DEPARTMENT OF
Linguistics
Faculty of Medicine, Health and Human Sciences

MACQUARIE University

Final Report

Scalable hearing rehabilitation for low- and middle-income countries (SHRLMIC)

UNOPS/CFP-2020/001/ATSCALE

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This document is the final output from the above-mentioned project.

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Abbreviations and Acronyms

4FA: Four frequency average hearing threshold

CHW: Community Health Worker

dB: Decibel

dBHL: Decibel Hearing Level

ENT: Ear Nose and Throat

LMIC: Low- and middle-income country

NGO: Non-government organization

PI: Primary investigator

PTA: Pure tone audiometry

RMS: Root mean square

SNHL: Sensorineural hearing loss

VQ: Vector quantization

WHO: World Health Organization

Executive Summary

The majority of global hearing loss and the associated disability occurs in populations residing in low- and middle-income countries, yet these areas receive only a tiny proportion of the world production of hearing aids and other associated hearing rehabilitation.

This report details the results of two studies focused on adult populations in low- and middle-income countries. The first examined the hearing profiles and characteristics of clinical samples from 23 sites across 16 low- and middle-income countries. The second study was a laboratory and clinical trial of conventionally customized hearing aids and pre-programmable hearing aids.

The data from the first study suggests that clinical populations in low- and middle-income countries differ from those in high income regions in several important ways. Firstly, low- and middle-income clinical populations showed higher proportions of severe and profound hearing loss. Secondly, the common patterns of hearing loss (hearing profiles) were flatter than those reported in studies from high income regions. Lastly, there was a high proportion of conductive and mixed hearing losses in the sample.

The large unmet need for hearing rehabilitation in low- and middle-income regions necessitates the consideration of alternative service delivery models. The use of pre-programmed hearing devices, which can be delivered by minimally trained healthcare workers, is of particular interest as this service delivery model can potentially be used on a large scale to meet the enormous unmet need.

The laboratory and clinical studies described in this report suggest a number of strengths and weaknesses associated with the use of pre-programmable hearing aids.

In the laboratory, objective measures of outcome showed that pre-programmable hearing aids were able to meet an adequacy criterion for a limited number of clinical profiles. However, results were poorer and less consistent across profiles than with conventionally customizable hearing aids. Similarly, in the clinical trial, objective outcomes were poorer than would be expected with conventionally customizable hearing aids with only approximately 50% of participants obtaining an adequate fitting. Despite this, the subjective outcomes of pre-programmable hearing aids were on par with those of conventionally customized hearing aids.

In order to replicate the service delivery model of a large scale pre-programmable hearing aid program, limited training and instruction were provided to participants, and unsurprisingly, some difficulties with hearing aid management, such as difficulty manipulating the volume control or cleaning the device, were noted.

The unique clinical presentation of hearing loss in low- and middle-income countries and the outcomes of the laboratory and clinical trials described in this report will allow healthcare planners to provide a more targeted response to hearing loss in low- and middle-income countries.

Despite some objective limitations, both users and clinicians reported that pre-programmable hearing aids were efficacious. The report finds that they are a highly scalable method, capable of supporting hearing rehabilitation to a significant proportion of the hearing impaired population in low- and middle-income countries.

A summary of the report recommendations are provided below:

- Pre-programmable hearing aids should include settings/amplification profiles that reflect the (flatter) hearing profiles seen in low to middle income countries.
- In order to meet the needs of a wider range of the target population, a pre-programmable device with adequate power to fit up to a moderately severe hearing loss should be selected. Alternatively, both a lower power and a higher power device should be utilized.
- A user adjustable volume control with a range of +/- 10dB should be considered a required feature on any pre-programmable hearing device targeted at adults.
- Pre-programmable hearing aids require a straightforward and reliable method of amplification profile selection.
- Consideration should be given to alternative service delivery methods such as first-fit prescription-based algorithms which appear superior to pre-programable devices in terms of objective outcomes.
- Pre-programmable hearing aid programs should target individuals with mild to moderately severe hearing loss. Triage of those with more severe to profound hearing loss to a more conventional fitting, or to manual communication programs should be considered.
- Methods of identification and referral pathways for those with surgically or medically treatable ear disease should be considered.
- Validated methods of measuring hearing in uncontrolled acoustic environments should be utilized if valid hearing aid fittings are to be achieved.
- Significant planning and development must inform the design of user guides for use in large scale hearing aid delivery programs to ensure participants obtain sustained benefit from their devices.
- A structured awareness campaign should be undertaken to notify relevant stakeholders of the findings of this report.
- Data obtained in this project will be shared via an international data searching/sharing service Research Data Australia (https://researchdata.ands.org.au/).

Introduction

Hearing loss is a common sensory impairment, with over 466 million people suffering from a significant loss of hearing globally. Hearing loss has an immense personal and economic impact. Human happiness and satisfaction strongly correlate with social interaction,(1, 2) and to paraphrase Helen Keller, hearing loss cuts us off from people. Hearing loss therefore endangers social connectedness and thus wellbeing and has also been shown to impact on educational and vocational attainment. Current estimates suggest that unaddressed hearing loss costs almost USD 1 trillion dollars annually, due to impacts on quality of life and lost productivity.

It is estimated that 80% of people with hearing loss reside in low- and middle-income countries (LMICs), yet only a small fraction of global spending on hearing rehabilitation is allocated to these regions. A significant proportion of global hearing loss is preventable. Much of the remaining impairment can be treated surgically, or the impacts mitigated by hearing aids, cochlear implants, or manual communication methods.

Hearing aids are a very effective method of reducing the impact of hearing loss in those with mild to moderately-severe hearing loss. But there are few opportunities for individuals in LMICs to access hearing aids. Hearing aid provision in high-income countries often involves a highly trained audiologist or technician individually adjusting a hearing aid to meet a prescriptive target utilising costly equipment in a specialized clinical setting – all of which are scarce in LMICs. Additionally, hearing aids are costly compared to average incomes in LMICs. Advances such as self-testing on mobile devices, low-cost diagnostic equipment, automated processes for characterizing hearing loss and ear disease, telehealth, self-fitting, and low-cost pre-programmable hearing aids all offer the potential to increase access to hearing rehabilitation in LMICs.

The scalable hearing rehabilitation for low- and middle-income countries (SHRLMIC) project aims to characterize the hearing needs of people in LMIC settings and investigate the potential for pre-programmable hearing aids to provide a low-cost, scalable solution to untreated hearing loss in LMICs.

Project Overview

Background

This project aimed to address two key challenges to increasing access to hearing rehabilitation in low- and middle-income countries:

Challenge 1: the lack of data on the audiological profiles of LMIC populations limits the ability to predict and meet local hearing aid requirements.

Challenge 2: the lack of quantitative and qualitative data on the outcomes of providing people with affordable pre-programmed digital hearing aids hinders evaluation of the possible benefits and limitations of such approaches.

Objectives

The primary objectives were to:

1. Develop a large database of audiological profiles for the 16 LMICs/23 clinics and derive a set of representative audiological profiles using a statistical categorization procedure.

2. Compare representative audiological profiles across LMICs and regions with published data from high-income countries and to determine whether profiles in LMICs differ from those in high-income countries and if region-specific profiles are needed for pre-programmable hearing aid provision.

3. Understand the experience with digital pre-programmable hearing aids in comparison to conventionally customized digital hearing aids for users, technicians who fit the hearing aids, audiologists, and other health professionals.

4. Compare digital pre-programmable hearing aids in comparison to conventionally customized digital hearing aids in terms of quality, cost, comfort, effectiveness in supporting improvement for hearing loss, ease of fitting, and ease of use.

Table 1. Study phases

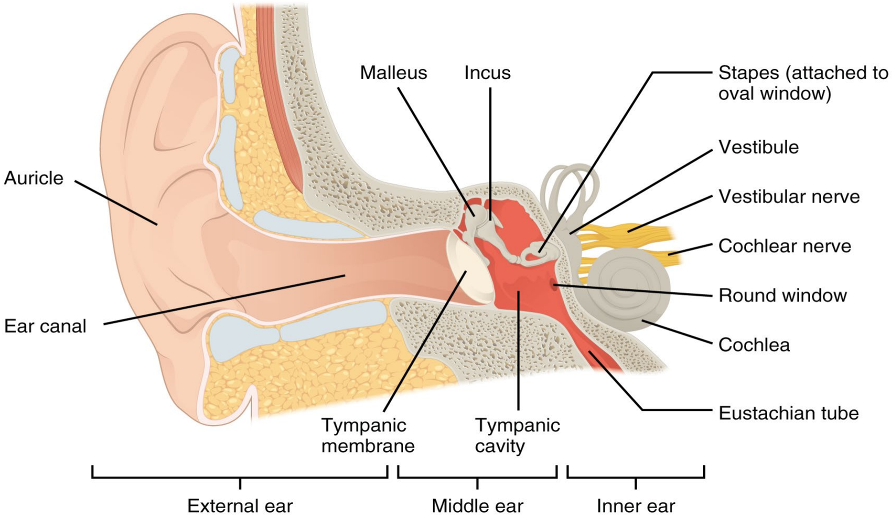
Phase	Components	Objectives
Phase1: Collect and analyze clinical data from 16 LMICs/23 clinics	Demographic description Machine learning algorithm	Compare hearing and rehabilitation characteristics of sample to high income countries Develop and compare audiological profiles in LMICs to high income profiles. Determine implications for pre-programmable device characteristics in LMICs.
Phase 2A: Technical comparison of pre-programmable and conventional hearing devices	Fit to real ear targets Feedback and distortion	Compare the quality and technical effectiveness of pre-programmable devices in comparison to conventional devices. Identify practical limitations to the use of low-cost pre-programmable devices
Phase 2B: Clinical trial of the objective and subjective outcomes of pre-programmable hearing devices	Objective measures Subjective measures Willingness to pay Clinician adjustments	Quantify the ability of pre-programmable devices to meet criterion performance. Compare pre-programmable device performance to published outcomes in conventionally customizable devices. Compare outcomes in pre-programmable devices to published outcomes in conventionally customizable devices. Evaluate willingness of patients to pay for services Evaluate additional benefits of clinician involvement in the fitting and adjustment process
Phase 2C: Semi-structured interviews with program participants	Study participants Clinicians	Explore the subjective experience of pre-programmable devices Understand professional opinions about benefits and limitations of pre-programmable devices to meet patient needs.

Hearing loss

Structures of the ear

The hearing organs comprise a variety of structures as shown in figure 1. The system can be divided into the outer, middle, and inner ears. The outer ear comprises the auricle and ear canal/external auditory meatus. The middle ear comprises the ear drum/tympanic membrane, the middle ear bones/ossicles/Eustachian tube, and their associated nerves and muscles. The inner ear comprises the cochlea, vestibular organ, and auditory and vestibular nerves.

Figure 1. Structures of the ear[a]



Pure tone audiometry

All partners in the study provided air conducted pure tone audiometric hearing data from 250Hz to 6000 or 8000Hz for all patients. Bone conduction thresholds between 250Hz to 4kHz were provided for many, but not all patients.

Pure tone audiometry is a universally used measure of hearing acuity. The procedure involves presenting a patient with tones of varying levels across a range of pitches or frequencies in order to obtain thresholds. This assessment can be carried out with calibrated headphones, in which case it is known as air conduction audiometry. In this situation the signal travels through the outer ear, middle ear, and inner ear before reaching the auditory centers of the brain. In addition, a bone conduction device can be utilized and in this case the signal largely bypasses the middle ear allowing a more direct measure of the inner ear sensitivity. A comparison of bone conduction and air conduction thresholds can be made, allowing some indication of the site of lesion.

A visual representation of pure tone audiometry called the audiogram shows hearing thresholds on the y-axis across frequency, which is shown on the x-axis. The audiological profiles shown later in the report are shown in this fashion (see “Audiological profiles” section).

Grades of hearing loss ranging from normal hearing to complete or total hearing loss/deafness are used to provide an indicator of the grade of the hearing loss. The World Health Organization has recently modified their standardized reporting criteria for grades of hearing loss and this report uses the newly revised system (see Table 2).(3) The grade of hearing loss is usually decided based upon an average hearing threshold taken across the frequency range. A well-recognized method, the four-frequency average (4FA), is utilized in this report. The 4FA is the average of the thresholds at 500Hz, 1kHz, 2kHz, and 4kHz.

[a] Chapter 14. Authored by: OpenStax College. Provided by: Rice University. Located at: openstaxcollege.org/files/textbook_version/low_res_pdf/13/col11496-lr.pdf. Project: Anatomy & Physiology. License: CC BY: Attribution. License Terms: Download for free at http://cnx.org/content/col11496/latest/.

Table 2. World Health Organization grades of hearing loss

Grade	Hearing threshold (dB)
Normal hearing	Less than 20 dB
Mild hearing loss	20 to < 35 dB
Moderate hearing loss	35 to < 50 dB
Moderately severe hearing loss	50 to < 65 dB
Severe hearing loss	65 to < 80 dB
Profound hearing loss	80 to < 95 dB
Complete or total hearing loss/deafness	95 dB or greater
Unilateral	< 20 dB in the better ear, 35 dB or greater in the worse ear

From World Report on Hearing. (2021). World Health Organization (3)

Site of lesion and types of hearing loss

Common pathologies affecting the outer ear include wax occlusion, otitis externa/external ear infections. Pathologies common in the middle ear include perforated tympanic membrane, otitis media/middle ear infection, and acquired or congenital ossicular abnormalities. Inner ear pathologies commonly seen include presbycusis/age related hearing loss, noise induced hearing loss, and congenital inner ear hearing loss.

Based upon the audiometric results an approximate site of lesion is often delineated and described as the "type" of hearing loss. The types of hearing loss are sensorineural, conductive, and mixed. A sensorineural hearing loss indicates a likely site of lesion in the inner ear (typically the cochlea). Conductive losses point to a site of lesion in the outer or middle ear. Finally, a mixed hearing loss describes a site of lesion in both the outer/middle ear and inner ear.

Identifying the type of hearing loss is important, as it may have a significant impact on the potential treatment pathway, with sensorineural pathologies almost exclusively managed with hearing aids or, in rare cases cochlear implants, whereas mixed or conductive hearing losses may be treated in the same way but also have the potential for medical or surgical methods of intervention.

Hearing aids

Benefits of hearing aids in adults

Hearing aids provide a cost effective method of rehabilitation for hearing loss.(4, 5) They provide both hearing specific and more general quality of life improvements. (6, 7) Increasing evidence also shows that early use of hearing aids can delay age related cognitive decline. (8, 9)

Types of hearing aids

In-the-ear style devices of various sizes and depths of insertion provide a cosmetic benefit and can be easier to insert for those with dexterity problems. These devices are generally custom made for each patient based upon an ear impression taken by an audiologist or technician, with the electronics housed inside the earmould. These devices are more prone to feedback and are less robust than other styles of hearing device and are hence not appropriate for large-scale, low-cost hearing aid programs.

Receiver-in-the-ear devices are increasingly popular in high income countries. These devices house the majority of the electronics in the body of the hearing aid, which sits behind the ear, but house the receiver/speaker in the patient's ear canal, which means that the body of the aid can be smaller and less tubing resonances occur than in behind-the-ear devices, potentially leading to a more comfortable fit for patients. They are less robust than behind-the-ear devices and are also thus not ideal for large scale programs in LMICs.

Behind-the-ear devices contain all the electronics in the body of the aid which sits behind the patient ear, with a tube and generic coupling or a customized earmould feeding the sound to the external auditory meatus. These devices are the most robust and are quite resilient to feedback, to earwax and to discharge. Behind-the-ear devices are available in a variety of power levels and can be used to cover almost any degree of hearing loss.

A range of other somewhat more specialized devices exist, including body worn devices, bone conduction devices, and various implantable devices. **Body worn** devices are largely obsolete but may still play a role in fitting those with profound hearing losses or where very low cost, robust, easily controlled and maintained devices are needed. **Bone conduction** devices are very useful for those with recurrent discharging ears and concomitant conductive hearing loss and in cases where the ear canal is not present (e.g. in congenital atresia). Bone conduction and **middle ear implants** provide a costly but highly effective solution for conductive, and some mixed hearing losses or when occlusion of the ear canal is contra-indicated. **Cochlear implants** provide a very costly but uniquely effective way to provide useable hearing to those with profound or total hearing loss as long as they have a functioning auditory nerve. In those with pathologies of the auditory nerve, auditory **brainstem or midbrain implants** are sometimes used to provide some auditory stimulation.

Fitting methodologies

Once a particular hearing device is selected, attention must then be turned to selecting the most appropriate device settings to achieve the best outcome for the individual using the device. There are two general approaches; one is comparative or evaluative, and one is prescriptive.

The comparative or evaluative method typically involves the user making a subjective evaluation of the outcomes as the device settings are varied. Because there are many potential hearing aid settings, an efficient method for identifying the ideal combination of these settings is a challenge. Although now more commonly used as a way to adjust or fine tune hearing aids after a prescriptive fitting, a pure comparative/evaluative approach has been used in recent applications of self-fitting hearing aids.(10)

The grade and type of hearing loss vary across individuals, as do listening needs, and preferences. Thus, no single profile of amplification will suit all individuals. The prevailing consensus is that to achieve maximum benefit and subjective listening comfort, the characteristics of the amplification (its gain/amplification at each frequency/pitch) should be selected based on a measure of the individuals hearing, usually an audiometric assessment (hearing test).(11) The set of desired amplification characteristics is termed a prescription target.

The prescription target itself is generally derived from complex models of loudness in normal and impaired ears, other theoretical considerations, and experimental data. There are now a small number of well validated, independently developed prescription formulae,(12, 13) and many less well validated commercial prescription formulae. As the models and data used to derive the prescription targets are based on averages, even when the target amplification is accomplished, it is expected that there will be some individual adjustment needed to achieve optimal benefit.

To achieve the desired comparative/evaluative setting, or prescription target there are various fitting methodologies. These can be categorized in various ways: here we will refer to un-conventional fitting methodologies, which would encompass self-fitting and pre-programmable fittings, and conventional fitting methodologies, which would encompass first-fitting, and real-ear measurement validated approaches.

Self-fitting

Increasing attention has been paid to hearing aids which can be purchased, as one might purchase consumer electronics, "over-the-counter". The patient would then typically connect the device to an application on their mobile phone and perform a self-assessment of hearing through the device, an algorithm stored in the device would then generate a prescriptive target and attempt to match the hearing aid settings to fit that target. Alternatively, the user may simply select and adjust the settings on the device to suit their listening preferences in a qualitative manner, without any self-assessment or prescription involved.

Pre-programable fitting

Pre-programmable devices can be set with a limited number of pre-determined amplification patterns. Although not always clearly documented, the manufacturer of the device would presumably have selected these patterns by looking at common hearing profiles seen in high income populations. However, there is little existing literature examining whether such patterns would reflect the needs of those in LMICs. Those common profiles would then have been used to create a corresponding set of prescription targets, and the device settings adjusted in an attempt to meet those targets.

A healthcare worker would select the most appropriate pre-programmed setting, usually by pressing a button on the hearing aid or via a remote method (typically a mobile phone). Usually, the appropriate setting would be identified based on an audiometric assessment (hearing test) but could also be accomplished in a comparative/evaluative fashion (by subjective report of the patient after listening to each program). The user or healthcare worker would then adjust the volume control to suit the users' comfort and needs. Because of its relative simplicity the fitting of these devices can be accomplished by a minimally trained healthcare worker with little or no other equipment required.

First-fitting

In a first-fit procedure, a healthcare worker (usually an audiologist or technician) conducts a hearing assessment, then connects a conventional hearing aid to a computer via a proprietary device. The manufacturer provided software generates a prescription target based on the hearing test data and then attempts to approximate a fit to prescriptive targets. The healthcare worker then has the ability to fine tune the device with many controls via the manufacturer software based on the users' feedback.

Real ear measurement validated fitting

The best practice model of hearing aid fitting is to use real ear measurement to validate the fitting. In this method, the steps in the first fitting procedure are replicated. However, rather than assuming that the prescription target has been achieved, a measurement of the hearing aids amplification characteristics is made in the patient's ear and compared to a prescriptive target. Subsequently adjustments are made via the manufacturer software until a match is obtained. To accomplish this a sensitive microphone is placed in the patient's ear canal whilst the hearing aid fitting is being conducted, this enables the healthcare professional to measure precisely how much amplification is being achieved.

This method requires expensive real ear measurement equipment, and additional training in its use. Therefore, it is not well suited to use by minimally trained healthcare workers.

Background and Methodology

Profiling Hearing Loss in Low- and Middle-Income Countries (Phase 1)

Background

There are a number of large, high quality, epidemiological studies investigating the prevalence of hearing loss in high income countries.(14-17) These studies allow public health officials, policy makers, researchers, and clinicians to make evidence-based decisions about health priorities, health spending, and guide effective service delivery methodologies.

A smaller number of studies also exist for LMICs, but with more variable quality, and with a smaller number of regions captured in this data (see Stevens(18) for a review). Indeed only a few, large, high quality, published studies exist reporting the prevalence of hearing loss in low and middle income regions (see Pascolini and Smith(19) for a review).

The lack of widespread, reliable data on hearing loss in LMICs makes hearing loss, already a somewhat hidden disability, even more invisible to those making health policy, allocating funds, and delivering services in these regions. It also makes the job of those advocating for funding and service delivery more difficult as they often do not have region specific data to point to when describing the local impact of the condition. Lastly, for groups attempting to develop locally appropriate service delivery models, the lack of reliable data negatively impacts on their ability to confidently model the needs and impacts of the proposed programs.

Insights from the Existing Literature

The existing literature on hearing loss in LMICs highlights the unique problems facing these regions.

Prevalence

One of the key correlates of hearing loss is age, with an exponential increase in hearing loss with increasing age above ~50 years of age.(17) Because LMICs tend to have a younger mean and median population than high income countries, the population prevalence of hearing loss in LMICs is sometimes reported to be lower than in high income regions. Care should be taken to ensure that these prevalence estimates do not obscure the seriousness of the burden of hearing loss in LMICs, because it belies two important facts. Firstly, as the majority of the world's population reside in these regions, the number of individuals with hearing loss (including unaddressed hearing loss) is substantially higher than in high income countries, with some estimates indicating that 80% of those with significant hearing loss reside in LMICs.(3) Secondly, the age adjusted prevalence rates of hearing loss in LMICs are significantly higher than in high income regions, across all age groups.(18)

Grade of hearing loss

Understanding regional variations in the proportions of the hearing-impaired population according to the grade of hearing loss is important. It is necessary to understand regional variation in the grade of hearing loss in order to estimate the burden of hearing loss, and to plan appropriate treatments and hearing health service models. Several investigations point to relatively greater proportions of people with severe to profound hearing loss in LMICs compared to high income countries.(20, 21)

Gaps in Knowledge

Existing data concerning hearing loss in LMICs is inconsistent, with very few countries sampled. Much of the existing data are outdated. The extent of ear disease and potential surgically remediable hearing loss in LMICs is also not well described, although characterized better in children than in adults, with

existing studies indicating comparatively high prevalence rates in LMICs versus high income countries.(22)
Large scale, high quality, region specific, hearing surveys are required to overcome the gaps in the current knowledge. This presents a difficult challenge as, despite advances in the methodology of hearing surveys,(23, 24) hearing surveys remain both resource and time intensive.

Phase 1 methodology

Data for this phase of the project were collected from the Global Hearing Co-operative, a group of 16 countries and 23 clinics (details provided in the "Project Region and Collection Site Overview" section below). Ethical approval from the Macquarie Human Ethics Committee was confirmed as of 22/10/20. All partner organizations have confirmed ethical approval for the project.

In the first phase of this project (Phase 1) we aimed to determine the most common audiological profiles of those seeking help for ear and hearing complaints across a wide range of LMICs in order to inform appropriate pre-programmable hearing aid settings.

We endeavored to collect representative clinical samples, rather than representative population samples from each region. The benefit of this methodology is that it is significantly cheaper and quicker to obtain data. Data can be collected in a retrospective manner from any region via existing ENT and audiological services. As the target population is those who present at hearing services, this sampling methodology is representative of people who feel they need help with ear and hearing problems in each country. We acknowledge that rural populations may be under-represented utilizing this sampling methodology given that most collaborating clinics were located in urban locations.

A minimum of 200 consecutive cases were obtained from each clinic involved in the study (see collection site overview section for a list of all clinics). Data preceding the COVID-19 pandemic (before 1st November 2019) was extracted in order to avoid the altered clinical load and case presentations due to impact of the pandemic. Inclusion criteria include: i) ≥18 years of age, ii) primary concern of hearing difficulties, iii) worse ear four-frequency pure-tone average (500, 1, 2 and 4kHz) >20 dB HL, iv) case did not present as part of a screening program. Potentially surgically remediable cases (e.g. due to conductive hearing loss) were included if they met all inclusion criteria.

The following data was extracted from clinical records by a member of the clinical team at each site: *Demographic data:* Age, gender, occupation (where possible), rural/urban, referral source, history of noise exposure, hearing device status (not previously aided/aided unilaterally/aided bilaterally/bone anchored device/cochlear implant), whether a hearing aid was recommended (at this visit), whether the case was referred for ENT or surgical remediation. *Audiometric data:* pure-tone audiogram thresholds (including bone conduction thresholds where available), otoscopic findings (where available), tympanometric findings (where available, either Jerger type or raw data), speech recognition scores (where available).

A machine learning approach – vector quantization (VQ) – was used to derive audiological profiles for each dataset. This approach is a data-driven way of describing common audiometric profiles in large data sets.(25)

Benefits and limitations of pre-programmed hearing aids in LMICs (Phase 2)

Background

As outlined previously, there is a significant evidence base for the benefits of hearing aids in adults. Whilst much of the research examining the outcomes of hearing aids has been conducted in high income regions, there is also some literature on the use and benefits of standard models of hearing aid rehabilitation in LMICs.(26-28)

Uptake of hearing aids in those with significant hearing loss is relatively low in high income countries ,(i.e. with around 10-15% of people with hearing loss using hearing aids,(29-31)) with a variety of barriers to uptake identified including cost, stigma, comfort and lack of perceived need.(32, 33) The literature identifies an even more alarmingly low of use of hearing aids in LMICs. There are indications that the low rate of use in LMICs is largely being driven by a lack of access to devices or unmet need, with factors like stigma, and awareness likely playing a part as well. (34, 35)

One key factor limiting access to hearing rehabilitation in LMICs is the significant deficiency of hearing healthcare professionals, with ear nose and throat surgeons, audiologists, speech and language therapists, and teachers of the deaf all in short supply in many regions.(36) Coupled with the lack of professionals, fewer than half of the regions sampled in one WHO report have a plan, program or policy for ear care, or prevention of hearing loss.(37)

The other factors limiting access to hearing aids in LMICs, are the high cost of devices (at an individual level) and relatedly, the limited budget allocations for hearing devices (at an organizational level) in LMICs.(3, 35, 38-40)

Insights from existing literature

Conventionally customized hearing aids

Hearing loss is largely a chronic condition which typically requires a rehabilitative rather than medical or surgical approach to treatment. Traditional models of rehabilitation largely involve individualized/customized clinically fitted hearing aids. Whilst hearing aids clinically fitted by audiologists is highly effective model of hearing rehabilitation, it is costly, requires highly trained health professionals, and specialized equipment. Given the scale of hearing loss and the lack of hearing health infrastructure in LMICs, alternative hearing health delivery models are needed.(3, 40)

Pre-programmable hearing aids

Low-cost pre-programmable hearing aids provide one potentially scalable solution to the large unmet need for hearing rehabilitation in LMICs, as they can be fitted by a minimally trained community health worker.

