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Primary Ear Care in Low-Income Settings: Hearing Loss Characteristics and Cerumen Management Efficacy

by

SELLO M. MANGANYE (19151285)

In fulfilment of the requirements for the degree **MA Audiology**
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Faculty of Humanities,
University of Pretoria

SUPERVISORS:
Prof. De Wet Swanepoel
Dr. Caitlin Frisby
Ms. Tarryn Reddy

2024

Sello M. Manganye
Department of Speech-Language Pathology and Audiology
University of Pretoria
Pretoria
South Africa
sellomarvenmms@gmail.com

UNIVERSITY OF PRETORIA

FACULTY OF HUMANITIES

DEPARTMENT OF SPEECH-LANGUAGE PATHOLOGY AND AUDIOLOGY

PLAGIARISM DECLARATION

Full Name: **Sello M. Manganye**

Student Number: **19151285**

Degree/ Qualification: **MA Audiology**

Title of Dissertation:

PRIMARY EAR CARE IN LOW-INCOME SETTINGS: HEARING LOSS CHARACTERISTICS AND CERUMEN MANAGEMENT EFFICACY

I declare that this thesis is my original work. Where secondary material is used and has been carefully acknowledged and referenced per the university requirements.
I understand plagiarism, and I am aware of university policy and its implications.

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ETHICS STATEMENT

The author, whose name appears on this dissertation's title page, has obtained, for the research described in this work, the applicable research ethics approval. The author declares that he has observed the ethical standards required in the University of Pretoria's Code of ethics for researchers and the Policy guidelines for responsible research.

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ABBREVIATIONS

AI	Artificial Intelligence
CHL	Conductive Hearing Loss
CHW	Community Healthcare Worker
HPCSA	Health Professions Council of South Africa
LMIC	Low- and Middle-Income Country
mHealth	Mobile Health
MHL	Mixed Hearing Loss
NGO	Non-Governmental Organisation
PHC	Primary Healthcare
PTA	Pure Tone Average
RETSPL	Reference Equivalent Threshold Sound Pressure Levels
SD	Standard Deviation
SNHL	Sensorineural Hearing Loss
SPSS	Statistical Package of the Social Sciences
WHO	World Health Organisation

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FORMATTING

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ABSTRACT

Hearing loss is estimated to affect 1.5 billion people globally, with higher rates in low- and middle-income countries (LMICs). Older adults frequently experience hearing and ear-related issues, such as age-related hearing loss and cerumen impaction. Access to ear and hearing services in LMICs, including sub-Saharan Africa, is challenged by limited resources, a scarcity of hearing care professionals, and underdeveloped economic infrastructures. Mobile technologies and task-shifting strategies are potential solutions to mitigate these challenges. This study implemented a community-based approach, utilising task-shifting to CHWs, to improve hearing care in these regions.

This study aimed to describe the prevalence and characteristics of hearing loss in a self-referred adult cohort in low-income South African communities and to evaluate the effectiveness of a community-based cerumen management protocol implemented in a community-based setting. This study employed a cross-sectional, predominantly quantitative design. A total of 227 participants, aged between 43 and 102 years, were recruited through self-referral from two community centres located in low-income communities (Khayelitsha and Mbekweni) in the Western Cape, South Africa. All participants underwent a hearing evaluation, and those identified with cerumen impaction received cerumen management.

Of the 448 ears evaluated, 57.9% had normal video otoscopy results, 29.1% had cerumen impaction, and 1.3% had other abnormalities. A high prevalence (97.8%) of confirmed hearing loss was observed, with mild hearing loss being the most common (45.8%). Sensorineural hearing loss was the predominant type (55.3%), followed by conductive hearing loss due to cerumen impaction (28.4%) and other conductive/mixed hearing loss (1.3%). Our cerumen management program successfully improved some participants' hearing thresholds and restored outer ear

canal integrity. After cerumen removal, 50.9% of participants with cerumen impaction had normal video otoscopy results, with mean hearing improvements of 16.2 dB (±17.9 SD) in the left ears and 15.8 dB (±17.2 SD) in the right ears. However, the overall improvement in hearing thresholds was limited in significance.

The rising rates of hearing loss in LMICs, particularly among older adults, underscore the importance of incorporating hearing care into primary healthcare (PHC) settings. Our community-based cerumen management plan effectively restored outer ear canal integrity and improved hearing thresholds for some individuals. Integrating community resources and task-shifting strategies holds significant potential in addressing ear-related issues through a cost-effective service model in resource-constrained settings.

KEYWORDS

- Hearing loss
- Low-income community
- Elderly population
- Task-shifting
- Cerumen impaction
- Cerumen management
- Community-based care

CHAPTER 1: INTRODUCTION

Hearing loss, a global challenge that transcends age groups and geographical boundaries is persistently on the rise. This increase has significant implications, as according to the Global Burden of Disease (2021), hearing loss stands as the fourth most significant cause of disability worldwide, affecting over 1.5 billion individuals in various forms (McDaid et al., 2021; World Health Organization, 2021). Given the widespread impact, it is crucial to understand the different types of hearing loss and their underlying causes to address this growing public health issue effectively.

There are three main types of hearing loss, namely, sensorineural hearing loss (SNHL), conductive hearing loss (CHL), and mixed hearing loss (MHL). SNHL is the most common type, followed by CHL and MHL, a combination of SNHL and CHL (Baltussen and Smith, 2012; Liu et al., 2020; Peñaranda et al., 2023). SNHL is often caused by sudden or progressive damage to cochlear hair cells. This damage can be due to factors such as ageing, genetics, ototoxicity, noise exposure, ear trauma, cochlear infection, and other disorders (Alshuaib et al., 2015; Keithley, 2020; WHO, 2021). CHL results from any abnormality in the outer and/or middle ear. These abnormalities can include a perforated tympanic membrane, ear infection, ear trauma, otosclerosis, and cerumen impaction (Moore et al., 1999).

Cerumen, a naturally produced substance that cleanses, safeguards, and lubricates the outer ear canal, can build up, causing impaction (Schwartz et al., 2017). While it often poses no harm, it remains the primary cause of ear canal obstruction and consequently CHL (Schwartz et al., 2017). Common symptoms of cerumen impaction include hearing loss, aural fullness, itching, tinnitus, otalgia, discharge, unpleasant odour, and even coughing (Schwartz et al., 2017). Conditions like cerumen impaction can be the primary target for the treatment of CHL. Addressing cerumen

impaction can potentially resolve existing CHL (WHO, 2021), thereby reducing a significant contributor to the global burden of hearing loss.

This burden is disproportionately high in low- and middle-income countries (LMICs), where access to ear care and treatment is often limited. Hearing loss rates vary between high-income and LMICs. About 8 in 10 individuals with moderate to more severe hearing loss worldwide live in LMICs (WHO, 2021). Evidence has shown that LMICs in sub-Saharan Africa are the most affected (Cunningham & Tucci, 2017; Mulwafu et al., 2016; WHO, 2021). The World Report on Hearing (2021) estimates that approximately 337 million Africans will present with hearing loss by 2050. Therefore, research in the sub-Saharan region is crucial to develop effective interventions and reduce the high prevalence of hearing loss.

Although available sub-Saharan African literature on population-based research indicates a high prevalence (15.7%) of hearing loss in individuals 15 years and older (Mulwafu et al., 2016), research in this area is limited (Louw et al., 2018a; Mulwafu et al., 2016). Adults aged 40 years and older are particularly vulnerable to developing hearing loss (Louw et al., 2018a; Ramkissoon & Buchanan, 2018). Age-related hearing loss is reported to be the most common sensory dysfunction among older adults (Bowl & Dawson, 2019) and the leading factor for global years lived with disability in those older than 70 years (GBD, 2021). In addition, age-related hearing loss is associated with an increased risk of cognitive decline (Bowl & Dawson, 2019). Hearing loss of any form often negatively impacts quality of life, communication, social interactions, and participation in daily activities (Powell et al., 2019). Among these impacts, there is a global economic consequence associated with unaddressed hearing loss.

The economic impact of unaddressed hearing loss is significant, with a global cost exceeding 980 billion US dollars annually (McDaid et al., 2021; Swanepoel et al., 2020; WHO, 2021). The negative consequences of unaddressed hearing loss emphasise the significance of timely intervention (Bowl & Dawson, 2019; Mulwafu et al., 2016; WHO, 2021). Provision of hearing healthcare services in LMICs is a critical challenge due to factors such as high rates of infectious diseases, scarcity of hearing healthcare professionals, inadequate economic structures, limited resources, and difficulties in accessing hearing services (Baum et al., 2019; Boisvert et al., 2023; Frisby et al., 2022a; Mulwafu et al., 2017; Spreckley & Kuper., 2018; Swanepoel, 2020). Understanding the distribution and prevalence of different types of hearing loss may be crucial in effectively addressing the destructive impact of unaddressed hearing loss.

Various prevalence rates have been reported across regions. While SNHL is the most common type of hearing loss globally, research on its prevalence in Africa is limited (Liu et al., 2020). A study in Cameroon found SNHL prevalence ranging from 61.7% to 94.4% across different age groups, while in Egypt, it was reported at 40.7% among adults over 65 years old (Abdel-Hamid et al., 2007; Fokouo et al., 2019; 2020; Tingang et al., 2015). CHL due to cerumen impaction was reported in 7% to 35% of cases across different age demographics, with a notable impact on older adults (Humes, 2024; WHO, 2021). A systematic review by Mulwafu et al. (2016) highlighted that cerumen impaction accounted for 24% of hearing loss in African community- and school-based studies.

The increasing rates of hearing loss, particularly in LMICs, underscore the urgent need for timely intervention. The intervention for hearing loss is highly dependent on the type of hearing loss. For instance, SNHL and MHL are typically treated with hearing aids (Brodie et al., 2018; Müller & Barr-Gillespie, 2015; Wardenga et al., 2020). MHL might necessitate extra measures such as

antibiotic treatment or even surgical intervention due to the involvement of the outer and/or middle ear (Hill-Feltham et al., 2021). CHL, which is often transient, can be managed with various approaches. These include medications like antibiotics and ear sprays or drops, surgical procedures such as grommet insertion, tympanoplasty, and ossicular chain restructuring, and removal of cerumen impactions (Mulwafu et al., 2016; Hirch et al., 2017; Vanneste and Page, 2019; Marchioni et al., 2020; WHO, 2021). The severity of cerumen impaction can influence the improvement in air conduction hearing thresholds, which can range from 5 to 40 dB following cerumen removal (Sharp et al., 1990; Roeser and Ballachanda, 1997; Schwartz et al., 2017; WHO, 2021). Therefore, untreated cerumen impaction can lead to mild hearing loss or exacerbate pre-existing SNHL.

