they are often not locally available in LMICs. Hearing aid batteries cost between US\$0.17 - US\$0.38 per battery across both LMIC and HIC markets, which translates to about US\$12 - US\$50 per year in battery costs depending on depletion rate. Experts suggest that rechargeable batteries are far more cost-prohibitive at the moment and make limited sense for hearing aids that must be worn for the majority of the day.

3.6. WHO global guidelines related to hearing aid provision in low-resource settings (LRS) are outdated and lack specificity, which has led to a variety of approaches to hearing aid provision.

WHO developed the “Guidelines for Hearing Aids and Services for Developing Countries”³⁵ in 2004. Since hearing aid provision should happen in the context of EHC, WHO supplemented these guidelines with the “Primary Ear and Hearing Care Training Resources”³⁶ in 2012 and with the “Preferred profile for hearing

³⁴Clinton Health Access Initiative.

³⁵World Health Organization, ‘Guidelines for Hearing Aids and Services for Developing Countries’ (World Health Organization, September 2014), https://apps.who.int/iris/bitstream/handle/10665/43066/9241592435_eng.pdf;jsessionid=F786E9D3B560BC51C927A025ACA7BE7D?sequence=1.

³⁶World Health Organization, ‘WHO | Primary Ear and Hearing Care’, WHO, accessed 18 June 2019, http://www.who.int/deafness/activities/hearing_care/en/.

aid technology suitable for LMICs” in 2017 (henceforth referred to as the WHO Preferred Product Profile or WHO PPP—refer to Appendix D).³⁷

The 2004 Guidelines lack specificity on personnel, provision and product:

- **PERSONNEL.** There is limited guidance on who is allowed to provide hearing aids and what the standards are for their training, accreditation, and long-term skills building. Some countries have very restrictive policies that require licensed audiologists or ENT surgeons to provide hearing aids and as a result curtail general access to this service, while others have limited regulation, which may lead to substandard service.
- **PROVISION.** Although new technologies (refer to section 4.10) for the detection and diagnosis of hearing loss exist, it is unclear how these may change the guidelines for provision and how they compare to existing audiometry technology. There is also limited guidance on the provision of earmoulds using the latest technology.
- **PRODUCTS.** Although the WHO PPP provides transparency on the desired product specifications for hearing aids, there remains contention among experts about the appropriateness of digital hearing aids that are manually programmable (“trimmer-based”) versus those that are software programmable. New classes of hearing aid products (refer to section 4.11) such as self-programmable, pre-programmable, and over-the-counter are mentioned, but there is no clear guidance, largely due to lack of evidence.

These also do not incorporate guidance on the latest advancements in technologies for screening and fitting, earmoulds or hearing aids (discussed in section 4.12). Lastly, specific training resources for hearing aid provision in LRS are limited. While audiologists and others in the sector may disagree on technical aspects of service delivery, there is a consensus that delivery must avail the use of audiometry, ensure appropriate fitting, and be provided in a context where long-term support is available. This consensus has been captured in the voluntary development of some guidelines and standards, such as the forthcoming “Suggested Guidelines for Humanitarian Hearing Care Outreach Programs” developed by the Coalition for Global Hearing Health.³⁸

While plans to update the WHO Guidelines or the WHO PPP do not currently exist, the WHO is open to developing new target service delivery profiles and product profiles through a consensus process with the hearing community.

3.7. While different types of hearing aids exist in the market, specific hearing aids appropriate for the LMIC context are described by the WHO PPP.

Hearing aids are not one size fits all, and are differentiated by amplification power (the more severe the hearing loss, the higher the amplification power required), amplification technology (analogue vs. digital), sound processing capabilities, style (refer to Table 3 on hearing aid styles), battery types used, and special features (such as Bluetooth, Artificial Intelligence, etc.). Telecoil facility and compatibility³⁹, direct audio input, directional microphones, etc. are also important functions of hearing aids that are necessary for long-term optimal use in various settings.

³⁷ World Health Organization, ‘Preferred Profile for Hearing-Aid Technology Suitable for Low- and Middle-Income Countries’, 2017, <https://apps.who.int/iris/bitstream/handle/1066>

³⁸ Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

³⁹ A telecoil picks up signals from an audio induction loop systems or FM radio system to stream amplified sounds directly to the hearing aid. Telecoil facilities are critical to increasing compatibility with other assistive technology. Loop systems are often found in concert halls, universities, and other public spaces to support hearing in noisy or large spaces.

TABLE 3: EXAMPLES OF HEARING AID STYLES⁴⁰

<p>BODY WORN</p> 	<p>BEHIND-THE-EAR (BTE)</p> <p>WHO PPP recommended</p> 	<p>RECEIVER-IN-CANAL (RIC)</p> 	<p>IN-THE-EAR</p> 	<p>COMPLETELY-IN-THE-CANAL/INVISIBLE-IN-THE-CANAL</p> 
<p>Least complex hearing aids that can be worn on the user's body with earbuds placed in the ear.</p>	<p>The technology is housed in a casing that rests behind the ear and a plastic, acoustical tube directs sound into an earbud or custom earmould.</p>	<p>RICs are a subset of BTE hearing aids where the receiver of the hearing aid is inside the ear canal.</p>	<p>Custom designed hearing aids that are complex to fit and require significant care. They are visible as they sit on the outer ear of the user.</p>	<p>Custom made to fit completely in the ear canal with only a small plastic 'handle' on the outside for removing it when not in use.</p>

The WHO PPP recommends Behind-the-Ear (BTE) hearing aids as the primary choice for public health distribution in LMIC as it has the widest coverage range for severity levels and is the easiest to fit among current styles.

Many hearing aids are able to serve multiple levels of severity, but not all levels. Table 4 provides rough estimates of the mix of devices that would be required to meet the needs of a population. However, the WHO PPP does not specify the mix of products, based on amplification power of user needs that should be procured by hearing programs or procurement agents to meet the population's needs. Hearing aids should be selected to meet the amplification and perceptive needs of the user. The PPP is also limited by the fact that it does not outline a target price for the total cost of ownership over the lifetime of the product nor does it support additional technical guidance for procurement. Additional limitations are covered in the next section on quality.

TABLE 4: ROUGH ESTIMATION OF THE PROPORTION OF DEVICES NEEDED IN LMICS⁴¹

HEARING LOSS SEVERITY	MILD	MODERATE	SEVERE	PROFOUND
Recommended proportion	10%	45%	35%	10%

⁴⁰Starkey, 'What Are Different Types, Styles of Hearing Aids?', accessed 14 June 2019, <https://www.starkey.com>.

⁴¹ Dr. Paddy Ricard et al., 'Community Ear and Hearing Health', *LSHTM Newsletters*, 2018.

3.8. No global standard for quality testing currently to differentiate quality hearing aids from poor quality products.

Measures of hearing aid quality should encompass a number of domains including sound quality, consistency of the audio output, durability, comfort for the user, moisture and dust resistance, and usability and effectiveness of the software programming interface. However, there is currently no single set of standards that allow for the differentiation between quality and lower or non-quality products.

Quality of hearing aids affects the user experience; poor sound quality, discomfort, or unreliability can lead to low usage rates or discontinuation. This limits the benefit that the user can derive from the hearing aids and makes it less likely that they will persevere until they find a quality product that works well. In addition, a poorer quality hearing aid can over-amplify some sounds, contributing to hearing damage. Lastly, while many products that are considered by experts as high quality meet moisture and dust resistant standards (such as IP67^{42,43}), they are not well-suited for LMIC climates, which tend to be harsher than HIC climates, and can often breakdown or get damaged quickly if not well protected.

The WHO PPP provides some guidance on aspects of quality but is not designed to be a rigorous quality standard. Many products match the WHO PPP on paper, but in practice have poor sound quality, are not durable, or are difficult to program by the provider. Unfortunately, there are no existing or planned standards for hearing aids that provide an objective measure of quality to inform procurement for low-resource settings.⁴⁴ According to experts, the US FDA and CE marks are not able to differentiate quality from non-quality products on the measure of hearing quality outlined above, and there is no globally recognised quality-testing programme. The FDA requires certification of gains and output of hearing aids through a third party agency to ensure they match specifications but that is not a certification of quality.⁴⁵ While WHO's forthcoming Assistive Product Specifications (APS) will providing further clarity to procurers, they will not serve as an established quality standard.

In the absence of objective quality standards, private providers are loyal to certain manufacturers where they and their clients have had positive experiences with specific products, typically one of the leading global manufacturers. To maintain brand reputation, these manufacturers rigorously enforce internal quality standards. In seeking lower-cost alternatives, audiologists may conduct a "field test" of products, by having users try them for a certain period and then reporting their experiences with the products. The results of these tests are rarely published.⁴⁶ This leaves procurers without guidance on which hearing aids are of high quality and they often award contracts for hearing aids to the lowest bidder.

3.9. Donor funding for procurement and provision of hearing aids in LMICs is limited and often comes from CSR programmes of leading suppliers.

The donor landscape in hearing aids is limited and fragmented with most funding for NGOs coming from corporate social responsibility (CSR) initiatives. There is no one bilateral donor that is heavily engaged in the hearing space; however, Canada Grand Challenges, GIZ, and others have provided limited grant support to NGOs and social enterprises, often through wider disability programmes, around the development of innovations in hearing screening and care, provision of hearing aids, and support of EHC strategies.

Three of the five leading suppliers of hearing aids have set up foundations to channel their philanthropic support: Hear the World Foundation (Sonova); Oticon Foundation (William Demant) and Starkey Foundation (Starkey). These foundations support both in-kind donation of new and refurbished product as well as grants to NGOs.

⁴² IP is the name of the standard developed by International Electrotechnical Commission (IEC) to determine how resistant an electrical device is to water, dust and sand.

⁴³Max Parker, 'IP67 vs IP68: Waterproof IP Ratings Explained', Trusted Reviews, 7 September 2018, <https://www.trustedreviews.com/opinion/what-is-ip68-ip-ratings-explained-2947135>.

⁴⁴Clinton Health Access Initiative, CHAI Expert Interview (see Appendix A).

⁴⁵Ibid.

⁴⁶Ibid.

The Starkey Foundation is the largest donor of hearing aids globally with ~100,000 units donated per year. Starkey Foundation organises and runs community-based hearing programs that include patient identification, hearing aid missions or community camps to fit hearing aids, and aftercare programs in partnership with governments or NGOs. Starkey Foundation hearing missions utilise mostly refurbished, donated hearing aids.

Most NGOs rely on individual donations, corporate donation matching schemes and support from CSR initiatives, such as those from leading supplier to fund their hearing aid screening and provision activities.

4. Market Assessment

4.1. The global hearing aids market focuses on high-income markets and is consolidated around five major manufacturers who control the value chain.

The global market for hearing aids is valued at US\$6 billion with more than 16 million hearing aids sold annually.⁴⁷ The market expects unit growth of 3% to 5% every year with 70% of units sold in Europe and North America.⁴⁸

The five largest manufacturers control more than 90% of the market. Leading global players, henceforth referred to as the 'Big 5', are: Sonova (Switzerland), WS Audiology (Singapore), William Demant (Denmark), GN Resound (Denmark), and Starkey (USA). Annual statements of two leading manufacturers suggest that these companies have earnings (before interest and taxes) margins of around 25% and gross margins of around 70-80%. Sales and marketing is the biggest cost driver and typically accounts for 40% of the cost. Acquisitions of smaller promising companies by the Big 5 keeps the market consolidated. The Big 5 players have multiple brands and subsidiaries whose products differ in features and price (anywhere from ~\$600 to over \$3000 per unit for high-end models), allowing them to capture different market segments. These holdings are the result of both in-house product development and acquisitions.