There is limited research reporting on the efficacy of pre-programmed hearing aids in LMICs, but the existing literature and expert opinion support the idea.(41, 42) An associated line of evidence is the research focused on investigating the benefits of initial fit algorithms (a similar but slightly more sophisticated form of non-customized fitting, discussed in detail later in this report) and over-the-counter devices (which allow users to self-adjust levels of amplification). These studies also provide support for the potential utility of pre-programmable models of service delivery. The literature suggests that in a high-income context, although a more customized clinically verified fitting is preferred by users, comparable (although reduced) objective and subjective benefit can be achieved with an initial fitting or over-the-counter approach.(43-45)

Monaural or Binaural Hearing aids

Hearing aids can be fitted in either one (monaural) or both (binaural) ears. Monaural hearing aids are indicated for cases of unilateral hearing loss. However, when bilateral hearing loss is present, as is more common, then either monaural or binaural hearing aid fitting can provide significant benefit.

Only a small amount of research exists examining the question of the comparative benefits of binaural hearing aids. A Cochrane review provided some very weak evidence for binaural benefits in terms of user preference when compared to monaural hearing aid fitting.(46) More recent prospective research suggests a stronger patient preference for modern binaural hearing aids over monaural aids,(47) but benefit on standardized measures of hearing-related quality of life was not consistently reported.(48) There is also some recent evidence supporting the potentially protective effects of binaural aiding to prevent auditory deprivation.(49) A practical benefit to binaural fittings is that if one hearing aid is malfunctioning, then the working hearing aid can be utilized whilst the other aid is being repaired.

Monaural versus binaural hearing aids is an important consideration when examining the cost effectiveness of interventions for LMICs, as the cost of a conventionally fitted hearing aid compared to GPD per capita, or other measures of local capacity to pay might be quite high. At present no literature examines the cost-effectiveness of monaural compared to binaural hearing aids in LMICs.

Partners from the Global Hearing Co-operative group involved in compiling the current report represent a wide variety of LMICs. The group reports that current practice with respect to monaural versus binaural hearing aids varies somewhat but that service providers prefer to fit binaurally where possible with monaural fittings necessitated largely by lack of personnel or program funding to cover the cost of binaural hearing aids. A recent review of hearing aid fittings in the United States of America suggest approximately 81% of fittings are binaural.(50)

Although not directly addressed in this study, funding agencies and intervention programs in LMICs should consider the cost-effectiveness of monaural or binaural fitting for the adult population.

Cost

Costs of hearing rehabilitation include the cost of devices, costs of service, and costs of follow up and maintenance for devices (e.g. batteries). In some cases, hearing devices are sold “bundled” with the device cost including the service costs (fitting and follow up) and even the maintenance (batteries and repair warranty), some service providers “unbundle” with the cost of devices, services, and maintenance billed and paid separately.

The cost of devices to consumers in a high income context has been estimated at $1798USD per device, with the wholesale cost estimated at $495USD per device. (50) Although rigorous data is not available for LMICs, a survey of the partners from the Global Hearing Co-operative group (authors of this report) report a minimum cost to consumer ranging from $50-1000USD, with an average minimum cost to consumers of $469.50USD. Although the cost of devices is significantly lower in LMICs the cost is often still very high when compared to average incomes, which would make hearing rehabilitation unaffordable for many.

Government procurement programs, and hearing device coverage through socialized healthcare can reduce or negate out of pocket costs to consumers, but vary in their availability across different regions.(3, 51)

Gaps In Knowledge

With respect to the cost of devices, one notable limitation of the existing literature relating to pre-programmed or over-the-counter hearing aids is that it has almost exclusively been carried out in high income countries in patients with a mild to moderate hearing loss, where most cases were closer to the milder side of the spectrum.(10, 52) It is not clear how well this research is generalizable to LMICs and to patients with somewhat more significant hearing loss. Several studies investigating existing over-the-counter devices in LMICs indicate that the characteristics of these devices may not be suitable for even those with a mild to moderate hearing loss.(53, 54)

With respect to service costs, the use of community based healthcare workers (CHW) with basic levels of training delivering hearing healthcare has been suggested.(36, 55) Indeed CHW have been successfully used in LMICs to provide vision healthcare.(56) However only one small scale report of hearing aid fitting by community healthcare workers in LMICs exists in the literature.(57) Further research, scoping, and the development of rehabilitation techniques suitable for use by community healthcare workers or others with low levels of training in hearing health care (e.g. nurses and technicians) is needed.

Phase 2 Methodology

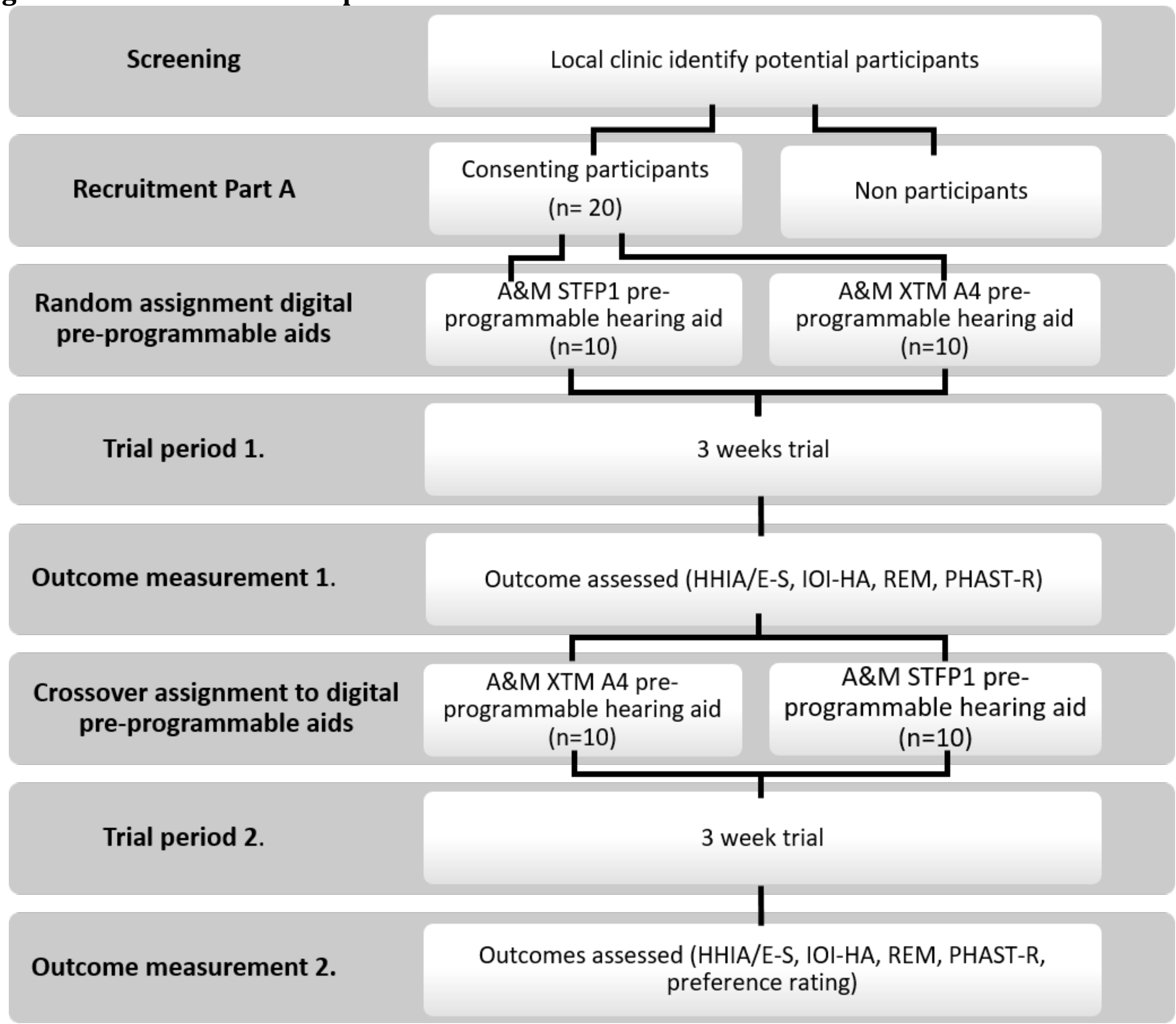
The second phase of the project had three components. In **Phase 2A** we aimed to compare and contrast the basic technical and electroacoustic characteristics of a low-cost pre-programmable hearing device to a conventionally customized device.

In **Phase 2B** a cross-over trial was used to compare the objective and self-reported outcomes of two pre-programmable hearing aids with the two devices varying in both power and number of selectable hearing profiles/programs (Figure 2).

Lastly, **Phase 2C** involved structured interviews with hearing aid users, technicians, audiologists, and other health professionals who fit the Phase 2B devices to ascertain their views and experiences with prescription, dispensing and use of the hearing aids. Phase 2B and Phase 2C were conducted in a subset of 4 clinics included in Phase 1 of this study: India (All India Institute of Speech and Hearing), The Philippines, Samoa, and South Africa.

Further details of the methodology can be found in the relevant Phase 1 and Phase 2 sections in text.

Figure 2. Phase 2B research protocol



Project Region and Collection Site Overview

Introduction

We obtained data from all World Bank regions (East Asia and Pacific, Europe and Central Asia, Latin America and the Caribbean, Middle East and North Africa, South Asia, and Sub-Saharan Africa) containing countries classified as low and middle income. Where possible multiple countries from each region were sampled to ensure that the sample was representative of global LMICs.

Partners from each country are listed below by region and collectively make up the Global Hearing Co-operative group. Each partner was asked to supply a general overview of hearing health services in their local region, their statements are included in appendix B.

East Asia and Pacific

Cambodia
All Ears Cambodia, Phnom Penh.

China
Jilin University, Changchun.

Indonesia
Kasoem Hearing & Speech Centre, Jakarta.

Malaysia
International Islamic University Malaysia, Selangor.

The Philippines
University of Santo Tomas, Manila.

Samoa
Tupua Tamasese Meaole Hospital, Apia.

Thailand
Department of Otolaryngology, Prince of Songkla University, Songkhla.

Europe and Central Asia

Russia
National Research Centre for Audiology and Hearing Rehabilitation, Moscow;
Laboratory of Hearing and Speech St. Petersburg State Medical University, St.Petersburg.

Turkey
İstanbul Aydın Üniversitesi, Istanbul;
İstanbul Medipol University, Department of Audiology, Faculty of Health Sciences, Istanbul;
Istanbul University Cerrahpasa Medical Faculty, ENT-Audiology and Speech Pathology Center. Faculty of Health Sciences, Istanbul;
University of Health Sciences, Audiology Department, Istanbul;
Hacettepe University Audiology Department, Ankara;
Ankara University, Medical Faculty, ENT-Audiology and Speech Pathology Center, Ankara.

Latin America and the Caribbean

Dominican Republic

EARS Inc Hearing Clinic Centro Cristiano de Servicios Medicos, Santo Domingo.

Middle East and North Africa

Egypt
Nile Center for Audiovestibular Medicine, Cairo.

Jordan
University of Jordan Hospital Hearing and Speech Clinic, School of Rehabilitation Sciences, Amman.

South Asia

India
All India Institute of Speech and Hearing, Mysore;
Dr. S. R. Chandrasekhar Institute of Speech and Hearing, Bengaluru.

Nepal
Ear Centre, Green Pastures Hospital, International Nepal Fellowship, Pokhara;
Department of Otolaryngology HSN, BP Koirala Institute of Health Sciences, Dharan.

Sub-Saharan Africa

Malawi
ABC Hearing Clinic, Lilongwe.

South Africa
Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria.

Demographics of people attending hearing clinics in LMICs (Phase 1)

A general overview of the project population demographics is shown in table 3.

Table 3. General demographic information

		Percent
Gender	Female	50.3%
	Male	49.7%
Rural	Rural	29.8%
	Urban	56.7%
	Unknown	13.4%
World Bank Country Income Group	Low income	3.5%
	Lower middle income	35.8%
	Upper middle income	60.8%
Age Grading	18-40	22.3%
	41-60	27.9%
	61-80	41.7%
	>80	8.1%
History of noise exposure	No	60.8%
	Yes	13.2%
	Unknown	26.0%
Type of hearing loss	SNHL	73.8%
	Mixed or CHL	26.2%

Age distribution

The characteristics of the populations sampled in this project are shown by total sample and by region in figures 3 and 4 respectively. The population trees show the distribution of the sample population age groups by gender. The population sample in Latin America and the Caribbean, the Middle East and North Africa, and to a lesser extent, South Asia show a flatter age distribution than the rest of the regions where a peak in the older age groups is seen. It is possible that population differences across the regions underly some of the variation seen in this sample.

However, a possible alternative interpretation is that the regions with flatter distributions have either cultural (e.g. attitudes to hearing loss in the elderly) or practical barriers to access (e.g. cost) that make it less likely that older people seek help for hearing problems. The differences in age distributions may also be due to sampling bias at the partner organizations. Although our partners included a mix of small local clinic and larger hospital-based centers, many were larger specialist centers. Referral pathways may direct older patients to smaller local providers (if such centers are available) and younger patients to more specialist providers, and this could be reflected in our data.

Regardless of the reason for this variation in age distribution it does highlight the need to consider referral pathways and clinical provider types when planning rehabilitation in LMICs.

Figure 3. Total sample population tree

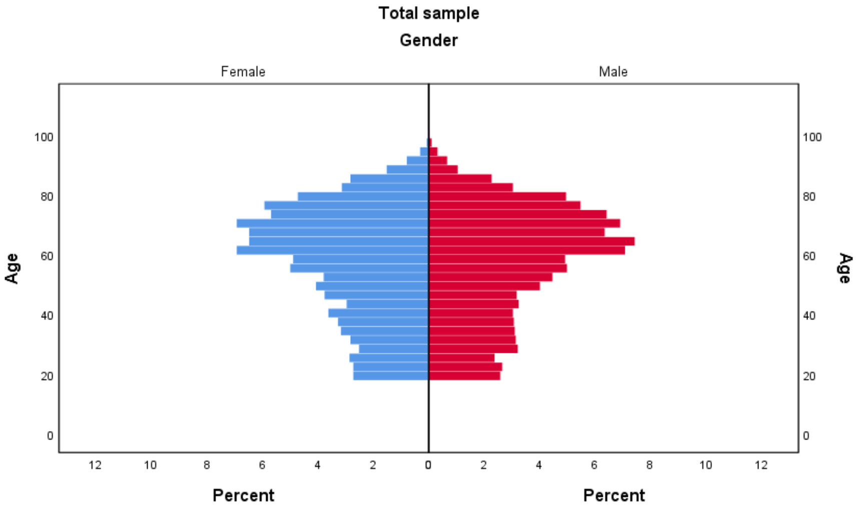
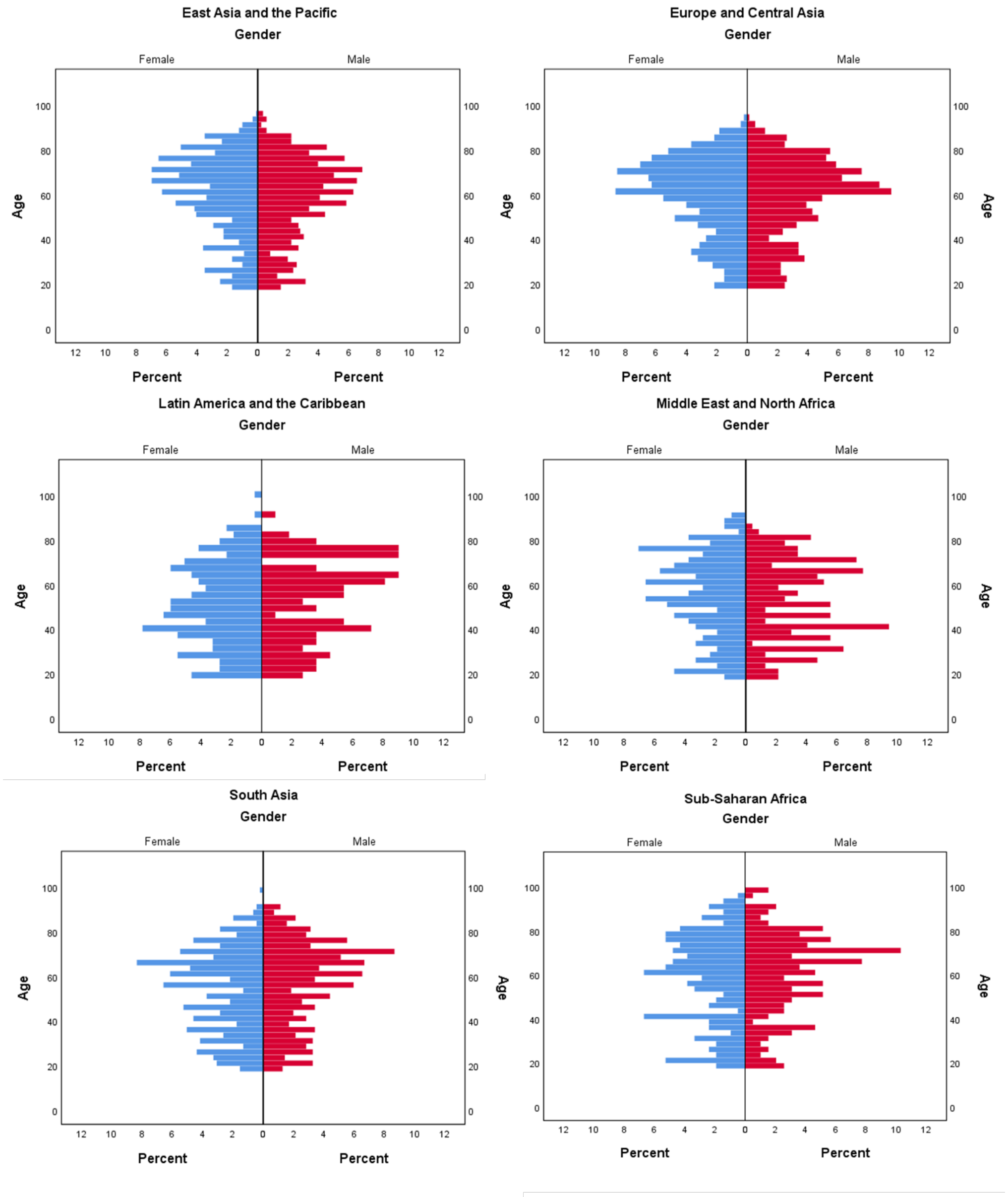


Figure 4. Population trees across regions



Gender distribution

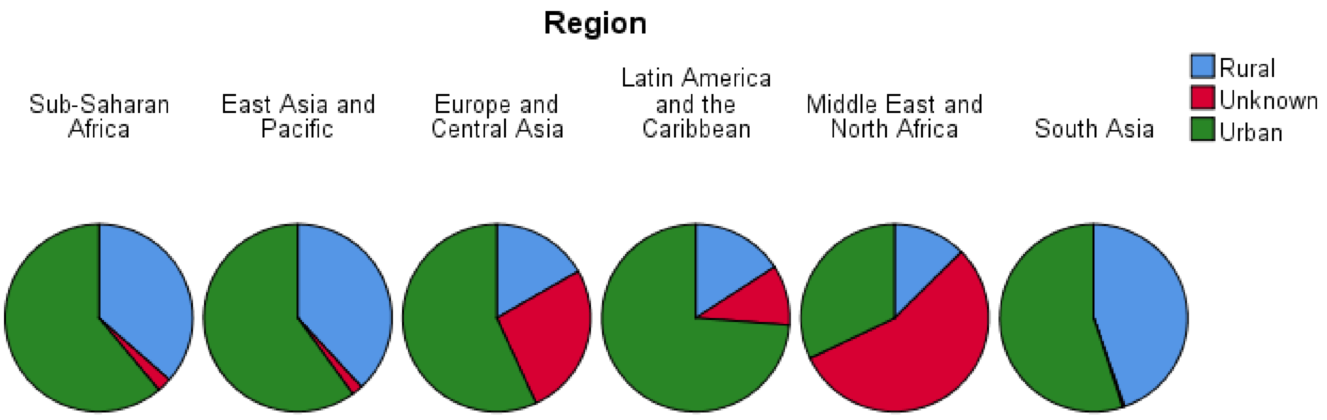
The proportions of males and females seen at sites sampled was close to 50:50 (table 1), with a slight female preponderance overall (except in the case of our collaborator from Latin American and the Caribbean, where there was a 60:40 male to female split). These figures are interesting in that studies suggest a greater prevalence of hearing loss in males (thought to be partly due to occupational noise exposure), yet the gender profiles in clinical populations reported here do not reflect this. There is some evidence that access to health services in general can be harder for women in LMICs. (58) The data from the current project suggest that difficulties in accessing health services by women may not hold true for access to hearing health, or at least that there is significant regional variation.

Urban/Rural Distribution

There are greater barriers to health service access in the rural populations of LMICs including distance-to-service, lack of facilities, and lack of specialized personnel, lower income, and poorer health education.(59, 60) This disadvantage for rural populations was reflected in the data from the clinics sampled – most data are from urban settings. However compared to World Bank general population estimates,(61) the Europe and Central Asia, and Latin America and the Caribbean samples were more reflective of the general population distributions within each of these regions than the East Asia and Pacific, Middle East and North Africa and sub-Saharan African regions (see figure 5, appendix C). The partner organizations collecting data were usually located in urban areas, which potentially biases the sampling towards urban populations. However, in many of these regions, rural clinics are scarce, and it is not unreasonable to suggest that the sample is truly reflective of rural access to services.

This result highlights the difficulties rural and remote populations have in accessing hearing health services. The results underscore the importance of considering alternative distribution channels when planning hearing health rehabilitation programs to ensure equitable distribution of services to rural and remote populations.

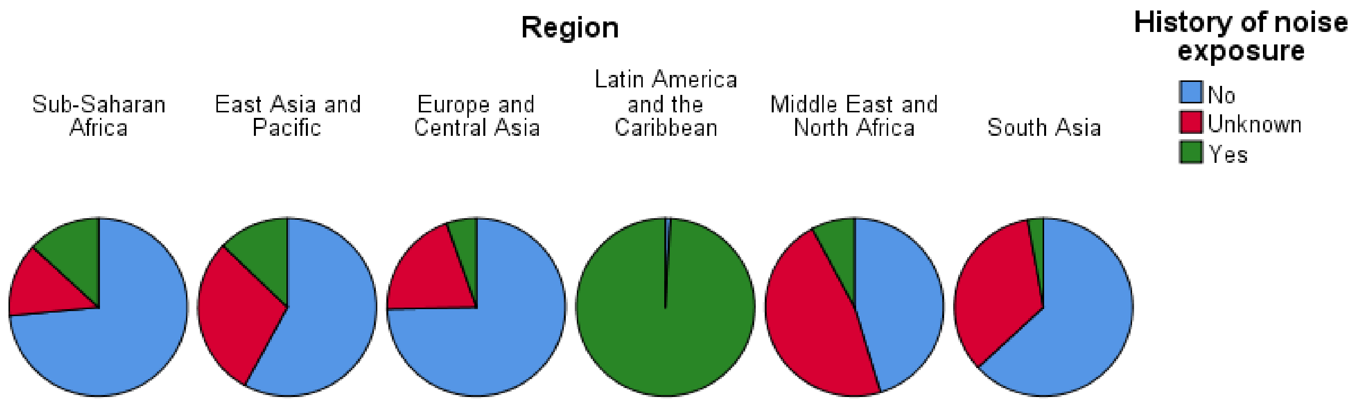
Figure 5. Urban/Rural distribution proportion



Noise exposure

There are widely divergent proportions of the populations with noise exposure across the regions in the current study (figure 6, appendix D). The variations here likely reflect the referral sources and locations of the collaborating organizations.

Figure 6. History of noise exposure



Project Population Hearing Characteristics

Four frequency average hearing loss

The 4FA (average of 0.5, 1, 2, and 4kHz hearing thresholds) of a particular population is a gross measure of the grade of hearing loss. Boxplots displaying the 4FA for the better and worse ear are shown across study regions in figure 7 (text table version in appendix E). Note that there is some variation across regions for both the median and mean 4FA in the better and worse ears, with a difference of almost 20dB between the lowest and highest median 4FA. In the sample there appear to be two groups, the first comprising South Asia, Sub-Saharan Africa, and East Asia and the Pacific with higher average level of hearing loss, and Europe and Central Asia, the Middle East and North Africa, and Latin America and the Caribbean with lower average levels of hearing loss.

Each country in the study sample was then coded by its GNI per capita PPP (current international $) (see appendix F for corresponding table). Figure 8 shows the relationship between GNI per capita and better ear 4 frequency hearing thresholds. There is an apparent improvement (i.e. reduction) in hearing thresholds as GNI increases. Statistical investigation of the relationship between GNI per capita and 4 frequency average better ear hearing threshold revealed that, accounting for age and gender, each $1000 increase in GNI was associated with 0.55dB improvement in hearing threshold. This equates to approximately a 15dB difference in hearing threshold between the lowest and highest GNI groups in the sample, $F(3,5767)=147.37$, $p<0.005$, $R2=0.071$ (see appendix G for coefficient table).

Findings of a relationship between health outcomes and measures of income per capita are well established in the literature.(62) A negative relationship between measures of income per capita and the proportion of those with disabling hearing loss has also previously been reported.(37) To our knowledge this is the first report to detail a relationship between average hearing thresholds, and per capita income across regions, in clinical populations.