Cerumen impaction can effectively be managed at primary healthcare (PHC) and community level (Munro et al., 2023; WHO, 2021). Managing cerumen may involve removal through various methods, such as using cerumenolytic agents, irrigation, manual removal, or a combination (Ogunleye and Awobem, 2004; Schwartz et al., 2017). These procedures are generally safe, though complications can still occur. The complications, although rare, may include vertigo, otalgia, tympanic membrane perforation, and bruised external ear canals (Ogunleye and Awobem, 2004; Gabriel, 2015). Unregulated practices such as self-treatment of cerumen impaction increase the risk of complications. Local and custom self-treatment methods are often chosen instead of considering the relative safety, effectiveness, and expenses associated with various treatment options (Loveman et al., 2011). In most cases, cerumen removal is carried out by professionals such as audiologists, otolaryngologists, and other healthcare personnel who have received appropriate training, such as nurses working in PHC facilities and community settings (Mulwafu et al., 2016; Munro et al., 2023). However, in low-income areas, these specialised professionals are often scarce. This lack of access can lead to improper treatment or

even neglect of conditions like cerumen impaction. This, therefore, highlights the importance of implementing task-shifting strategies (WHO, 2021).

Task-shifting is a growing service delivery approach which was introduced to mitigate the shortage of healthcare professionals and thus allows for the sharing of certain tasks across the healthcare sector (Suen et al., 2019; WHO, 2021). By training community healthcare workers (CHWs) to conduct hearing screening and handle common ear problems, including cerumen impaction, access to primary care in these areas can significantly improve (Dawood et al., 2020; Suen et al., 2019; WHO, 2021). Not only does task-shifting address the lack of specialised healthcare providers, but it also offers a cost-effective solution for ear health management in LMICs (Orji et al., 2020; Suen et al., 2019; WHO, 2021). Moreover, as the CHWs are generally part of the same community where services are rendered, they can provide culturally sensitive care, further enhancing the effectiveness of the treatment (Chadha et al., 2018; Yousuf Hussein et al., 2018; Orji et al., 2020; WHO, 2021).

Evidence shows that community-based service delivery models are effective in providing hearing care services in LMICs (Frisby et al., 2022a; WHO, 2021). The 2021 World Report on Hearing emphasises the significance of following such an approach, thereby decentralising hearing care services to the PHC level. Efficient detection and management of hearing loss in LMICs is crucial to ensure that individuals with hearing loss receive necessary care (Baum et al., 2019; Frisby, 2022a; 2022b; Mulwafu et al., 2017; WHO, 2012; WHO, 2021). Decentralisation can be facilitated by integrating task-shifting and innovative mobile health (mHealth) technologies. These strategies could potentially improve access and provide cost-effective, scalable solutions for hearing care in LMICs (Frisby et al., 2022a; Swanepoel et al., 2010; van Wyk et al., 2019; WHO, 2021; Yousuf Hussein et al., 2016). These strategies can build capacity within the community, empowering

communities to take ownership of their health and potentially lead to sustainable improvements in hearing care (WHO, 2021). Furthermore, the use of mHealth technologies can enable remote consultations and follow-ups via telehealth, making hearing care more accessible and convenient (Frisby et al., 2022a; Swanepoel et al., 2010; Taha et al., 2022; Yousuf Hussein et al., 2016; WHO, 2021). Telehealth, an effective method for delivering healthcare services and sharing information electronically, facilitates remote consultations, enables professionals to support CHWs, and streamlines referrals (Taha et al., 2022). Telehealth and mHealth solutions increasingly transform the world of hearing healthcare delivery, making it possible to provide accessible and affordable hearing care services to individuals in remote areas, monitor their hearing health in real-time, and offer personalised treatment plans without the need for physical appointments (Dawood et al., 2020; Taha et al., 2022; WHO, 2021).

Various mHealth solutions have been introduced to enhance the provision of hearing care (Dawood et al., 2020). These include application-based automated audiometry, which features transducers that reduce background noise (Swanepoel, 2023; Yousuf Hussein et al., 2018). Automated audiometric equipment has proven effective in conducting hearing screenings and pure tone audiometry for both adults and children (Dawood et al., 2020; Swanepoel, 2023; Yousuf Hussein et al., 2018). A minimally trained non-specialist CHW can successfully carry out audiological services using these mHealth tools (Dawood et al., 2020; Frisby et al., 2022; Swanepoel, 2023; van Wyk et al., 2019; Yousuf Hussein et al., 2016; Yousuf Hussein et al., 2018). Other mHealth solutions include simple triaging tools like the artificial intelligence (AI)-assisted classification of ear status, which is based on smartphone video-otoscopy (Jayawardena et al., 2020; Pendersen, 2020; Swanepoel, 2023). Furthermore, mHealth solutions have been employed in the investigation of treatment strategies and management of hearing loss (Borg et al., 2018; Frisby et al., 2022a, 2022b; Keidser et al., 2019; Lingamdenne et al., 2013).

Due to the limited number of prevalence studies and limited research on cerumen management in African LMICs, this study focused on describing the prevalence and characteristics of hearing loss, along with the initial treatment in a self-referred adult cohort in an LMIC in South Africa. This study underscores the importance of scalable, community-based service models, particularly those led by CHWs and supported by innovative mHealth technologies, as a key strategy to improve access to hearing care in economically disadvantaged environments (Frisby et al., 2022a; Swanepoel, 2023; WHO, 2021). This approach fills a significant research gap regarding the clinical and cost-effectiveness of cerumen management in PHC settings and adds to the expanding evidence supporting innovative, community-based hearing care models. Findings from this study, derived from a robust methodological framework, offer practical guidance for the effective implementation of such models in low-income settings and can inform the design of future hearing care initiatives.

CHAPTER 2: METHODOLOGY

2.1. Research Aim(s)

This research study aimed to describe the prevalence and characteristics of hearing loss in a self-referred group of adults from low-income communities in South Africa and determine the effectiveness of a community-based cerumen management protocol.

2.2. Ethical Considerations

Ethical approval was obtained from the Research Ethics Committee in the Faculty of Humanities at the University of Pretoria (HUM011/0822); (HUM032/0523) (Appendix A; B). A collaboration letter was received from the hearX Foundation on 01 August 2022. (Appendix C). Prior to the initiation of data collection, informed consent letters (Appendix D) containing all the information about the research study were signed by all participants to ensure the protection of human rights during and after data collection procedures.

2.2.1. Autonomy

The informed consent letters provided (Appendix D) indicated that participation was completely voluntary, and participants had the right to withdraw from participation at any stage without affecting any of the services they were receiving. Participants could, therefore, decide whether they wanted to proceed with participation in the study. Individuals were given an opportunity to exercise their full right of autonomy as they could decide for themselves if they wanted to participate in the research study or not, based on the information provided.

2.2.2. Protection from harm (non-maleficence)

All participants were protected from any form of harm by ensuring only evidence-based practices and eliminating potentially dangerous measures by keeping all procedures non-invasive throughout. All equipment was disinfected before and after each participant (i.e., the video otoscope specula and headphones used for pure tone audiometry were cleaned with alcohol-based swabs). The CHWs and nurse washed their hands with soap and water or used an alcohol-based sanitizer to disinfect their hands throughout testing procedures.

2.2.3. Beneficence

The Health Professions Council of South Africa (HPCSA) emphasised that the benefits of a research study should outweigh the risks (HPCSA, 2008). A sub-aim of this study was to investigate and promote a simple but efficient treatment approach for cerumen impaction. Participants were not exposed to any risk or discomfort during testing. Participants who required additional follow-up services and further management were referred to the nearest public health facilities offering hearing aids or Ear, Nose, and Throat (ENT) services.

2.2.4. Confidentiality

The research data received from the hearX Foundation did not include participants' personal or identifying information. Alphanumeric values were assigned to participant names to eliminate any possibility of identifying them. No identifying participant information (i.e., participant names, contact details, and home addresses) was used for data analysis or publication purposes. All participant information was kept confidential and was not shared with any other party.

2.3. Research Design

A cross-sectional study design following a predominantly quantitative, descriptive research approach was used in this study (Manchiah, 2022). This study aimed to describe the prevalence and characteristics of hearing loss in a self-referred group of adults receiving hearing services through a community-based model implemented in South Africa. A secondary objective was to evaluate the effectiveness of community-based treatment for cerumen impaction. This study retrospectively analysed existing research data of a project that commenced in October 2022 by the hearX Foundation, collaborating with the University of Pretoria. Permission to conduct analysis and publish research findings of the data was granted by the hearX Foundation. The hearX Foundation is a non-profit organisation (NPO) that aims to implement hearing healthcare solutions using innovative technologies.

2.4. Participants & Selection Criteria

Individuals were recruited through self-report mechanisms, community referrals, or snowball sampling (Leedy & Ormrod, 2015). CHWs were required to contact leaders of various community networks, such as community NGOs and elderly groups, to explain the study and raise awareness. Those interested were given the CHW's contact details to facilitate their participation in the study. All participant information, including contact details, was kept confidential, with access limited to the CHWs.

2.4.1. Hearing evaluation

Individuals had to meet the following inclusion criteria in order to be considered as potential participants: They needed to be aged 18 years or older, have a self-reported hearing loss, and be a community member at the Ikamva Labantu or Mbekweni Kuyasa centre.

2.4.2. Participants with cerumen impaction

For individuals to be included in cerumen management procedures, they additionally had to meet the following criteria: Have had video otoscope-identified cerumen impaction in at least one ear and be willing to use sweet oil and undergo cerumen removal by the onsite nurse to treat the cerumen impaction.

2.5. Equipment & Material

All equipment and materials used for this research study are listed below.