In HICs, products and services are often bundled to the end user. The Big 5 hold considerable control over the value chain in HICs in order to maximise returns to the company and protect market shares. They do this via:

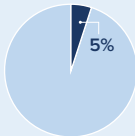
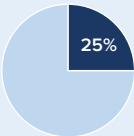
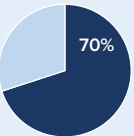

- **EXCLUSIVE CONTRACTS WITH AUDIOLOGISTS.** The Big 5 have strong bargaining power with audiologists and can leverage exclusive contracts with them in exchange for discounted pricing.
- **TECHNICAL HURDLES TO SWITCHING MANUFACTURERS.** Each supplier has its own proprietary fitting software, complicating the learning process for audiologists when they to shift to another supplier.

In the United States and other HICs, hearing aids are sold wholesale to retailers and audiologists for around US\$300-600. The retailers and audiologists then add a service price between US\$1,900-2,100 per hearing aid, which includes professional fitting and after-care services. Bundled prices to users in HICs – which include the hearing aids, clinical and product service, and warranty – average about US\$2,400 per standard hearing aid or US\$4,800 for two hearing aids, making hearing aids the third largest purchase for many after a house and a car. This bundled pricing strategy reduces the transparency of services provided and may have stipulations that limit the user's choice. For instance, some hearing aids can only be serviced by the original dispenser, which limits the ability of the user to change service providers if they are dissatisfied.

⁴⁷ Sonova, 'Sonova Investor Presentation - June 2019' (Sonova, June 2019), https://www.sonova.com/en/system/files/ir_presentation_june_2019_final.pdf.

⁴⁸ Oticon, 'Trends and Directions in the Hearing Healthcare Market. Niels Jacobsen, President & CEO, William Demant Holding Søren Nielsen, President, Oticon - PDF', accessed 14 June 2019, <https://docplayer.net/27118938-Trends-and-directions-in-the-hearing-healthcare-market-niels-jacobsen-president-ceo-william-demant-holding-soren-nielsen-president-oticon.html>.

TABLE 5: VALUE CHAIN IN THE PRIVATE SECTOR

	COMPONENT SUPPLIERS	HEARING AID MANUFACTURERS	RETAILERS/AUDIOLOGISTS	COST TO PAYERS
Percentage of value chain				
US\$ Value	US\$20-30	+ US\$300-600	+ US\$1,900-2,100	Total = ~US\$2,400
Role in Value Chain	<ul style="list-style-type: none"> Supply of hearing aid components (e.g. microphones) 	<ul style="list-style-type: none"> R&D Manufacturing Marketing & Sales Distribution Warranty 	<ul style="list-style-type: none"> Retail (usually standalone) Fitting Services/Maintenance 	

4.2. The Big 5 are focused on premium products to generate market value and have limited commercial interest in LMICs.

The Big 5 have a limited presence in non-Western markets. For example, for William Demant, the Asia-Pacific accounts for 21% of unit sales, mostly from Japan and China. South America and Africa account for only 7% and 2% of unit sales, respectively.⁴⁹ The Big 5 see limited commercial interest in LMICs due to the following factors:

- **LOW AWARENESS AND STIGMA.** Awareness of hearing loss is very low in LMICs. Even when people are aware, stigma associated with the use of hearing aids exists.
- **LIMITED ACCESS TO HEARING CARE PROFESSIONALS.** The low availability of audiologists is often cited as a barrier to scale by many major hearing aid suppliers.
- **REGULATORY CHALLENGES.** In some LMIC markets, registration of new hearing aid products can be time-consuming, particularly when compared to HIC markets. In addition, in many LMICs low-cost products that are often unregulated exist. Big 5 products cannot compete on price with these low-cost hearing aids and personal sound amplification devices.
- **LOW PURCHASING BY USERS OR GOVERNMENTS.** LMIC governments are typically not prioritising hearing aids within a constrained resource envelope. Where governments do procure hearing aids or cover them through an insurance scheme, suppliers have faced long sales cycles, late payments, and government reimbursement rates that are too low to cover costs, which limits their desire to interact with government as a customer (refer to Case Study 4).

While prices for hearing aids are often prohibitive to LMIC buyers, manufacturers are reluctant to reduce rates due to concerns about price erosion. The above-mentioned challenges, in combination with a HIC market that is not yet saturated (e.g. HIC market has ~20% market penetration), lead to companies focusing on high-value markets. New generation products are launched every 3 years and are the main driver of market value growth. In the absence of public spending and given the constrained size of the private market in most contexts, NGOs and CSR initiatives are sometimes the only hearing aid provision occurring within a country.

⁴⁹Oticon, 'Trends and Directions in the Hearing Healthcare Market. Niels Jacobsen, President & CEO, William Demant Holding Søren Nielsen, President, Oticon - PDF'.

CASE STUDY 4: LOW GOVERNMENT REIMBURSEMENT RATES IN INDONESIA⁵⁰

The Hearing Solutions Company, a Starkey subsidiary, is the leading Big 5 company in Indonesia and sells its lowest priced hearing aids at ~US\$280 per unit. As part of its health coverage scheme, the Government of Indonesia reimburses ~US\$70 for either one or both hearing aids every 5 years. Few users opt to use the reimbursement towards The Hearing Solutions Company product and then pay the difference out of pocket. Instead most opt to purchase a lower-quality, but also lower-priced hearing aid that would be fully covered by the reimbursement.

4.3. To meet the needs of lower-income market segments, approaches exist in the private sector that can deliver quality hearing aids in more affordable ways to the end-user.

Commercially viable enterprises exist that are seeking to work with or around the Big 5 in order to provide a lower cost but high-quality product and service, both in HICs and LMICs:

- **DIRECT-TO-CONSUMER.** IntriCon (US), the largest manufacturer outside of the Big 5, is developing a “direct-to-consumer” distribution channel as they believe that the conventional retail model is inefficient and costly. This model sells a hearing aid to the user similar to those from Big 5 at a price between US\$350-500.
- **WHITE LABEL BUNDLED PRODUCT AND SERVICE.** Costco (US) is the second-largest provider of hearing aids in the US after the US Veteran Affairs. The retailer’s bundled price is US\$1,499 for a pair of hearing aids,⁵¹ offering significant costs savings to users compared to traditional retail channels. It does so by:
 - **LEVERAGING PREVIOUS GENERATION TECHNOLOGY** and white-label product. Costco procures its hearing aid from leading hearing aid manufacturers, selling some with name brands and some under the ‘Kirkland’ private label. They often buy products that are one generation behind, thereby accessing discounted prices.
 - **VOLUME PURCHASING.** Costco has an 11% market share, which enables them to bulk purchase from manufacturers and transfer these savings to its customers. They retender on an 18-month cycle.
 - **LOWER OVERHEADS.** Costco utilises its current brick and mortar infrastructure to reduce overhead costs by building a hearing aid centre within its existing shops.
 - **LOWER-SKILLED PERSONNEL.** Costco employs hearing aid specialists who require minimal training. Individuals with a high-school diploma are required to pass a licensing exam, administered by Costco, and then be engaged in a brief apprenticeship. This allows them to pay lower wages compared to an audiologist. The compensation model does not rely on sales commissions, further reducing cost to users.
- **SELLING ENTRY-LEVEL PRODUCTS VIA LOCAL PHARMACY CHAINS.** earAccess, a Canadian social enterprise, also utilises white labelling. In 2018, the company launched two entry-level products (ACCESS 1 BTE: US\$250-300; ACCESS 2 BTE Power: US\$750-1,300) in collaboration with a local pharmacy chain in the Philippines⁵² that has placed audiologists in select stores for the provision of hearing aids.^{53,54} They are targeting a 70% reduction in price for consumers compared to currently available hearing aids through volume-based purchasing from a contract manufacturer, reduced product margins, and leveraging this alternate distribution channel.⁵⁵

⁵⁰Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

⁵¹Costco, ‘Costco Hearing Aid Center | Costco’, accessed 21 July 2019, <https://www.costco.com/hearing-aid-center.html>.

⁵²OpinYon, ‘Quality but Affordable Hearing Aids Launched in the Philippines’, 28 July 2018, <http://www.opinyon.com.ph/index.php/3433-quality-but-affordable-hearing-aids-launched-in-the-philippines/>.

⁵³earAccess, ‘EarAccess Hearing Aids To Be Available In The Philippines - Orange Magazine’, accessed 17 June 2019, <https://orangemagazine.ph/2018/earaccess-hearing-aids-to-be-available-in-the-philippines/>.

⁵⁴OpinYon, ‘Quality but Affordable Hearing Aids Launched in the Philippines’.

⁵⁵GE Healthcare, ‘One Hearing Aid at a Time, This Woman Is Changing the Lives of Thousands - GE Healthcare The Pulse’, accessed 21 July 2019, <http://newsroom.gehealthcare.com/one-hearing-aid-at-a-time-this-woman-is-changing-the-lives-of-thousands/>.

- **SUBSCRIPTION-BASED MODEL.** One of the key challenges with increasing access to low-income customers is the high upfront cost of device acquisition in the retail sector. New concepts are emerging whereby a company partners with mobile money operators, local NGOs, and basic health service providers to screen patients and then provide hearing aids on the spot. The hearing aids are financed via a subscription model in which the user pays an affordable rate per week for a fully serviced hearing aid plan, including earmoulds and batteries, over a period of 36 months, via mobile money transfers.

The above suggests that innovation in sales models may be able to expand the reach of the private sector to new consumers. Direct-to-consumer approaches may be challenging due to the fact that many potential users are not technological savvy enough to engage with the self-fitting technologies, or are limited in ability to access online ordering. However, principles of using white labelling and volume purchasing to provide an affordable option to consumers, or lowering delivery costs by leveraging existing pharmacy chains both show promise. Subscription-based models, if able to demonstrate profitability and sustainability, could also change the way that end-users are able to sustainably afford hearing aids.

4.4. In the absence of a global standard, quality products struggle to compete in unregulated markets as many low-cost suppliers have emerged that have products of variable or unknown quality.

In order to respond to the need for hearing aids at lower price points in LMICs, multiple smaller manufacturers, primarily Chinese, offer products at lower prices but of unknown quality. These include suppliers who are either manufacturing in LMICs or primarily supplying to LMICs. These companies have not been able to establish any reputation and due to the lack of global quality certifying mechanisms, it is difficult to differentiate between high and low quality in this category.

Anecdotally, quality concerns include poor sound amplification, over-amplification, lack of directional microphones, and poor durability. Products, as seen in Figure 4, are commonly sold through an unregulated market at retail points, such as small electronics shops, at price points as low as US\$4 and often without appropriate tests or provision.