Figure 7. Four frequency average hearing loss in best ear and worse ear by region

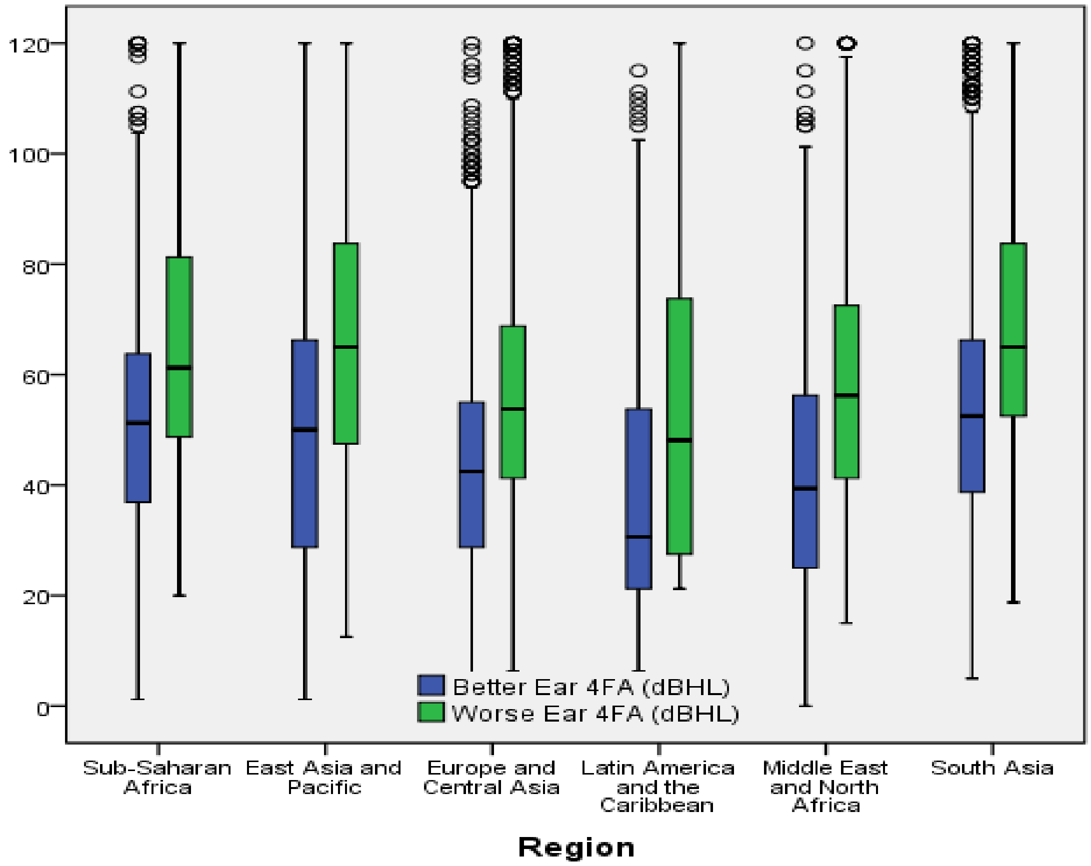
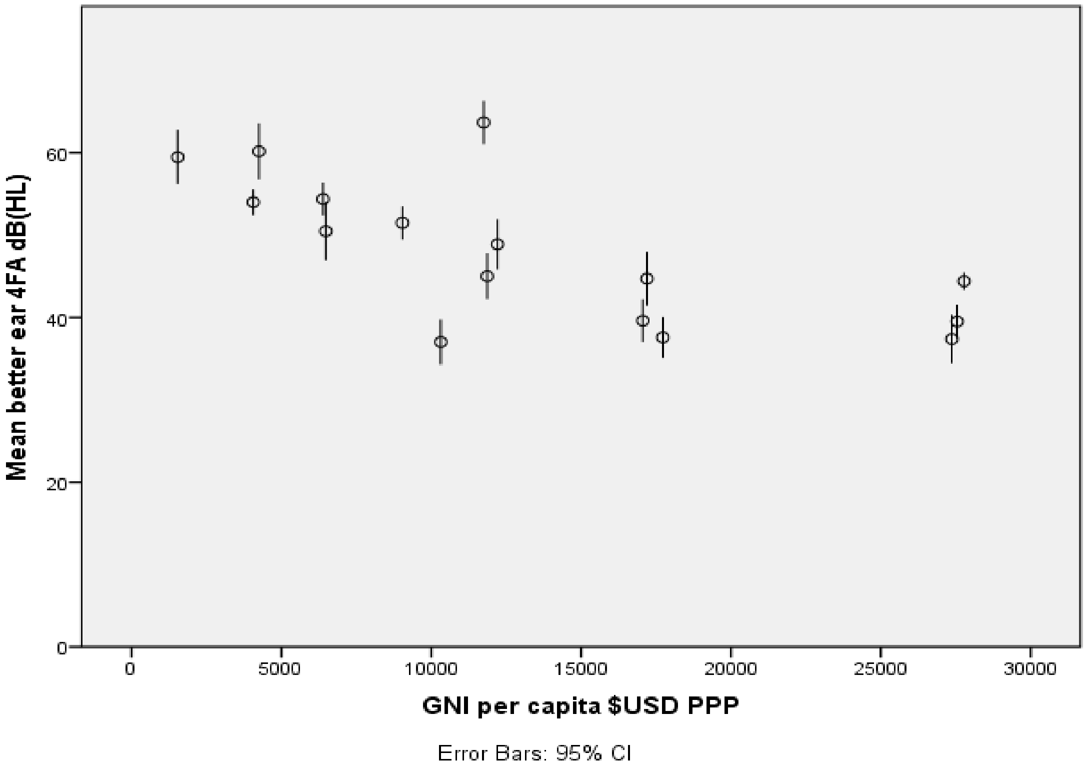


Figure 8. Mean better ear hearing thresholds by GNI per capita PPP (current international $)



Hearing loss configuration

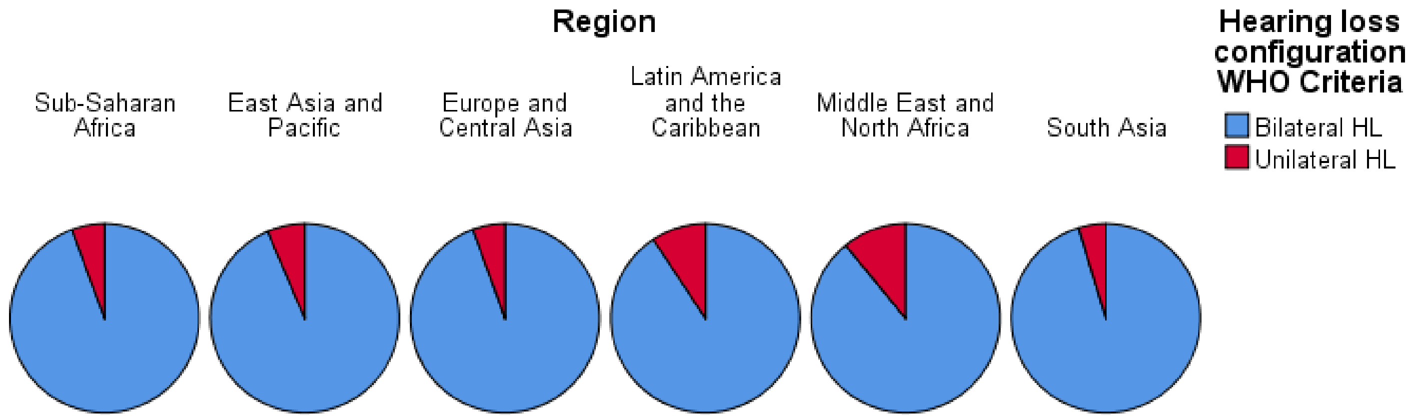
Rates of unilateral hearing loss (classified as per the WHO grades of hearing loss as cases with better ear hearing <20dBHL, and worse ear thresholds ≥35dB) were around 6% (figure 9, appendix H), with some areas seeing a higher proportion of unilateral hearing loss (Latin America and the Caribbean and the Middle East and North Africa). Similar rates have been shown in other studies of clinical populations in LMICs.(63) A comparative sample from a high income region suggested a 1% rate of unilateral hearing loss in a clinical population.(64) Despite some variation in definition of unilateral hearing loss, our data suggest that unilateral hearing loss may be much more common in LMIC clinical populations compared to high income countries. It is not clear whether this represents a difference in the underlying population prevalence of unilateral hearing loss, or whether this represents a bias in clinical presentation of such cases in these regions. A previous survey of the Philippines pointed to a population prevalence of ~20% for unilateral hearing loss,(20) whereas a study from a high income country (the United States) reported rates closer to 7% (65).

In summary, data across studies suggest higher prevalence of unilateral hearing loss in LMICs than in high income countries. It is possible that the comparatively higher prevalence of unilateral hearing loss seen in LMICs relates to differences in the underlying causes of hearing loss in these populations, for instance higher proportions of hearing loss related to infectious, or other preventable causes which tend to be unilateral. The younger average age of populations in LMICs will also lead to lower proportions of common bilateral hearing loss related pathologies such as presbycusis.

High prevalence of unilateral hearing loss: Implications for pre-programmable hearing aids

Unilateral hearing losses are associated with increased hearing disability in adults, although to a much less significant extent than bilateral hearing loss. Hearing aids are effective in reducing the impact of unilateral hearing loss. Given that, in general less disability results from unilateral hearing loss, careful consideration of the costs and benefits must be made before including this group as a priority for hearing aid provision in a LMICs context.

Figure 9. Proportion of bilateral and unilateral hearing loss (WHO criteria) by region



Grades of Hearing Loss

The grades of hearing loss are shown by region in figure 10 with most regions showing a median hearing loss in the moderate to moderately-severe range. The exception to this is the Latin America and Caribbean region which has a lower median grade of hearing loss. Whilst this variation could reflect a true difference in the help seeking behavior or the clinical characteristics of patients from this region it is possible that it is peculiar to the site where the data were gathered in this region as only a single partner/collection site was used here.

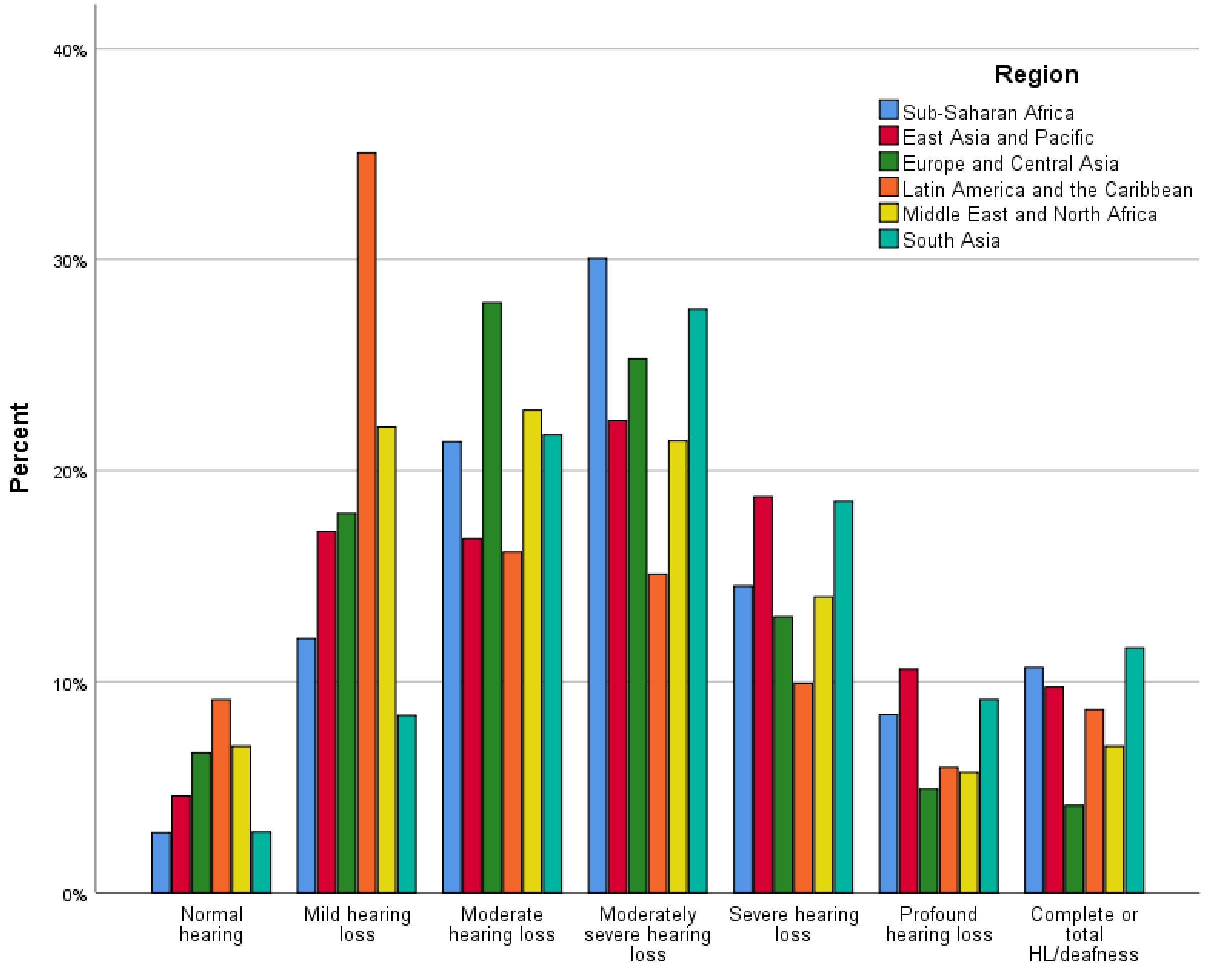
Interestingly, the average hearing loss seen in the current study is more severe than is seen in similar clinical populations from high income countries,(64) but appears similar to that reported by other previous studies from LMICs.(63) In clinical populations in high income countries, the proportion of people with severe to complete hearing loss made up only 13% of the total sample. In the current study, approximately 25 to 40% of the sample were in the severe to complete grades of hearing loss, which is three to four times higher than in high income countries.

This point is further highlighted by Figure 11, which shows that even within our sample of LMICs there are decreasing proportions of more significant grades of hearing loss as GNI per capita PPP (current international $) increases.

The increased proportion of people with severe hearing loss in clinical populations in this study compared to populations in high income regions and in lower GNI per capita regions compared to higher GNI per capita regions, could indicate a delay in help-seeking for hearing problems in people from LMICs, particularly those at the low-income end of the spectrum.

Alternatively, evidence from epidemiological studies (20), suggest that the higher proportion of severe hearing loss in clinical populations in LMIC counties reflects poorer hearing in the general population, rather than reflecting delayed help seeking.

Figure 10. Hearing loss in the study sample by WHO grades of hearing loss



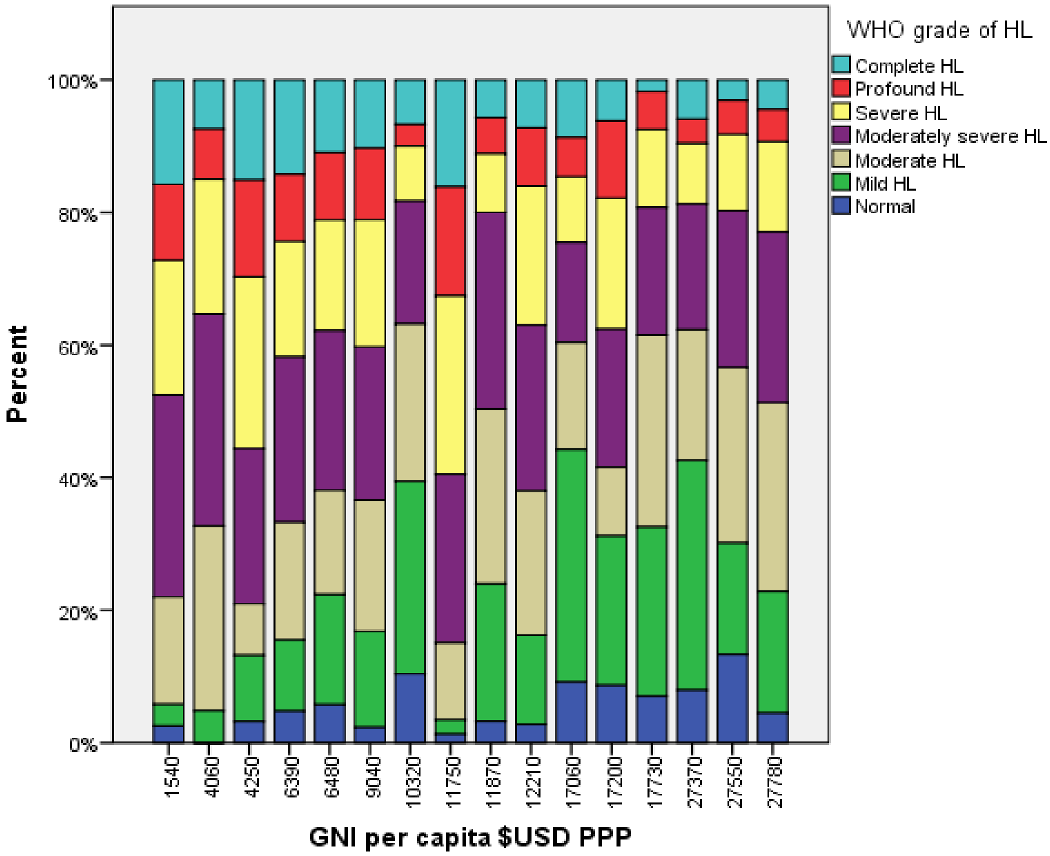
Grades of hearing loss: Implications for pre-programmable hearing aids
The finding that severe hearing loss is very common among clinical populations in LMICs has implications for hearing rehabilitation services in LMICs, and the distribution models for pre-programmable hearing aids in these regions. Hearing aids in general, and pre-programmable hearing aids more specifically, are well suited to addressing up to a moderately severe level of hearing loss. The WHO has previously recommended that priority groups for hearing aid distribution include adults with a moderate to severe hearing loss.(40)

Our findings suggest that a larger proportion of both the clinical and general population of hearing impaired individuals in LMICs fall outside the level of hearing loss that is treatable with pre-programmable hearing aids.

Our study supports the predictions of some of previous research in terms of the distribution of grades of hearing loss and a need for more powerful hearing devices than might be required in a high-income region.(66)

If pre-programmed hearing aids are to be distributed in LMIC settings, it would be important to triage candidates to identify those with mild to moderate severe hearing loss who would be candidates for pre-programmed aids, as well as those with more severe hearing loss for whom a pre-programmed aid would not be suitable. Such a strategy could, for example, involve minimally trained community based healthcare workers equipped with low cost, portable audiometry devices who would then be able to triage people to pre-programmed hearing aid or other to a more conventionally customized hearing aid based on the grade of hearing loss.(67)

Figure 11. WHO grade of hearing loss (per ear) by GNI per capita PPP (current international $)



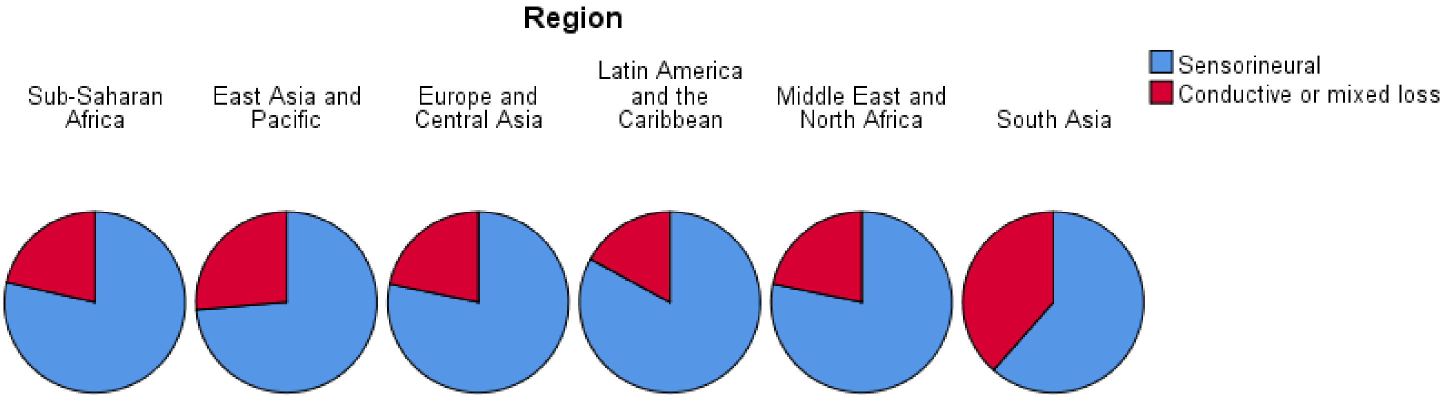
Mixed and Conductive Hearing loss

As previously outlined, a conductive hearing loss suggests an outer or middle ear site of lesion, and a sensorineural hearing loss indicates a lesion at the cochlear or higher level. A mixed hearing loss has both conductive and sensory components, suggesting both an outer or middle ear lesion and a cochlear lesion. Mixed and conductive hearing loss was very common in the clinical samples from all regions, ranging from 21.2-40% (see figure 12, appendix I). East Asia and the Pacific, and South Asia showed higher proportions of mixed and conductive hearing losses than is seen in high income regions, with the other regions showing rates close to those described in high income regions.(64)

Binary logistic regression shows that several predictor variables were associated with the presence of mixed or conductive hearing loss (Chi-Square=234.87, df=4, and p<0.001). GNI per capita showed a negative relationship with mixed or conductive hearing loss, that is for every $10,000 increase in GNI there was a 33% reduced risk of mixed or conductive hearing loss (see appendix J). For every 10-year increase in age there was a 13% decrease in the odd of conductive hearing loss. Finally, those residing in rural regions were 11% more likely to have a mixed or conductive hearing loss. Gender was not associated with mixed or conductive hearing loss in this sample.

There are known regional variations in the prevalence of key pathologies associated with conductive hearing loss (such as otitis media/middle ear infection).(68) There are also known associations between such pathologies and socioeconomic status within high income countries.(69) The current study suggests that GNI per capita may be predominantly responsible for the regional variations in the prevalence of conductive hearing loss. However, care must be taken extrapolating the results from the clinical sample described here to the general population.

Figure 12. Sensorineural, conductive or mixed hearing loss



High prevalence of mixed and conductive hearing loss: Implications for pre-programmable hearing aids

The presence of high proportions of mixed and conductive hearing loss in the clinical populations in this study presents some challenges to the delivery of hearing aids in general, and pre-programmable hearing aids specifically.

Although hearing aids are a suitable rehabilitation approach for those with mixed or conductive hearing loss in terms of reducing hearing difficulties, in some cases these types of losses may respond equally well or better to medical or surgical interventions (e.g. otitis media or otosclerosis) and fitting a hearing aid in these cases may delay potentially more effective medical treatment. In some cases, aiding a patient with conductive hearing loss may be contra-indicated as it can exacerbate outer or middle ear problems, bone conduction or bone anchored hearing devices are alternative intervention strategies.

The high cost and limited access to such surgical services should be considered when examining the potential for pre-programmable hearing aids as a treatment of mixed and conductive hearing loss in LMICs.

Delaying appropriate medical treatment for mixed or conductive hearing loss can lead to complications, which can lead to increased hearing disability and in some cases may be potentially life threatening (e.g. in the case of large cholesteatomas, or mastoiditis). Additionally, in some cases of mixed or conductive hearing loss, caused by earwax occlusion, or acute outer or middle ear disease, a hearing aid is a poor rehabilitative option, and may be largely ineffective.

A complicating factor is that it is difficult to differentiate mixed and conductive hearing losses from sensorineural hearing losses with current low cost, portable diagnostic audiometric equipment. Conversely, research suggests that minimally trained health care workers can be trained to identify and treat some contra-indications to hearing aid fitting that cause conductive or mixed hearing loss (such as earwax occlusion and discharging ears).(55, 70)

An effective referral pathway to medical facilities and an adequate supply of ENT and attendant surgical personnel would still be necessary to maximize the benefits of a model of service delivery equipped to identify and treat conductive or mixed hearing loss. Unfortunately, the option for medical management of conductive or mixed hearing loss is not available in LMICs. Even when specialist medical staff are available, cost and distance to these medical services may reduce access.

Pre-programmable hearing aid programs should ideally include the development of effective local referral pathways, linking primary healthcare workers to those at secondary and tertiary levels. This will facilitate the triage of potentially serious and easily treatable conductive or mixed hearing losses and allow a narrower focus on those losses which are suitable for treatment with pre-programmable devices.

Project Population Rehabilitation Characteristics (Phase 1)

A general overview of the population hearing rehabilitation characteristics is shown in table 2.

Hearing rehabilitation uptake

In the current study between 8.9 to 26.6% of clinical cases had received hearing rehabilitation, and in almost all cases this was hearing aids (see figure 13, appendix K). This is despite much of the clinical population having very significant hearing loss. One clinic survey from Malawi shows rates on the higher side of this distribution, with hearing aid uptake of ~28% in the adults in the study.(71) Of note, approximately 50% of those who were aided, were aided monaurally despite having a bilateral hearing loss.

Table 4. Hearing rehabilitation characteristics of people attending hearing clinics in LMICs

		Percent
Hearing device status	Aided binaurally	9.1%
	Aided monaurally	10.0%
	Cochlear implant	0.6%
	Not previously aided	69.8%
	Unknown	10.4%
Hearing aid recommended	No	28.4%
	Yes	63.6%
	Unknown	8%
Hearing device funding source	Donation	3.7%
	Government	10.9%
	Private	26%
	Unknown	59.4%

Only a tiny proportion (~4.5%) of those with a severe or worse hearing loss in the better hearing ear were fitted with a Cochlear implant, and an alarming 52% of this group had no hearing device fitted at all. Cochlear implantation is a very significant challenge in LMICs. Availability of experienced surgeons and adequate surgical facilities are a challenge, cost is often prohibitive at an individual level and even when covered by socialized healthcare wait times can be extremely long.

Binary logistic regression was used to investigate the relationship between current hearing device (hearing aid or cochlear implant) ownership, gender, better ear 4 frequency average hearing threshold, and GNI per capita. Both hearing threshold and GNI per capita were significant predictors of hearing device ownership (Chi-Square=749.49, df=3 and $p<0.001$) (see appendix L for odds ratios and device ownership proportions by GNI). Gender was not a significant predictor. The results suggest that for each $10,000 increase in GNI per capita, ownership of a hearing device was 1.5 times as likely. The odds of ownership also increased by 1.4 times for each 10dB increase in better ear hearing threshold.