2.5.1. Pre-evaluation material

Prior to the hearing evaluation, all selected participants were required to complete:

- **Informed consent** (Appendix D; E): Form (in English) explaining the study details, including purpose, procedures, risks, benefits, confidentiality, and rights of the participants.
- **Pre-testing questionnaire** (Appendix F): A set of brief questions (written in English) presented to participants (in either English or IsiXhosa) prior to the commencement of the hearing evaluation to learn about their otologic history. This information was used to determine participant candidacy for inclusion in the study.

2.5.2. Equipment/materials for data collection

Table 1: List of equipment/materials used for data collection

Equipment	Description & use
Digital video otoscope	The hearScope™ (hearX Group; South Africa) was used to capture and evaluate the integrity of the outer ear canal and tympanic membrane. The digital video otoscope is equipped with an integrated AI algorithm to interpret image results by classification. This tool was used to identify possible outer ear defects (e.g., cerumen impaction, otitis externa/media, tympanic membrane perforation, etc.).
Automated smartphone audiometer	The hearTest™ (hearX Group; South Africa), a certified smartphone-based audiometer (IEC 60645-1) with Supra-aural Sennheiser HD 280 Pro headphones (Sennheiser; Germany) calibrated to ISO/SANS standards. Assessment of hearing – Threshold-seeking (500 to 8000 Hz)
Cerumen removal kit	The *OtoClear® Ear Wash Kit (Bionix Medical Technologies, Ohio, USA),* filled with lukewarm water, was used to irrigate the cerumen from the ear canal. The *Lighted Ear Curette™ (Bionix, Medical Technologies, Ohio, USA)* was used to remove the cerumen from the ear canal whenever necessary manually.
Sweet oil bottles	The sweet oil was used as a cerumen-softening agent and was handed out to participants with cerumen impaction.
Alcohol-based swabs	For disinfection of instruments such as the specula of the video otoscope and headphones.
Hand and surface sanitiser	For disinfection of hands and surfaces around the testing area such as chairs, tables, testing equipment, etc.
Data collection form (Appendix G)	A hard-copy form was used to record all individual participants' hearing evaluation results/findings.

Script for cerumen participants (Appendix H)	A guideline designed to aid the CHW in following the same procedure for management of participants with cerumen impaction and to give a structured, easy-to-follow explanation to participants.

2.5.3. Post-evaluation material

Following the hearing evaluation, a referral form (Appendix I) was used to refer participants requiring further ear and/or hearing management. For instance, participants requiring ear-related medical attention were referred to ENT specialists, and those with hearing loss were referred to a local clinic/hospital for hearing aid fitting.

2.6. Data Collection Procedures

All participants received an informed consent letter (Appendix D) with the study details and participants' rights and responsibilities during the study, which they were required to sign before commencing with data collection. The consent letters were distributed to available community members and signed by those willing to participate, who met the selection criteria and were thus selected for participation. Given the potential language barrier and potential misunderstanding of the informed consent letters (originally developed in English), the CHW translated and thoroughly explained the informed consent letter in isiXhosa whenever necessary, as it is the most common first language among residents of Khayelitsha and Mbekweni.

2.6.1. Pre-evaluation

For each participant, a brief pre-testing questionnaire (Appendix F) was administered by the CHW to gather a case history about the participant’s hearing abilities.

2.6.2. Hearing evaluation

After obtaining the participant's hearing information, the CHW proceeded with an audiological evaluation, which comprised:

- **Digital video otoscopy**: Imaging of the ear canal and tympanic membrane to detect and classify the outer ear condition/integrity using the integrated AI-system. For any outer/middle ear defects (e.g., discharge, ear infection, cholesteatoma, perforated tympanic membrane, etc.), other than cerumen impaction, detected by the video-otoscope, the CHW made appropriate referrals as outlined in Appendix I. For cerumen impaction, cerumen management was recommended to participants as described in subsection 2.6.3.
- **Automated pure tone audiometry**: Hearing thresholds were obtained at 500, 1000, 2000, 4000, 6000, and 8000 Hz for the Ikamva Labantu participants, while 500, 1000, 2000, and 4000 Hz thresholds were obtained for the Mbekweni Kuyasa participants, bilaterally. The Ikamva Labantu participants were tested using a minimum output level of 20 dB at each frequency. This choice accounted for potential background noise interference. In contrast, the Mbekweni Kuyasa participants were tested at 0 dB. The maximum output protocol was consistent for both groups attending the community centres. Specifically, the maximum output levels were set as follows: 90 dB for frequencies ranging from 500 to 4000 Hz, 80 dB for 6000 Hz, and 70 dB for 8000 Hz. Participants had two response options during the assessment. They could either raise their hand in response to pure tones or choose to self-test (operating the digital audiometry smartphone themselves) while the CHW facilitated all procedures. Before the pure tone audiometric assessment began, the CHW provided participants with clear instructions for the test and a conditioning phase to ensure accurate results. Since the audiometric assessments were facilitated by CHWs using automated audiometric testing techniques, bone conduction

audiometric information could not be included due to the lack of validity data for automated bone conduction testing (Mahomed-Asmail et al., 2013). For each participant, assessment results were recorded on individual data collection sheets (Appendix G). Feedback on audiological test results was individually provided to the participants after evaluation.

2.6.3. Cerumen management

Cerumen management was recommended to participants if cerumen impaction was identified by the video-otoscope.

1) **Sweet oil**: First, participants were offered a bottle of sweet oil (a cerumenolytic agent) to use at home over a period of five days to allow softening and natural discharge of the cerumen. Participants were instructed to place 2-3 drops of the sweet oil into their ear(s) with impacted cerumen once a day for five days. After five days of sweet oil use, participants returned for a follow-up appointment, where video-otoscopy was conducted again.

2) **Cerumen removal**: Upon follow-up, if the cerumen was still found (occluding or partial) after sweet oil use, the on-site nurse would then remove the cerumen through irrigation (with lukewarm water) or by manual removal (using lighted curettes).

2.6.4. Follow-up hearing evaluation

- **Video otoscopy**: Post-removal, video otoscopy was conducted again to evaluate the integrity of the outer ear and determine if the participant could be discharged from cerumen management procedures or be referred for further management.
- **Automated pure tone audiometry**: Follow-up pure tone audiometry was conducted post-removal to compare participants' hearing thresholds pre- and post-cerumen removal. The significance of this information was that it provided evidence of whether cerumen management was effective in improving hearing abilities (air conduction thresholds).

2.7. Data Processing and Analysis

Raw research data was received from the hearX Foundation as per the collaboration agreement (Appendix C) as a Microsoft Excel spreadsheet. For analysis purposes, the raw data set was separated into multiple sheets according to different categories, including *demographics, initial hearing evaluation,* and *follow-up hearing evaluation results*. The raw data was imported onto the Windows version of the IBM ® SPSS ® Statistics 28 software for analysis.

2.7.1. Data processing

The raw research data set was analysed using the following layout:

2.7.1.1. Demographic information:

Included the total population tested, gender distribution (number of males versus females), average age, standard deviation (±SD), and range.

2.7.1.2. Hearing evaluation:

For the hearing evaluation, initial video otoscopy results were categorised into bilateral and unilateral findings. Bilateral findings were classified as normal, abnormal, impacted cerumen, or undetermined. Unilateral findings were further broken down into combinations of normal, abnormal, and impacted cerumen, including categories such as normal/abnormal, normal/impacted cerumen, and abnormal/undetermined. Audiometric results were described with statistical information for hearing thresholds per frequency and averages of the pure tone average (PTA) for the left, right, and all ears. Hearing loss severity was graded using the four-frequency

PTA (500, 1000, 2000, and 4000 Hz), with categories ranging from normal hearing (0-20 dB) to complete deafness (≥95 dB). Hearing loss was also categorised as unilateral or bilateral and further classified into types such as sensorineural hearing loss, conductive/mixed hearing loss, and cerumen impaction with hearing loss.

2.7.1.3. Participants with cerumen impaction

For participants with cerumen impaction, the analysis included total demographics such as the age range and gender of cerumen management participants. It also noted the number of participants who were offered sweet oil and those who underwent cerumen removal. Follow-up video otoscopy findings were categorised similarly to the initial evaluation and compared pre- and post-removal. Audiometric results were analysed with descriptive statistical information for hearing thresholds per frequency and PTA averages for the left, right, and all ears, comparing pre- and post-removal data. The difference in PTA averages before and after cerumen removal was also calculated and analysed.

2.7.2. Statistical analysis

This study adopted a $p<0.05$ statistical significance level (p-value). Mean and standard deviation (SD) values of participant ages and audiometry thresholds were determined. The otoscopic results were descriptively analysed using subcategories based on whether participants had the same or different otoscopic findings in both ears. We identified bilateral cases, where both ears of a participant showed the same result, and unilateral pairs, where each ear showed different results. For unilateral pairs, we matched the different otoscopic findings from each participant's left and right ears. These pairs included normal and abnormal, normal and cerumen impaction,

normal and undetermined, abnormal and cerumen impaction, and cerumen impaction and undetermined.

To evaluate the distribution of the hearing thresholds and pure tone average (PTA) data, the Kolmogorov-Smirnov test of normality (Razali and Wah, 2011) and visual inspection of the Q-Q plots for hearing thresholds at each frequency and PTA were performed for each ear. The value for level of significance was accepted to be $p<0.05$. A paired sample t-test was performed to examine left and right ear differences in audiometric data for all participants, and no overall significant difference was found between the left and right ears across frequencies 500 to 4000 Hz ($p>0.05$). Therefore, the hearing status (hearing thresholds and PTA) data was pooled for the left and right ears (Coren and Hakstian, 1990). An independent sample t-test for gender difference could not be performed due to the skewed distribution of males (n=41) compared to females (n=186).

2.8. Reliability & Validity

Validity of research data refers to the extent to which a concept is accurately measured (Heale & Twycross, 2015). In this study, validity was ensured by collecting data from a group of adults aged 18 years and older with self-reported hearing difficulties at the community centers (Ikamva Labantu and Mbekweni Kuyasa). The various types of hearing problems presented by these individuals were classified into different categories, including sensorineural hearing loss (SNHL), conductive/mixed hearing loss (C/MHL), and hearing loss with cerumen impaction. This classification allowed for an accurate description of the prevalence and characteristics of hearing loss in LMIC communities in South Africa, thus aligning with the study's aims. Additionally, the study investigated and described the outcomes of a community-based treatment for cerumen impaction. The effectiveness of the cerumen impaction treatment procedures was evaluated by

recording the total number of participants who presented with cerumen impaction and underwent management using sweet oil and removal through irrigation or manual methods. The success of the treatment was measured by comparing video otoscopy results and hearing thresholds before and after cerumen management.