FIGURE 4: HEARING AID SOLD THROUGH SMALL ELECTRONIC STORES

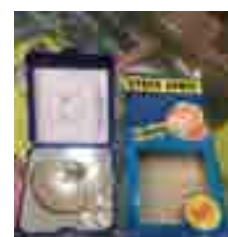


Photo Credit: Razali Kapor/ICRI

4.5. National health insurance systems in HICs have been able to increase adoption rates, sustainably deliver services and reduce prices obtained on Big 5 models through volume-based negotiation.

By having a centralised payer or provider, public systems are able to conduct centralised procurement and leverage volumes to achieve reduced prices, thereby increasing adoption and accessibility of hearing aids. For example, while the penetration of hearing aids in many HIC is on average only 20%, in countries such as Norway and the UK, the strength of a publicly supported provision system has contributed to ~45% market coverage.^{56,57} In these countries, governments play a critical role in providing the funding for products and provision, and negotiating terms with suppliers, while service provision may be delivered by either the public sector or contracted out to the private sector.

For example, NHS England is a public procurer that conducts volume-based negotiation to drive down prices (refer to Case Study 5). UK tender information is made available on the EU website and is often consulted by EU countries that are procuring hearing aids. However, under UK regulations, other countries

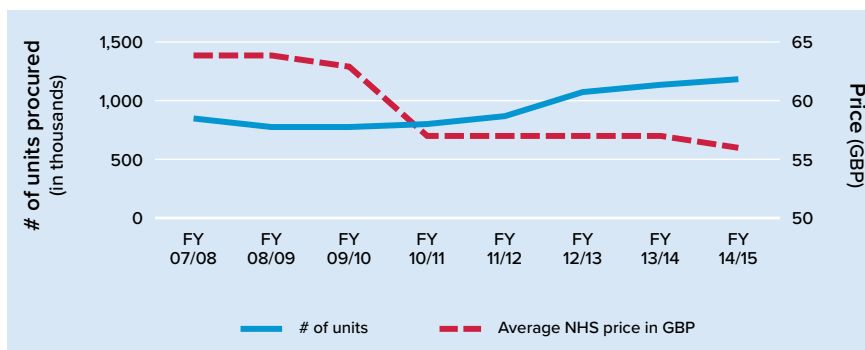
⁵⁶Holly Hosford-Dunn, 'Consumers, Consumers...Where Art Thou? – Holly Hosford-Dunn', Hearing Economics, 31 August 2016, <https://hearinghealthmatters.org/hearingeconomics/2016/price-as-factor-in-us-hearing-aid-adoption/>.

⁵⁷IntriCon, 'IntriCon Investor Relations Presentation - May 2019', accessed 17 June 2019, <https://investorrelations.intricon.com/static-files/c35b14e5-2e40-46f2-92a2-11c4485b0222>.

are not able to procure from the procurement framework.⁵⁸ Over time, the prices have proved sustainable, and as volumes have increased, prices have further decreased.⁵⁹ The Clinical Commissioning Group for each local area within the NHS sets the tariff for reimbursement of providers (both public and private) contracted to provide hearing services. The recommended tariff for 2016/2017 for hearing assessment, fitting of two hearing aids device, cost of two devices, and three years of follow up was around GBP£370 but can vary based on a number of adjustment factors.⁶⁰

CASE STUDY 5: NHS ENGLAND HEARING AID PROCUREMENT^{61,62}

NHS England provides hearing aids free of charge to end-users as part of the UK's system of universal health coverage. NHS England purchases and dispenses 1.2 million hearing aids every year through more than 300 hearing service clinics.⁶³ Over



time, the NHS has developed a system that allows them to procure high-quality hearing aids from Big 5 manufacturers at an affordable rate, averaging GBP£56 (US\$68). The approach is led by the NHS Supply Chain office and is characterised by the following:

- Consultations with potential suppliers in advance of the release of the tender specification documents;
- Clear specifications around a limited range of products that cover the entire spectrum of needs and that focus on items with basic features;
- Consolidated volumes across NHS departments that procure hearing aids, allowing for volume-based negotiations with multiple suppliers, including minimum order commitments in some cases;
- Extensive quality testing.

4.6. While there is potential to increase adoption of affordable and quality hearing aids, there is currently a considerable lack of effective public procurement in LMICs.

Unlike the examples of HICs provided above, in LMICs current investment in procurement and provision of hearing aids by the public sector is low or non-existent. Governments are not prioritising procurement of hearing aids within limited budget envelopes. Where a limited number of countries do procure hearing aids for public provision, procurement volumes tend to be far below the immediate need, as characterised by growing waiting lists and the projected need that could be addressed with hearing aids.

Additionally, tendering practices related to hearing aids demonstrate significant weaknesses, further limiting access to optimal products:

- **POOR SPECIFICATIONS.** In some cases, tender documents do not provide sufficient specifications on the types of product required and do not align with WHO PPP as governments and decision-makers are unaware of the PPP or have not fully adopted it. In other cases, the specifications

⁵⁸Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

⁵⁹British Academy of Audiology, ASG, and Sydserff, 'Audiology Supplies Group...what's That All about Then?', https://www.baaudiology.org/files/1414/5796/1687/1145_Peter_Sydserff.pdf

⁶⁰NHS England, 'Commissioning Services for People with Hearing Loss: A framework for clinical commissioning groups.' 2016, <https://www.england.nhs.uk/publication/commissioning-hearing-loss-framework/>

⁶¹ British Academy of Audiology, ASG, and Sydserff.

⁶²Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

⁶³NHS England, 'Action Plan on Hearing Loss' (UK NHS, n.d.), <https://www.england.nhs.uk/wp-content/uploads/2015/03/act-plan-hearing-loss-upd.pdf>.

promote the proliferation of products. This results in a fragmented market with multiple products that are similar in functionality, and lack of consensus on which products would be best included in a public model of provision. Experts suggest that meeting a range of user needs only requires a few, adjustable hearing aid models.

- **PRICE OVER QUALITY.** In the absence of strong specifications and clear quality standards, national procurements tend to go to the lowest bidder, regardless of whether it is an appropriate or quality product. At these low prices, Big 5 manufacturers do not see the value of competing. There are also examples in LMICs where the government tenders local manufacturers, regardless of cost or quality considerations.
- **IMPORT DUTIES AND TAXES.** In many countries, hearing aids are not exempt from import duties and taxes, such as sales or VAT, which can have a significant impact on the price of the product to the consumer and the ability for governments to procure. In one middle income country for example, import duties on hearing aids are as high as 15% and VAT is 10%. This essentially increases the price of the product by 26.5% to the buyer.⁶⁴

4.7 NGOs have found ways to access quality hearing aids at an affordable rate and provide cost-effective services, pointing to potential approaches that LMIC governments could use to access affordable, quality products.

NGOs have been able to access quality products at lower cost for humanitarian use (refer to Case Study 6). NGOs, benefiting from these pricing agreements, believe that these humanitarian prices still incorporate a small profit margin for the manufacturer. Other models for procurement that NGOs use, but that are less likely to be replicable at scale, include refurbishing donated product and accepting donated product from hearing aid companies through CSR.⁶⁵

CASE STUDY 6: AFFORDABLE PRODUCT: THE INTERNATIONAL HUMANITARIAN HEARING AID PURCHASING PROGRAMME (IHHAPP)

Started in 1995, IHHAPP “provides new high-quality, BTE digital hearing aids to qualified Humanitarian Programs and Not for Profit Organizations with long term relationships to their clients/recipients.”⁶⁶ To fulfil its mission, it employs the following strategies:

- **CONSOLIDATED VOLUMES.** Procures three models of hearing aids from a Big 5 supplier that covers the full range of disabling hearing loss.
- **SIMPLE TECHNOLOGY.** The models of hearing aids were selected because they are digital hearing aids that incorporate manual adjustment using a trimmer, a technology that is no longer used in HICs, but that IHHAPP determined would be more straightforward to adjust in LMIC environments. They were also selected for ruggedness. Trimmer-based hearing aids, however, are not recommended by many experts due to the fitting complexity it entails.
- **HUMANITARIAN RESTRICTION.** All procurers are required to submit an application confirming that they will use the hearing aids for humanitarian purposes in an eligible country, and in the context of long-term service delivery.

To combat limited awareness and stigma associated with hearing loss, NGOs have adopted service delivery models in LMICs that bring services closer to people. These models often involve using lower cadres of workers (refer to Case Study 7). Examples include door-to-door screening for hearing loss and provision of care; campaigns and outreach programs at schools and in communities; partnerships with government health facilities; and standalone hearing clinics, sometimes in partnership with universities or private health facilities.

⁶⁴Clinton Health Access Initiative, CHAI Expert Interview (see Appendix A).

⁶⁵Ibid.

⁶⁶IHHAPP, 'IHHAPP Home Page', accessed 18 June 2019, <https://ihhapp.org/>.

These models also help overcome the need for the user to visit the audiology clinic multiple times before the hearing aids are working optimally and help reduce high drop-out or conversion rates. A study conducted in Malawi outlined that referral uptake for ear and hearing services was only 3% due to a variety of factors including location of the hospital, other indirect costs of seeking care, procedural problems within the outreach programme, awareness and understanding of hearing loss, and lack of visibility and availability of services.⁶⁷

CASE STUDY 7: USING TASK SHIFTING TO EXPAND THE REACH OF EAR AND HEARING CARE⁶⁸

World Wide Hearing (WWH) International, a global non-profit, trains local audio-technicians on-site to identify ear problems, test for hearing loss and correctly fit and program a hearing aid. This helps expand the reach of the organisation in providing hearing aid services. In Peru, for example, WWH trained 50 community hearing aid technicians who have subsequently been able to screen more than 1000 children per day through school screening programs. They have been able to reduce the cost of screening to less than US\$1 per child in schools. “In these screening programmes, audiologists are present to serve as supervisors and examine more complex cases. Similarly, in Jordan, WWH tested the “Hearing Express” model—an entrepreneurial, home-to-home distribution model that trains local women and uses innovative technology to screen, diagnose and fit hearing aids.

4.8 There is limited scope to optimise or relocate manufacturing to generate additional cost reductions in the price of hearing aids.

Bulk manufacturing of hearing aids in centralised production factories is the standard manufacturing model employed by global suppliers. Production follows standard methods for small electronics manufacturing. Components such as microphones and transducers are sourced, while the hearing aid manufacturer is adding a plastic case and the proprietary software and assembles the final product. The production facilities, which are fairly automated,⁶⁹ are set up across the globe - most commonly in Asia - to optimise sourcing of components, assembly and distribution of hearing aids in LMICs and HICs.

Establishing a localised approach to production and assembly can in some cases lead to lower cost, high-quality assistive products for users. Potential advantages of localised production include potential avoidance of import taxes, reducing shipping costs, producing a product that is optimal for the local environment, and creating employment locally. However, in the case of hearing aids, it is unlikely that localised manufacturing would be able to lower costs in this way, because:

- **LIMITED SCOPE TO REDUCE THE COST OF COMPONENTS.** Microphones and transducers are the most expensive components for hearing aids and there is limited buying power for hearing aid manufacturers to negotiate prices. The global supply of microphones and transducers is controlled by two suppliers, Knowles and Sonion. These companies provide technologies for a range of different applications and hearing aid manufacturers are relatively smaller clients of these companies compared to other large technology companies.
- **ASSEMBLY REQUIRES SKILLED LABOUR.** While most of the hearing aid process is automated, the final production step of encasing the technology within a plastic frame is manual and requires significant training in electronics.
- **HIGH UPFRONT COSTS.** Since hearing aids are small and sensitive hearing technology, production requires relatively high up-front investments in specialised equipment and production facilities to assemble the miniature electronics at high quality.