General population studies and reports in LMICs have found as few as 1% of patients with mild or worse hearing loss, or 7% of patients with moderate or worse hearing loss possessed hearing aids. (72, 73). These figures differ significantly from figures in high income countries which suggest closer to 10% and 40% of people with mild and moderate hearing loss own hearing aids respectively, with an uptake rate of approximately 25% in those who report the need for hearing assistance.(74, 75)

Low hearing aid uptake: Implications for pre-programmable hearing aids

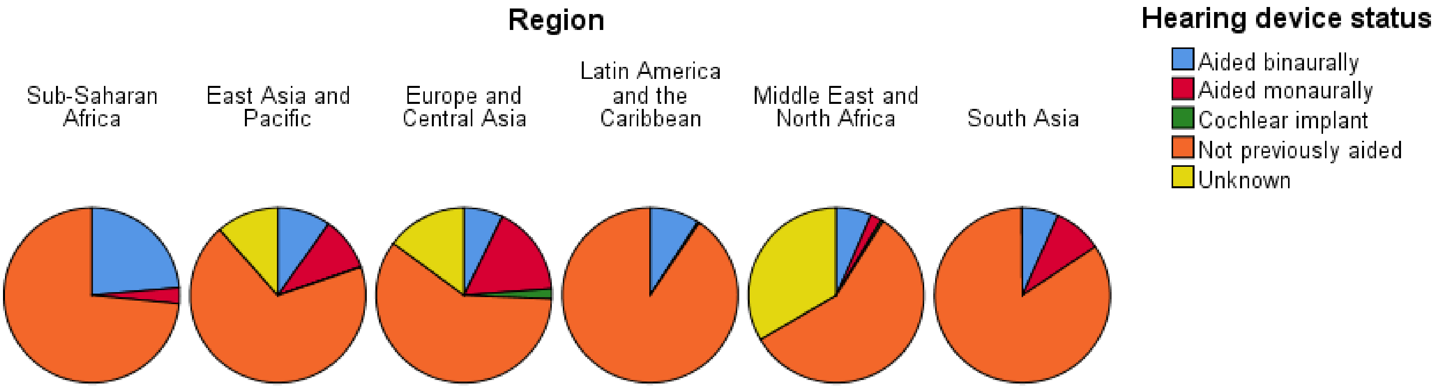
The relatively low uptake rate of hearing aids in the clinical populations investigated in this study, and the available population-based literature from LMICs suggest an urgent need for accessible hearing rehabilitation in these regions. Whilst the current study did not investigate the reasons for low uptake, other studies have suggested a range of reasons for low hearing aid uptake rates in both high and LMICs, including cost, stigma and lack of perceived benefit.(3, 32, 76)

The high percentage of monaural fittings in those with aidable, bilateral hearing loss highlights the financial barriers to access for many of those with hearing loss; supplying one hearing aid is a sub-optimal treatment for bilateral hearing loss, although it offers a less expensive option with a favorable cost benefit ratio.(3)

Whilst a relatively high quality, low cost, pre-programmable hearing aid may assist in overcoming the cost and physical access as barriers to hearing aid fitting, consideration should be given to addressing other important barriers to access and use such as awareness of treatment options, stigma of hearing aids, and ongoing support needs.

The need for improved efforts at early detection of hearing loss and early intervention in LMICs is highlighted by the poor uptake of hearing devices and higher proportions of more significant hearing loss described in this report.

Figure 13. Hearing rehabilitation uptake among those with hearing loss attending hearing clinics in LMICs by global region



Audiological Profiles of People Attending Hearing Clinics in LMICs (Phase1)

Introduction

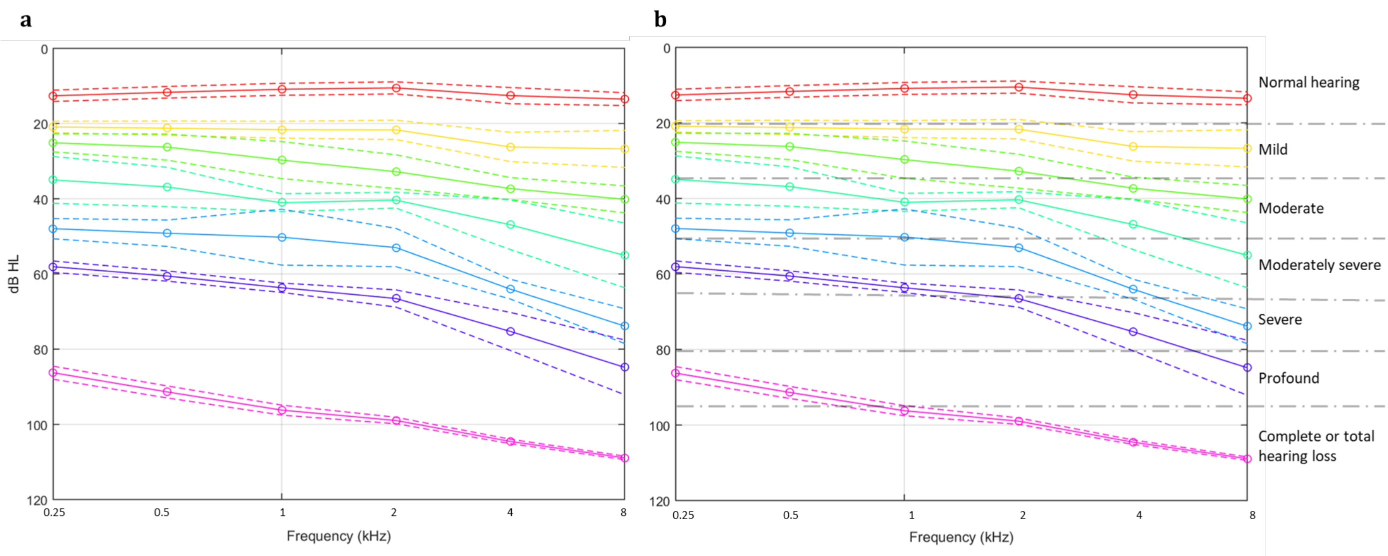
Pre-programmable hearing aids offer a low cost, scalable solution to meet the needs of a significant proportion of people requiring hearing rehabilitation in LMICs. One limiting factor in understanding potential for pre-programmable hearing aids to meet the needs of people with hearing loss in LMICs is the lack of data from LMICs regarding the common profiles of hearing loss. These profiles are needed to identify those with mild/moderate hearing losses that are suitable candidates for pre-programmed hearing aids and to specify appropriate pre-programmed amplification/gain settings in pre-programmable hearing aids.

The current project collected and collated audiometric data from LMICs across all World Bank regions, East Asia and the Pacific, Europe and Central Asia, Latin America and the Caribbean, the Middle East and North Africa, South Asia, and Sub-Saharan Africa. The audiometric data were then analyzed using a machine learning algorithm known as vector quantization. This method allows the user to specify several desired groups of data (in this case, a number of representative audiogram shapes). The algorithm will then attempt to find patterns in the data which best fit or represent that number of groups. One significant limitation to such data driven processes is that they require a significant amount of data to make useful predictions about the most representative patterns. The current project was planned to provide enough audiometric data to generate reliable characterization of audiological profiles using this machine learning method.

Total sample audiological profiles

Over 11,000 ears audiometric results were analyzed to create reliable audiological profiles. The analysis was conducted repeatedly with increasing the numbers of audiological profiles extracted. A figure of 7 profiles was determined to provide a good combination of detail and acceptable deviation. Figures with 4 profiles are also presented as they better represent the number of profiles in more basic pre-programmable hearing devices. Figures 14. 15. 16, 17 and 18 show the 7 profiles extracted from the data with the vector quantization approach for all hearing losses, sensorineural hearing losses only, age and type of hearing loss respectively.

Figure 14. a) Audiological profiles for the total sample shown in solid-colored lines, with standard deviations shown in dashed lines b) Audiological profiles with WHO grades of hearing loss overlayed



We identified one normal audiometric configuration (red), representing the normal hearing ears of those with unilateral hearing loss. The rest of the configurations are mildly sloping in the mild (yellow and bright green), mild to moderate (aqua green), moderate to moderately severe (blue), moderately severe to profound (purple) and profound (pink) regions.

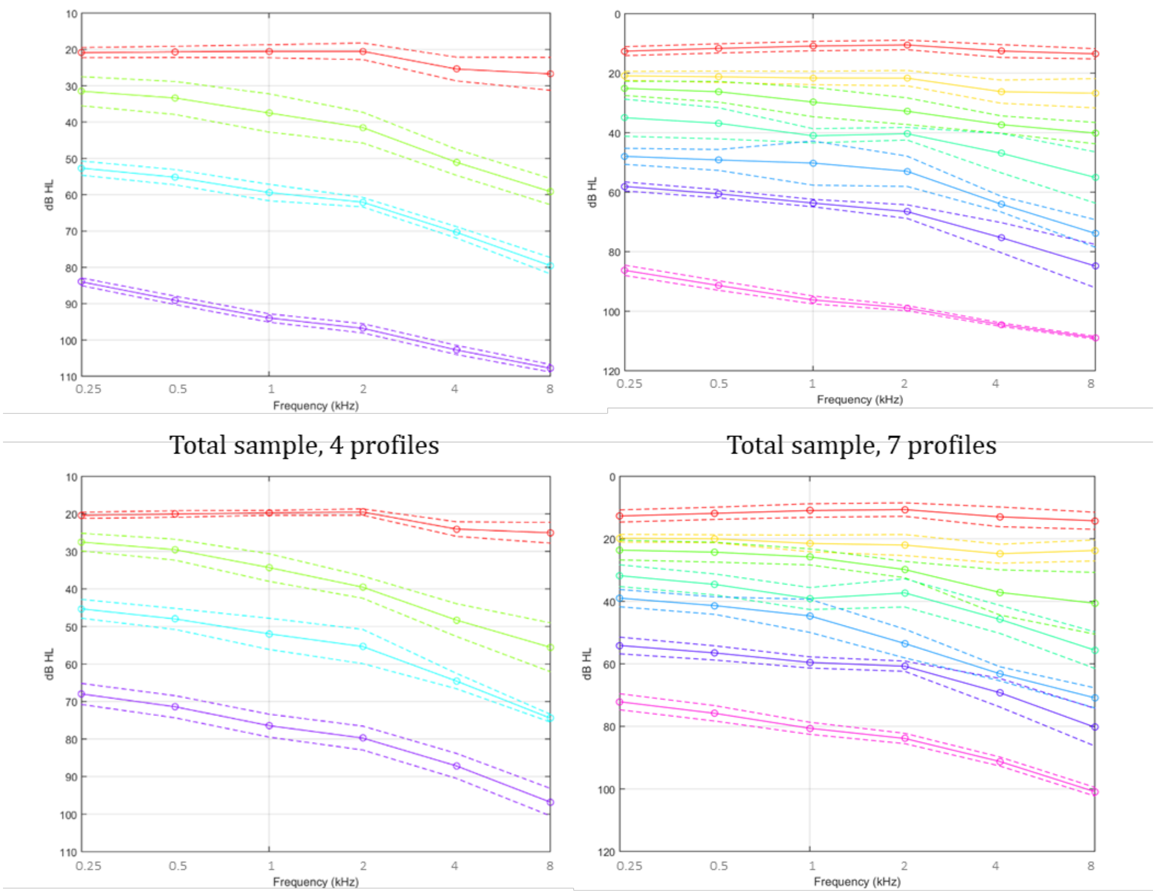
The standard deviations shown in figure 14 (dashed lines) are within an acceptable range indicating that each profile captured most of the variability in hearing among people with hearing losses. Standard deviations tend to be higher in the higher frequencies, suggesting more between-individual variability within high frequency hearing thresholds among the profiles generated in this vector quantization model.

Compared to the existing literature the data present some similarities, but also some clear differences. The audiometric profiles are flatter than those reported in several previous studies even when comparing the patterns in the literature with sloping losses excluded.(77, 78) The flatter profiles of hearing loss may be truly representative of the characteristic shapes of losses in the regions sampled. Given the high proportion of conductive and mixed hearing loss (which was purposely excluded in some of the earlier studies,(77, 78)) which tend to have a flatter profile than sensorineural hearing loss, this is not unexpected. However, as is seen in figure 15, even when only sensorineural hearing losses were examined, the flatter profiles predominate. It is also possible that the specific methodology utilized to extract the audiometric patterns in the current study has prioritized flatter losses in some way. The analysis by Bisgaard et al.(25) utilized a similar methodology, and the audiological profiles described in that paper are similar to the profiles found in the present study, in that somewhat flatter shapes predominate.

The other interesting result concerns the gap in the profiles where one might expect a profile representative of a severe hearing loss to fall. Given the number of severe hearing losses in the sample (as judged by 4FA thresholds) this is surprising. One possible explanation may be that, although many losses averaged across the frequency range were in the severe category, the shapes or patterns of the losses may have varied more across the frequency range and thus may have been assigned to either the higher or lower profiles.

To ensure that the flatter losses seen in the current data are representative rather than an artefact of the vector quantization model used in this study, an analysis of publicly available audiometric data from the National Institute of Occupational Safety and Health (NIOSH) was conducted using the same methodology. The NIOSH data showed both sloping and flatter patterns more consistent with the patterns seen in high income regions.(25, 78) This suggests that the results seen in the present analysis are not an artefact of the vector quantization method being utilized and that the results are truly representative of the data.

Figure 15. Audiological profiles in total sample and in those with sensorineural hearing loss only



Total sample, 4 profiles

Total sample, 7 profiles

Sensorineural hearing loss, 4 profiles

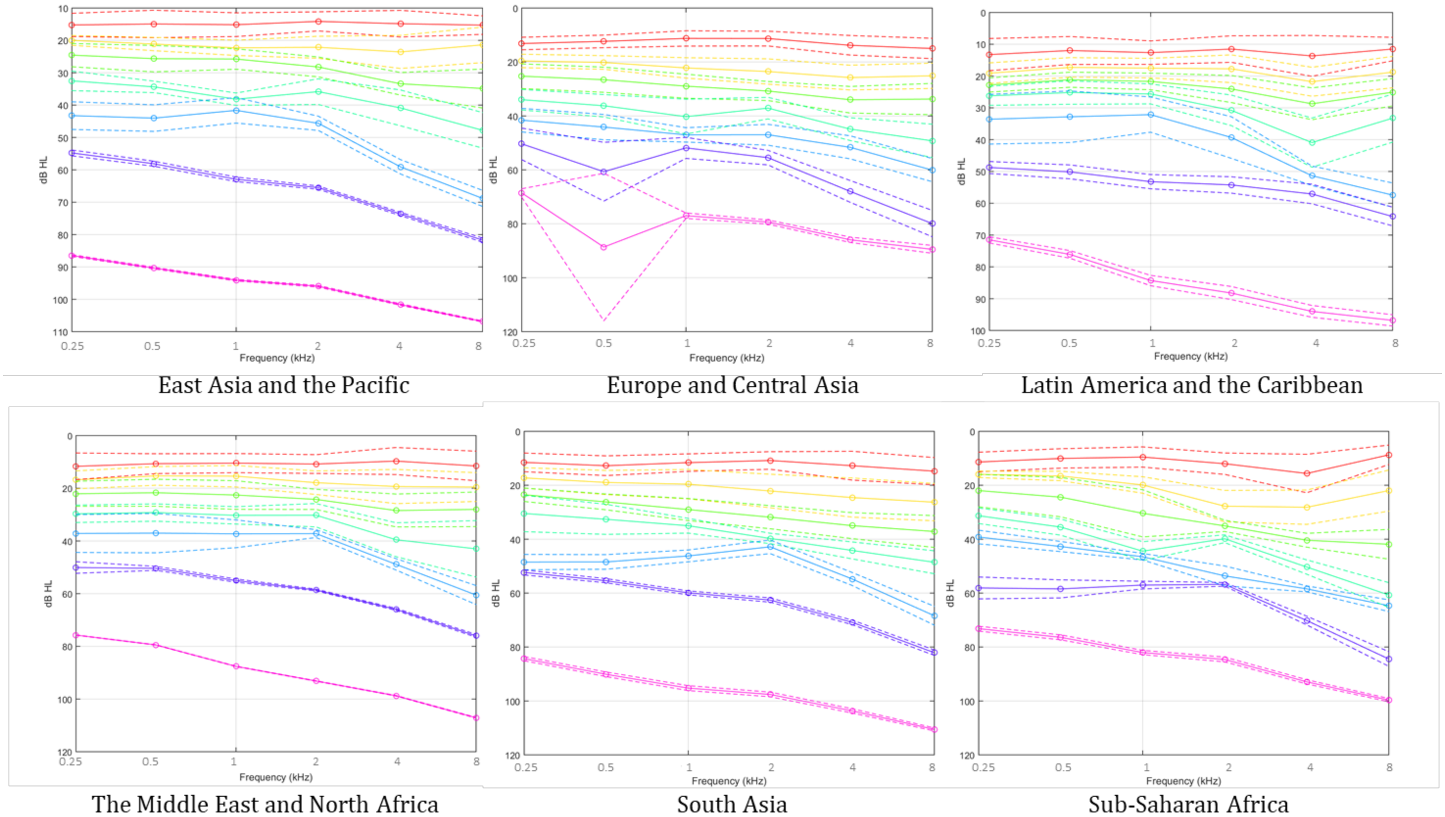
Sensorineural hearing loss, 7 profiles

Whilst a relatively detailed understanding of the representative audiometric shapes is provided by the 7 characteristic shapes described above, a less detailed description of the audiometric patterns in the sample may also be instructive. This is particularly pertinent due to the simplified nature, and very limited numbers of profiles available on many low-cost pre-programmable devices. To this end, an examination of the 4 most representative audiometric patterns was also undertaken and is shown in comparison to the 7 representative patterns previously described in figure 14 (see figure 15 with associated standard deviations in appendix M).

Region specific audiological profiles

Region specific audiological profiles are shown in figures 16 and 17, with the associated standard deviations in appendix N and O. Because of the lower number of audiograms in each data set the reliability of the models may be reduced compared to the model of the full data set. However, we were able to obtain up to seven groups or profiles for the regional data sets without significant increase in the standard deviations just as in the total sample and the patterns show remarkable similarities to both the whole sample profiles, and to each other. Some variation is noticeable, particularly in terms of the more severe to profound profile (pink) which varied somewhat in severity. There is also some variation notable in the moderate to severe profile (purple) which varied from mildly sloping to flat sloping across the regions. Models of the regional data for only four groups or audiometric profiles are shown in appendixes P and Q.

Figure 16. Audiological profiles by region



Age specific audiological profiles

Age specific audiological profiles are shown in figure 18, with the associated standard deviations in appendix R. We were able to reliably obtain up to seven groups or profiles for the age ranges just as in the total sample and here as well the patterns show remarkable similarities to both the whole sample profiles, and to each other. Some variation is noticeable, particularly in terms of the lower to mid frequencies which varied somewhat in severity with age. Models of the age data for only four groups or audiometric profiles is shown in appendix S.

Type of hearing loss profiles

Patients with conductive or mixed hearing loss may require a different and more complex treatment pathway following diagnosis, than those with sensorineural hearing loss. For this reason, we chose to investigate the audiological profiles of those with sensorineural hearing loss for comparison with the profiles of the whole sample (which also includes those with conductive and mixed hearing loss). Audiological profiles by type of hearing loss are shown in figure 15, with the associated standard deviations in appendix M. For both the 4 profile and 7 profile models, whilst the mild to moderate profiles are largely similar, the profound (4 sample: purple, 7 sample: pink) profiles seen in total sample were approximately 10dB better in the sensorineural sample.

Figure 17 Audiological profiles by region in those with sensorineural hearing loss only

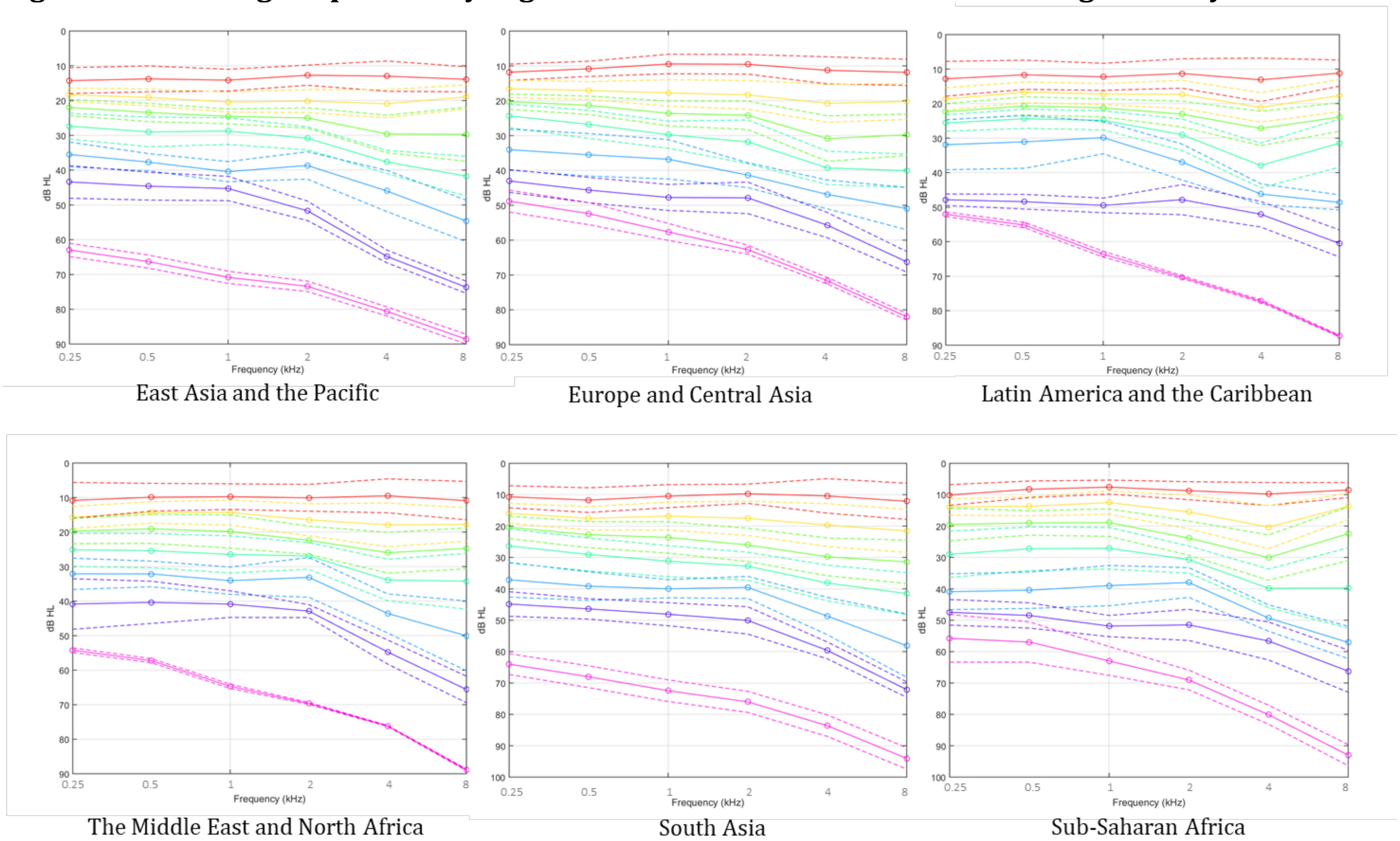
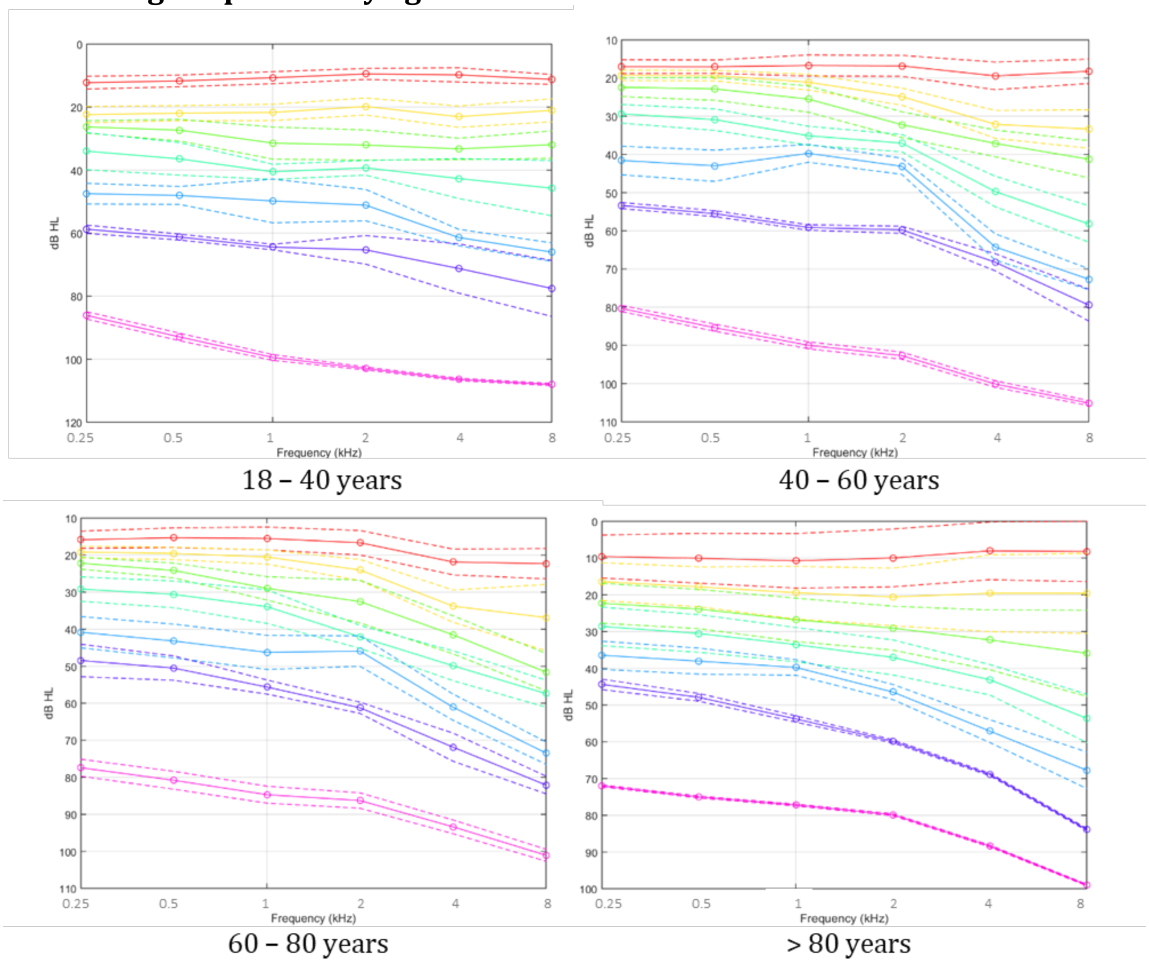


Figure 18. Audiological profiles by age



Limitations of methodology

As representative population samples were not being collected in this project, assertions could not be made about overall population prevalence of hearing loss and ear disease based on the data sample collected. However, the methodology does allow assertions about the characteristics of hearing loss and ear disease in those **seeking help for ear and hearing problems** in each of the regions sampled. The strength of these assertions varies according to both the size of the sample collected at each location, and the representativeness of the population sampled.
We achieved our aim in gathering at least 200 participants (400 ears) from each of the 23 sample sites included in the study. Where possible we aimed to have multiple sample sites for each country or World Bank region.

Conclusions

The consistency of the audiometric profiles seen across the regional samples, and in comparison, to the LMIC sample as a whole is encouraging in terms of making assertions about the typical audiological profiles for LMICs. The seven profiles shown in figure 14 offer a good characterization of typical hearing loss profiles in the clinical populations of the LMICs in this survey.