Reliability pertains to the consistency of a measure (Heale & Twycross, 2015). Equivalence, an attribute of reliability, involves the agreement of results among different observers (inter-rater reliability). In this study, reliability by equivalence was confirmed through consistent results obtained by different facilitators and assessment methods (self-test or raising of hand during automated audiometry). Regardless of the method used, the results remained consistent (Sandström et al., 2020; Corona et al., 2020). The smartphone-based automated audiometry used in this study demonstrated good reliability and validity, comparable to conventional audiometry testing (Corona et al., 2020). The AI-assisted video otoscopy also proved effective in reliably detecting ear pathologies (Alenezi et al., 2022).

CHAPTER 3: RESEARCH ARTICLE

Primary Ear Care in Low-Income Settings: Hearing Loss Characteristics and Cerumen Management Efficacy

Authors: Sello M. Manganye, Caitlin Frisby, Tarryn M. Reddy, Tersia de Kock, & De Wet Swanepoel

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Status: IN REVIEW (Appendix J)

3.1. ABSTRACT

Aim: To describe the prevalence and characteristics of hearing loss in a self-referred adult cohort in low-income South African communities and to evaluate the effectiveness of a cerumen management protocol within a community-based service setting.

Background: Hearing loss affects 1.5 billion people globally, with a disproportionate impact on individuals in low- and middle-income countries (LMICs) and the elderly, often attributed to age-related factors and cerumen impaction. Despite the high prevalence, access to ear and hearing care remains challenging, particularly in LMICs, such as Africa.

Methods: A total of 227 participants aged 43 to 102 were recruited from two community centres in low-income South African communities for hearing evaluation and cerumen management for those with cerumen impaction. A cross-sectional, predominantly quantitative approach was used.

Findings: Video otoscopy of 448 ears revealed normal findings in 57.9%, cerumen impaction in 29.1%, and other abnormalities in 1.3%. The prevalence of confirmed hearing loss was 97.8%, primarily mild (45.8%), and sensorineural hearing loss (SNHL) was the most common (55.3%).

Cerumen impaction accompanied hearing loss in 28.4% of cases. Post-treatment, 50.9% of participants with cerumen impaction showed normal otoscopy results, with mean hearing improvements of 16.2 dB (±17.9 SD) in the left ears and 15.8 dB (±17.2 SD) in the right ears, though overall significance was limited.

Conclusion: The high prevalence of hearing loss and cerumen impaction in low-income communities, emphasises the importance of ear care in primary healthcare (PHC) settings, especially for the elderly. Effective community-based cerumen management highlights the potential of integrating community resources and task-shifting strategies for cost-effective ear care in resource-limited settings.

3.2. KEYWORDS

Hearing loss, Low-income community, Elderly population, Task-shifting, Cerumen impaction, Cerumen management, Community-based care.

3.3. BACKGROUND

Globally, hearing loss is the fourth leading cause of disability, impacting over 1.5 billion individuals (Global Burden of Disease, 2021; McDaid et al., 2021; World Health Organization, 2021). Adults aged 60 and above are the most affected, with prevalence rates exceeding 42% (WHO, 2021). Furthermore, age-related hearing loss was reported as the primary cause of global years lived with disability in those older than 70 years (GBD, 2021). The burden is higher in low- and middle-income countries (LMICs), where factors including higher rates of infectious diseases, environmental risks, economic constraints, shortage of hearing healthcare professionals, and limited access to hearing care contribute to elevated prevalence rates (Mulwafu et al., 2016; Cunningham and Tucci, 2017; Mulwafu et al., 2017; Spreckley and Kuper, 2017; Baum et al., 2019; Swanepoel, 2020; GBD, 2021; WHO, 2021; Frisby et al., 2022a; Boisvert 2023). In sub-

Saharan Africa, where approximately 15.7% of individuals aged 15 years and older have hearing loss (WHO, 2012; Mulwafu et al., 2016), there is a persistent shortage of research on hearing loss prevalence and causes (Mulwafu et al., 2016; Louw et al., 2018a). The implications of unaddressed hearing loss are profound and multifaceted, influencing participation in daily activities, overall health, well-being, social livelihood, and the economy, particularly in resource-constrained LMICs (Smith et al., 2015; Spreckley and Kuper, 2017; Swanepoel, 2020). Furthermore, approximately $980 billion is lost globally annually due to unaddressed hearing loss (Swanepoel et al., 2020; McDaid et al., 2021; WHO, 2021) . As a result, raising awareness and exploring innovative technologies and service-delivery approaches is an urgent priority (WHO, 2021).

The most common type of hearing loss in adults is sensorineural hearing loss (SNHL), followed by conductive (CHL) and mixed hearing loss (MHL) (Baltussen and Smith, 2012; Liu et al., 2020). However, research on the prevalence of SNHL in Africa is limited (Liu et al., 2020). A Cameroonian population-based review study reported a 61.7 to 94.4% prevalence of SNHL across different age groups (>15 years) (Tingang et al., 2015; Fokouo et al., 2019; 2020). A study conducted in Egypt reported a 40.7% prevalence of SNHL in adults over 65 years (Abdel-Hamid et al., 2007). Cerumen impaction or excessive cerumen is a common cause of CHL, contributing to 7 to 35% of cases across different age groups, particularly affecting adults over 65 years (WHO, 2021; Humes, 2024). A systematic review by Mulwafu et al. (2016) highlighted that cerumen impaction accounted for 24% of hearing loss in African community- and school-based studies.

Treatment options for hearing loss vary based on the type and severity, with hearing aids most commonly used to treat SNHL and MHL (Müller and Barr-Gillespie, 2015; Brodie et al., 2018;

Wardenga et al., 2020). However, less than 2% of individuals with disabling hearing loss in sub-Saharan Africa use hearing aids due to access and affordability issues (Bisgaard et al., 2022). CHL, often transient, may be addressed with medications or surgeries, with cerumen impaction requiring removal (Mulwafu et al., 2016; Hirch et al., 2017; Vanneste and Page, 2019; Marchioni et al., 2020; WHO, 2021). Cerumen removal may include the use of cerumenolytic agents for softening and natural discharge of the cerumen, removal through irrigation, manual removal, or a combination of these strategies (Ogunleye and Awobem, 2004; Schwartz et al., 2017) . Removal procedures are generally safe, and rare complications may include vertigo, otalgia, tympanic membrane perforation, and bruised external ear canals (Ogunleye and Awobem, 2004; Gabriel, 2015). Depending on the severity of the cerumen impaction, cerumen removal may reportedly improve air conduction hearing thresholds by 5 to 40 dB (Sharp et al., 1990; Roeser, and Ballachanda, 1997; Schwartz et al., 2017; WHO, 2021). Consequently, untreated cerumen impaction can lead to mild hearing loss or exacerbate pre-existing SNHL, underscoring the importance of timely and appropriate management.

In low-income community settings, where cerumen impaction is a prevalent concern, local practices for self-treatment often prevail, which might include unregulated use of home remedies or over-the-counter solutions. While culturally ingrained, these practices may overlook the effectiveness and cost implications of various medically approved methods (Loveman et al., 2011). Typically, cerumen removal services are provided by audiologists, otolaryngologists, or other trained healthcare personnel, such as nurses in primary healthcare (PHC) facilities and community settings (Mulwafu et al., 2016; Munro et al., 2023). However, the scarcity of these professionals in low-income areas often leads to the neglect or absence of proper cerumen impaction treatment. This underscores the necessity for task-shifting strategies, where training community healthcare workers (CHWs) to manage common ear problems, like cerumen

impaction, could significantly enhance access to care at a primary level (WHO, 2021). Such an approach not only mitigates the shortage of specialised healthcare providers but also ensures cost-effective and culturally sensitive management of ear health in these communities (Chadha et al., 2018; Yousuf Hussein et al., 2018; Orji et al., 2020; WHO, 2021).

The World Report on Hearing (2021) acknowledges the importance of providing accessible and affordable hearing care services within communities. Decentralised and community-based hearing care services are a potential tool to provide services to individuals with hearing loss in LMICs (WHO, 2012; Mulwafu et al., 2017; WHO, 2021; Frisby et al., 2022a). Shifting audiological services to PHC facilities is a crucial step toward efficient identification and management of hearing loss in LMICs, enhancing early detection and intervention (WHO, 2012; Louw et al., 2018b; Baum et al., 2019; O'Donovan et al., 2019; WHO, 2021; Frisby et al., 2022b; WHO, 2023). Integrating innovative mobile health (mHealth) and telehealth technologies is a key recommendation to support this decentralisation. These technologies, including remote hearing assessments and data management tools, facilitate broader reach and efficient service delivery. (Swanepoel et al., 2010; Yousuf Hussein et al., 2016; Van Wyk, 2019; WHO, 2021; Frisby et al., 2022a).

Mobile technologies demonstrate increasing promise for community-based hearing care, particularly in resource-limited settings. For example, digital application-based automated audiometry, equipped with transducer features to attenuate background noise, offers a practical solution for conducting quick and reliable hearing tests for both adults and children (Yousuf Hussein et al., 2018; Dawood et al., 2020; Swanepoel, 2023). These user-friendly technologies enable minimally trained non-specialist CHWs to operate automated audiometric equipment successfully, thus facilitating task-shifting in hearing care services (Bright et al., 2019; Dawood et al., 2020). Additionally, innovative tools such as artificial intelligence (AI)-assisted classification of

ear status, utilising smartphone video otoscopy, exemplify the advanced mHealth solutions available to support community-based hearing care. These tools provide simple yet effective triaging capabilities, enhancing early detection and management of ear conditions (Jayawardena et al., 2020; Penderson, 2020; Swanepoel, 2023). Importantly, the implementation of these technologies can be facilitated by CHWs who receive remote support and follow-up by audiologists (Yousuf Hussein et al., 2018; Van Wyk et al., 2019; Dawood et al., 2020; Frisby et al., 2022a; Swanepoel, 2013).