⁶⁷ Tess Bright et al., 'Reasons for Low Uptake of Referrals to Ear and Hearing Services for Children in Malawi', accessed 25 June 2019, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5736203/#pone.0188703.ref010>.

⁶⁸ World Wide Hearing, 'World Wide Hearing', World Wide Hearing, accessed 25 June 2019, <https://www.whhearing.org/>; Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

⁶⁹ Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

Local assembly of hearing aids has taken place in some countries such as Brazil, India, Botswana, Vietnam and the Philippines to attempt to reduce the burden of import duties on hearing aids. In such a model, manufacturers might be incentivised, if volumes are sufficient, to supply semi-knocked-down kits to local businesses that then assemble hearing aids.⁷⁰ Semi-knocked down kits usually require only soldering the transducer(s) onto the printed circuit board and closing the unit with small screws.

The assembly model has had limited success because cost reductions are small, manufacturers are wary of quality control of the final product, and manufacturers may have to disassemble existing stock of hearing aids to provide the broken-down kits.

Several suppliers of lower cost hearing aids—often based in Asia—have emerged and experts suggest that some companies are offering products of sufficient quality for global markets. While limited opportunities may exist to negotiate better prices of components, streamlining the production of a range of basic generation models may result in favourable manufacturing economics such as: fewer change-overs/down-time of manufacturing lines; more efficient planning; optimised logistics and a higher degree of standardisation in sourcing and production.

4.9. The advent of new technologies for hearing loss screening and diagnosis and hearing aid fitting may address service delivery capacity constraints and create opportunities to reach more people.

Since 2004, when WHO guidelines on hearing aids provision were last updated, there has been considerable innovation in the field of otoscopy and audiometry, decreasing the skill level required for these services and creating the potential to increase access.

4.9.1. Otoscopes

Traditional otoscopes are used for ear examinations and cost US\$100 to US\$4,000. Low cost otoscopes have been developed for use in LMICs including the Arlight costing around US\$10-15 and mobile-based otoscopes such as CellScope and Medtronic’s Ear Screening Kit (refer to Case Study 8). While these otoscopes do not have the same levels of magnification, have some functional limitations, and have had limited clinical validation to date,⁷¹ they are often preferred by NGOs since they are lightweight, affordable and easy to use.

CASE STUDY 8: SHRUTI – A MOBILE-PHONE BASED INNOVATIVE EAR CARE PROGRAMME⁷²

In July 2013, Medtronic launched Project “Shruti” in India to introduce lower cost otology services. With an ENT surgeon as the central point of care, the programme is operationalised through community health workers (CHWs) equipped with an “Ear Screening Kit”. This CE-marked kit, is priced at US\$1,120 and consists of: an otoscope, a digital image capturing and transmitting device (smartphone), a light source for the otoscope and a mobile data plan.

The “Ear Screening Kit” enables CHW to gather patient details, complaints and other information including an image of the outer ear. The smartphone application has a built-in algorithm for field triaging of ear diseases including infections, impacted wax, foreign body, etc. Patients that require treatment are referred to the hospitals within the Shruti network.

As of February 2017, CHWs have screened more than 270,000 people. Over 25% of the screened population needs some form of ear care, about 8% of those screened need a combination of medical and surgical intervention, and 3-5 % require hearing aids.

⁷⁰Bradley McPherson and Ron Brouillette, *Audiology in Developing Countries* (Nova Science Publishers, Inc. New York, 2008).




⁷¹Tess Bright and Danuk Pallawela, “Validated Smartphone-Based Apps for Ear and Hearing Assessments: A Review”, *JMIR Rehabilitation and Assistive Technologies* 3, no. 2 (23 December 2016), <https://doi.org/10.2196/rehab.6074>.

⁷²Medtronic, ‘Shruti’, accessed 10 August 2019, <https://www.medtronic.com/in-en/about/shruti.html>.

4.9.2. Audiometers

Pure-tone audiometry is the gold standard to identify people with hearing loss, but most audiometers that are currently in use are complex, require extensive training and experience that only audiologists have, and require a sound-proofed environment. Mobile audiometers such as those by SHOEBOX, HearX and KUDUWave address some of these critical challenges (Table 6). HearX and SHOEBOX are tablet-based audiometers, with specialised software and headphones. KUDUwave is a headset that is able to perform automated audiometry. These devices are clinically validated and have also undergone some field-testing.

TABLE 6: MOBILE AUDIOMETERS

PRODUCT NAME	SHOEBOX AUDIOMETRY ⁷³	KUDUWave	HearTest
			
Manufacturer	SHOEBOX Ltd. (Canada)	eMoyo (South Africa)	HearX Group (South Africa)
Description	iPad-enabled software screening and diagnostic software	Portable and boothless screening and diagnostic audiometer	Portable, Android mobile-enabled screening and diagnostic software
Audiogram Output	Yes	Yes	Yes
Included in upfront bundled costs	iPad with Software, calibrated Radioear headphones, cloud-based data management, warranty, annual calibration	Sound-booth equivalent noise blocking headset audiometer, consumable pieces, software, internal microphones, ear tips, 3-year warranty, digital calibration	Samsung phone with software, calibrated audiometric headphones, cloud-based data management, subscription-based software, 2-year warranty, annual calibration
Upgrade options	Bone oscillation, customized managed service, custom integration	Bone oscillation (Plus + Pro); Built-in tympanometer (Pro TMP)	Extended high-frequency audiometry, Advanced attenuation option, video-otoscope (hearScope) integration
Personnel Requirements	Standard – Minimal Training	Minimal Training Required	Minimal Training Required
Power	iPad charger	Requires connection to a PC/Laptop	Battery or phone charge, offline & online
Tele-audiology enabled	Yes	Yes	No

Product photos used with company permission.

Some of the advantages of these devices include:

- **LOWER SKILL REQUIREMENTS.** Automated audiometry capabilities allow lower-skilled workers to provide diagnostic services in uncomplicated cases. The training to effectively operate these devices can be between 1-3 days for nurses, primary healthcare workers or community health workers.

⁷³ At the end of 2018, Shoebox announced that they had entered into a strategic partnership with Sivantos, one of the Big 5 companies. Shoebox is an independently managed entity within Sivantos.

- **POTENTIAL FOR SELF-CALIBRATION.** Although annual calibration is not clinically required with the current generation of equipment, this has been set as an industry requirement and is often mandated by the government. These calibrations are usually performed by local distributors, but if none is available locally, audiologists are required to incur shipping costs to send the product to their closest distributor for re-calibration. Calibration can, therefore, be a costly service and disruptive to service delivery. However, SHOEBOX re-calibration services are included in the annual subscription fee. HearX is currently setting up remote calibration facilities for its devices and also offer swap-out options to ensure minimal downtime for customers. KUDUwave includes digital calibration verification where the device completes its own calibration electro-acoustically and the manufacturer eMoyo only requires regular calibration every three years.
- **LOWER INFRASTRUCTURE REQUIREMENTS.** Current screening and diagnostic protocols also require the use of a sound booth among other related infrastructure requirements. Not only are these sound booths expensive and difficult to build, but they are not portable. This limits the ability to conduct outreach services. Mobile audiometers, because they use noise-cancelling headphones and algorithms that address noise interference in the environment, can be used in a quiet setting.
- **LOWER COSTS.** Lower device costs, lower skill and training requirements, and reduced time per screening support overall reduced costs per screening.

Many of these companies are already working with governments or humanitarian programs. For example, KUDUWave works with the government of South Africa for their school screening program and has been used by healthcare workers for hearing screening within other public health programs. Uptake of these devices is limited by lack of field evidence to support use at scale and across a variety of different contexts.

4.9.3. Tele-audiology

The advent of new technology has also enabled the use of tele-audiology (refer to Case Study 9). This allows audiologists to diagnose, fit and provide rehabilitation services to people remotely, allowing for increased reach of services and stronger referral networks, as well as training and mentorship for hearing aid technicians. Recent reviews of tele-audiology have noted that there is an increasing role for tele-audiology and that it is feasible and likely effective, but may be limited by a lack of evidence protocols and models of service delivery, perceptions of tele-audiology by end users and clinicians, and resource constraints.⁷⁴

CASE STUDY 9: USE OF TELE-AUDIOLOGY IN HEARING AID FITTING⁷⁵

The Rotary Hearing Center established a model for hearing service delivery using tele-audiology to complement face-to-face care. In this model, two audio-technicians work with people at the San Felipe clinic while audiologists observe and support from Arizona State University (ASU). The tele-audiology setup utilises the following items:⁷⁶

- Desktop computer
- GSI AMTAS audiometer
- NOAH Hearing Aid Fitting Software
- Interacoustics Viot Video Otoscope
- Interacoustics Titan Tympanometer

Local technicians are trained to do otoscopy using a video otoscope and tympanometry and have also started doing audiometry. Audiologists can remotely see all the results, confirm the diagnosis post facto and are also responsible for complex cases. In addition to improving quality of care, this model allows training up of the technicians. Over time, the technicians have demonstrated increasing proficiency and ability to fit hearing aids in uncomplicated cases, and the ASU audiologists have shifted to reviewing their work and only dialling in for complex cases.

⁷⁴Tao, K.F.M. et al. 'Teleaudiology Services for Rehabilitation With Hearing Aids in Adults: A Systematic Review,' (July 2018), JSLHR Vol. 61:1831-1849.

⁷⁵Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

⁷⁶Coalition for Global Hearing Health, 'CGHH Conference', accessed 20 June 2019, https://cghh.usu.edu/schedule/Grid_Details.cfm?pg=none&aid=9815&ty=grid&des=reg.

4.9.4. Earmould Innovations

Novel methods have allowed earmoulds to be developed on the spot within two hours and this can have an impact on hearing aid fitting and usage.

- **MOBILE EARMOULD LAB:** EARS Inc. set up a mobile earmould lab using proprietary earmould equipment that allows them to produce hundreds of earmoulds in a day using local material, reducing the wait times that could be upwards of one year from a centralised earmould lab to same day. This enabled children to wear hearing aids from the day that they were prescribed and therefore increased hearing aid uptake.⁷⁷
- **3D PRINTING OF EARMOULDS:** 3D printing techniques can be incorporated to create custom earmoulds. For most 3D printing technology, an ear impression must still be taken using silicone or methyl methacrylate. The impression is then scanned into a 3D design computer program, where the 3D image is refined and sent to a 3D printer for printing. The material used for printing varies based on the type of printer. Digital ear scanning technologies that use lasers and membranes to scan the inside of the ear have recently come to market, such as the Lantos Technologies 3D scanner or the Otometrics Otoscan. As the price of 3D scanners and printers comes down, 3D printing of ear moulds may become a viable option to produce a higher number of earmoulds at the point of care than through traditional methods.