The key differences between the current LMIC sample and high-income regions are i) flatter audiometric profiles, and ii) lack of a distinct profile in the 'severe' range of hearing loss in LMICs.

Importantly, looking at sensorineural hearing loss, these results suggest that LMIC-specific audiometric profiles should be used to inform pre-programmed hearing aid interventions in low- and middle-income regions. For example, typical amplification strategies in high income settings assume a sloping hearing loss profile that may be inappropriate for LMIC populations.

Other considerations include the high proportion of clinical cases with conductive or mixed hearing loss which indicates the need for a careful triage and referral pathway. Lastly the high proportion of severe to profound hearing losses presenting for treatment should be considered. These cases are difficult to fit with conventionally customized hearing aids and in a high-income context would be referred for cochlear implantation. Referral pathways should be considered for this group as they may not be suitable for pre-programmable devices.

Comparison of pre-programmable and conventionally customized hearing devices (Phase 2A)

Sample Demographics

We aimed to recruit 10 participants for the laboratory comparison of pre-programable and conventionally customizable hearing aids, owing to COVID restrictions we were only able to complete data collection from 7 participants. All participants were normal hearing adults and were used to model realistic real ear measurement and feedback characteristics of pre-programmable and conventionally customized hearing aids.

Technical characteristics of devices

The devices compared in this part of the study were two low-cost pre-programmable hearing aids; the A&M XTMA4, and A&M STFP1 and two higher cost conventionally customizable hearing aids; the Phonak B90-M BTE and Phonak B90-SP BTE. All devices have key desirable features such as feedback protection and robust construction.

The A&M XTMA4 is a relatively low cost and low specification, pre-programmable device with 6 audiological profiles which can be selected via a mobile phone application. Some fine tuning of the frequency response is possible via the mobile application. The device has no program button or volume control.

The A&M STFP1 has an even more limited specification set, with 3 pre-programmable profiles which are selected on the aid itself rather than through a mobile phone application. A volume control is present on the STFP1 device, but no further customization of the sound profile is possible.

Importantly, the gain of the two low-cost devices varies, with the STFP1 being a more powerful device than the XTMA4.

The Phonak B90-M and Phonak B90-SP BTE are relatively high cost, high specification, conventionally customizable hearing aids. These hearing aids have 20 fine tuning channels, and a range of premium features including sophisticated automatic environmental adaptation and noise reduction. The frequency response of these hearing aids can be adjusted via custom PC computer software across 20 channels allowing very specific customization of the sound profile.

The B90-M BTE is a low to moderate gain hearing device, the Phonak B90-SP BTE is a super power device. These devices were chosen to approximate the power/gain profiles of the XTMA4 and the STFP1 respectively.

All devices were fitted with a comfort coupling set which includes standard hearing aid tubing and a choice of a small or large plastic power dome (occlusive, non-customized earpiece).

Fitting of devices

Best practice conventionally customizable hearing aids

One key objective measurement of the success of a hearing aid fitting is a real ear measurement appraisal. Here a measurement of the hearing aids output is made in the patient's ear and compared to a prescriptive target. Previous research suggests that closer fits to prescriptive target produce better sound quality rating, speech discrimination, and subjective outcomes including patient preference (43, 79, 80). Although there are no definitive criteria for what is to be considered adequately fitted to target, expert opinion seems to suggest something between 5-10dB may be acceptable,(81) but recent data from clinicians suggest a figure of between 3-5dB is required.(82)

Previous research establishes the ability of conventionally customizable devices to fit closely to prescription targets when measured on the real ear. Several seminal studies show that a four frequency average fit-to-target of approximately 3dB is achievable with quite basic, conventionally customizable, hearing aids, it is important to consider that these figures were achieved only after clinician adjustment of the device.(43, 83) The 3dB figure is useful to keep in mind when evaluating the outcomes reported in Phase 2A and 2B of this study.

First-fit conventionally customizable hearing aids

Whilst best practice suggests the use of clinician adjustment to real ear measured prescription targets, in practice conventionally customizable hearing aids are often fitted using a "first-fit" procedure. In the first-fit procedure the manufacturer software attempts to approximate a fit to prescriptive targets using basic information about the hearing device, client, and normative data. The limitation of this method is that the prescription target calculations are based on average values and does not account for the significant individual variability. Research suggests that this process does not produce as close a fit to prescription target as the best practice approach.(80)

We chose to use this approach when fitting the conventionally customizable device in Phase2A of the study to isolate the difference in outcomes attributable to the device and fitting software, rather than the intervention of the clinician.

Pre-programmable hearing aid fitting

When fitting a pre-programmed hearing aid, a set of stored fitting profiles in the device are compared to the patient's audiogram and the most appropriate profile is selected. The selection can be accomplished by the clinician, usually guided by a table or basic equation, or by an algorithm stored in a computer or mobile device. Pre-programmable hearing aid profiles are also sometimes selected by user preference particularly when audiometric data is not available, here the patient would trial each setting and select the one which provided the best subjective outcome.

The manufacturer recommended fitting method was utilized in this case, with the STFP1 fitted via clinician selection and the XTMA4 fitted by an algorithm in the hearing aid fitting software on a mobile device.

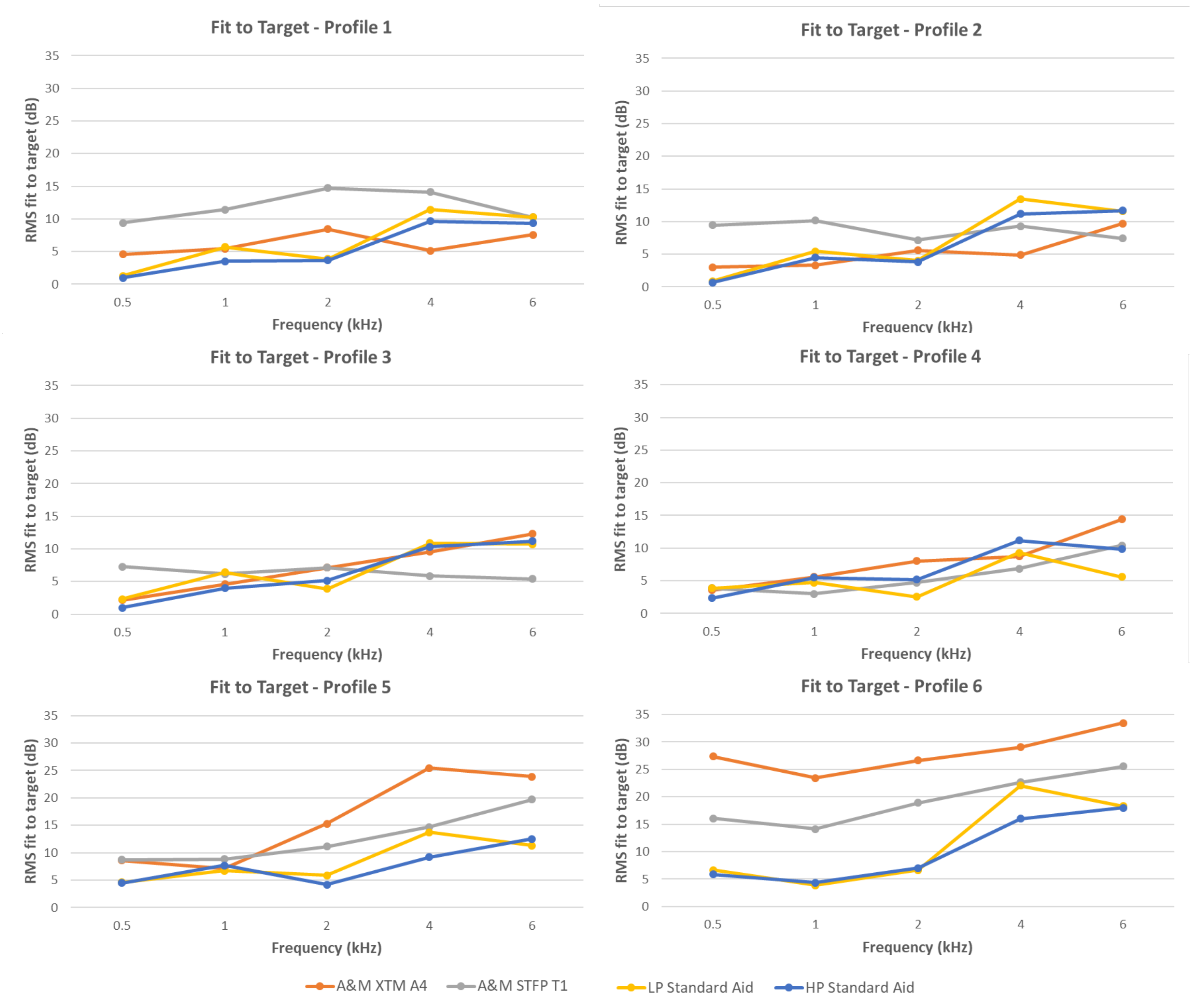
Real ear measurement outcomes

Fit to target

The closeness of the hearing aids fit to NAL-NL2 target was established using a calibrated Affinity real ear measurement system with a 65dB ISTS stimulus. The root mean square (RMS) difference between the gain of the fitting and the gain of the target was calculated as an indicator of outcome (hereafter referred to as "RMS fit to target").

What is clear from the data is that the average fit to target of the conventionally customizable hearing aids is significantly better for the more severe hearing losses as shown in profiles 5, and 6 (see figure 19). The more powerful pre-programmable device (STFP1) also provided a poor fit to target for milder losses (profiles 1 and 2). The pre-programmable devices were quite close to targets for moderate hearing losses (profiles 3 and 4).

Figure 19. Average RMS fit to target by frequency for each hearing profile



Averaged across frequencies the percentage of fittings meeting a strict or loose criteria for fit to target is shown in Table 5 for each device. Relatively few participants were fit to target with any of the hearing aids when utilizing the strict criteria. When the looser criteria greater proportions of fit to target are seen in all devices, and although the conventionally customizable hearing aids are more consistent across the profiles, some of the profiles seem relatively well fit by the STFP1 (profiles 3 and 4) and XTMA4 (profiles 1 and 2).

Over and underfitting

Both over and under-fitting of hearing devices when compared to prescription targets are problematic. Over fitting can produce an aversive sound quality and potentially cause noise/hearing aid induced hearing loss. As mentioned previously, underfitting produces poorer objective and self-reported benefit

Table 5. Percentage of hearing aids fitted to strict and loose criteria (50% or greater in bold)

Hearing device	Criteria	Fitted to target					
		Profile 1	Profile 2	Profile 3	Profile 4	Profile 5	Profile 6
STFP1	Strict (+/- 3dB)	0%	14%	43%	**57%**	0%	0%
	Loose (+/- 5dB)	14%	29%	**57%**	**86%**	0%	0%
XTMA4	Strict (+/- 3dB)	43%	**71%**	43%	29%	0%	0%
	Loose (+/- 5dB)	**71%**	**71%**	43%	43%	0%	0%
LP Standard Aid	Strict (+/- 3dB)	14%	0%	14%	**57%**	29%	0%
	Loose (+/- 5dB)	**71%**	43%	**71%**	**71%**	29%	29%
HP Standard Aid	Strict (+/- 3dB)	33%	17%	**50%**	33%	**50%**	17%
	Loose (+/- 5dB)	**83%**	**83%**	**67%**	**50%**	**50%**	**50%**

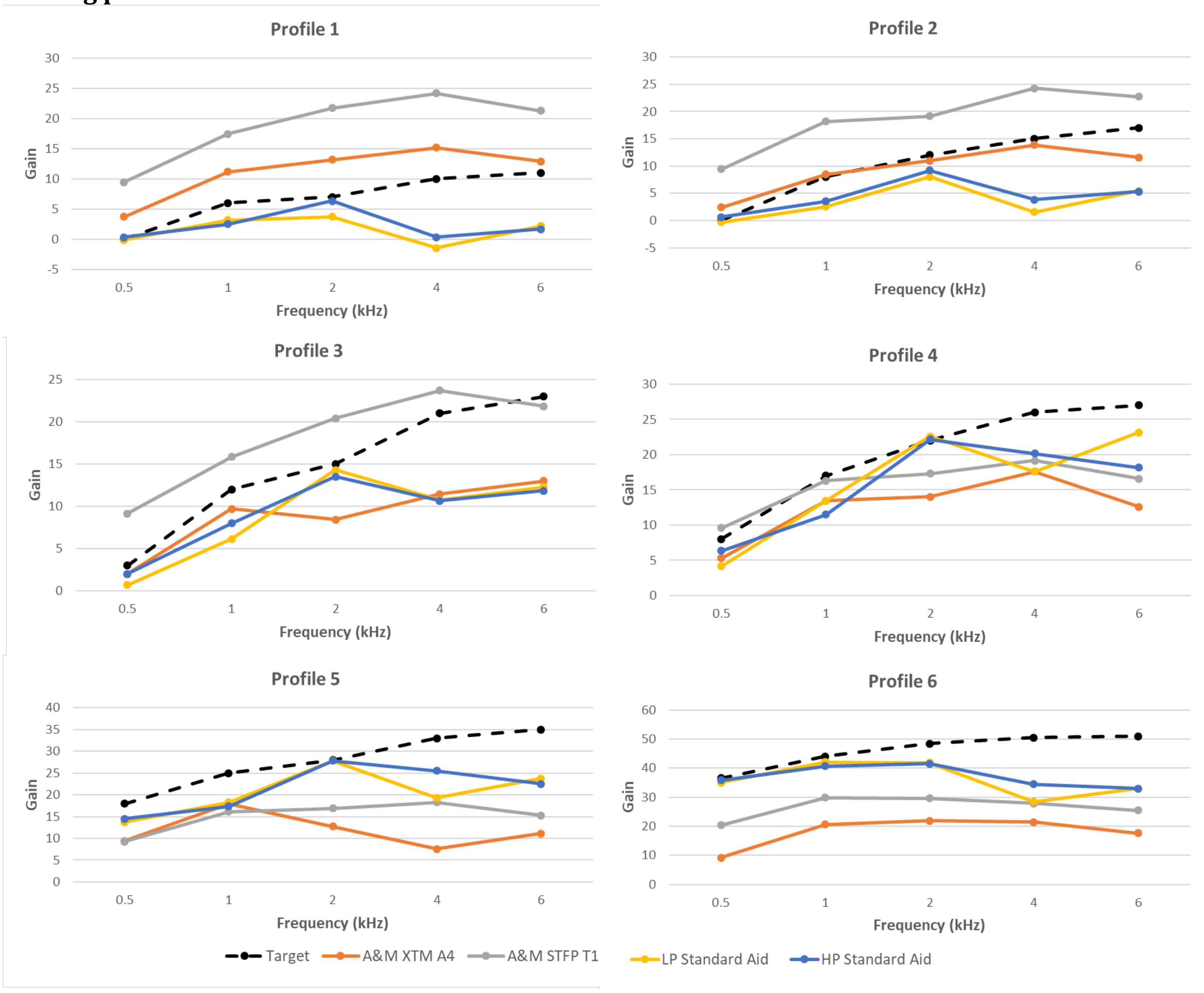
Both pre-programmable devices, but particularly the STFP1, had a tendency to overfit the milder hearing losses as shown in profiles 1, 2 and 3. The XTMA4 fared better than the STFP1 in terms of over-fitting, however the XTMA4 had a high proportion of under-fitting for the more severe hearing losses.

On average, conventionally customizable devices were never over fitted, but were under fitted in the high frequencies for all profiles (see figure 20 and appendix T for percentage over and under fitted with a 3 and 5dB criteria).

Feedback
All hearing aids in the current study were fitted with a closed/power dome and all had feedback reducing systems. The sophistication of the conventionally customizable devices feedback protection is likely to be superior (although comparisons are difficult due to the proprietary nature of the technology).

None of the devices suffered from significant feedback for any of the fittings.

Figure 20. Average measured real ear gain and prescription targets by frequency for each hearing profile



Conclusions

Looking at the objective measures of fit to target, the lower power XTMA4 is suitable for some of the milder hearing profiles seen in LMICs, with the STFP1 being more suitable for the mild to moderately severe hearing profiles. Neither pre-programmed device was particularly suited to those with more than a moderately-severe hearing profile.

This data indicates that careful consideration should be given to the intended target group when a pre-programmable hearing aid intervention is being designed. Pre-programmed hearing aids appear most appropriate for mild to moderately severe hearing losses. Having a single device type would be most practical for a large-scale program delivered by hearing healthcare workers with minimal training, as it simplifies the training, fitting, and supply processes. If this is desirable, then a more powerful device like the STFP1 is to be preferred as it covered a wider spectrum of hearing profiles.

The main modification needed to increase the proportion of profiles fitted well with this device would be the inclusion of one or two lower-level amplification profiles.

Ideally a pre-programmable hearing device program would be coupled with the triage of severe to profound hearing loss to a more conventionally hearing rehabilitation program.

It is likely that poorer fit to target seen in the pre-programmable devices was largely due to the limited number of hearing profiles available, rather than to some technical characteristics of the devices themselves (i.e. a software rather than hardware problem).

An alternative strategy to improve the objective outcomes would be to develop a low-cost aid which can be fitted using a first-fit prescription-based algorithm rather than in a pre-programmable format. Practically speaking, at present this would require the device to be fitted using a mobile device, rather than with controls on the hearing aid itself. Whilst this increases the complexity of the delivery model somewhat, the ubiquity of relatively low-cost mobile devices makes this a very reasonable possibility. The cost of licensing of the first-fit prescription algorithm would also have to be considered, but at scale this would likely be a very minor additional cost.

Objective and self-reported outcomes for two pre-programmable hearing aids (Phase 2B)

Sample Demographics

We aimed to recruit 20 participants from each of our 4 partner clinics located in LMICs (India, The Philippines, Samoa, and South Africa). There was some attrition in participants, mainly attributable to COVID-19, experiences leaving a total of 74 participants who completed trial periods with both devices. The demographic details of the participants are shown in table 6.

Of interest, was the finding that almost 20% of fitted ears with data available had a mixed or conductive component to their hearing loss, and although a slightly lower percentage than in the population sample (~25%), it still represents a significant group and potential challenge to hearing aid fitting and management.

Table 6. Hearing rehabilitation characteristics

		Mean	Percent
Patient age		62.2 years	
Four frequency average air conduction HTL	Left	55.6 dBHL	
	Right	55 dBHL	
Income category (within country)	Unknown		1.4%
	Low		36.5%
	Lower-middle		39.2%
	Upper-middle		20.3%
	High		2.7%
Past history of aid use	Unknown		1.4%
	New user		64.9%
	Experienced		33.8%

Technical characteristics of devices

The devices compared in this part of the study were both low-cost pre-programmable hearing aids; the A&M XTMA4, and A&M STFP1. The characteristics of these hearing aids are described in Phase 2A.

All devices were fitted with a comfort coupling set which includes standard hearing aid tubing and a choice of a small or large plastic power dome.

Real ear measurement outcomes

The importance of fitting to prescription targets using real ear measurement is discussed in detail in Phase 2A. The fit to prescription target can be used as an objective measure of the efficacy of the fitting.

Real ear measurements were conducted with a variety of calibrated equipment utilizing a 65dB modulated, speech shaped, broadband signal. The root mean square (RMS) difference between the gain of the fitting and the gain of the target was calculated as an indicator of outcome (hereafter referred to as "RMS fit to target").

There was a relatively good mean fit to prescriptive target for both hearing aids, although neither typically fell within the very strict criteria for a good fit (within 3dB of target averaged across the frequency range). The more powerful STFP1 device was an average of **6dB** from target with the XTMA4 an average of **8dB** from target.

Although a small number of devices were over-fitted, patients were predominantly under-fitted (below prescription target).

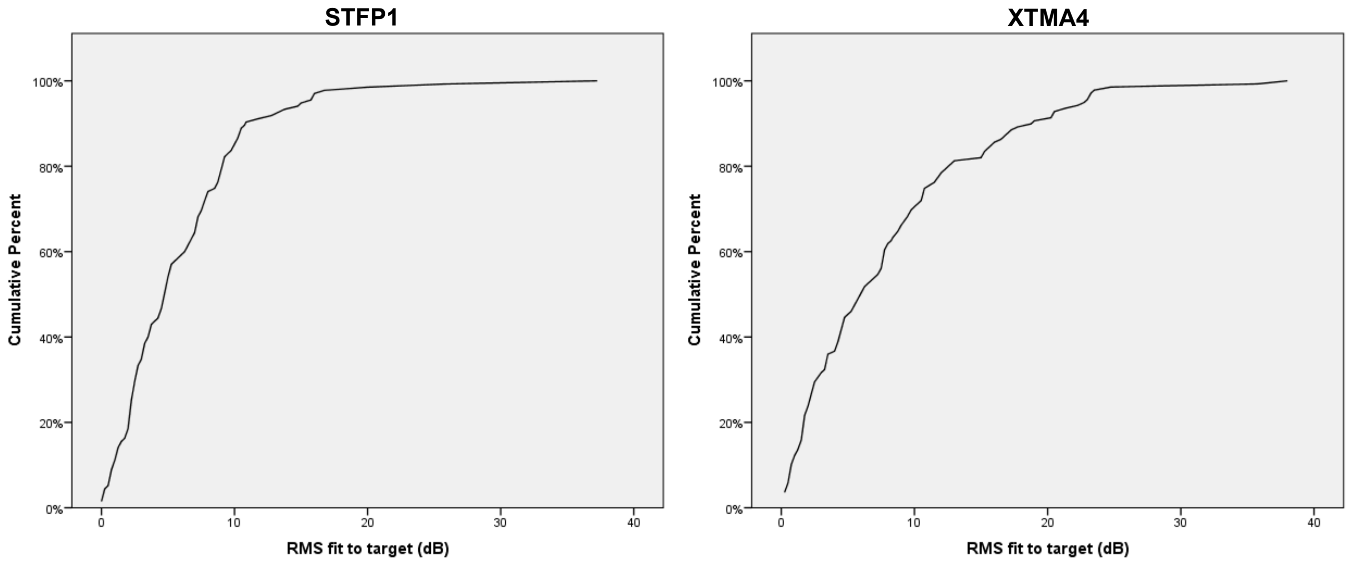
For both the STFP1 and XTMA4 there was an almost exact 70:30 split for those not fitted to target and those fitted to target using a strict +/- 3dB criteria. Figures improved with a looser criterion (see table 7) with close to 50% meeting criteria.

Figure 21 shows the cumulative percentage of ears by the RMS fit to target, revealing that for both the STFP1 and XTMA4 hearing aids approximately 80% were within 10dB of the RMS fit to target.

Table 7. Percentage of hearing aids fitted to target in Phase 2B

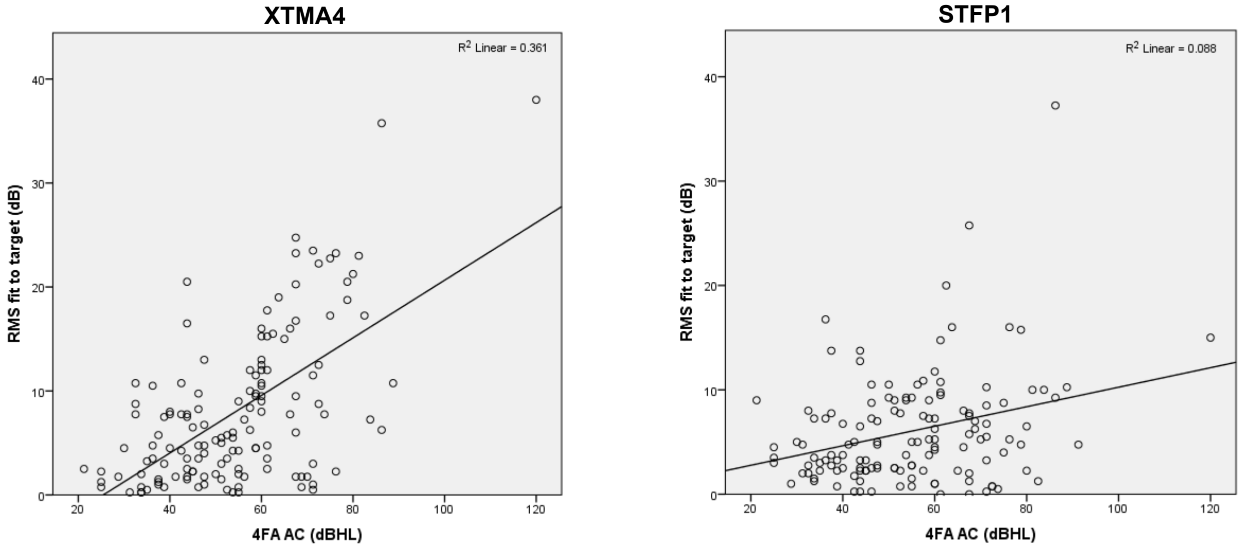
Hearing device	Criterion	Fitted to target
STFP1	Strict criterion (+/-3dB)	32%
	Loose criterion (+/-5dB)	49%
XTMA4	Strict criterion (+/-3dB)	30%
	Loose criterion (+/-5dB)	43%

Figure 21. Cumulative RMS fit to target for the STFP1 and XTMA4



The RMS fit to target varied by average hearing loss, with those with milder and moderate losses more likely to be fitted close to target, and those with more severe losses more likely to have poorer fits to target (see figure 22). Stronger correlation was seen between the XTMA4 RMS fit to target and the average hearing loss than for the STFP1, but both were significant r(139)=0.6, p<0.001, and r(135)=0.3, p<0.001 respectively).

Figure 22. RMS fit to target for the XTMA4 and STFP1 by four frequency average hearing threshold.



Influence of the clinician

At the conclusion of the trial, participants were asked to select a preferred device. Clinicians were then asked to adjust the preferred hearing aid to better suit the participants hearing loss, adjustments could include adjusting the hearing profile selection, the volume control, tone control (where available), or the acoustic coupling of the device. A final fit to target measurement was then conducted.

Clinician adjustment of the preferred device resulted in 42% and 56% of devices fitted to prescription target with a strict and loose criterion, respectively. This suggest that only a modest improvement in the proportions fitted to target (7-10%) was possible with clinician intervention.