The implementation of scalable, community-based service-delivery models, especially those led by CHWs supported by innovative technologies, has emerged as an important priority for enhancing access to hearing care in low-income environments (WHO, 2021; Frisby et al., 2022a; Swanepoel, 2023). Addressing this need, this study explored adult hearing loss and cerumen management within a community setting, specifically employing mHealth technologies facilitated by CHWs. This approach bridges a notable gap in the current research concerning the clinical and cost-effectiveness of cerumen management in primary healthcare settings (Loveman et al., 2011) and adopts a robust methodological framework to yield insightful data. Consequently, this study contributes to the growing body of evidence for innovative, community-based hearing care models and provides practical insights for implementing such models effectively in low-income settings.

3.4. METHODS

IRB approval was granted by the Faculty of Humanities Research and Ethics Committee of the University of Pretoria (Approval number HUM032/0523), and all participants had to provide informed consent before participating. This study was done in collaboration with the hearX Foundation and two non-governmental organisations (NGOs).

3.4.1. Study design

A cross-sectional study design, following a predominantly quantitative, descriptive research approach, was used in this study. This study aimed to describe the prevalence and nature of hearing loss in a self-referred group of adults receiving hearing services through a community-based model. A secondary objective was to evaluate the effectiveness of community-based treatment for cerumen impaction.

3.4.2. Participants

Participants were recruited through a partnership with the hearX Foundation at the Ikamva Labantu Community Centre in Khayelitsha and the Mbekweni Kuyasa Elderly Centre in Paarl, Western Cape, South Africa. Both facilities are located within low-income communities. Khayelitsha is one of the largest and highly populated residential townships within the City of Cape Town municipality, with 400,000 people reported to reside there more than 10 years ago (Statistics South Africa, 2011a). It is characterised by informal settlements alongside more formalised housing, and is faced with multiple socio-economic challenges, including high unemployment rates, inadequate access to basic services such as healthcare and education, contributing to broader social disparities. Mbekweni is situated between Paarl and Wellington within the Drakenstein municipality, with over 30 000 residents (Statistics South Africa, 2011b). It is characterised by a mix of urban and rural elements, high unemployment rates, and low education levels.

The community-based NGOs (Ikamva Labantu and Mbekweni Kuyasa) aim to empower older community members through community-led projects. The responsible NGOs indicated that all members and their family members with concerns about their hearing could participate in the study.

Community members had to meet the following inclusion criteria to be considered participants: i) 18 years and older, ii) self-reported hearing difficulties, iii) community member at the Ikamva Labantu or Mbekweni Kuyasa community centres. Only participants who presented with cerumen impaction either unilaterally or bilaterally and were willing to undergo cerumen management procedures were considered for cerumen management.

The project was facilitated by two trained CHWs with over three years of experience, who were employed by the hearX Foundation and responsible for implementing the service-delivery model. Their training, conducted by a qualified audiologist (project manager), covered various hearing healthcare services, including hearing screening, hearing assessment, video otoscopy, digital automated audiometry, hearing aid fittings, and device care. Additionally, an on-site nurse was responsible for performing cerumen management procedures including offering sweet oil bottles, and removal through irrigation.

3.4.3. Material and apparatus

Digital video otoscopy (hearScope™, hearX Group, Pretoria, South Africa) connected to a smartphone (Samsung Galaxy A3 smartphone) was conducted to visualise the ear canal and tympanic membrane. A beta version of the hearScope™ AI classification algorithm was used to provide an automated classification of the tympanic membrane image. Therefore, the CHW was not responsible for interpreting otoscopic results. Smartphone-based (Samsung Galaxy A3 smartphone) automated audiometry was conducted on an audiometry application (hearTest™, hearX Group, Pretoria, South Africa), coupled with headphones (Supra-aural Sennheiser HD 280 Pro headphones, Wedemark, Germany) to obtain hearing thresholds. The Sennheiser HD 280

Pro headphones were calibrated according to reference equivalent threshold sound pressure levels (RETSPL), adhering to equivalent threshold sound pressure levels approved for these headphones (Madsen and Margolis, 2014). Cerumen was irrigated from the ear canal with lukewarm water (OtoClear® Ear Wash Kit, Bionix Medical Technologies, Ohio, USA). Lighted curettes (Lighted Ear Curette™ with Magnification, Bionix, Medical Technologies, Ohio, USA) were also used to manually remove the cerumen if necessary.

3.4.4. Procedures

The CHW administered a brief pre-testing questionnaire (Supplementary material I) in an interview format to gather information about the participant's hearing abilities. The CHW then facilitated the hearing evaluation, which included video otoscopy and automated pure tone audiometry. For any outer and/or middle ear defects (e.g., discharge, ear infection, perforated tympanic membrane, etc.) other than cerumen impaction found during AI-assisted video otoscopic evaluation, the CHW made appropriate referrals. The AI classification beta version of the video otoscope classified findings into four main categories: i) Normal, representing a clear and healthy outer ear and tympanic membrane with no abnormalities detected; ii) Abnormal, indicating any structural anomalies of the outer/middle ear (any disorder of the outer or middle ear); iii) Cerumen impaction, any ear with occluding, impacted cerumen and iv) Unable to determine, which represents all otoscopic results that could not be classified into any of the other categories by the video-otoscope due to factors such as low-resolution imaging of the ear canal, lack of training data (limited exposure to diverse sample ear canal images), and complex or atypical cases.

Air conduction pure tone audiometry was then obtained for hearing thresholds at 500, 1000, 2000, 4000, 6000, and 8000 Hz bilaterally for the Ikamva Labantu participants, while frequencies 500, 1000, 2000, and 4000 Hz were tested for the Mbekweni Kuyasa participants. The Ikamva Labantu

participants were tested using a minimum output level of 20 dB at each frequency (to account for potential background noise interference), while 0 dB was used for the Mbekweni Kuyasa participants. The maximum output protocol was the same for both the community centre's participants; 90 dB for frequencies 500 to 4000 Hz, 80 dB for 6000 Hz, and 70 dB for 8000 Hz. Participants had the choice of responding to pure tones by raising their hand, thus facilitated by the CHW, or to self-test, wherein the participant operated the digital audiometry smartphone themselves. Prior to the commencement of the pure tone audiometric assessment, the CHW provided the participants with instructions for the test and a conditioning phase.

Once a complete hearing evaluation was conducted, participants identified with cerumen impaction through the video otoscopy and AI classification were encouraged to undergo cerumen management. The cerumen management plan consisted of a cerumenolytic agent (sweet oil) used for a minimum of five days, followed by nurse-administered syringing or manual removal at the community centre. The participants with cerumen impaction were instructed to place 2-3 drops of the sweet oil into their ear(s) with impacted cerumen once a day for five days. This was to allow softening and natural discharge of the cerumen. Once the sweet oil had been administered for five days, the participant had to return to the centre for a follow-up appointment, where video otoscopy was conducted again. If the cerumen was still found to be impacted an onsite nurse subsequently removed the cerumen through irrigation or manual removal. If the cerumen was not soft enough for removal, the nurse recommended another week of sweet oil use. Follow-up video otoscopy and pure tone audiometry re-assessment were conducted following cerumen removal. Data collection procedures are summarised below (Figure 1).

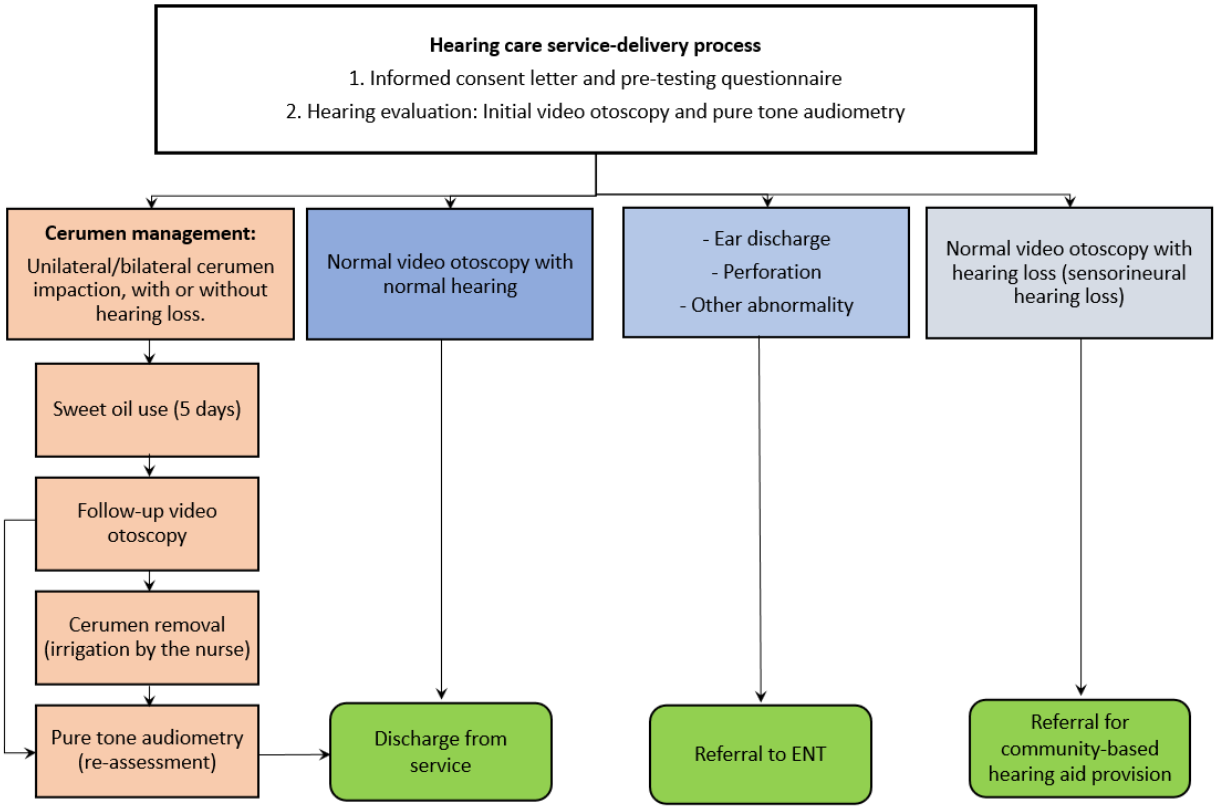

Figure 1: Community-based hearing healthcare service-delivery model.