4.9.5. Rechargeable Batteries

While some experts and innovators have advocated and investigated the use of rechargeable batteries, including solar, in certain instances, innovation in this space has been limited but is expected to grow. Currently, the incremental benefits of rechargeable batteries do not outweigh the costs as users may buy two sets of rechargeable batteries so that they can use one while recharging the other. Use of internal batteries that can be charged via USB has also been investigated, similar to how many other electronic devices are charged. The product may not be used when charging. There are concerns that the uneven electrical discharge from some rechargeable hearing aids can damage the signal processors in hearing aids and can result in sub-optimal sound quality. Companies, such as Solar Ear, have developed a solar charging dock on which the entire hearing aid can be placed.

4.10. Innovative models of hearing aids have the potential to facilitate greater access to hearing aids in LMICs.

Although most of the innovation in hearing aids at present is driven by Big 5 investment in high-end product, some of the latest innovations in hearing aid technologies may present opportunities to improve the availability of hearing aids in LMICs.

4.10.1. OTC (Over the Counter) hearing aid regulations in the United States

In 2017, the US Government passed the OTC Hearing Aid Act that required the FDA to create regulations on a new class of OTC devices for users with mild and moderate hearing loss with the goal of improving accessibility. As the regulations are expected to be released and implemented in 2020, it is difficult to ascertain the exact products that will be covered and the impact that this regulation will have on the market.

Discussions with experts⁷⁸ suggest that OTC regulations could have a variety of benefits:⁷⁹

- **INCREASED COMPETITION.** OTC hearing aids would increase competition by bringing in new players among established technology companies such as Apple, Samsung, and Bose, all of whom are expected to participate.

⁷⁷ Clinton Health Access Initiative, CHAI Expert Interview (refer to Appendix A).

⁷⁸ Clinton Health Access Initiative.

⁷⁹ Dr. Frank Lin, 'Where We Are and Where We're Headed: The Importance of Over-the-Counter Hearing Aids to the Future of Hearing Health Care', *Hearing Loss Magazine*, n.d.

- **AFFORDABILITY.** Increased competition could put downward pressure on price and disrupt the current bundled pricing model. Products are expected to retail for US\$500/pair, improving affordability and potentially putting pressure on the prices of other types of hearing aids. The direct purchase price of OTC hearing aids is expected to improve price transparency by informing customers on device costs unbundled from services.
- **ACCESSIBILITY.** OTC model will likely reduce the number of visits to the clinic and might attract new users.
- **QUALITY STANDARDS.** OTC hearing aids are expected to meet the performance criteria set by the FDA, and thus, there would be an assurance that users would be able to access a basic level of hearing technology through direct purchase.

Potential challenges associated with the advent of OTC hearing aids could include users self-classifying as mild to moderate loss and eschewing professional diagnosis and service. Additionally, these devices may still be out of reach for many based on pricing levels.

4.10.2. Self-fitting hearing aid models

In 2018, the FDA granted an application for the first Self-fitting Hearing Aid (SFHA) by Bose, which is yet to come to market.⁸⁰ According to the FDA, an SFHA is a wearable sound-amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software that allows users to program their hearing aids through a smartphone.⁸¹ Approval was granted because Bose submitted studies demonstrating that their SFHAs can provide similar sound amplification performance and experience to users as traditional hearing aids provided by a professional.⁸² These devices are classified as a Class II medical device by the FDA and are targeted towards users over the age of 18 with mild to moderate hearing impairment.⁸³ These devices are currently considered to be separate from the OTC hearing aid devices classified above as regulations on OTC hearing aids are not yet established. Other SFHAs available in the market include devices that have been designated as hearing aids or personal sound amplification products, dependent on country regulations, from Sound World Solutions and NuHeara. While SFHAs have not been extensively used in LMICs, demonstration projects utilised Sound World Solutions' devices have shown that there is potential to use SFHAs to simplify provision. Low-skilled healthcare personnel can be more easily trained to fit self-fitting hearing aids as they allow for the automation of more complex tasks in the assessment and fitting process, reducing training requirements and expertise level.

4.10.3. Pre-programmable hearing aids

Pre-programmable hearing aids are based on the premise that most hearing aid users within a population can be served using a few, select hearing aid models with pre-set amplification protocols. Rather than generating a custom fit for each user, the pre-set protocols would mimic common “shapes” of hearing loss audiograms, and then volume could be adjusted up or down by the user or a low-skilled provider. The supplier could preload a hearing aid with the present shapes and a hearing professional could select a pre-set shape in response to the audiogram. Experts suggest that there can be a strong benefit to these hearing aids in LMICs. While there has been limited research on which present audiological profiles would best serve specific populations, there has been growing interest within the hearing health community to investigate the technical and operational potential for these types of hearing aids. Research would be required on the shape of audiological profiles in the population, as well as operational experience with using different models of pre-programmable hearing aids to determine if there is a significant benefit.

⁸⁰FDA, 'Device Classification under Section 513(f)(2)(de Novo)', accessed 26 June 2019, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN180026>.

⁸¹Hearing Review, 'Self-Fitting Hearing Aid', Hearing Review, accessed 26 June 2019, <http://www.hearingreview.com/2018/10/new-self-fitting-hearing-aid-class-special-controls-described-fda-letter/>.

⁸²Gitte Keidser and Elizabeth Convery, 'Outcomes With a Self-Fitting Hearing Aid', *Trends in Hearing* 22 (1 May 2018), <https://doi.org/10.1177/2331216518768958>.

⁸³Geoffrey Cooling, 'Meet The New Bose Hearing Aid, Quite Like The Old Bose Hearing Aid', *Hearing Aid Know*, 15 March 2019, <https://www.hearingaidknow.com/meet-the-bose-hearing-aid>.

5. Market Challenges

The market landscape identified a number of demand and supply dynamics that have challenged the development of a low cost, high quality, high volume market, which are characterised below.

5.1. Demand	
Stigma & Awareness	<p>Stigma associated with against hearing loss and the use of hearing aids combined with a lack of awareness around the need for and importance of ear and hearing care services, including hearing aids, among policymakers, service providers, and end users limits uptake.</p> <ul style="list-style-type: none"> • POLICYMAKERS: Policymakers lack awareness and data on the need, importance, and impact of hearing aids and the prevalence of hearing loss. This negatively affects prioritisation in policy, programmatic, personnel, training, and financing decisions. Few countries have adopted national strategies around EHC. Where strategies have been adopted, implementation is very limited. • PROVIDERS: Health providers, teachers, elder care providers, parents and others who would be well-equipped to identify hearing loss at an early stage are not informed about the potential signs of hearing loss, the need to have it assessed, and where to refer or how to potentially remedied with a hearing aid. Children with hearing loss are incorrectly characterised as having a learning disability and do not get access to the services they need. • USERS: Users may not recognise the signs of hearing loss and may not be aware that there is a device that can correct hearing loss. They may also fear stigma if they wear a hearing aid, either preventing them from seeking services or causing them to discontinue wearing their hearing aid. • PUBLIC: The public can stigmatise a person for using a hearing aid, preventing or limiting use. Low awareness or stigma may also contribute to why individuals fail to recognise signs of hearing loss. <p>Compounding the above is limited available evidence on social attitudes and stigma around deafness, hearing loss, and use of hearing aid to support proper design and delivery of awareness campaigns, and services.</p>
Political Will	<p>Government involvement is low due to competing priorities.</p> <p>Hearing services straddle health, education, and social welfare agencies that address disability, and are rarely a priority for any of these, due to limited budgets, relatively low awareness of hearing loss, and advocacy towards other issues. Low prioritisation from governments results in limited to no financing for the purchase and provision of hearing aids, or in some cases fragmented financing across different ministries, with lack of coordination.</p>
Financing	<p>There is a lack of public, private and donor financing for the purchase of appropriate hearing aids.</p> <ul style="list-style-type: none"> • PUBLIC SECTOR: Governments lack policies or insurance schemes that allocate funds for hearing aid procurement and provision. When funds are available, they are insufficient. Poor availability of funds also leads to providing hearing aids in a suboptimal manner, such as only providing one hearing aid per user, or providing them at events without appropriate fitting and follow up support. • PRIVATE SECTOR: The private sector in LMIC has not been geared towards low-income clients, so sales are limited to wealthier, urbanised populations. For many people who need a hearing aid, even lower cost hearing aids are priced above the ability to pay. As a result, people procure items that are not technically hearing aids, such as devices that simply amplify surrounding sounds without any fitting but are not appropriate for those with disabling hearing loss. • DONOR: No large donor financing is available for the purchase of appropriate hearing aids. Main donor funders are CSR initiatives of Big 5.

Global Policy	<p>Current guidelines for service delivery and product selection are outdated or inadequate.</p> <ul style="list-style-type: none"> • SERVICE DELIVERY: The 2004 <i>WHO Guidelines for Hearing Aids and Services for Developing Countries</i> are considered outdated and do not incorporate the use of latest technology for screening and diagnostic services. The guidelines also do not provide adequate information on task-shifting protocols to reduce the need for audiologists in LMICs. • PRODUCT SELECTION: The 2017 <i>WHO Preferred Product Profile (PPP)</i> provides clarity on model selection and specifications for basic, quality hearing aids for LMICs but does not define a limited set of hearing aid specifications that would be able to serve the majority of clients, leading to procurers buying a proliferation of products, complicating procurement and provision. Furthermore, innovative products that can simplify provision in the long run are not addressed by the PPP and thus there is a need for additional evidence and guidance.
Provision	<p>Service provision capacity is constrained and fragmented.</p> <p>Existing guidelines propose a service delivery model that requires highly skilled providers and significant clinical infrastructure, which therefore makes it difficult to scale.</p> <p>There is little investment by governments to set up hearing aid provision systems and train providers, and donors, philanthropy and CSR have not filled this gap. Poor coordination between different ministries and NGOs along with insufficient investment leads to fragmented, small-scale provision programs that do not reach most users and fail to provide support over time. The quality of non-profit provision varies widely with limited coordination with the government. Provision takes place through one-off events where hearing aids are distributed with limited long-term support and aftercare.</p> <p>Audiologists are scarce and often concentrated in a few urban areas or in specialised hospitals, and technician-level support cadres are often not defined or effectively deployed. Lack of adequate referral networks prevents users from receiving services needed in the cascade at appropriate points of care.</p>

5.2. Supply

Appropriate Design	<p>Hearing aids with basic features are a good starting point for LMIC provision.</p> <p>The Big 5 release new hearing aids on a 3-year cycle. This rapid pace of innovation has resulted in products with advanced features that may not be required for all users. However, older models with basic features have excellent sound quality and signal processing. If there is sufficient demand for these products, they can be profitable at much lower prices as R&D costs have already been recouped. Opportunities may exist to transfer technology of older generation models to manufacturers who would be willing to supply them in LMICs.</p> <p>The Big 5 release new hearing aids on a 3-year cycle. This rapid pace of innovation has resulted in products with advanced features that may not be required for all users. However, older models with basic features have excellent sound quality and signal processing. If there is sufficient demand for these products, they can be profitable at much lower prices as R&D costs have already been recouped. Opportunities may exist to transfer technology of older generation models to manufacturers who would be willing to supply them in LMICs.</p> <p>Innovations in self-fitting technology may present the opportunity to expand the reach of hearing aids as new models and software become available, but this will need to be complemented by operational research in LMIC contexts to understand user experience and effectiveness of the new products, and to develop appropriate service delivery models around the products.</p>
Production Economics	<p>Cost of hearing aid production is high, so even though price reduction can be achieved through volume-based negotiations, the final purchase price may still be rather high to the end-user.</p> <p>Current manufacturers have optimised their production processes to reduce costs to the extent possible. While there are no expected constraints on the production capacity of components given that component manufacturers serve other markets that are much larger than hearing aid markets, no pathway was identified to reduce component costs further.</p>