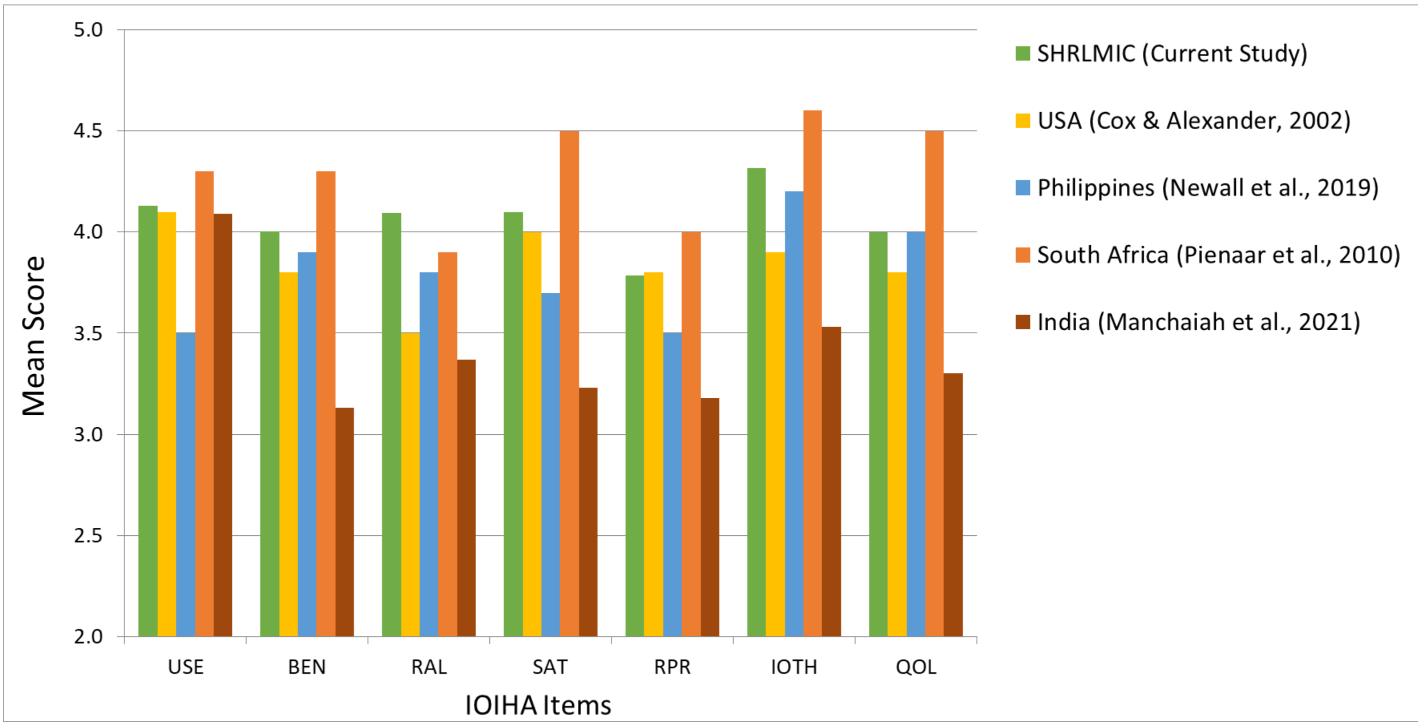
Subjective outcomes

Two key outcome measures were used to assess participant outcomes, the International Outcome Inventory for Hearing Aids (IOI-HA) and the Hearing Handicap Inventory for the Elderly/Adults (Screening version) (HHIE/A-S). These measures are frequently used internationally, and norms and comparative data are plentiful.

The IOI-HA contains items on usage, benefits/limitations, and residual disability and is delivered post intervention as a measure of outcome. The HHIE/A-S measures activity limitation, participation restriction and emotional impact of hearing loss. It contains social and emotional subscales and is generally used with a pre-post delivery methodology. However, in this study we used only the scale post intervention as a way of comparing two hearing aid interventions (the XTMA4 and STFP1).

The results of the IOI-HA for the participants averaged across both hearing device types with comparative data from previous studies are shown in figure 23. The results from this study are comparable to previous studies across all items.

Figure 23. Comparative International Outcome Inventory for Hearing Aids mean scores



Practical concerns

General difficulties with practical management of hearing aids has been reported as a factor limiting hearing aid use.(87) The Practical Hearing Aid Skills Test—Revised (88) was used to assess participants practical handling skills with the hearing devices. The participants were provided with a very abbreviated pictorial instruction sheet showing basic maintenance of the hearing aid. No other specific training was provided to patients with management of the hearing aids.

Despite minimal instruction the participants showed very few problems with basic handling of their hearing aids. Changing the battery, removing, and to a lesser extent inserting the device were all completed without much difficulty by the majority of the participants.

For both types of devices there were some difficulties cleaning the hearing aids. 30-40% of participants had some difficulty or were unable to complete the task and experienced confusion about how to best use the phone (over 50% had difficulty or unable to complete the task). For the STFP1, which had a volume control, approximately 30% of participants either could not change the volume or had some difficulty. Similar findings of difficulty with volume manipulation and telephone skills have been reported in the literature.(89)

Despite the success for most patients with basic practical skills, which is encouraging, the findings of some challenges with more complex tasks does highlight the limitations of delivering hearing aids without significant clinical instruction and follow-up training. It should also be noted that hearing aid management skills have been shown to reduce following initial fitting/instruction, but that targeted re-instruction by clinicians at follow up appointments can reduce the degradation of hearing aid management skills.(90)

One potential avenue to improve hearing aid management skills is the use of written instruction. Previous studies suggest that commercially available hearing aid user guides may have too high a reading level and are of an unsuitable design for patients, but that careful construction of user guides can result in improvements in patient outcome.(91) The user guide provided to participants in this study was largely pictorial. It appears that this had the intended effect of making basic management easier for participants to understand, but it may have provided insufficient instruction regarding cleaning and phone use.

Consideration of alternative methods to reinforce practical management skills must be considered in a LMIC context. These might include well-constructed and planned user guides, instructional videos (where possible or appropriate), and the use of follow up appointments for re-instruction with a trained local healthcare worker.

Statistical analysis

The crossover design of the study, with each participant trialing each device, allowed us to make a strong statistically valid evaluation of the fit to target for the two pre-programmable devices.

Fit to prescription target varied by hearing device type ($F(1,129) = 17$, $p < 0.001$, $\Lambda = 0.884$). A better fit to target was obtained with the STFP1 (mean 6dB from target), compared to the XTMA4 device (mean 8dB from target). Fit to target for the two devices covaried by four frequency average hearing threshold, where the STFP1 device showed a more stable fit to target as hearing thresholds increased, and the XTMA4 fitted more closely for better hearing thresholds but moved further from target as thresholds increased (see Figure 22). There was also a significant between subject effect for 4FA hearing thresholds ($F(1,129) = 57.586$, $p < 0.001$), with poorer thresholds associated with a poorer fit to target.

Neither IOI-HA nor HHIE/A-S outcomes varied by hearing device type, indicating that subjective outcomes were essentially the same for both devices.

Willingness to pay

All participants were asked to specify what they would be willing to pay for their preferred hearing device at the completion of the trial. Participants reported a willingness to pay an average of $311USD per device. There was significant variation between participants and across regions, with the average willingness to pay $50USD in Samoa, $311USD in India, $341USD in The Philippines, and $537USD in South Africa. The regional variation in willingness to pay could be due to a number of factors, one being local average incomes, another might be an element of selection bias due to the client base of the collaborating clinics and lastly expectation may vary, based on previous experience receiving subsidised or unsubsidised healthcare.

Limitations of methodology

The completion of the project was delayed by interruptions to data collection forced upon us by COVID-19. The methodology was somewhat altered due to difficulties sourcing hearing devices in a timely fashion, which again was influenced by COVID-19.

Only a small number of participants were recruited for Phase 2A of this study, potentially limiting the generalizability of the results.

Phase 2B utilized a strong cross-over design with adequate participants when grouped across the 4 centers, allowing us to make strong assertions about the preferred device. However, the difficulties in comparison of devices which varied in power, size, and number of profiles/programs means that the individual factors responsible for any variation in objective or subjective outcomes are harder to establish.

Ideally, a conventionally customizable hearing device would also have been included as a comparison condition in Phase 2B. Unfortunately, difficulty in sourcing a suitable low-cost, customizable device which could be fitted utilizing a mobile device (to ensure real-world feasibility) meant that this condition was not included. However, the combined results from Phase 2A and 2B allow comparison of conventionally customizable and pre-programmable hearing devices.

Conclusions

The subjective outcomes of both pre-programmable devices in this study were similar to those seen in high income regions with conventionally customizable hearing aids. Whilst it is encouraging to see these comparable subjective outcomes, the objective outcomes were more mediocre. A similar pattern of results has been reported in the literature with a low-cost, free-to-patient hearing aid interventions.(92)

The proportion of devices fitted within an acceptable criterion was less than 50% However figure 21 shows that many were quite close to the criterion (within 10dB of the RMS fit to target). A typical volume control has at least a 10-15dB range, which would put almost 80% of the participants within volume control range of an acceptable fit to target.

Theoretically, a participant (or clinician) could adjust the aid volume control to be well within even quite a strict criterion of adequate fit to target. In practice this would require that the hearing aid has adequate power, would not produce acoustic feedback, and assumes that the patient and/or clinician are able to subjectively identify the need for the adjustment.

Based on the results of Phase 2A we anticipated difficulty fitting those with more severe or profound hearing loss, and this was indeed the case. The study sample included approximately 20% of participants in this more severe hearing loss range. If these participants are excluded from the analysis, an acceptable fit to target is achieved for over 50% of the remaining participants for both devices.

Clinician involvement in the fitting improved the proportions of participants fitted within an acceptable criterion, but not substantially. This likely reflects the technical limitations of the pre-programmable devices, particularly their lack of substantial control over the frequency response.

The hearing aid coupling (thick tube, elbow, and closed dome/earpiece) used in this study was well tolerated by users with minimal feedback reported. It should be noted that, for those with severe to profound hearing loss, a customized earmould would be recommended and for those with a milder loss a more open dome than used in the present study would be required.

A final but important concern not directly addressed in this report is the quality of the hearing assessment and its impact on the fitting of hearing aids. An accurate hearing assessment is required for an accurate amplification profile selection or first-fit prescription. Participants in this report were assessed in fairly optimal acoustic conditions, this may not be the case in a large-scale hearing service delivery program, and this will impact outcomes (colloquially this is known as the; "garbage in-garbage out" problem). The literature shows that accurate hearing assessment can be made in the field, (67, 93) and how this may be achieved should be considered when designing an intervention program.

Patient and Clinician Semi-structured Interview (Phase 2C)

Sample demographics

At the conclusion of the trial described in Phase 2B a subset of participants and clinicians involved in the project completed a semi-structured interview regarding their experiences with the two pre-programmed hearing aids and (where relevant) conventionally customized hearing aids. In all, 5 clinicians (one from India, Samoa, and South Africa, and two from the Philippines) and twenty-five participants (four from Samoa and seven each from the remaining sites) were interviewed.

Clinician experiences

Ease of fitting and adjustment

Overall, the clinicians found both the pre-programed aids easy to fit, although there were comments that the XTMA4 was easier to fine tune and fit to target, whereas there were issues reported with push button programming on the STFP1 aid itself. One clinician reported that they would have no trouble training a nurse or community healthcare worker to complete a fitting.

> *"....WITH HOW FAST THE DELIVERY OF SERVICES IS AND HOW CHEAP IT COULD BE. I DON'T THINK THERE ARE CHALLENGES WITH PRE-PROGRAMMABLE HEARING AIDS IN TERMS OF SERVICE DELIVERY." (CLINICIAN PHILLIPINES)*

Counselling

One clinician stated that they spent less time counselling those with the pre-programmed aids as they could not be customized in the way conventional aids could.

(With conventional aids) "You get to build a rapport with the individual one on one, which helps an audiologist know better in terms of his/her listening needs. And cater to those particular needs and customize is the biggest advantage. You can keep tabs on your subject on how they are doing with the hearing aids with follow ups" (India)

This same clinician later stated a concern that these aids, without proper counselling, could lead to rejection of the aids.

"While I am trying to think that something is better than nothing, (no hearing aid at all), I also am hoping that it does not lead to drop outs in the hearing aid users, specially with no counseling or follow ups, making them think that it is doing no help. Again, setting the expectations right would go a long way especially for a first time user." (India)

However, another clinician felt the pre-programmed devices allowed more time for counselling clients, as less time was spent on the fitting.

"The trial devices were easier to fit and that left time for more other counselling of the patients." (Samoa)

Features

Clinicians reported that clients were drawn to the small size of the XTM, even though it was not appropriate for greater degrees of hearing loss. Client also appreciated the volume control of the STFP1. The phone-based application control of the XTM was reported by both clients and clinicians to be a problem with respect to connectivity and ease of use.

Whilst all clinicians reported that both pre-programmable aids were accepted by the clients, easy to use, manage and change batteries, there was concern from the clinician's perspective that the devices were not fully customizable for multiple listening situations, and that adjustments would be hard if the hearing deteriorated. Interestingly, one clinician reported that a client who had previously lived overseas and had been fitted with conventionally customized devices complained at the inequity of a situation where they were now forced to live with, what they saw as a less sophisticated hearing aid, because they could not afford a conventional device.

Other benefits identified by clinicians included speed and ease of fitting, cost and accessibility.

The clinicians themselves had had little to no experience with pre-programmed aids prior to participating in this study, they stated they were not widely available at this stage, but that they certainly saw potential benefits for some clients (for instance those with low income, or with poor access to health services).

Trial participant experiences

There was no clear preference for the XTMA4 or STFP1 in the client cohort, however there were clear and consistent reasons for each participants choice of preferred device. Clients overwhelmingly reported being motivated to wear the aids for themselves, their family members, and their work. They also reported feeling capable of managing and using the aids, and those that were unsure were happy to ask family members or their clinician for assistance.

> *"… YES. I CAN HEAR SOUNDS I COULDN'T HEAR BEFORE. BEFORE, I COULD HEAR WITHOUT A HEARING AID BUT I COULDN'T HEAR CLEARLY WHAT [PEOPLE] WERE SAYING. NOW THAT I HAVE A HEARING AID, I CAN CLEARLY HEAR WHAT THEY'RE SAYING…." (PARTICIPANT)*

Ease of fitting and adjustment

The clients reported that they were happy with the process of the fitting and trial of the aids. They all found the aids useful and were planning on continuing to use their preferred aids now the study was complete. Both aids were reported as easy to use and manage.

Benefits of devices

Clients that chose the XTMA4 as their preferred device reported that they liked the compact size, it was comfortable and felt secure in the ear. The sound quality was also discussed- this aid was reportedly not as loud but was clearer and more balanced than the STFP1.

For those that chose the STFP1 the primary reasons for doing so were the volume control and the increase in loudness.

Limitations of devices

Criticisms of the XTMA4 were that it did not have a volume control, even though it could be adjusted with an app, some clients did not have a smart phone, or preferred not to carry it with them. There were also comments that the clarity and loudness of the XTMA4 were not as good as the STFP1.

The main objections clients report to the STFP1 were size (too big, noticeable, sat badly behind the ear, got caught in facemasks, uncomfortable with glasses) and accidently hitting the volume control and changing the settings. There were also comments that the STFP1 was too loud.

Despite these concerns most clients reported being happy with both aids and had chosen their preferred aid based on size and/or volume

> *"… SOMETHING FEELS MISSING. I DON'T THINK I WAS ABLE TO ASK HOW TO USE THE CELL PHONE. HOW DO I PROPERLY HANDLE IT? WHERE THE JACK IS FOR THE OUTPUT OF [THE HEARING AID], WHAT THE CORRECT HANDLE IS." (PARTICIPANT)*

control. Many clinicians and clients reported that the ideal aid would be compact with a volume control.

Barriers to fitting
Overwhelmingly, clients reported cost as a potential barrier to hearing aid fitting. Access (transport, proximity to services) was also reported as a barrier.

Conclusions
Clinicians clearly found the pre-programmable fittings to be quick and relatively easy, a response which bodes well for a potentially scalable delivery model. They were less impressed with the limited fitting range of the smaller device (XTMA4), and the adjustability of the larger device (STFP1).

Both trial participants and clinicians acknowledged that the smaller device was generally cosmetically preferable, but that loudness of the STFP1 was superior.

There were some concerns from clinicians that poor pre-programmable experience might reduce expectations and put people off the future use of hearing devices (pre-programmable or otherwise).

Another minor theme in the clinicians' responses, is a concern about follow up services for those fitted with pre-programmable devices. Poor medium to long term outcomes are seen in hearing aid delivery programs which fail to provide provision for follow up, service, and repair of devices.(92, 94) Hearing loss is a chronic condition requiring long term care and management and this must be considered when planning an intervention program.

Ideally it seems that a cosmetically appealing device, with a volume control, and adequate adjustability to meet the hearing profiles encountered in LMICs would be preferrable. This constellation of features is difficult, but perhaps not impossible, to obtain with the additional need for the device to be very low-cost, rugged, and reliable.

Report Conclusions

The two key challenges this report set out to overcome were: the lack of data on the common audiological profiles of clinical populations in LMICs, and the potential benefits and limitations of pre-programmable hearing devices for these populations. The lack of representative data makes planning hearing health interventions in these regions difficult, reducing our ability to predict the hearing rehabilitation needs and optimal rehabilitation methods for local populations.

One of the reports main objectives involved the development of a large database of audiological profiles from a representative set of countries across all LMIC World Bank regions. This goal was achieved, allowing us to examine the demographic and rehabilitative characteristics of clinical populations in LMICs. This large clinical sample also allowed us to derive a set of representative audiological profiles.

A second objective was to compare the derived audiological profiles to those published in high income countries to determine whether LMIC specific audiological profiles are needed for these countries. The data suggests that the audiological profiles seen in LMICs as a group are not well represented by the configurations seen in high income regions. There is significant variation in both the configuration and level of hearing loss comparative to high income regions.

There was much less variation in the configuration of hearing loss across LMIC regions. However, a country level analysis shows a clear association between measures of per capita income and the severity of hearing loss, with poorer average hearing thresholds, and greater proportions of more severe hearing loss seen in lower-income regions.

Accordingly, pre-programmable devices targeted for use in LMICs should have hearing aid profiles tailored specifically to these regions. The profiles should be flatter, and the devices should be capable of fitting up to a moderately severe hearing loss. Whilst individualized country or region profiles may not be needed, the variation in average hearing thresholds across countries should be considered during program design. If both a lower and higher power pre-programmable device is available, the mix of these devices should be altered based on the target countries per capita income.

This report also identifies the importance of considering the high rates of mixed and conductive hearing loss found in those presenting for ear and hearing care in LMIC populations. Practical difficulties often arise when fitting mixed and conductive hearing losses, medical and surgical referral pathways must be considered, and altered amplification characteristics may be needed to maximize patient benefit in these cases. Further implementation research is needed in order to evaluate the effectiveness of community-based health worker mediated screening and triage in hearing aid programs.

The poor uptake of hearing rehabilitation in the clinical samples, even in those with quite severe impairments, attests to the large unmet need for hearing services in LMIC populations. The poor uptake is likely to primarily reflect financial barriers and lack of available services, with factors such as distance to service (for rural and remote populations), poor awareness and health education, and stigma also playing a role. A pre-programmable hearing aid approach in LMICs is well suited to overcoming the cost and service hurdles but will not address the other barriers identified. Education and awareness campaigns should be undertaken in concert with hearing aid programs to maximize device uptake and promote earlier intervention.

The third and fourth objectives of the report were to investigate the benefits and limitations of pre-programmable hearing aids in comparison to conventionally customizable devices. In order to undertake a laboratory and clinical trial, relatively low-cost, easy to fit, pre-programmable devices were procured from commercially available sources and were evaluated for their suitability in addressing the hearing needs of those in LMICs.

The subjective outcomes of the pre-programmable devices evaluated in this report were of a high standard and comparable to those seen in conventionally customizable hearing aid fittings. The generally positive opinion of the devices was corroborated by in-depth interviews with trial participants.

Measurements of objective benefit showed some clear weaknesses in the pre-programmable devices, in particular with their ability to fit a wide variety of hearing profiles. The development of amplification profiles, which better reflect the hearing profiles of those in LMICs is likely to significantly improve the objective outcomes, as is the selection of at least a moderately powerful hearing aid with a volume control to allow for increased fitting range and adjustability.

Consideration should also be given to the development or selection of a low-cost device utilizing a first-fit prescription-based algorithm, as objective outcomes are substantially improved with this fitting strategy. Consideration must be given to any extra costs involved, including the increased cost of service delivery which would require a mobile phone for those fitting the devices.

Previous research has identified concerns with lack of follow up services in hearing aid programs delivered in LMICs.(92, 94) These concerns were further highlighted in this report, with both device users and hearing healthcare workers expressing concerns about ongoing device management. Service delivery models must include a provision for ongoing local support services in order to maximize the long-term outcomes of device users.

The data set collected during the course of this study will be made freely available via Research Data Australia (https://researchdata.ands.org.au/), allowing other potential stakeholders the chance to glean further insights from the material.

Overall, with careful application, pre-programmable hearing aids offer a scalable solution suitable for a sizable portion of the world's hearing impaired population, whom up till now have received little in the way of hearing rehabilitation.

Appendices

Appendix A. Global Hearing Health Co-operative collaborating partners and organizations

Name	Country	Organisation/Clinic
Dr John Newall	Australia	Macquarie University
Dr Rebecca Kim	Australia	Macquarie University
Assoc. Prof. Piers Dawes	Australia	Macquarie University
Dr Fadwa Alnafjan	Australia	Macquarie University
Mr Glyn Vaughan	Cambodia	All Ears Cambodia
Xuewei "Brad" Zhou	China	Jilin University
Ms Donna Carkeet	Dominican Republic	EARS Inc Hearing Clinic Centro Cristiano de Servicios Medicos
Mr Miguel Evangelista	Dominican Republic	EARS Inc Hearing Clinic Centro Cristiano de Servicios Medicos
Dr Heba Ghannoum	Egypt	Faculty of Medicine Helwan University/Nile center for Audiovestibular medicine
Prof. Bradley McPherson	Hong Kong China	University of Hong Kong
Prof. Nitish Patel	India	Dr. S.R. Chandrasekhar Institute of Speech and Hearing, Bangalore
Mr Nitin Daman	India	Dr. S.R. Chandrasekhar Institute of Speech and Hearing, Bangalore
Prof. Megha Sasidharan	India	Dr. S.R. Chandrasekhar Institute of Speech and Hearing, Bangalore
Prof. S.P Goswami	India	All India Institute of Speech and Hearing
Dr C. Geetha	India	All India Institute of Speech and Hearing
Dr Dahlia Sartika	Indonesia	Kasoem Hearing & Speech Centre
Dr Siti Fatimah	Indonesia	Kasoem Hearing & Speech Centre
Dr. Sara Al-Hanbali	Jordan	University of Jordan Hospital Hearing and Speech clinic, School of Rehabilitation Sciences
Peter and Rebecca Bartlett	Malawi	ABC Hearing Clinic
Dr Noor Afzarini Hasnita Binti Ismail	Malaysia	Department of Audiology and Speech-Language Pathology, International Islamic University Malaysia, Kuantan Campus, Pahang.
Dr Mike Smith	Nepal	Ear Centre, Green Pastures Hospital, International Nepal Fellowship, Pokhara, Nepal
Anup Ghimire	Nepal	Ear Centre, Green Pastures Hospital, International Nepal Fellowship, Pokhara, Nepal
Dr Shankar Shah	Nepal	Department of Otolaryngology HSN, BP Koirala Institute of Health Sciences, Dharan, Nepal
Dr Sudip Misra	Nepal	Department of Otolaryngology HSN, BP Koirala Institute of Health Sciences, Dharan, Nepa
Dr Shyam Thapa Chetri	Nepal	Department of Otolaryngology HSN, BP Koirala Institute of Health Sciences, Dharan, Nepal
Prof Norberto Martinez	The Philippines	University of Santo Tomas- Faculty of Medicine and Surgery
Prof. Hubert Ramos	The Philippines	University of Santo Tomas- Faculty of Medicine and Surgery

Ms Ultima Anglea Alparce	The Philippines	University of Santo Tomas- Faculty of Medicine and Surgery
Prof. George Tavartkiladze	Russia	National Research Centre for Audiology and Hearing Rehabilitation, Moscow
Dr. Polina Kredina	Russia	National Research Centre for Audiology and Hearing Rehabilitation, Moscow
Dr Vigen Bakhshinyan	Russia	National Research Centre for Audiology and Hearing Rehabilitation, Moscow
Prof. Maria Boboshko	Russia	Laboratory of Hearing and Speech St. Petersburg State Medical University, St.Petersburg.
Dr Annette Kasper	Samoa	Tupua Tamasese Meaole Hospital
Dr. Sione Pifeleti	Samoa	Tupua Tamasese Meaole Hospital
Prof. De Wet Swanepoel	South Africa	University of Pretoria
Prof. Herman Myburgh	South Africa	University of Pretoria
Caitlin Frisby	South Africa	University of Pretoria
Assistant Professor Dr Pittayapon Pitathawatchai	Thailand	Prince of Songkla University
Prof. Dr. Ahmet Ataş	Turkey	Istanbul University - Cerrahpasa
Prof. Dr. Bülent Şerbetçioğlu	Turkey	Istanbul Medipol University
Prof. Dr. Gonca Sennaroğlu	Turkey	Hacettepe University
Prof. Dr. Özlem Konukseven	Turkey	Istanbul Aydın University
Prof. Dr. Suna Yilmaz	Turkey	Ankara University
Prof. Dr. Didem Türkyilmaz	Turkey	Hacettepe University
Assoc. Prof. Zahra Polat	Turkey	University of Health Sciences
Assoc. Prof. Merve Batuk	Turkey	Hacettepe University
Dr. Eyyup Kara	Turkey	Istanbul University - Cerrahpasa
MSc. Duygu Hayir Şenkaya	Turkey	Istanbul University - Cerrahpasa
MSc. Merve Çinar Satekin	Turkey	Ankara University
MSc. Gizem Babaoğlu Demiröz	Turkey	Hacettepe University
MSc. Yeşim Oruç	Turkey	Istanbul University - Cerrahpasa
MSc. Zehra Ayaz Aydoğan	Turkey	Ankara University
Büşra Nur Eser	Turkey	Istanbul Medipol University
Şeyma Tuğba Öztürk	Turkey	Istanbul Medipol University
Sude Keyaki	Turkey	Istanbul Medipol University
Melek Başak Özkan	Turkey	Istanbul Aydın University
Ms Merve Meral	Turkey	Istanbul Aydın University
Dr. Aysenur Kucuk Ceyhan	Turkey	Istanbul Aydın University
Dr. Inci Adali	Turkey	Istanbul Aydın University

Appendix B. Collaborating partner statements

East Asia and Pacific

Cambodia

Hearing health services are underdeveloped in Cambodia. The public sector remains unable to provide high quality, high volume healthcare with equitable health outcomes yet to be achieved. Accessibility remains a problem in rural areas and out-of-pocket health expenditures remain high.

There is one adequate quality public service location available (the National Eye and ENT Hospital), and a few other multi-disciplinary hospitals in the capital, Phnom Penh, providing ENT, but not audiological services. NGOs contribute significantly to the delivery of hearing healthcare services in the country, despite there being only a handful of groups focused on this specialist field.