Classification of hearing loss

Hearing loss was classified according to the WHO (2023) [41] classification system with minor adjustments. Normal hearing was defined as a four-frequency (500, 1000, 2000, and 4000 Hz) PTA of 20 dB based on the minimum testing level implemented. Mild hearing loss was defined as the four-frequency PTA between >20 to <35 dB HL.

Type of hearing loss was classified based on otoscopy and pure tone audiometry results. Four groups were used, including sensorineural hearing loss (SNHL), conductive or mixed hearing loss, cerumen impaction with hearing loss, and undefined hearing loss. SNHL was classified based on normal video-otoscopic results with a PTA hearing loss. Normal video-otoscopic

classification results were assumed to represent no obvious abnormalities in the external ear canal, tympanic membrane, or middle ear structures (Caroça et al., 2017). Hearing loss with abnormal otoscopy was thus classified as either conductive or mixed hearing loss. If video otoscopy identified cerumen impaction, participants were classified as cerumen impaction with hearing loss. The undefined classification covers all those whose otoscopic results could not be classified by the video-otoscope (unable to determine group) and those who did not have otoscopy results.

3.4.5. Analysis

Analysis of statistical data was performed using the IBM SPSS version 28 for Windows. Mean and standard deviation (SD) values of participant ages and audiometry thresholds were determined. The otoscopic results were descriptively analysed using subcategories based on whether participants had the same or different otoscopic findings in both ears. We identified bilateral cases, where both ears of a participant showed the same result, and unilateral pairs, where each ear showed different results. For unilateral pairs, we matched the different otoscopic findings from each participant's left and right ears. These pairs included normal and abnormal, normal and cerumen impaction, normal and undetermined, abnormal and cerumen impaction, and cerumen impaction and undetermined.

To evaluate the distribution of the hearing thresholds and pure tone average (PTA) data, the Kolmogorov-Smirnov test of normality (Razali and Wah, 2011) and visual inspection of the normal Q-Q plots for hearing thresholds at each frequency and PTA were performed for each ear. The value for level of significance was accepted to be $p<0.05$. A paired sample t-test was performed to examine left and right ear differences in audiometric data for all participants, and no overall significant difference was found between the left and right ears across frequencies 500 to 4000

Hz (p>0.05). Therefore, the hearing status (hearing thresholds and PTA) data was pooled for the left and right ears (Coren and Hakstian, 1990). An independent sample t-test for gender difference could not be performed due to the skewed distribution of males (n=41) compared to females (n=186).

3.5. RESULTS

A total of 227 self-referred adults (81.9%; n=186 females) aged between 43 and 102 years (mean 71.8 ± 8.6 SD) were assessed at the community centres. Video otoscopy and pure tone audiometry results for all participants are presented below.

Hearing evaluation

Initial video otoscopy

Video otoscopy was conducted for 98.7% (n=224) of participants. Three participants did not receive an otoscopic examination. Reasons included technical issues with the system (n=2) and difficulty understanding instructions (n=1).

Table 2: Initial video otoscopy AI classification results across ears (n=448) and participants (n=224).

Category	Ears % (n)	Participants % (n)
	(n=448)	*(n=224)*
Normal	57.9 (263)	46.3 (105)
Cerumen impaction	29.1 (132)	19.4 (44)
Unable to determine	10.4 (47)	7.0 (16)
Abnormal	1.3 (6)	0.4 (1)
Normal / Cerumen impaction	-	17.2 (39)
Normal / Unable to determine	-	4.8 (11)
Cerumen impaction / Unable to determine	-	1.8 (4)
Normal / Abnormal	-	1.3 (3)
Abnormal / Cerumen impaction	-	0.4 (1)

Across the total of 448 ears tested, based on the AI classification (hearScope Beta AI classification, hearX Group, South Africa) normal otoscopic results were the most common (57.9%). In contrast, abnormal classifications only occurred in 1.3% of ears. A combined 70.5% of participants (n=158/224) had normal otoscopy in at least one ear, 39.3% (n=88/224) had cerumen impaction in at least one ear, and 2.2% (n=5/224) had abnormal otoscopy in at least one ear.

Degree of Hearing loss

Of the 227 adults tested, 56.4% required assistance from the CHW during the hearing assessment and thus raised their hand as a response indication. Table 2 displays the mean hearing thresholds obtained for all participants.

Table 3: Average hearing thresholds (dB HL) for all participants (n=227).

		Frequency (Hz)					
		500	**1000**	**2000**	**4000**	**6000**	**8000**
Left ears	n	226	227	227	227	190	191
	Mean (SD)	43.5 (20.7)	41.4 (21.4)	44.9 (24.0)	47.4 (22.5)	50.4 (21.9)	50.3 (19.3)
Right ears	n	227	227	227	227	190	191
	Mean (SD)	43.5 (19.5)	41.3 (20.5)	42.2 (21.9)	45.3 (22.8)	50.8 (21.6)	51.9 (18.5)
Ears combined	n	453	454	454	454	380	382
	Mean (SD)	43.5 (20.1)	41.3 (20.9)	43.6 (22.9)	46.3 (22.7)	50.6 (21.8)	51.1 (18.7)

Mean hearing thresholds (dB) = Decibel(s); Frequency (Hz) = Hertz; SD = Standard Deviation.

Generally, the hearing thresholds sloped towards the higher frequencies (Figure 2; Table 2). The PTA of the combined ears had a mean hearing threshold of 43.7 dB (±19.3 SD) and a minimum and maximum range of 15 to 90 dB. Almost all (97.8%) participants presented with some degree of hearing loss, 95.2% (n=216) of which had bilateral hearing loss, while 2.2% (n=5) had normal

bilateral hearing, and none had unilateral hearing loss (Table 3). Mild hearing loss was the most common degree of loss (45.8%; Table 3).

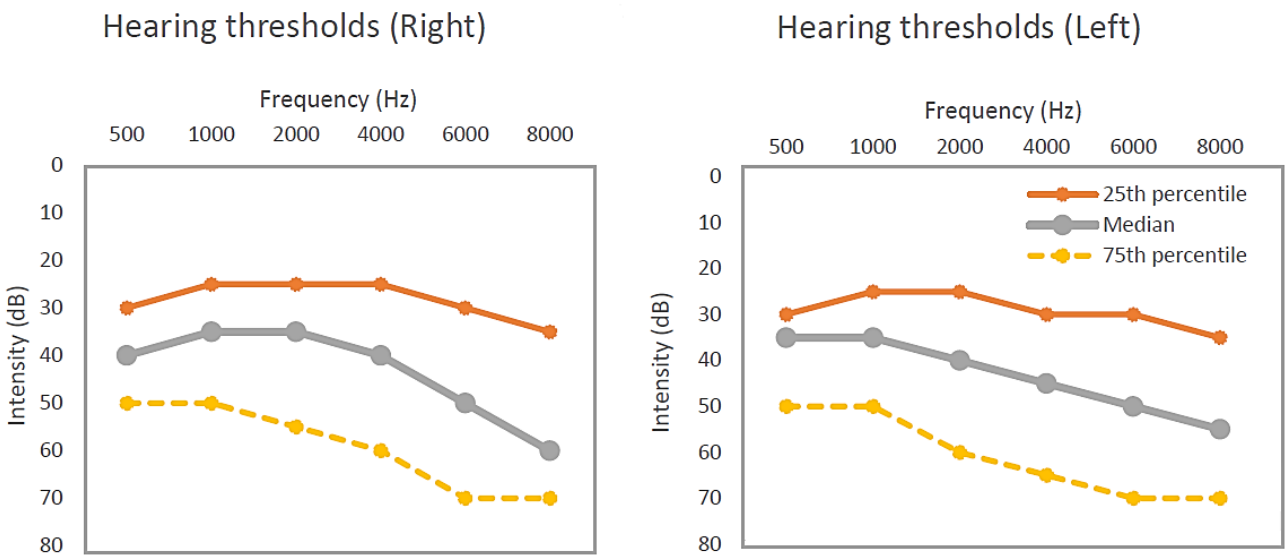

Figure 2: Distribution of hearing thresholds for participants' left and right ears.

Table 4: Grading of hearing loss for all participants assessed (n=227).

* Degree of hearing loss	Male *(n=41)* % (n)	Female *(n=186)* % (n)	All participants *(n=227)* % (n)
Normal hearing *(0 - 20 dB)*	4.9 (2)	4.8 (9)	4.8 (11)
Mild hearing loss *(21 - 34 dB)*	43.9 (18)	46.2 (86)	45.8 (104)
Moderate hearing loss *(35 - 49 dB)*	22.0 (9)	26.9 (50)	26.0 (59)
Moderately severe hearing loss *(50 - 64 dB)*	17.1 (7)	10.2 (19)	11.5 (26)
Severe hearing loss *(65 - 79 dB)*	4.9 (2)	8.1 (15)	7.5 (17)
Profound hearing loss *(80 - 94 dB)*	7.3 (3)	3.8 (7)	4.4 (10)

* Degree of hearing loss: Graded according to each participant's better ear four-frequency PTA (WHO, 2023).

Type of hearing loss

Across 454 ears, SNHL was the most common (n=251; 55.3%), followed by cerumen impaction with hearing loss (n=129; 28.4%), undefined hearing loss (n=53; 11.7%), normal hearing (n=15; 2.6%), three of which were with cerumen impaction, and conductive or mixed hearing loss (n=6; 1.3%).

Participants with cerumen impaction

Of the 227 total participants in this study, 88 (39.3%) were identified with cerumen impaction in at least one ear and were all offered sweet oil by the CHW. Of these, 17 (19.3%) participants were not willing to take part in the cerumen management procedures. Furthermore, only 54 (76.1%) out of 71 participants who received sweet oil returned for a follow-up session. Several factors led to non-participation in the cerumen removal and follow-up assessment, including discontinuation of community centre membership (n=2), loss of contact (n=3), unavailability (n=4), illness (n=2),

referral for further evaluation (n=4), and refusal to undergo cerumen removal procedures due to denial of ear and/or hearing problems (n=1), and other non-disclosed personal reasons (n=1).