Competitive Landscape	<p>The Big 5 dominate the industry, with limited opportunity for lower-cost entrants to break through, even in highly underserved markets in LMIC.</p> <p>The Big 5 have created market entry barriers to cement their position in their industry. At the same time, their primary focus is geared towards premium products, indicating that there may be opportunities at the lower end of the spectrum. The Big 5's participation in public tenders, which demand high volumes for lower cost, quality products demonstrates that with sufficient volumes, even low margin products make a sufficient business case for major players.</p>
Cost-Efficient Supply Chains	<p>The sales model adds mark-ups along the supply chain, increasing cost to the buyer.</p> <p>In the licensed provider model within the private sector, the bundled pricing model obscures the levels of mark-ups for both products and services in the final price to the consumer.</p> <p>Most hearing aid manufacturers do not respond directly to government tenders in LMICs and therefore their products are provided by local distributors who add an additional margin when responding to tenders. It is not known if the margins added are commensurate with the value provided by the local distributor. Furthermore, import duties and taxes in some cases can also add additional cost for the buyer.</p>

5.3. Enablers

Quality	<p>Lack of an objective quality standard means that procurers and providers do not have a way to differentiate quality from non-quality products.</p> <ul style="list-style-type: none"> • DEMAND: Where countries have funding, they often select low quality, cheaper products that do not meet the needs of users. Quality standards and product specifications for what constitutes appropriate product and provision are not in place. When a government puts out a tender for hearing aids, often the only information they have to differentiate products is price. • SUPPLY: The existing quality regulation mechanisms, including FDA and CE mark, are not able to fully differentiate quality products and no global quality standard for testing exists.
Procurement	<p>Low funding and inadequate procurement practices lead to lower-quality and more expensive products purchased.</p> <ul style="list-style-type: none"> • NGO SECTOR: NGOs do not have sufficient funds to procure hearing aids and often rely on support from CSR initiatives and in-kind donations that may not lead to the optimal product being available for provision. • PUBLIC SECTOR: Poor availability of funds in the public sector limits the ability to procure appropriate, high-quality hearing aids to meet the current need. Where a public payer does exist in LMICs, funding is fragmented across ministries or difficult to access. Even when procuring products, some governments buy across an overly wide range of specifications or tender without rationalising specification assortments.
Market Visibility	<p>There is limited visibility on the potential and current market in LMIC.</p> <ul style="list-style-type: none"> • BUYERS: Lack of understanding of available and quality suppliers and their product offerings limits purchasers' ability to make informed choices when navigating a market of suppliers with a vast product mix. The lack of clarity of specifications and quality standards leads to confusion about which hearing aids to procure. • SUPPLIERS: Lack of demand information, such as visibility on government tenders and capacity to respond to government tenders that do exist, limits market entry options into LMIC markets. Lack of presence in LMIC markets, combined with a distributor-focused model, prevents suppliers from developing a stronger understanding of LMIC demand.

CHAPTER 2:

STRATEGIC APPROACH TO MARKET SHAPING

6. Strategic Approach to Market Shaping

Developing a market for hearing aids in LMICs will require affordability and availability of optimal hearing aids and services. Products and services can be defined as “optimal” if they meet a target/preferred product profile, meet the needs of the end user and are of suitable quality (i.e., compliant with high engineering and clinical standards). To achieve this, we propose five strategic objectives (SO) that can strengthen the market in both the near and longer-term:

- **SO#1:** Strengthen global policy guidance around service delivery standards, product selection and product quality;
- **SO#2:** Support LMIC governments to strengthen hearing aid provision including demand generation and investing in service delivery capacity, government purchasing and procurement support;
- **SO#3:** Engage the private sector to expand delivery of affordable, quality hearing aids and related services;
- **SO#4:** Work with suppliers to enter LMIC markets with affordable, quality hearing aids;
- **SO#5:** Spur innovation to support simplified provision models and introduction of optimal products.

A healthy market, defined as sustainable where demand meets supply, requires consensus around service delivery norms and product selection (SO #1). This consensus would serve as the foundation to build service delivery infrastructure via the public and private sector and rationalise procurement mechanisms (SO #2&3). More predictable and growing demand will enable economies of scale and support market shaping interventions proposed in SO #4 to support suppliers and distributors entering LMIC markets. There are game-changing technologies that can help increase coverage emerging and would benefit from investments now (SO #5).

STRATEGIC OBJECTIVE 1: Strengthen global policy guidance around service delivery, product selection and product quality

<p>Barriers addressed</p>	<p>Service Delivery</p> <ul style="list-style-type: none"> Global service delivery guidelines are considered outdated and define a model that requires significant technical expertise, equipment, and infrastructure, limiting scalability. Clarity is needed in terms of: use of new audiology technologies; the scope of practice for different levels of providers; mechanisms for ongoing support related to batteries, rehabilitation and re-fitting; and the range of hearing aids that should be offered at different levels. <p>Product Selection</p> <ul style="list-style-type: none"> WHO PPP lacks specificity to clearly define a limited set of optimal products. Global standards do not allow for differentiation of quality from non-quality products.
<p>Rationale</p>	<p>Service Delivery</p> <ul style="list-style-type: none"> A simplified model has the potential to standardise provision requirements at multiple levels and to resolve questions around the appropriate scope of practice for different hearing aid providers. <p>Product Selection</p> <ul style="list-style-type: none"> Lack of clear and comprehensive product quality standards prevents procurers from identifying supplies of affordable, quality products, increasing reliance on known quality suppliers that charge unaffordable prices and/or increasing procurement of lower cost products that are of low quality. Effective quality protocols are being utilised by national hearing procurement programs that could provide a template for developing standards at a global level.
<p>Proposed Activities</p>	<ul style="list-style-type: none"> Develop and disseminate a “Preferred Service Delivery Profile” that is evidence-based, simplified, and task-shifted for provision of non-complex hearing aid services, using a consensus-based process, ideally driven by the WHO. The profile should include considerations of the role of new types of audiometric equipment, the required range of hearing aids, appropriate standards and scope of practice for hearing aid technicians. Create selection guidance for procurement of optimal hearing aids by: <ul style="list-style-type: none"> Providing additional detailed guidance to the current PPP and APS; Incorporating global quality standards; Defining the limited set of products required and generating a list of quality basic products with associated price. Develop training modules for the simplified hearing aid service delivery model. Establish clear global quality protocols and processes that allow manufacturers to achieve accreditation.
<p>Target Outputs</p>	<ul style="list-style-type: none"> Guidelines on the use of technology and task-shifting approach in hearing aid service delivery in LMICs Quality standards for hearing aids in low-resource settings
<p>Long-term Outcome</p>	<ul style="list-style-type: none"> Broad adoption of simplified service delivery models that are cheaper and more effective in addressing the unmet need with optimal hearing aids Clarity on quality hearing aids appropriate for procurement, which enhances market transparency between buyers, providers and suppliers

STRATEGIC OBJECTIVE 2: Support LMIC governments to strengthen hearing aid provision including demand generation and investing in service delivery capacity, government purchasing and procurement support

<p>Barriers addressed</p>	<p>Awareness and Political Will</p> <ul style="list-style-type: none"> • Low interest to improve EHC, especially when positioned among competing priorities, leading to low levels of global and domestic financing. <p>Service Delivery Infrastructure</p> <ul style="list-style-type: none"> • Provision of hearing aids should be within the broader context of the provision of EHC, which is able to both detect hearing loss and resolve many of the medical causes of hearing loss. • Much of the service delivery of hearing aids is taking place outside the government framework of healthcare provision. This results in inconsistent service delivery protocols, challenges in providing quality and reduced coverage. <p>Procurement</p> <ul style="list-style-type: none"> • Low levels of government procurement of hearing aids. • Existing government practices do not result in the procurement of optimal or sufficient products. • LMICs do not currently have access to the lowest priced products because of low procurement volumes.
<p>Rationale</p>	<p>Awareness and Political Will</p> <ul style="list-style-type: none"> • Although many governments do not prioritise hearing loss, some have taken first steps to institute EHC, and appropriately channelled resources could accelerate their efforts. • Regional advocacy initiatives are underway that provide a starting point to generate increased political will. <p>Service Delivery Infrastructure</p> <ul style="list-style-type: none"> • EHC programs should be at least implemented at the Primary Health Care Level within the existing government framework of healthcare provision, and thus require government support. • By demonstrating the feasibility and benefits of effective EHC, further investment from external donors can be generated. <p>Procurement</p> <ul style="list-style-type: none"> • Public procurement of hearing aids increases coverage, provides an affordable or free option for users, and enables volume-based negotiations on a concise set of basic models, generating the lowest cost quality options.
<p>Proposed Activities</p>	<ul style="list-style-type: none"> • Incorporate demand generation into national plans, i.e. development and dissemination of national awareness raising campaigns on hearing loss and hearing aids and support of associations representing hard of hearing persons. • Provide investment or technical support to countries with the political will to implement programs in alignment with global policies and standards once developed. • Develop investment case and conduct budget impact analysis to support the incorporation of EHC with hearing aid provision into national UHC or health insurance/reimbursement models. • Strengthen country procurement of hearing aids by: <ul style="list-style-type: none"> ▪ Identifying existing procurement budgets and challenges; ▪ Strengthening public procurement via the adoption of specifications and standards; ▪ Improving participation of quality companies in public tenders. • Invest in regional advocacy networks to encourage the development of EHC national plans, develop and support awareness raising and anti-stigma campaigns, amplify current successes and encourage implementation of adopted EHC national plans.

Target Outputs	<ul style="list-style-type: none"> • Development and implementation of EHC national programs that include the provision of hearing aids • Tiered service delivery models developed and implemented in a country, with examples of best practice and cost-effective approaches • Increased procurement of quality hearing aids in the public sector at lower cost • Increased donor interest and engagement with EHC stakeholders to build national EHC programs
Long-term Outcome	<ul style="list-style-type: none"> • Routine public procurement and provision of quality hearing aids and services, as part of in-country EHC programs that are integrated with the health systems, deliver appropriate care at appropriate levels and are sustainable.