Services (both diagnostic and rehabilitative) are delivered in most cases by primary ear and hearing healthcare clinicians (through NGO-related programs), with a smaller number by ENT physicians and a few minimally-trained commercial hearing aid dispensers. The ratio of ENT and audiologists per capita is low compared to global averages.

The public health service and NGOs recognize government health equity funds registration to ensure free services for the poor. Typically, NGOs run multi-tiered cost recovery schemes with those able to afford services subsidizing the majority caseloads – the poor. There are very few private hearing aid dispensers in the capital. Hearing aid costs vary greatly from around US$50 to US$ 1500.

Most Cambodians live rural lives in scattered villages. Infrastructure is poor and transportation for many is impractical or unaffordable. In response, a few NGOs run outreach clinics across multiple provinces, additionally some NGOs, such as All Ears Cambodia also target vulnerable and high-risk populations. There are multiple special interest groups in the region including; children living with HIV, individuals with cranio-facial abnormalities, victims of landmines, and patients with leprosy.

Data from Cambodia was collected by one partner organization, All Ears Cambodia.

China

Hearing services in China are developing. Many ENTs are trained each year, but the number per-capita is still lower than in high income regions. Audiologists are in much shorter supply with numbers per-capita extremely low. Full audiological training programs have only developed in China (excluding Hong Kong) in relatively recent times. Technicians also deliver services in China, many being trained by and working for manufacturers and private hearing aid dispensing companies. Development of hearing services in the region is ongoing and includes the introduction of newborn hearing screening, and increasing numbers of cochlear implants, particularly in children. Services for adults and children are available in urban areas, but the rural population remains under-served. Cost of services can be a significant barrier to rehabilitation for the majority of the hearing impaired population.

Data from China was collected by one partner organization, Jilin University, Changchun, China.

Indonesia

Indonesia, with an estimated population 275 million (World Population Review, 2021), lacks resources for the diagnosis and rehabilitation for those with hearing impairment/deafness. There is a deficit of human resources, such as teachers of the deaf, speech therapists and audiometricians.

However, there is some reason for optimism. Training of ENTs is relatively well developed, with audiology training now undertaken in the country. Technically trained clinicians with 3- 6 months in-house training in private institutions are the primary hearing health care providers in the country and, with a much smaller proportion, academically trained clinicians (audiometrists) with 3-year undergraduate training in a public institution. There is still a significant deficit of well-trained clinicians in the region, particularly audiologists. Currently, there are only 3 audiologists with international standard (graduated from Australian institutions) and 1 audiological physician (trained at University College London, England).

ENT and hearing clinicians are concentrated largely in urban areas leaving the rural population underserved. Hearing aids are largely delivered through private companies, with some NGOs assisting with hearing service delivery. Based on research data from the Indonesian research institution and health development (Badan Penelitian dan Pengembangan Kesehatan, Riset Kesehatan Dasar (2013)), 2.6 % of the population ≥ 5 years of age was hearing impaired. The age distribution and its prevalence was > 75 years of age = 36.6 %, 65 – 74 years of age= 17.1 %, 15 – 24 years of age = 0.8 % and 5 – 14 years of age= 0.8 %. Some estimates suggest that 91% of Indonesians who need hearing aids do not have them. A significant reason for this may involve cost and physical access to services (Australia Indonesia Partnership for Economic Governance, Monash University, 2017).

Data from Indonesia was collected by one partner organization, Kasoem Hearing & Speech Centre.

Malaysia

In Malaysia, hearing health services are still developing. Audiologists (4-year undergraduate training) are the primary hearing health care provider, delivering diagnostic services in both public (~80%) and private (~20%) institutions. The ratio of audiologists per capita is considered moderate compared to global averages. Access to audiological services is relatively easy for those in the urban areas as compared to rural areas. In term of hearing aids, eligible Malaysians can obtain financial assistance for their hearing aids from various government agencies (e.g. the Ministry of Health, the Department of Social Welfare, the Public Service Department and the Department of Veterans Affairs). Otherwise, hearing aids can also be purchased privately with the cost per hearing aid starting from ~$360 USD.

Data from Malaysia was collected from one partner organization, International Islamic University Malaysia

The Philippines

While the Philippines has adopted the universal healthcare approach to public health, ear and hearing health services are lagging behind due lack of a national program, limited hearing health professionals, and poor awareness on hearing disability and its negative effects. Since 2003, two strategic planning workshops were co-hosted by CBM through Better Hearing Philippines (International and local philanthropic organizations respectively) and the Department of Health, but unfortunately their recommendations have not been fully realized. Although a Masters program leading to an audiology degree was established at two local universities in 1999, the ratio of audiologists has changed very little over time, and is still low with a ratio of approximately 1:1,050,000 population. The ratio of ENTs is somewhat better at 1:160,000 population, but most ENTs practice in major cities, hence access to ear and hearing health services in many provinces is still limited.

Most audiologic diagnostic facilities are available privately with less than 10 operated by government hospitals. Diagnostic services for both private and government facilities are paid out of pocket ranging from USD $10 - 15 for pure tone audiometry. Though support for hearing aids is available through the government health insurance program (USD $700 covering hearing aids which can be fitted every 5 years), only two government facilities are licensed to dispense them hence the very poor uptake. Privately, a six channel hearing aid would cost USD $700 on average, with more high end hearing aids priced up to USD $6,000 per unit.

Data from Philippines was collected by one partner organization, the University of Santo Tomas.

Samoa

Ear and hearing health services are virtually non-existent throughout the Pacific Islands. As in other Pacific countries, hearing services in Samoa until recently consisted only of short-term overseas philanthropic visits, with some training provided in ear/hearing healthcare to local non-health professionals. The ENT Department of the national hospital was established in 2017 by General/ENT Surgeon Dr Sione Pifeleti and Australian public health/development and research audiologist, Dr Annette Kaspar, joined the team in 2019. ENT consultations are conducted on two days a week with the support of audiometry as required. Dr Pifeleti and Dr Kaspar are committed to developing public health initiatives for three days a week and providing clinical outreach services, aimed at reducing the burden of preventable hearing loss in Samoa. Participation in the UNOPS Project was seen as a useful opportunity to assess the feasibility of providing this type of hearing aid to older adults in the resource-limited Samoan context. Our experience with the project may enable the development of locally sustainable auditory rehabilitation services in the Pacific Islands.

Data from Samoa was collected by one partner organization, Tupua Tamasese Meaole Hospital.

Thailand

Hearing health services in Thailand are moderately developed in urban but underdeveloped in rural areas. Although there are a considerable number of Ear Nose and Throat Surgeons in Thailand, there is a tremendous shortage of audiologists and speech therapists, the ratio for these professions lis ower than 1:100,000 and most are available only in urban settings. Diagnostic services and hearing aid provision in the country are delivered both in public and private centers. Hearing aids are generally provided under the Universal Health Coverage and the Civil Servant Medical Benefit Scheme without cost to the patient, at a maximum price of $390 and $435 USD for each ear, respectively. Even though the Universal Health Coverage can provide great benefits in overall health care for Thai citizens, the severely limited number of audiologists is still a main barrier for hearing-impaired persons to get access to a hearing health service in Thailand.

Data from Thailand was collected by one partner organization, the Department of Otolaryngology at Prince of Songkla University.

Europe and Central Asia

In Russia hearing health services are included in the program of State guarantees of free medical care for all citizens, including neonatal hearing screening, audiological diagnostics and medical treatment of hearing disorders. These services are paid for by the Fund of Mandatory Medical Insurance. At the moment there are 267 state regional specialized audiological centers. The number of private audiological facilities is estimated at about 400. Recently a model of private-state partnership has been established. This means that private audiological services can be funded by local mandatory medical insurance funds. Services are delivered in most cases by audiologists (post-graduate trained) or ENT specialists. The ratio of ENT specialists and audiologists per capita is considered lower than global averages. Hearing aids are distributed through state and private audiological centers as well as by individual representatives of various foreign hearing aid manufacturers. Once per 4 years the cost of hearing aids of Russian manufacture fitted is covered from the Fund of Social Insurance for disabled children under 18 and adults with bilateral severe or profound hearing loss, as well as for those of older age. Costs of more expensive hearing aids can be partly reimbursed. People with hearing loss can also be provided with individual earmolds, other hearing-assistive devices such as mobile phones, TVs with speech capture technology, and the services of sign-language interpreter, by the Fund of Social Insurance if these needs are required in an individual program of rehabilitation/habilitation. Diagnostic and rehabilitative services are readily available to those in urban canters, but only to a lesser extent in rural settings.

Data from Russia was collected from two partner organizations, the National Research Centre for Audiology and Hearing Rehabilitation, Moscow and the Laboratory of Hearing and Speech, St. Petersburg State Medical University, St. Petersburg.

Turkey

Hearing health services in Turkey are generally funded by the public system (~85% public service delivery). Audiology-related services are provided by hospitals and private clinics. The ratio of ENT and audiologists per capita is considered moderate compared to global averages. Most of the audiologists work in public and private hospitals, with others working in private special education centers and hearing aid sales centers.

The newborn hearing screening program has been continuing for approximately 16 years and good coverage has been obtained, with approximately 92% of newborns being screened.

Everyone under the age of 18 falls under the public health umbrella, and public support for hearing aids is provided on a limited basis. Hearing aid prices are between USD$ 500 and USD$ 2000, and public support is between USD$ 100-200 (for each aid).

Cochlear implants are provided with public guarantee, bilateral cochlear implant costs are covered for those between 0-4 years of age and the cost of unilateral cochlear implants for children over 4 years old is also covered by the public system.

Data from Turkey was collected by six partner organizations: İstanbul Aydın Üniversitesi, İstanbul Medipol University, Department of Audiology, Faculty of Health Sciences, Istanbul University Cerrahpasa Medical Faculty, ENT-Audiology and Speech Pathology Center. Faculty of Health Sciences, Sağlık Bilimleri Üniversitesi, Hacettepe University Audiology Department, and Ankara University, Medical Faculty, ENT-Audiology and Speech Pathology Center.

Latin America and the Caribbean

Dominican Republic

Hearing health services in the Dominican Republic are under-developed. NGO and local partner organizations have made great strides in establishing audiological services and training programs in the country, but there is still a very significant lack of both ENT and audiological personnel in the region. With only one not-for-profit hospital (Centro Cristiano de Servicios Médicos) and a handful of private hearing and ENT clinics, mostly concentrated in the major cities, access to hearing services can be difficult for the urban poor, and rural populations. Hearing aid costs are prohibitive for much of the population, and although some can obtain hearing aids from public funds, or through NGO donations of hearing aids, there is a vast unmet need for rehabilitation in the country.

Data from the Dominican Republic was collected by one partner organization, EARS Inc Hearing Clinic Centro Cristiano de Servicios Medicos.

Middle East and North Africa

Egypt

Hearing health services in Egypt are delivered by ENT surgeons and audiologists (who are audio-vestibular medicine physicians). The number of ENT physicians exceeds by far the number of audiologists available per capita. Diagnostic services are being carried out within both the public and the private sectors. Appointments can be made at public hospitals and institutes and there is a waiting list. An immediate service is available at private clinics and centers of audio-vestibular medicine, but not all patients will be able to afford the financial burden. With regard to rehabilitative services, school-aged children are funded by the national health insurance system whenever hearing aids are needed. Also, some employees working in the private sector receive private health insurance which can cover hearing aid fittings. The majority have to pay privately for their hearing aids. This poses quite a burden as the average cost of a hearing device is $700 USD which is significant when compared to the average wage in Egypt. Unfortunately, in rural and remote areas of Egypt, there is a lack of both diagnostic and rehabilitative hearing services and patients have to travel to the nearest governorate to receive a proper service.

Data from Egypt was collected from one partner organization, the Nile Center for Audiovestibular Medicine.

Jordan

Hearing Health services in Jordan are quite well developed. Hearing health services are provided by Ear Nose and Throat surgeons or audiologists who have an undergraduate degree in audiology. There are three universities in Jordan that offer a bachelor's degree in Speech and Hearing Sciences. Therefore, the ratio of audiologists and ENT's per capita is comparatively high. Diagnostic services are delivered both in public and private institutions. Public providers service the majority of the population, resulting in some time pressures on service. There is less time pressure on patients seen in the private sector where hearing rehabilitation services would seem to be of better quality. Unfortunately, the cost of services in the private sector are prohibitive for individuals with low or middle incomes.

Hearing aids are mainly dispensed through the private sector. The cost of a hearing aid can range from $700 to 3000 USD. The relatively high cost of hearing aids acts as a barrier to use by a large number of individuals with hearing impairment in Jordan. There is a general lack of awareness about audiology and hearing health among the Jordanian population. Newborn hearing screening is also not available in Jordan. The aforementioned factors contribute to the increased numbers of unaided hearing-impaired individuals and to a delay in the age of hearing aid fitting for most children with hearing impairment. Most hearing services are located in the urban centers, with minimal availability of hearing services in rural areas. As a result of this, individuals living in rural areas generally lack awareness about hearing services and solutions and tend to suffer from poorer hearing health.

Data from Jordan were collected by one partner organization University of Jordan Hospital Hearing and Speech Clinic, School of Rehabilitation Sciences.

South Asia

India

India is one of the rapidly emerging countries, with a fairly high prevalence of the hearing problems. In fact, according to the National Sample Survey Office, 291 per 100,000 people have disabling hearing loss in India. Audiological practice in India is developing rapidly, with efforts to increase awareness regarding hearing health and increasing hearing health seeking behavior.

Audiological services in India are available in both public and private sectors, including assessment, selection and fitting of hearing aids or cochlear implants, and aural rehabilitation. For the most part those with an ear or hearing problem consult an ENT doctor, who redirects to a qualified audiologist. In many places, audiologists work with ENT doctors in an integrated set up to provide hearing care services. The All India Institute of Speech and Hearing is one of the primary institutes that cater to India's hearing impaired needs.

However, two main barriers act as hindrances to access of hearing services– workforce and cost. Firstly, per capita, the ratio of qualified hearing care providers (ENT doctors and audiologists) is relatively low. This lack of access is even more of an issue in the rural population. Secondly, hearing care services – diagnostic and rehabilitation – are not always a part of a publicly funded program. While the middle and higher-income groups in the urban areas can often afford effective hearing care costs, the rural population often cannot bear these costs. Because the cheapest available digital hearing aid, which is approximately Rs. 7000 (approximate 100 USD) is well above what can be afforded by those on the poverty line, the overall costs of hearing care are often beyond the reach of those in the lower-income groups. However, the government has initiated the Assistance to Disabled Persons for Purchase/Fitting on Aids and Appliances (ADIP) scheme, where the underprivileged are given hearing aids for free or subsidized rates. Several steps have been taken to increase the reach of audiological services to the rural population. The National Program for the Prevention and Control of Deafness (NPPCD) by the Government of India has now successfully reached most districts of all states in India and provides primary hearing care to most of the country's rural population. Additionally, several NGOs like Audiology India are also actively involved in imparting hearing care services. All in all, even though hearing health care access and affordability is still a concern, there is great hope for future improved hearing health in India.

Data from India was collected by two partner organizations; the All India Institute of Speech and Hearing, and the Dr. S. R. Chandrasekhar Institute Of Speech And Hearing.

Nepal

Nepal has a very high prevalence of chronically discharging ears (7.4 per cent of general population have ear drum pathology). To cater for such a high burden of disease there are currently few ENT surgeons or audiologists, most of whom are based in the capital Kathmandu. Geographically Nepal is mountainous and has limited transport and health infrastructure, many roads are seasonal and subject to natural disasters such as landslides and flooding. Ear services in the country are provided mainly by Government hospitals, medical colleges and numerous charitable organizations like Impact Nepal, Ear Aid Nepal, and CBM to name a few. Most of these are in the relatively accessible parts of the country such as the Kathmandu valley or the Terai along the Indian border. Outside major cities, services are extremely limited. Even in cities, reliable audiology is rarely available and there are only a handful of centers offering hearing aids and hearing rehabilitation. Overwhelmingly, the rural population has little or no access to expert services. Over the years ear camps have evolved as a way of providing surgical services to the less privileged people in the remote parts of the country (though few are held in the more mountainous districts). They are also a tool for training primary health personnel who in time learn to identify and manage straightforward ear problems themselves, and to refer the surgically manageable ears to upcoming camps or refer to the local hospital or medical colleges. Ear camps have come to play an indispensable role in the management of ear disease. There is no national provision or specific practical training for primary ear care outside the routine primary health worker generic training.

Despite laws about noise exposure, many work in noisy workplaces without ear protection. Only a couple of small projects offer newborn hearing screening. The incidence of congenital or early onset profound nerve deafness is high, and despite many small schools for the deaf, which mainly offer a sign language education, many Deaf non-verbal people live in the rural communities without even this form of education.

Hearing rehabilitation is mainly in the form of hearing aids imported from neighboring countries with varying prices often beyond the means of the common people many of whom come to accept the deafness as a way of life. Rural people have no access to hearing aid repair or even batteries. Philanthropic organizations are involved in donating hearing aids to the needy in some areas, but usually with no maintenance or regular supply system in place. The recent introduction of partial funding for 20 cochlear implants per year by the Ministry of Health is a welcome step in the right direction. Bone conduction hearing aids are almost entirely unavailable.

Data from Nepal was collected by two partner organizations; Ear Centre, Green Pastures Hospital, International Nepal Fellowship, Pokhara, Nepal and the Department of Otolaryngology HSN, BP Koirala Institute of Health Sciences, Dharan, Nepal.

Sub-Saharan Africa

Malawi

Audiological services in Malawi are significantly underdeveloped. Hearing and ear services are provided by professional and technically trained staff. There is a severe shortage of ENT specialists, and only a handful of audiologists. A recently developed BSc in Audiology program at African Bible College (ABC) started graduating students in mid-2021, significantly increasing the number of trained hearing healthcare professionals in the country. There are also a small number of Kenyan or Zambian trained audiology technicians in country. There are two public hospitals in Malawi providing basic audiology services for a small fee. Public hospitals provide some limited outreach services and hearing aids when funding is available. One UK trained Malawian audiologist supports the small number of cochlear implanted children in the country free of charge.

A significant proportion of services are delivered by a not-for-profit organization, the ABC Hearing Clinic in Lilongwe. This is the only clinic providing more sophisticated testing for children and electrophysiological testing. The clinic provides hearing services to low-income earners for a small fee or for free. Monthly outreach services are also provided by ABC Hearing Clinic to three northern locations at no cost. The clinic also covers transport costs where necessary for all children as transport cost was found to be a barrier to access. A philanthropic organization Hear The World Foundation provides funding for good quality aids for children identified with hearing loss. Private hearing aids cost between $150USD to $1500USD.

Data from Malawi was collected by one partner organization, the ABC Hearing Clinic.

South Africa

South African hearing health services are divided into public and private sectors serving approximately 85 and 15% of the population, respectively. Audiologists (4-year undergraduate training) and ENTs typically provide services. Public health services are typically under-resourced in terms of numbers of audiologists and ENTs to patients requiring care and the availability of equipment and hearing aids is often restricted. Whilst hearing aids are provided free of charge in the public health system (with a minimal administration fee) there are often excessive waiting lists, up to a few years, to obtain devices. Service-delivery is particularly limited and often entirely unavailable in rural settings. The private sector sells hearing aids at a price that varies from around USD $1000 to $4000 with private insurance covering part of these costs.

Data from South Africa were collected by one partner organization, the University of Pretoria's Department of Speech-Language Pathology and Audiology.

Appendix C. Urban/Rural distribution

Region	Rural	Urban	Unknown
Sub-Saharan Africa	36.5%	61.0%	2.5%
East Asia and Pacific	38.2%	60.0%	1.9%
Europe and Central Asia	16.7%	56.8%	26.4%
Latin America and the Caribbean	15.9%	73.8%	10.4%
Middle East and North Africa	12.6%	32.1%	55.4%
South Asia	44.7%	55.0%	0.3%

Appendix D. History of noise exposure

Region	Yes	No	Unknown
Sub-Saharan Africa	13.2%	73.4%	13.4%
East Asia and Pacific	12.9%	57.9%	29.2%
Europe and Central Asia	5.4%	74.7%	19.9%
Latin America and the Caribbean	99.1%	0.9%	0.0%
Middle East and North Africa	7.8%	45.3%	46.9%
South Asia	2.8%	63.2%	34.0%

Appendix E. Four frequency average hearing loss in best ear and worse ear by region

	Statistic	Better Ear 4FA	Worse Ear 4FA
Sub-Saharan Africa	Mean	52.18	66.20
	Median	51.25	61.25
	Variance	537.69	591.46
	Std. Deviation	23.19	24.32
	Range	118.75	100.00
	Interquartile Range	27.50	32.50
East Asia and Pacific	Mean	49.98	66.51
	Median	50.0	65.0
	Variance	581.85	655.13
	Std. Deviation	24.12	25.60
	Range	118.75	107.50
	Interquartile Range	37.50	36.25
Europe and Central Asia	Mean	43.19	56.26
	Median	42.50	53.75
	Variance	389.25	486.25
	Std. Deviation	19.73	22.05
	Range	123.75	113.75
	Interquartile Range	26.25	27.50
Latin America and the Caribbean	Mean	39.60	54.58
	Median	30.63	48.13
	Variance	558.28	823.50
	Std. Deviation	23.63	28.70
	Range	108.75	98.75
	Interquartile Range	32.50	46.25
Middle East and North Africa	Mean	42.33	59.65
	Median	39.38	56.25
	Variance	510.201	613.0
	Std. Deviation	22.59	24.76
	Range	120.00	105.00
	Interquartile Range	31.25	31.25
South Asia	Mean	54.22	68.65
	Median	52.50	65.0
	Variance	555.27	539.63
	Std. Deviation	23.56	23.23
	Range	115.00	101.25
	Interquartile Range	27.50	31.25

Appendix F. GNI per capita PPP (current international $) by country

Clinic	GNI per capita PPP (current international $)
Malawi	1540
Nepal	4060
Cambodia	4250
India	6390
Samoa	6480
Philippines	9040
Jordan	10320
Indonesia	11750
South Africa	11870
Egypt	12210
Dominican Republic	17060
China	17200
Thailand	17730
Malaysia	27370
Russia	27550
Turkey	27780

Appendix G. Regression coefficients table for linear regression model evaluating 4 frequency average hearing threshold, GNI, age and gender

Variable	**Unstandardized Coefficients**				**95.0% Confidence Interval for B**	
	B	Std. Error	t	Sig.	Lower Bound	Upper Bound
(Constant)	45.239	1.093	41.39	.000	43.096	47.382
GNI per capita USD PPP	-.00055	.000	-17.72	.000	-.001	.000
Age	.176	.016	11.11	.000	.145	.207
Gender	1.990	.587	3.39	.001	.839	3.142

Appendix H. Proportion of bilateral and unilateral hearing loss (WHO criteria) by region

Region	**Unilateral HL WHO Criteria**	
	Bilateral HL %	Unilateral HL %
Sub-Saharan Africa	94.4%	5.6%
East Asia and Pacific	93.6%	6.4%
Europe and Central Asia	94.5%	5.5%
Latin America and the Caribbean	90.7%	9.3%
Middle East and North Africa	89.1%	10.9%
South Asia	95.3%	4.7%

Appendix I. Sensorineural, conductive or mixed hearing loss

Region	Sensorineural	Conductive or mixed loss
Sub-Saharan Africa	75.6%	24.4%
East Asia and Pacific	71.4%	28.6%
Europe and Central Asia	76.3%	23.7%
Latin America and the Caribbean	78.8%	21.2%
Middle East and North Africa	75.3%	24.7%
South Asia	60.0%	40.0%

Appendix J. GNI per capita PPP (current international $) by type of hearing loss

GNI per capita USD PPP	Type of hearing loss	
	Sensorineural HL	Mixed or conductive HL
1540	77.8%	22.3%
4060	62.9%	37.1%
4250	75.1%	24.9%
6390	60.6%	39.4%
6480	76.1%	23.9%
9040	66.2%	33.8%
10320	81.7%	18.3%
11750	62.1%	37.9%
11870	79.3%	20.7%
12210	74.0%	26.0%
17060	82.9%	17.1%
17200	92.1%	7.9%
17730	82.3%	17.8%
27370	74.9%	25.1%
27550	79.7%	20.3%
27780	77.8%	22.2%

Appendix K. Table of hearing rehabilitation uptake among those with hearing loss attending hearing clinics in LMICs by global region

Region	Aided monaurally	Aided bilaterally	Cochlear implant	Not previously aided	Unknown
Sub-Saharan Africa	3.0%	23.6%	0.0%	73.4%	0.0%
East Asia and Pacific	9.9%	9.8%	0.1%	68.7%	11.5%
Europe and Central Asia	16.6%	7.2%	1.9%	59.4%	14.9%
Latin America and the Caribbean	0.0%	9.1%	0.3%	90.5%	0.0%
Middle East and North Africa	2.0%	6.5%	0.4%	57.6%	33.4%
South Asia	9.0%	6.6%	0.0%	84.3%	0.1%

Appendix L. Binary logistic regression coefficients for model evaluating hearing device ownership by GNI per capita, 4 frequency average better ear hearing threshold, and gender, with corresponding device status proportions.

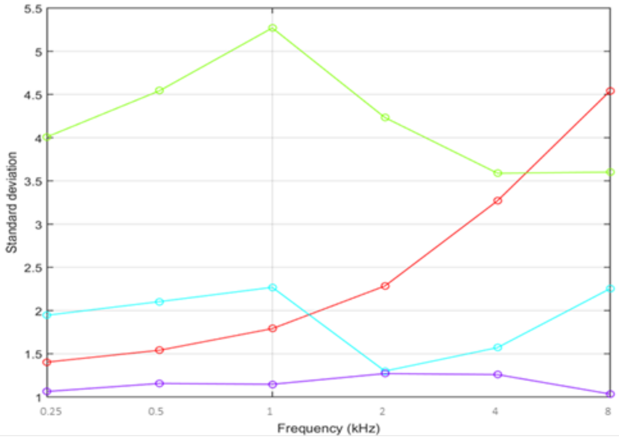
Variables	B	S.E.	Wald	df	Sig.	Exp(B)
GNIPerCapita	.000	.000	186.211	1	.000	1.000055
BetterEar4FA	.042	.002	578.036	1	.000	1.043
Gender(1)	-.047	.073	.416	1	.519	.954
Constant	-4.336	.146	882.806	1	.000	.013

a. Variable(s) entered on step 1: GNIPerCapita, BetterEar4FA, Gender.