Follow-up video otoscopy

Video otoscopy was successfully done for 47 (87%) of the 54 follow-up participants. Video otoscopy could not be done for 7 participants due to technical issues with the video otoscope. Table 4 displays the follow-up otoscopy results after the cerumen removal.

Table 5: **Follow-up video otoscopy AI classification results across ears (n=94) and participants (n=47) post-cerumen removal.**

Category	Ears % (n)	Participants % (n)
	(n=94)	*(n=47)*
Normal	50.9 (55)	38.9 (21)
Cerumen impaction	31.5 (34)	18.5 (10)
Unable to determine	2.8 (3)	1.9 (1)
Abnormal	1.9 (2)	-
Normal / Cerumen impaction	-	22.2 (12)
Cerumen impaction / Unable to determine	-	1.9 (1)
Normal / Abnormal	-	1.9 (1)
Abnormal / Cerumen impaction	-	1.9 (1)

Post-cerumen removal, more than half (n=55; 50.9%) of the affected ears presented with normal video otoscopy classifications.

Follow-up hearing loss classification

Within the total 108 ears initially presenting with cerumen impaction (pre-cerumen removal), 105 (97.2%) ears presented with hearing loss, while 3 (2.8%) had normal hearing. Post-cerumen removal, 106 (98.1%) ears presented with hearing loss, while 2 (1.9%) had normal hearing. Of those with hearing loss post-cerumen removal (106 ears), 54 (50.9%) presented with SNHL, 34 (32.1%) cerumen impaction with hearing loss, 16 (15.1%) undefined hearing loss, and 2 (1.9%) conductive or mixed hearing loss.

The mean difference between the pre- and post-cerumen removal PTA was 3.9 (±20.4 SD) for the left ears (n=54), 1.6 (±20.7 SD) for the right ears (n=54), and 2.7 (±20.5 SD) for all ears combined (n=108). Of the total participants, 29 (53.7%) and 27 (50%) had PTA improvement ranging from 1.2 to 68.8 dB and 1.2 to 67.5 dB in the left and right ears, respectively post-cerumen removal. There were 14 left and 12 right ears with an improvement of 10 dB or more. Two left and right ears each had a ≥40 dB PTA improvement post-cerumen removal. All pre-cerumen removal mean PTA values were slightly higher than post-cerumen removal mean PTA values, however, there was no statistically significant difference ($p>0.05$) between them. A significant difference was observed in the mean hearing thresholds at 2000 Hz pre- and post-cerumen removal for the left ear and for both ears combined ($p<0.05$). However, this significant change was not observed at any other tested frequencies (500 to 8000 Hz) for the left ear, right ear, or when both ears were

considered together ($p>0.05$). The mean threshold differences and their respective p-values are displayed in Table 5.

Table 6: Comparison of Hearing Thresholds (dB) Before and After Cerumen Removal in Participants (n=54).

		Frequency					
		500	**1000**	**2000**	**4000**	**6000**	**8000**
Left ears	n	54	54	54	54	41	44
	Ave dB improvement (SD)	1.6 (23.8)	2.0 (24.7)	7.6 (27.7)	4.5 (22.9)	3.5 (18.3)	4.1 (13.9)
	p-value	0.63	0.55	0.05*	0.15	0.22	0.06
Right ears	n	54	54	54	54	41	44
	Ave dB improvement (SD)	-0.1 (23.7)	-0.3 (22.8)	4.5 (25.0)	2.0 (24.6)	-0.1 (25.9)	0.9 (13.1)
	p-value	0.98	0.93	0.19	0.55	0.99	0.65
All ears	n	108	108	108	108	82	88
	Ave dB improvement (SD)	0.7 (23.7)	0.9 (23.7)	6.1 (26.3)	3.3 (23.7)	1.7 (22.4)	2.5 (13.5)
	p-value	0.75	0.70	0.02*	0.15	0.49	0.09

Average dB improvement (improvement in hearing from pre- to post-cerumen removal); dB = Decibel(s); Hz = Hertz; SD = Standard Deviation.

3.6. DISCUSSION

This study describes the prevalence and nature of hearing loss in a self-referred adult cohort within a low-income community while evaluating the effectiveness of a simple community-based cerumen management protocol. While the majority of participants had normal otoscopic findings, a high prevalence of cerumen impaction was observed, alongside a spectrum of hearing loss severities, with SNHL being predominant. This study is the first to assess the outcomes of a community-based treatment approach for cerumen impaction, using a combination of digital otoscopy and AI classification to support CHW-led interventions. Successful management of cerumen impaction in communities emphasises the importance of cerumen management in primary ear health strategies, particularly in low-income settings.

The incidence of hearing loss was almost universal (97.8%) in this sample of self-referred older adults. Prevalence rates in the current study are higher than those in both low- and high-income settings that reported varying rates of between 52 and 82% in older adults (>60 years) (Olaosun et al., 2013; Homans et al., 2017; WHO, 2021; Li et al., 2023; Reed et al., 2023). The high prevalence in the present study is most likely due to the inclusion criteria, which required participants to have self-reported hearing difficulties. Studies have shown that adults who self-report hearing loss present with significantly higher rates of confirmed hearing loss (Sindhusake et al., 2001; Torre, 2006; Louw et al., 2018b). The limited number of participants with normal hearing in the self-referred group emphasises the value of self-reported hearing difficulties as an initial screening tool in resource-constrained settings (Torre et al., 2006; Louw et al., 2018b). Furthermore, the unique geographic and socio-economic characteristics of the low-income, LMIC-based community also potentially contributed to the elevated rates in this study due to environmental risks (Cunningham and Tucci, 2017; WHO, 2021).

The severity of hearing loss in our study ranged from mild to profound, with mild hearing loss being the most common, affecting 45.8% of participants. This contrasts with findings from other studies in Africa, where moderate to moderately severe hearing loss was more prevalent among adults over 55 years (Olaosun et al., 2013; Abdel-Hamid et al., 2017). However, this is in line with the global trend reported by WHO (2021), which indicates that mild hearing loss is most prevalent worldwide. In Africa, the age-standardised prevalence of hearing loss of moderate or greater severity was reported to be 5.4%, which is greater than in other regions including Europe and America (3.5 and 4.7% respectively) (GBD, 2021). In our study, moderate or more severe hearing loss was observed in 51.9% of the cases, which is lower than the 67% reported in a Nigerian study (Olaosun et al., 2013) of patients aged 65 and older and higher than the 30% observed in a Dutch study (Homans et al., 2017) of adults aged 65 and over. However, it is also important to note that the higher rates of moderate to severe hearing losses reported in African studies, including ours, likely reflect a broader trend within low-income settings. As opposed to other regions, the higher prevalence and severity of hearing loss in Africa is attributable to a range of environmental, socio-economic, and healthcare access factors.

While SNHL was the predominant type of hearing loss observed in our study (55.3%), a relatively small percentage of participants (1.6%) had ear conditions such as conductive or mixed hearing loss requiring medical attention. This aligns with findings from a Nigerian hospital-based study (Ologe et al., 2005), which reported a conductive or mixed hearing loss prevalence of 0.3 to 1.3% in adults aged 60 and above. Consistently, research studies from both African and European countries have indicated a low prevalence of middle ear-related hearing loss (Mulwafu et al., 2016; Louw et al., 2018a; Hoff et al., 2020), suggesting that middle ear pathologies contribute minimally to overall hearing loss prevalence in adults. Conversely, cerumen impaction was a significant issue, affecting 28.4% of our study participants. Similarly, Ologe et al. (2005) found a 34.4% prevalence of cerumen impaction among adults over 60, and Lewis-Cullinan & Janken

(1990) reported a 35% rate in adults over 65. These figures correspond closely with our findings, where cerumen impaction affected 39.3% of participants in at least one ear. Studies have demonstrated that cerumen impaction can be found in up to 57% of older adults (McCater et al., 2007; WHO, 2021). Lower rates of excessive cerumen were reported (18.6-22.4%) from an American national survey data set in those aged >70 years (Humes, 2024). The variation in these results may stem from the utilisation of different otoscopy categorisations. Humes (2024) distinguished between cerumen impaction and excessive cerumen. In contrast, in the present study, cerumen impaction was treated as inclusive of all observations of significant cerumen identified by the video otoscope AI, irrespective of whether it constituted excessive or obstructing cerumen.

The subgroup of participants with cerumen impaction demonstrated the effectiveness of community-based cerumen management, employing sweet oil and irrigation techniques. This approach, validated by previous studies (Ogunleye et al., 2004; Loveman et al., 2011; Gabriel, 2015; Munro et al., 2023), highlights the feasibility and efficacy of simple, accessible treatments within a primary ear and hearing care framework. Furthermore, task-shifting, as advocated by the WHO and supported by various studies (Yousuf Hussein et al., 2016; Bright et al., 2019; Van Wyk et al., 2019; WHO, 2021; Frisby et al., 2022a), represents a cost-effective solution to the treatment of cerumen impaction, particularly in PHC settings. Non-specialist healthcare workers, alongside nurses, play a crucial role in the PHC sector for successfully assessing and treating ear and hearing problems such as cerumen impaction when adequately trained (Mulwafu et al., 2016; Dawood et al., 2020; Frisby et al., 2022a; Munro et al., 2023). This is particularly significant as studies have demonstrated an unmet need for cerumen management, predominantly in the PHC sector (Gabriel, 2015; Munro et al., 2023).

The improvement of hearing thresholds post-cerumen removal varied among individuals, with more than half the participants presenting with some improvement. Our improvement rates were lower compared to a study by Lewis-Cullinan & Janken (1990), which reported hearing improvements in 75% of hospitalised participants post-cerumen removal. This difference could be attributed to the distinct study methodologies, including our employment of AI for assessments and the involvement of CHWs and nurses, in contrast to the specialists in the comparison study. Nonetheless, a subset of our participants experienced significant auditory improvement. Post-cerumen removal, 14 left and 12 right ears had PTA improvements of at least 10 dB, with a minority (two left and two right ears) exceeding 40 dB. While cerumen removal improved hearing thresholds for some individuals, the overall impact on the subgroup was not significant. This could be partly explained by the varying severity of cerumen impaction among participants, ranging from partial to full blockage. The AI-integrated video-otoscope used in this study was not designed to distinguish between degrees of impaction severity, but rather the broad otoscopy categories.