STRATEGIC OBJECTIVE 3: Engage the private sector to expand delivery of affordable, quality hearing aids and related services

Barriers addressed	<ul style="list-style-type: none"> • Private sector currently focuses primarily on high-income segments and geographies and has limited reach compared to its potential. • Few LMIC governments are productively engaging with the private sector to expand access, despite the potential.
Rationale	<ul style="list-style-type: none"> • Private sector delivery and its capacity to reach customers at a lower price vary by country and may not be well understood. There is also a need to understand the barriers to a low cost business model. • Public-private partnership may be a strategy to rapidly increase coverage without requiring substantial additional investment in government service provision, but it requires rational structuring in order to ensure that payments and contract structures are aligned with the targeted outcomes. • Some existing business models show promise for reaching new market segments, but require additional investment to scale.
Proposed Activities	<ul style="list-style-type: none"> • Support private sector to innovate new sales and distribution models in LMICs that reach lower-income market segments to reduce government pressure to provide hearing aids to everyone by investing in promising models and generating evidence of feasibility, increased access and profitability. • Address in-country barriers to private companies providing an affordable, quality product and service such as information gaps, registration processes, and import taxes.
Target Outputs	<ul style="list-style-type: none"> • Cost-effective public-private partnerships for hearing aid service delivery developed • Additional access points through private sector engagement
Long-term Outcome	<ul style="list-style-type: none"> • Robust private sector providing quality products and service at low cost

STRATEGIC OBJECTIVE 4: Work with suppliers to enter LMIC markets with affordable, quality hearing aids

Barriers addressed	<ul style="list-style-type: none"> • Current market are dominated by 5 manufacturers that focus on high-value markets and have limited commercial interest in LMICs • Lack of market transparency for buyers, who do not have visibility on appropriate products and prices, and for sellers, who do not understand LMIC demand • The private sector to date has not effectively served low-income users, and high upfront costs are a major barrier to purchasing quality hearing aids
Rationale	<ul style="list-style-type: none"> • Big 5 manufacturers are limited by the lack of market visibility and have a low understanding of LMIC context and potential volumes • A well-brokered negotiation may require increasing transparency of volumes across countries, based on countries' existing procurement budgets, given that current procurement volumes are too low for any one country to have a strong buying power • Lower cost manufacturers with quality products are unable to leverage economies of scale
Proposed Activities	<ul style="list-style-type: none"> • Increase market visibility for manufacturers and improve transparency on product availability and pricing for procurers. • Explore the potential for volume-based negotiations with quality hearing aid suppliers to ensure the availability of affordable, quality hearing aids that match global product selection guidelines, by identifying consolidated volumes via financial and non-financial supplier incentives. • Engage donors to invest in catalytic procurement to incentivise and optimise improved procurement conditions for countries.
Target Outputs	<ul style="list-style-type: none"> • Strategic demand forecast informs the global market on hearing aids • Improved pricing and availability of quality basic hearing aids for procurement in LMIC
Long-term Outcome	<ul style="list-style-type: none"> • High-quality hearing aids available at low cost for purchase in LMICs

STRATEGIC OBJECTIVE 5: Spur innovation to support simplified provision models and introduction of optimal products

Barriers addressed	<ul style="list-style-type: none"> • Available hearing aids in the market are complex to fit, requiring technician intervention over multiple visits, creating a significant burden on provision systems and users • Innovative technologies for screening and diagnosis currently have limited functionality and reach • Most of the current private sector R&D budget is invested towards high-end products, not products that would better serve LMIC users
Rationale	<ul style="list-style-type: none"> • Early evidence related to innovative technologies for screening, diagnosis, and fitting demonstrates a reduction in barriers related to personnel, infrastructure, costs and reach of services • Future generation products have the potential to further simplify service delivery, empower users, and expand access • Current sales models lead to prohibitive costs for users paying out of pocket; therefore, innovation is required to identify sales models that reduce out of pocket costs

Proposed Activities	<ul style="list-style-type: none"> • Support research and operational evidence generation for innovative devices that can simplify service delivery, including but not limited to screening and diagnostic equipment, self-fitting hearing aids, and pre-programmable hearing aids. • Provide strategic and investment support to existing innovative screening and diagnostic equipment manufacturers to expand reach, increase volumes, and reduce prices. • Engage donors to invest in catalytic procurement to incentivise and optimise improved procurement conditions for countries (e.g. adoption of quality standards, consolidated purchasing, long-term purchase agreements).
Target Outputs	<ul style="list-style-type: none"> • New evidence around innovative provision, product, and sales models
Long-term Outcome	<ul style="list-style-type: none"> • New generation technology enables a wider reach of hearing aid service provision

7. Next Steps

This document was developed to support the identification of activities that will increase and sustain access to appropriate, affordable hearing aids. ATscale is currently developing a prioritisation process to inform which of the market shaping activities proposed above will be incorporated into the Partnership’s initial action and investment plan to guide activities and investment in the short-term. While that is underway, some of these proposed activities will be undertaken in the immediate term by the UK aid funded AT2030 programme in line with its aim to test what works to increase access to affordable AT.

As interventions are shown to be effective and learnings and outputs from initial investments emerge, they will support a longer-term sector-wide strategic plan. It is expected that different large-scale investments and financial instruments will be needed to achieve long-term outcomes. For example, system strengthening grants may be needed to support the integration into the health system, while match funding or co-investments may catalyse government procurement and investment. On the supply side, donor investment may be leveraged to de-risk private investment in cost-effective supply mechanisms.

ATscale welcomes feedback on the articulated approach and seeks collaboration with partners interested in aligning their activities with the proposed strategic approach to market shaping as outlined in this document.

APPENDICES

APPENDIX A: INDIVIDUALS INTERVIEWED OR CONSULTED

ORGANISATION	NAME
American Audiology Association	Dr Jackie Clark
Sonrisas que Escuchan	Dr Patricia Castellanos
Arizona State University	Dr Ingrid McBride
Brighton & Sussex University Hospital	Dr Mahmood Bhutta
Britain Nepal Otology Service	Dr Robin Youngs
CBM	Sally Harvest
	Dr Diego Santana
Ear Science Institute, Australia	Dr Rob Eikelboom
Independent Audiologist	Dr Aldo Calleja
John Hopkins University	Dr Frank Lin
LSHTM and CBM	Dr Andrew Smith
University of North Carolina	Dr Erika Gagnon
University of Arizona	Dr Ron Brouillette
University of Hong Kong	Dr Bradley McPherson
China Assistive Device and Technology Center	Li Xi
China Disabled People's Federation	Chi Jungchang
Myanmar Ministry of Health	Dr Win
East and Central Africa EHC Forum	Dr Isaac Macharia
Sound Hearing International	Dr Suneela Garg
Amplivox	Joy Monaghan
	Shaun Kelly

ORGANISATION	NAME
AMTAS	Dr Bob Margolis
Arclight	Dr William Williams
Grason-Stadler	Tony Lombardo
HearX Group	Dr De Wet Swanepoel
	Tersia de Kock
Interacoustics	Cammy Bahner
Jacoti	Jacques Kinsbergen
KUDUWave	Dr Dirk Koekemoer
Mimi	Philipp Skribanowitz
Otometrics	Tom Switalski
Shoebox MD	Natalie Mai
AcoSound	Barie Bai
ALPS India	Anup Narang
IMHear	Kiki Liang
Mark Su	Mark Su
NuHeara (OTC hearing aid manufacturer)	Russell Rogers
Oticon	Don Schum
	Peter Ladischensky
Retone	Mina Hsu
Solar Ear	Howard Weinstein
Soroya	Mark Su
Starkey Indonesia	Manfred Stoifl
Widex	Julie Dunphy
All Ears Cambodia	Dr Glyn Vaughan
EARS Inc.	Dr Peter Bartlett
	Dr Donna Carkeet
	David Pither

ORGANISATION	NAME
Global Foundation for Children with Hearing Loss	Paige Stringer
Himalayan Hearing	Lew Tuck
International Federation of Hard of Hearing People (IFHOH)	Ruth Warick
Ndlovu Group	Karin Joubert
SoundSeekers	Kavita Prasad
	Dr Bhavisha Parmar
World Wide Hearing	Audra Reyni
	Youla Pompilus-Touré
Costco	Paul Wesner
International Humanitarian Hearing Aid Purchasing Programme (IHHAPP)	Dr Debra Fried
	Dr Anita Stein-Meyers
	Dr James Saunders
	Mark Falk
UK National Health Service	Dr Adrian Davis
	Dr Ruth Thomsen
Amplifon	Tabatha Erck
Entheos	Laurel Gregory
Georgia Institute of Technology	Dr Saad Bhamla
Independent Consultant	Dr Thomas Powers
Independent Consultant	Joel Beilin
World Health Organization	Dr Shelly Chadha

The ATscale Forming Committee was consulted throughout the report development process. The ATscale Forming Committee is comprised of China Disabled Persons' Federation, Clinton Health Access Initiative, Global Disability Innovation Hub, Government of Kenya, International Disability Alliance, Norwegian Agency for Development Cooperation, Office of the UN Secretary-General's Special Envoy for Financing the Health Millennium Development Goals and for Malaria, UK Department for International Development, UNICEF, United States Agency for International Development, and the World Health Organization.

APPENDIX B: PROVISION OF EHC SERVICES ACROSS DIFFERENT HEALTHCARE LEVELS IN LMICS (BASED ON EXPERT INTERVIEWS)⁸⁴

LEVEL (PERSONNEL)	PREVENTION / AWARENESS	SCREENING / DETECTION	TREATMENT / REHABILITATION
Community (community health workers)	<ul style="list-style-type: none"> • Awareness generation 	<ul style="list-style-type: none"> • Simple screening for hearing loss 	
Primary health centres (nurses, clinical officers)	<ul style="list-style-type: none"> • Immunisation for diseases that cause hearing loss 	<ul style="list-style-type: none"> • Screening of newborns • Diagnosis of non-complex hearing loss for adults • Simple examination of the ear 	<ul style="list-style-type: none"> • Fitting of hearing aids for non-complex cases • Provision of aftercare • Treatment of common ear conditions
Secondary health centres and hospitals (medical officer, ENT clinical officer, hearing instrument specialist, speech therapist, audiologist)	<ul style="list-style-type: none"> • Antenatal care to minimise hearing loss related to maternal and neonatal causes 	<ul style="list-style-type: none"> • Diagnosis of hearing loss for children under the age of 5 and complex cases • Large-scale EHC outreach programs 	<ul style="list-style-type: none"> • Fitting of hearing aids for paediatrics and complex cases • Refitting if automated fitting unsuccessful • Earmould production • Basic ENT services (including basic surgery) • Speech and language rehabilitation
Tertiary hospitals (ENT surgeon, specialised audiologist, speech therapist)		<ul style="list-style-type: none"> • Diagnosis of hearing loss for children under the age of 5 and extremely complex cases 	<ul style="list-style-type: none"> • Complex ENT services and cochlear implants • Complex audiology services and speech and language rehabilitation

⁸⁴ Items in bold signify activities related to hearing aid delivery

APPENDIX C: HEARING AID FITTING PROCESS

SCREENING⁸⁵ involves identifying early signs of whether a person has hearing loss. In adults, it is usually through self-screening, as many are able to identify if there are suffering from hearing loss. This, however, is not always the case as stigma associated with hearing loss prevents many people from acknowledging that they have hearing loss. For children under the age of five, there are objective tests such as:

- **Otoacoustic Emissions** measures the sounds given off in the inner ear when responding to external sound waves (or emissions). The device consists of a small probe that creates sound waves in the patient's ear to measure if hair cells in the inner ear respond to the sound by vibrating. If there is no blockage in the middle or outer ear, then the cochlea (inner ear) may not be functioning properly. If the patient does not respond positively to the otoacoustic emissions test, then they are referred for Auditory Brainstem Response.
- **Auditory Brainstem Response** involves the use of non-invasive electrodes that are placed on the patient's head to test whether the brain pathways are working in response to the sounds heard via earphones.