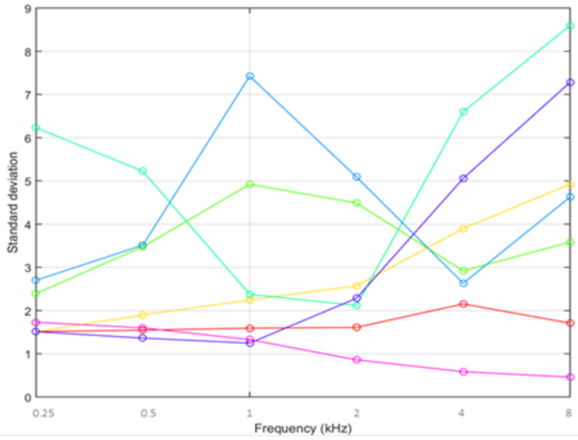
GNI per capita PPP (current international $) by hearing device status

GNI per capita USD PPP	Hearing device status	
	Not previously aided	Hearing device
1540	87.5%	12.5%
4060	97.1%	2.9%
4250	82.4%	17.6%
6390	76.3%	23.7%
6480	0.0%	0.0%
9040	73.8%	26.2%
10320	89.7%	10.3%
11750	51.3%	48.7%
11870	59.6%	40.4%
12210	85.0%	15.0%
17060	90.5%	9.5%
17200	95.0%	5.0%
17730	93.5%	6.5%
27370	79.3%	20.7%
27550	75.4%	24.6%
27780	67.6%	32.4%

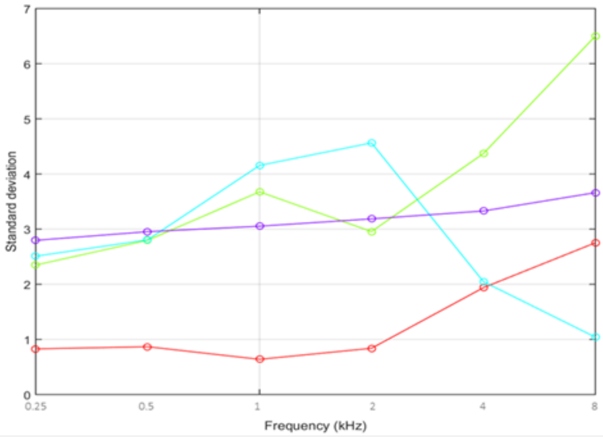
Appendix M. Standard deviation of audiometric profiles by type of hearing loss



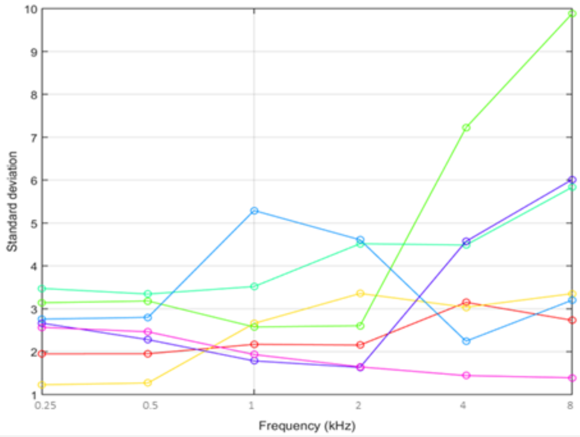
Total sample, 4 profiles



Total sample, 7 profiles

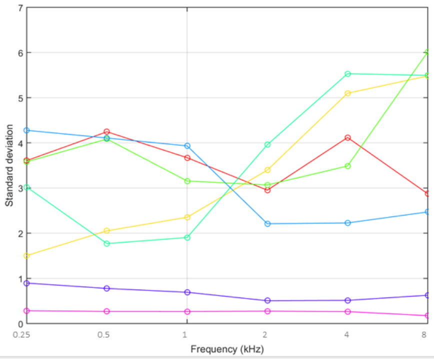


Sensorineural hearing loss, 4 profiles

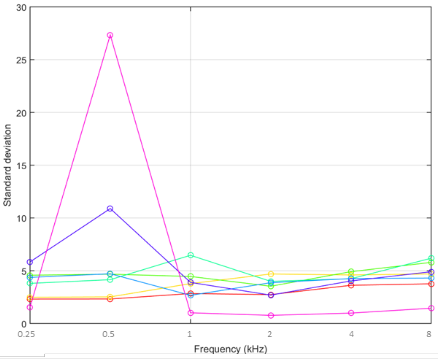


Sensorineural hearing loss, 7 profiles

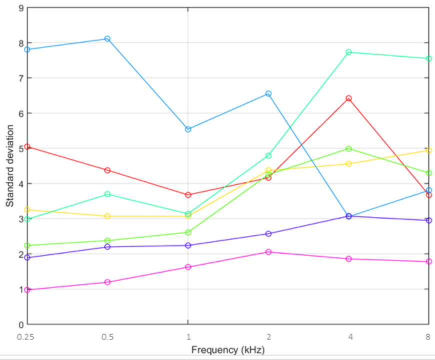
Appendix N. Standard deviation of audiometric profiles by region



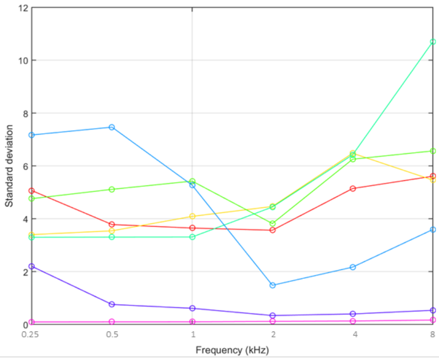
East Asia and the Pacific



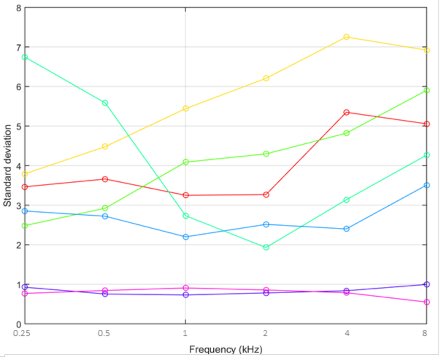
Europe and Central Asia



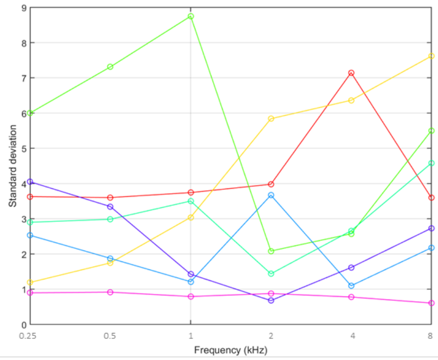
Latin America and the Caribbean



The Middle East and North Africa

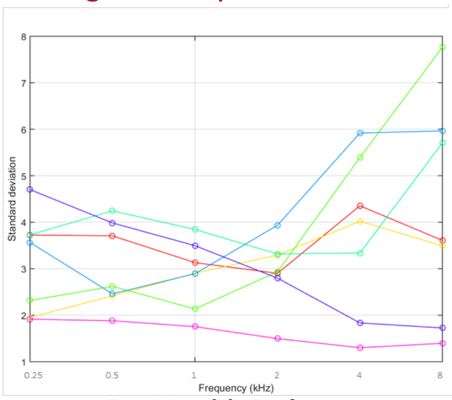


South Asia

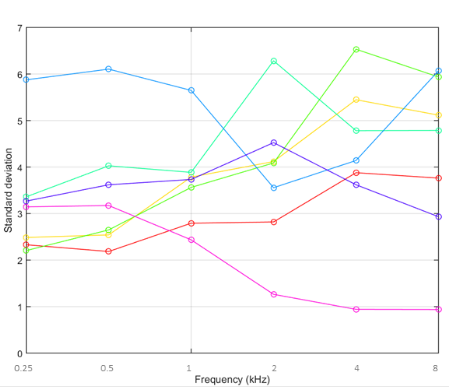


Sub-Saharan Africa

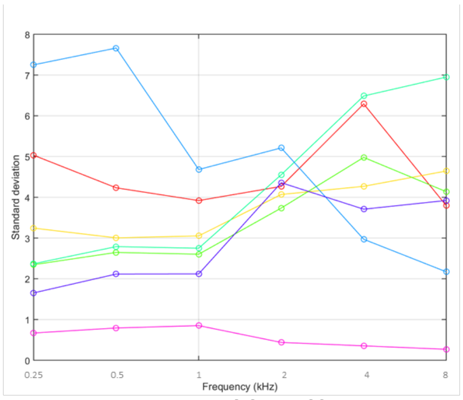
Appendix O. Standard deviation of audiometric profiles by region in those with sensorineural hearing loss only



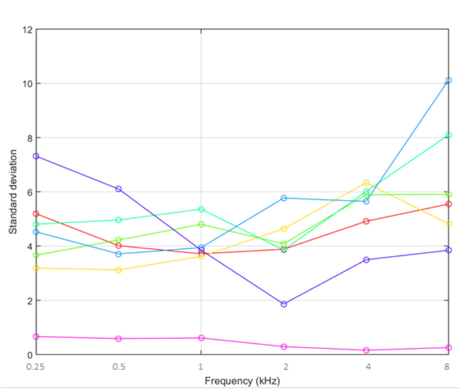
East Asia and the Pacific



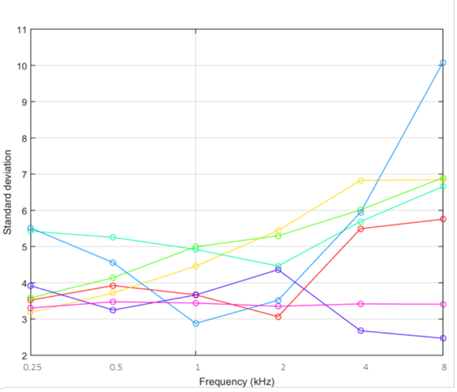
Europe and Central Asia



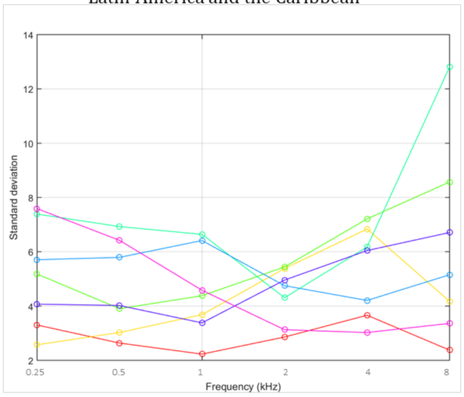
Latin America and the Caribbean



The Middle East and North Africa

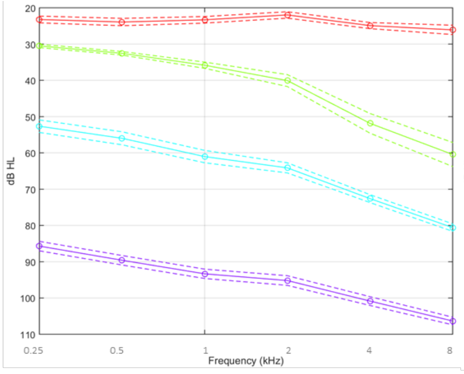


South Asia

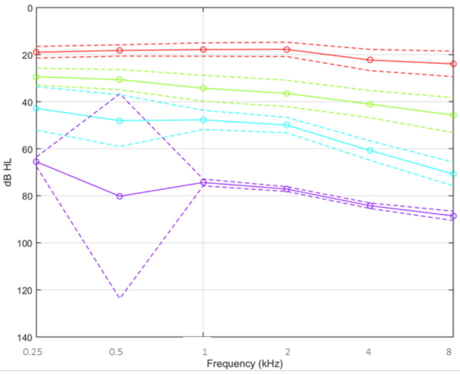


Sub-Saharan Africa

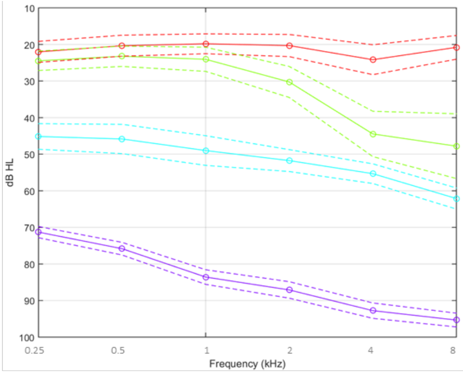
Appendix P. Audiological profiles by region (4 profiles)



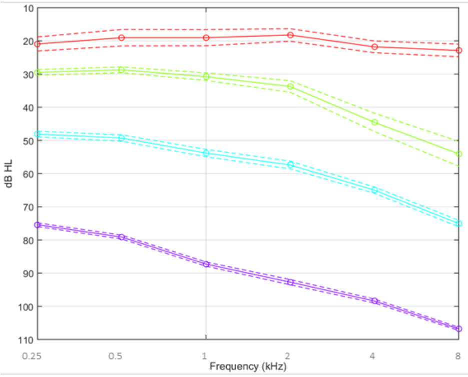
East Asia and the Pacific



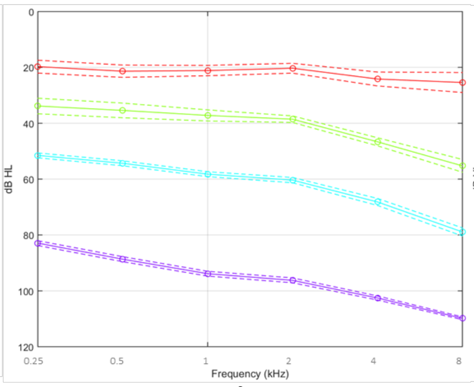
Europe and Central Asia



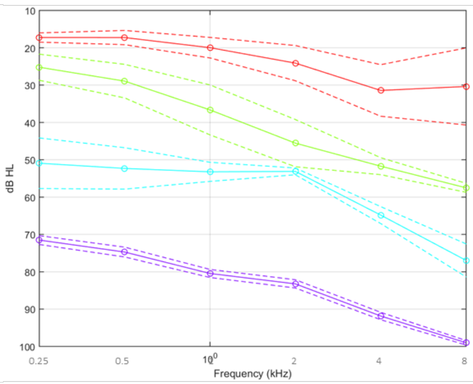
Latin America and the Caribbean



The Middle East and North Africa

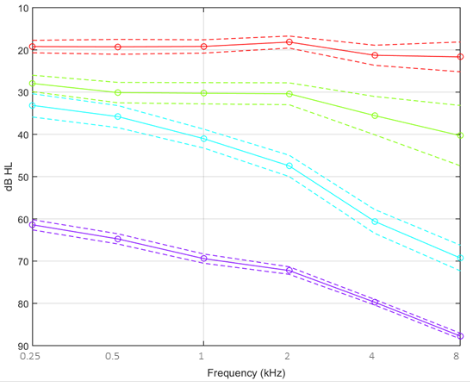


South Asia

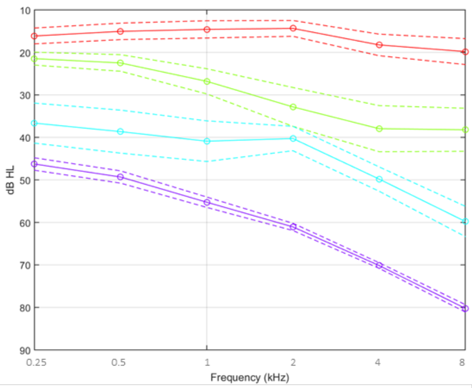


Sub-Saharan Africa

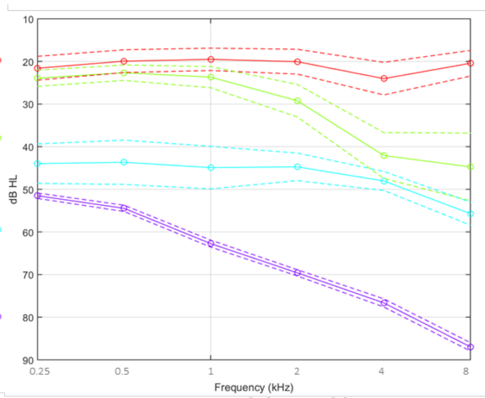
Appendix Q. Audiological profiles by region in those with sensorineural hearing loss only (4 profiles)



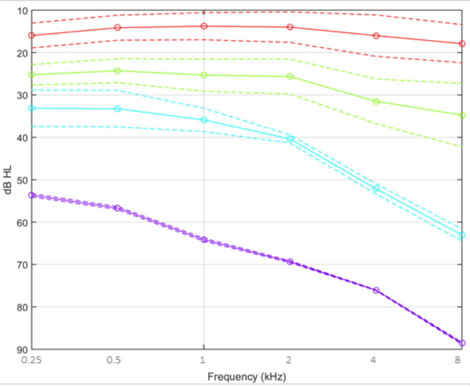
East Asia and the Pacific



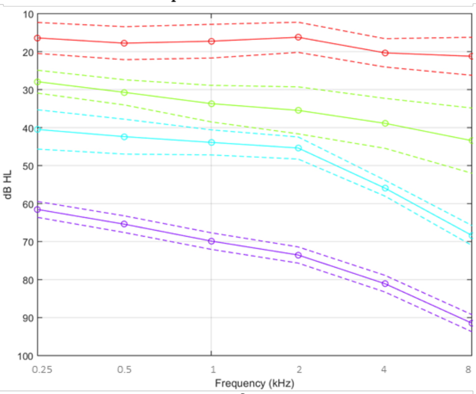
Europe and Central Asia



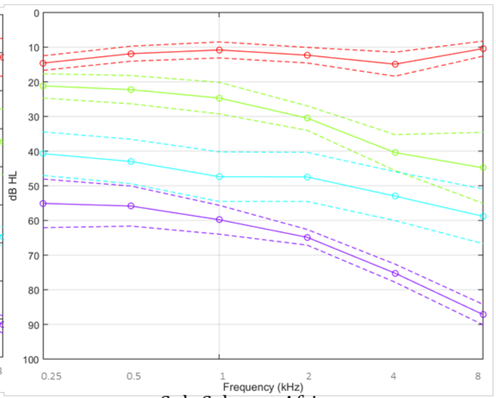
Latin America and the Caribbean



The Middle East and North Africa

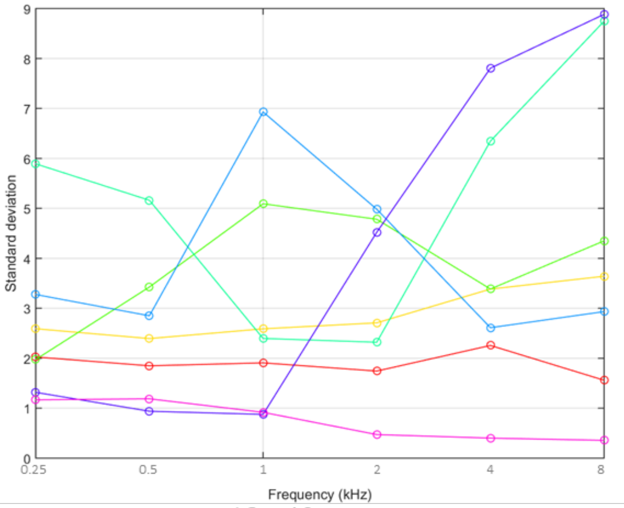


South Asia

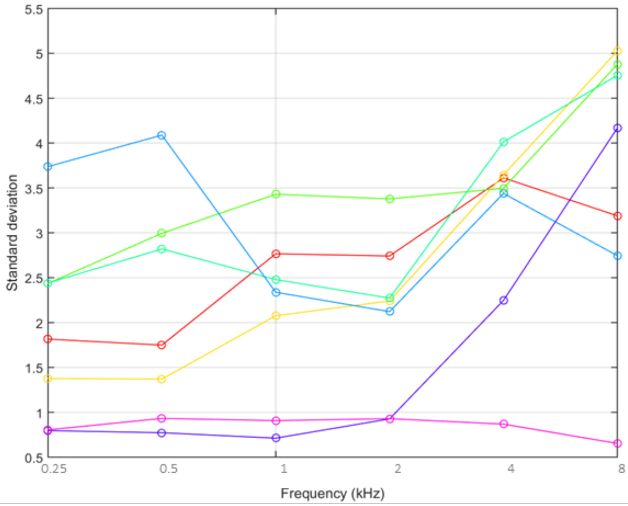


Sub-Saharan Africa

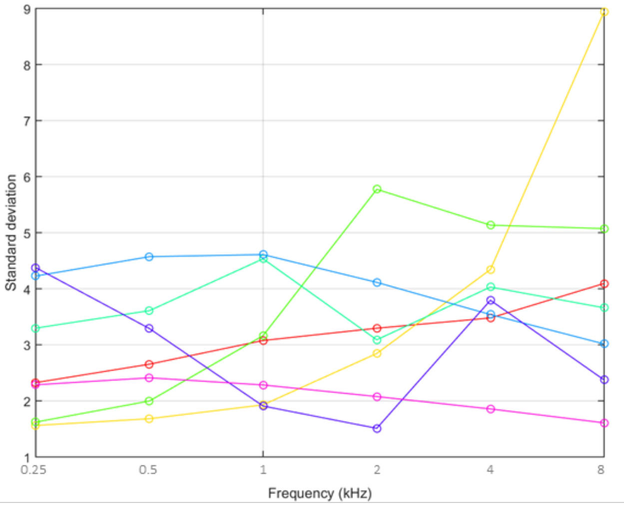
Appendix R. Standard deviation of audiometric profiles by age



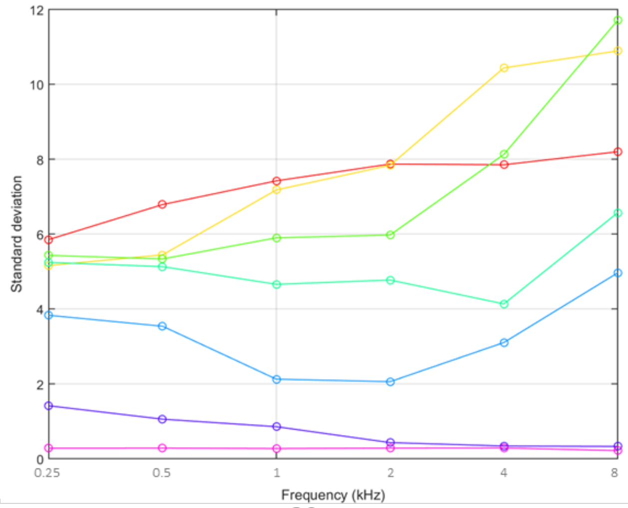
18 – 40 years



40 – 60 years

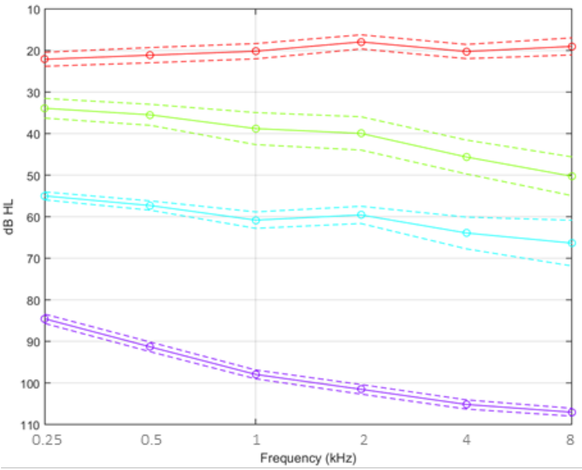


60 – 80 years

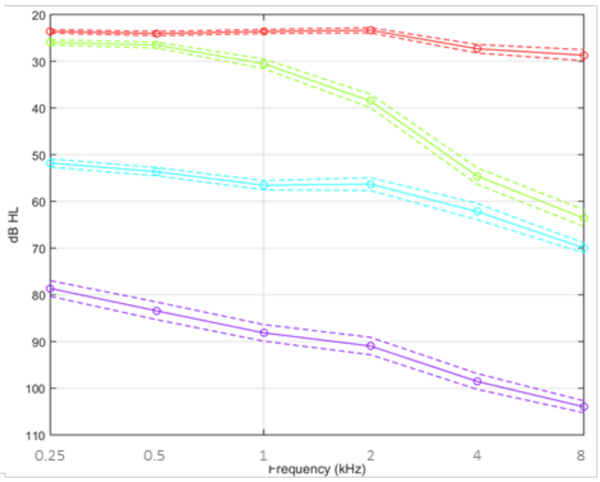


> 80 years

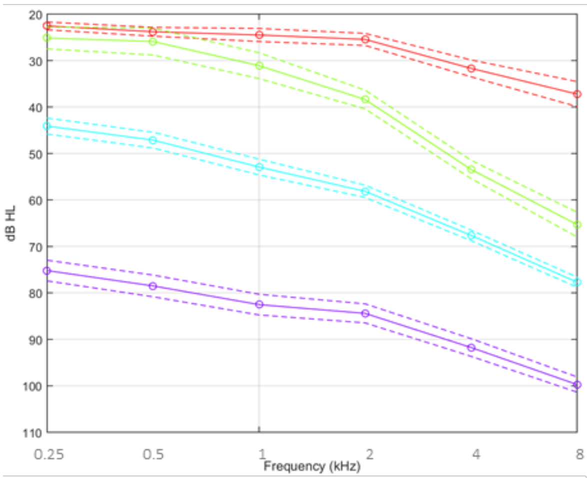
Appendix S. Audiometric profiles by age (4 profiles)



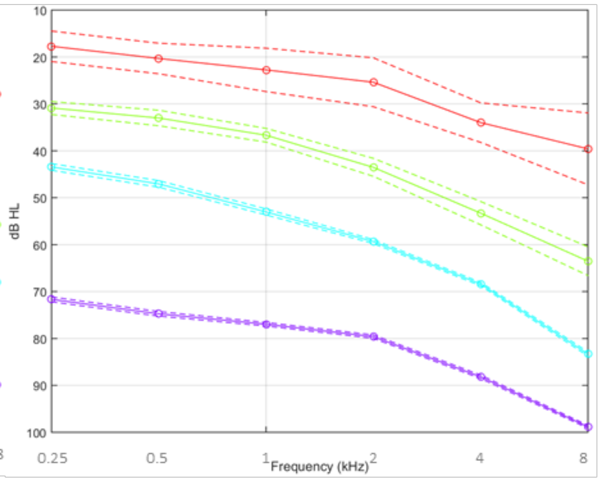
18 – 40 years



40 – 60 years



60 – 80 years



> 80 years

MACQUARIE University

Appendix T. Proportions of hearing aids over and under fitted with a strict and loose criteria

Hearing device	Criteria	
STFP1	Strict criteria (+3dB)	7%
	Strict criteria (-3dB)	12%
	Loose criteria (+5dB)	14%
	Loose criteria (-5dB)	17%
XTMA4	Strict criteria (+3dB)	17%
	Strict criteria (-3dB)	17%
	Loose criteria (+5dB)	21%
	Loose criteria (-5dB)	19%
LP Standard Aid	Strict criteria (+3dB)	2%
	Strict criteria (-3dB)	17%
	Loose criteria (+5dB)	2%
	Loose criteria (-5dB)	50%
HP Standard Aid	Strict criteria (+3dB)	8%
	Strict criteria (-3dB)	31%
	Loose criteria (+5dB)	8%
	Loose criteria (-5dB)	61%

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