DIAGNOSIS for hearing loss can be complicated as there can be multiple causes for hearing loss. Therefore, diagnosis requires multiple steps to identify the appropriate treatment for the person with hearing loss:

- **Otoscopy:** a special torch with a lens is used to examine the ear to see whether there are any infections, lacerations, or foreign objects.⁸⁶
- **Tympanometry** measures the air pressure in the middle-ear to identify whether the sound is travelling properly through it. While Tympanometry is not always conducted, it should be considered an important step in the diagnostic process to document or rule out the presence of fluid in the middle ear, a middle ear infection, or perforations in the middle ear that could lead to hearing loss but require medical/surgical attention rather than hearing aids.^{87,88}
- **Pure tone audiometry** (also known as air conduction audiometry) yields an audiogram by testing the person's ability to hear tones of different pitches in each ear. A series of tones are played at varying frequencies and volumes, and the person indicates they have heard the tone by raising a hand or pressing a button.
- **Bone conduction audiometry** is an advanced step to further diagnose where the hearing loss has occurred. It uses a bone oscillator, placed behind the ears, that transmits sounds through bone vibration to the cochlea or inner ear, bypassing the middle and outer ear.⁸⁹ This test is helpful in determining if the hearing difficulty is due to a problem in the middle or outer ear. This test is not conducted regularly and only used in non-standard cases where diagnosis after pure-tone audiometry is not confirmed.

FITTING OF HEARING AIDS is the next step in the process. Based on the hearing loss severity, lifestyle and configuration, the audiologist prescribes a hearing aid that would best aid the person to hear well. There are three primary steps in fitting a hearing aid:

- **Creation of earmoulds** is often the most time-consuming step in the fitting process. In most places, earmould impressions are sent to a distant lab where a trained earmould technician develops it and in such instances, it can take up to a week for the user to be fitted with a hearing aid. Alternatively, there are novel fitting methods that have allowed earmoulds to be developed on the spot within 2 hours. Earmoulds are highly recommended in children, but in non-complex, adult cases, users can opt to use eardomes that are readily available.

⁸⁵American Speech Language Hearing Association, 'Hearing and Balance', American Speech-Language-Hearing Association, accessed 18 June 2019, <https://www.asha.org/public/hearing/>.

⁸⁶World Health Organization, *Guidelines on the Provision of Manual Wheelchairs in Less-Resourced Settings*, accessed 21 May 2019, <https://www.who.int/disabilities/publications/technology/wheelchairguidelines/en/>.

⁸⁷Brande Plotnick, 'What Is Tympanometry and How Is It Used?', *Healthy Hearing*, 19 August 2016, <https://www.healthyhearing.com/report/33583-What-is-tympanometry-and-how-is-it-used>.

⁸⁸World Health Organization, *Guidelines on the Provision of Manual Wheelchairs in Less-Resourced Settings*.

⁸⁹William Newton Hospital, 'Pure Tone Air & Bone Conduction Audiometry', accessed 1 April 2019, http://www.wnhcares.org/getpage.php?name=pure_tone.

- **Fitting of hearing aids** typically requires the use of PC-based software, but there are digital hearing aids that have screws (or trimmers) to fit them as well. Most companies have their own proprietary fitting software, but there is an open-source fitting software called NOAH⁹⁰ also available that can be used for most hearing aids available in the market.
- **Real Ear Measurements** are an optional step that is often undertaken to measure the sound pressure level in the hearing aid user's ear while the hearing aid is being worn. It measures how the volume and frequency response of the hearing aid affects the ear to identify the best hearing aid settings for the user. This step is not that common. For example, only 30% of audiologists in the US routinely perform this test.⁹¹

AURAL REHABILITATION AND AFTERCARE are critical for sustainable and effective rehabilitation of hearing loss via hearing aids:

- **Aural/Audiologic Rehabilitation.** The fitting of hearing aids is just one aspect of aural rehabilitation. Users should be counselled, trained and instructed on how to use, adjust and manage their hearing aid as well as on visual cues, conversational strategies, and environmental training. Counselling supports the acceptance of hearing loss, reduces product abandonment and improves satisfaction with hearing aids with an overall goal to reduce the negative effects of hearing loss on function, participation and quality of life. Rehabilitation plans should be developed in close partnership with the user and caregiver, if applicable.
 - In children, habilitative or rehabilitative services may vary based on current age, age of onset of the hearing loss, age at diagnosis, severity and type of the hearing loss and the age at which hearing aids were introduced. Habilitation and rehabilitation services for children may involve training in auditory perception, using visual cues, improving speech and developing language as well as care-giver training and counselling.
 - Aural rehabilitation plans may also be influenced by the communication mode the individual is using, which may include auditory-oral, sign language, total communication, cued speech, among others.
 - Aural rehabilitation may also include peer support groups with other individuals with hearing loss to build confidence, skill sets and social support.
- **Availability of batteries.** Hearing aids need to be used continuously and daily and therefore, they consume a lot of batteries. Batteries usually last between 3-20 days and therefore, it is vital that the user has ample stock or easy access to batteries.
- **Replacing earmoulds.** Earmoulds need to be regularly replaced as they are susceptible to wear and tear. In adults, earmoulds need to be replaced every 2-3 years.⁹² Because children and infants will outgrow their earmoulds quickly, they need to be replaced even faster. In older children, earmoulds need to be replaced every 6-12 months whereas they need to be replaced every 3-6 months for infants and younger children.
- **Readjustment and refitting.** Hearing loss is not a static condition and the user's hearing loss can change over time. Further, the user's comfort with the initial amplification can change over time. Thus, there need to be adequate follow-up services to allow users to get their hearing aid re-adjusted and re-fitted.
- **Hearing Aid Replacement.** Hearing aids usually need to be replaced every 3-5 years.

⁹⁰William Newton Hospital, 'Pure Tone Air & Bone Conduction Audiometry', accessed 1 April 2019, http://www.wnhcares.org/getpage.php?name=pure_tone.

⁹¹American Academy of Audiology, 'Real-Ear Measures', Audiology, 7 December 2017, <https://www.audiology.org/news/real-ear-measures>.

⁹²World Health Organization, 'Preferred Profile for Hearing-Aid Technology Suitable for Low- and Middle-Income Countries'.

APPENDIX D: SUMMARY OF WHO PREFERRED PROFILE FOR HEARING AID TECHNOLOGY SUITABLE FOR LMICS⁹³

	ESSENTIAL & DESIRABLE FEATURES	REQUIREMENT
Type of hearing aids	Hearing Aid Format	Behind-the-ear, with accompanying earmoulds, are preferred to body-worn or in-the-ear devices. They provide greater ease of fit, are less prone to malfunctioning and only the earmould needs to be replaced due to growth. Should be of appropriate size and shape for the user's ear and can be securely fitted behind the ear.
	Digital technology	Digital technology is standard in HICs and offers advantages over analogue sound processing. Allows greater flexibility in shaping the output signal to accommodate a wide range of hearing loss configurations and permits better use of residual hearing
	Performance requirements	The Profile provides the minimum electroacoustic performance requirement parameters for manufacturing hearing aids including: maximum output sound pressure level, maximum full-on acoustic gain, basic frequency response, total harmonic distortion at 70 dB SPL input, equivalent input noise at 1 kHz, battery current drain, battery life, and telecoil sensitivity.
	Prescription-based amplification	The fitting of hearing aids should follow an evidence-based prescription formula method that calculates the amount of amplification appropriate for the degree of hearing loss. Hearing threshold-based prescription procedures are preferred.
	Robust design	Hearing aids should be designed to withstand mild impact shocks, light rain showers and dust, and should provide at least five years' continuous usage.
Low Battery Alert	Compression	Some form of compression is required for wearer comfort and optimal intelligibility. Compression prevents loud amplification of higher-intensity sounds, preventing amplification-induced hearing loss, and allows higher amplification of soft noises.
	Feedback Management	Feedback management reduces the feedback loop (whistling) that occurs in hearing aids. It is often the result of loose or ill-fitting custom or non-custom earmoulds, which are common in LMICs. An added stable gain, the measure of additional amplification available when feedback management is activated, of 10 dB is recommended.
	On/off switch	A dedicated on–off switch or simple alternative means of powering down is required to facilitate user management of the hearing aid and battery conservation.
	Volume control	A user-directed control to manage volume amplification of the hearing aid is required. The volume control should have a range of at least 30dB and be clearly numbered
	Adaptive noise reduction	Adaptive noise reduction systems are a desirable feature and improve ease of listening in situations where significant background noise is present.
	Climate resistance	The potential for humidity-related damage can be reduced by “tropicalizing” hearing aids during manufacture, using spray- or dip-applied coatings of water-repellent materials. Liquid-repellent nano-coatings that can be applied to all hearing-aid components at the molecular level, resulting in high resistance to water (and oil and wax) are desirable. Use of water-repellent fabric for the microphone inlet port and of waterproof membranes for receivers and battery compartments is also desirable.
	Telecoil facility	A telecoil is a small copper coil that allows the hearing aid to detect an electromagnetic induction signal. It picks up the signal from a compatible telephone or other electromagnetic looped systems, enabling their use. This is a desirable feature.
	Direct Audio Input	Direct audio input allows a hearing aid to be attached to other audio equipment, such as a cellular or landline telephone, MP3 player, television, microphone or FM wireless receiver and is desirable.
Low-battery alert	An audio signal to alert the user to the need to replace a battery is a desirable feature.	

⁹³This is an adapted summary of the Profile. The full profile can be found through the following citation: WHO. Preferred profile for hearing-aid technology suitable for low- and middle-income countries. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. Online: <https://apps.who.int/iris/rest/bitstreams/1087770/retrieve>

ESSENTIAL & DESIRABLE FEATURES		REQUIREMENT
Other Characteristics	Affordability	As cost is a key barrier to uptake, hearing aids must be affordable. Efforts should be made to ensure that bulk purchases can be made at favourable prices from manufacturers and that government policy does not inflate consumer costs.
	Hearing-aid labelling	Each hearing aid should be permanently marked with the name of the manufacturer or distributor, the model name, serial number and year of manufacture and a “+” symbol to indicate location of positive terminal for battery.
	Hearing-aid packaging	Packaging, and the associated labelling, should be able to withstand exposure to excessive moisture and other impacts associated with the long distribution chain and ensure safe storage. Packaging should include technical specifications, contraindications and user guide with clear instructions in the national language.
	Power supply	Hearing aids should be designed to accept a battery type that is readily obtainable in the local region. Batteries should be clearly labelled and difficult for children to open. Rust resistant and/or rechargeable battery systems are desirable, but not essential.
	Appropriate earmoulds	Earmoulds should be compatible with the type of hearing aid, device gain/output, and user requirements. Various options may be satisfactory, including stock earmoulds (pre-configured), custom earmoulds, instant earmould products, and disposable standard flexible dome moulds. Custom earmoulds are desirable but often sustainable production facilities are not available and therefore non-custom dome earmoulds are preferred for LMICs.
	Hearing aid repair	Hearing aid housing should be able to be opened for maintenance purposes and to allow preset controls (if provided) to be adjusted without risk of damage to the housing or internal components. Facilities must be available for minor repairs such as device cleaning, replacement of earhooks, adjustments of battery contacts, changing of switches, and trimmer and volume controls.

The full WHO Preferred Profile can be accessed at: <https://apps.who.int/iris/rest/bitstreams/1087770/retrieve>



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