A number of limitations may have influenced the results and interpretation of this study's findings. The implications of the selection bias in this study require careful consideration when generalising the findings to broader populations, as the estimates may not accurately reflect the true extent of hearing loss in the wider community. Although minimal, the exclusion of individuals without video otoscopy data (n=10) for both pre- and post-cerumen removal may have affected the sample's representativeness, potentially leading to an underrepresentation of certain categories. The inability to distinguish between various cerumen impaction severities may have influenced the ability to fully assess the impact of cerumen removal on hearing thresholds.

3.7. CONCLUSION

The persistent need for enhanced hearing care services in the PHC sector, particularly in low-income and elderly populations, is underscored by the study's findings. The novel community-based cerumen management plan was effective in restoring the integrity of the outer ear canal, even without complete restoration of hearing thresholds for some participants. Task-shifting, involving CHWs and nurses, utilising mHealth technologies proved effective in identifying and addressing ear and hearing problems through a cost-effective service delivery model. The integration of community resources and task-shifting strategies has the potential to enhance ear and hearing care accessibility in resource-constrained settings.

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3.10. CONFLICT(S) OF INTEREST

TdK is the director of the hearX Foundation. CF is a consultant for the hearX Foundation. DWS is a co-founder and scientific advisor for the hearX Group, South Africa.

3.11. DISCLOSURE STATEMENTS

Dr. Swanepoel has a relationship with the hearX Group (Pty) Ltd, which includes equity, consulting, and potential royalties.

3.12. ETHICAL STANDARDS

Ethical approval was provided by the Research Ethics Committee within the Faculty of Humanities at the University of Pretoria (HUM032/0523). Prior to the initiation of data collection, informed consent letters were signed by all participants.

3.13. AUTHORSHIP & CONTRIBUTORSHIP

In accordance with the International Committee of Medical Journal Editors (ICMJE) criteria, each author has made equal contributions to this work and has fulfilled the stipulated authorship requirements.

3.14. ORCID

Sello M. Manganye https://orcid.org/0000-0002-5722-2275

Caitlin Frisby https://orcid.org/0000-0002-9922-2927

Tarryn M. Reddy https://orcid.org/0000-0002-0056-8486

Tersia de Kock https://orcid.org/0000-0003-2850-1598

De Wet Swanepoel https://orcid.org/0000-0001-8313-1636

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CHAPTER 4: DISCUSSION, CLINICAL IMPLICATIONS, & CONCLUSION

4.1. OVERVIEW OF FINDINGS

This study investigated the prevalence and characteristics of hearing loss in a self-referred adult cohort residing in an LMIC in South Africa, along with the effectiveness of a community-based cerumen management plan. The quantitative metrics used in this study provided informative data on the prevalence and nature of hearing loss, as well as the efficacy of community-based interventions in restoring normal outer ear canal integrity and hearing thresholds. A high prevalence of SNHL and cerumen impaction in older adults within the low-income communities (Khayelitsha and Mbekweni, South Africa) was noted. As a result, this high prevalence underscores the necessity for timely community-based interventions. mHealth technologies, such as automated audiometry and digital video otoscopy equipped with AI classification algorithms, were successfully utilised to support hearing care programs facilitated by CHWs. These CHW-led initiatives have demonstrated significant potential for task-shifting in resource-limited settings (Dawood et al., 2020; Frisby et al., 2022a). The implications of these findings are discussed in detail within this chapter, along with proposed future research directions and recommendations for integrating community-based models into broader healthcare policies.

4.1.1. Prevalence and Nature of Hearing Loss

Hearing loss prevalence

The global health challenge of hearing loss represents a significant and growing public health concern. In this study, hearing loss was widespread among 97.8% of individuals who reported to the community centres (Ikamva Labantu and Mbekweni Kuyasa). This rate is higher compared to

other studies in both low- and high-income countries, where rates range from 52% to 82% among older adults (Homans et al., 2017; Li et al., 2023; Olaosun et al., 2013; Reed et al., 2023; WHO, 2021). The high prevalence observed in our study likely results from the inclusion criteria, requiring participants to self-report hearing difficulties. Therefore, the hearing loss prevalence observed is not representative of the general population but highlights the effectiveness of self-reported hearing loss as an initial screening tool in resource-constrained contexts. Research has consistently demonstrated that adults who self-report hearing loss tend to have significantly higher rates of confirmed hearing loss (Louw et al., 2018b; Sindhusake et al., 2001; Torre, 2006). Only 2.2% of participants had confirmed normal hearing, emphasising the significance of self-reported hearing difficulties. Individuals who recognise and report their hearing issues are more likely to seek professional evaluation, enabling timely intervention and management (ASHA, 2021). Besides self-referral, the distinct geographic and socio-economic features of LMIC-based communities may have also contributed to higher rates in this study (Cunningham & Tucci, 2017; WHO, 2021).

Severity of hearing loss

The severity of hearing loss in our study ranged from mild to profound, with mild hearing loss being the most common (45.8%). This contrasts with findings from other African LMIC studies, where moderate to moderately severe hearing loss was more prevalent among adults over 55 (Abdel-Hamid et al., 2017; Olaosun et al., 2013). However, our results align with the global trend reported by WHO (2021), indicating that mild hearing loss is the most prevalent worldwide.

In Africa, the age-standardised prevalence of moderate or greater hearing loss is 5.4%, slightly higher than in Europe and America (3.5% and 4.7%, respectively) (GBD, 2021). Our study found that moderate or more severe hearing loss affected 51.9% of cases, which is lower than the 67%

reported in a Nigerian study of patients aged 65 and older (Olaosun et al., 2013) and higher than the 30% observed in a Dutch study of adults aged 65 and over (Homans et al., 2017). Recognising that the higher prevalence and severity of hearing loss in Africa likely reflect broader trends within low-income settings is essential. Factors such as environmental conditions, socioeconomic status, and limited healthcare access contribute to these disparities (Mulwafu et al., 2017; WHO, 2021).

Types of hearing loss

SNHL was the most prevalent type of hearing loss (55.3%) identified in this study. A small percentage (1.6%) had ear conditions such as conductive or mixed hearing loss requiring medical attention. These findings are consistent with those of a Nigerian hospital-based study (Ologe et al., 2005), which reported a 0.3% to 1.3% prevalence for conductive or mixed hearing loss in adults aged 60 and above. Studies from both African and European countries consistently indicate a low prevalence of middle ear-related hearing loss (Mulwafu et al., 2016; Louw et al., 2018a; Hoff et al., 2020), suggesting that middle ear pathologies contribute minimally to overall hearing loss prevalence in adults.

Cerumen impaction emerged as a significantly common issue (28.4%) in our study, with 39.3% having cerumen impaction in at least one ear. Similarly, hospital-based studies found a 34.4% prevalence of cerumen impaction in Nigerian adults over 60 (Ologe et al., 2005) and a 35% rate in American adults over 65 (Lewis-Cullinan & Janken, 1990). Additionally, other studies have demonstrated that cerumen impaction can be found in up to 57% of older adults (McCater et al., 2007; WHO, 2021). Interestingly, an American national survey data set reported lower rates (18.6% to 22.4%) of excessive cerumen in those aged >70 years (Humes, 2024). The variation in these results may stem from differences in otoscopy categorisations. While Humes (2024)

distinguished between cerumen impaction and excessive cerumen, our study treated cerumen impaction inclusively, considering all significant cerumen identified by the video otoscope AI, regardless of whether it constituted excessive or obstructing cerumen.

4.1.2. Effectiveness of a Community-Based Cerumen Management Protocol

In a subgroup of participants with cerumen impaction, community-based cerumen management using sweet oil and irrigation techniques was effective in removing cerumen in 71.2% (n=34/47) of participants in at least one ear. Post-cerumen removal, the improvement in hearing thresholds varied among individuals. Of the participants who underwent cerumen management, 53.7% showed a PTA improvement of 1.2 to 68.8 dB in the left ear and a 50% improvement of 1.2 to 67.5 dB in the right ear after cerumen removal. These improvement rates were lower compared to those of a study by Lewis-Cullinan & Janken (1990), which reported hearing improvements in 75% of hospitalised participants after cerumen removal. The difference could be attributed to distinct study methodologies. In our case, AI-empowered video otoscopy was used for assessments involving CHWs and nurses, whereas the comparison study used specialists. Moreover, Lewis-Cullinan & Janken (1990) defined cerumen impaction as “an inability to visualise the tympanic membrane due to cerumen blocking the ear canal,” whereas our AI-empowered video otoscope classified any form of cerumen detected in the ear canal as cerumen impaction, and not by tympanic membrane obstruction per se.

Nonetheless, a subset of our participants experienced significant auditory improvement. There were 25.9% (n=14/54) left and 22.2% (n=12/54) right ears with PTA improvements of at least 10 dB. Some (two left and two right ears) demonstrated improvements in hearing ability that exceeded 40 dB. However, overall, the impact of the cerumen management on pre- versus post-

removal thresholds on the subgroup was not statistically significant. This lack of significance may be partly explained by the varying severity of cerumen impaction among participants, ranging from partial to complete blockage. The AI-integrated video-otoscope used in our study was not designed to distinguish between different degrees of impaction severity; instead, it focused on broader otoscopy categories.

4.1.3. Task-Shifting and mHealth Tools

Professional hearing care services are largely absent in LMICs where appropriate skills are lacking (Mulwafu et al., 2017; WHO, 2021). Task-shifting to CHWs supported by mHealth technologies was implemented effectively in our study. mHealth tools such as the AI-assisted digital otoscope and automated audiometry aided in the successful delivery of hearing care services to community members in the communities of Khayelitsha and Mbekweni. Similarly, various LMIC-based studies have demonstrated the effectiveness of mHealth technologies used to deliver audiological services through a community-based model facilitated by CHWs (Dawood et al., 2020; Frisby et al., 2022a; Swanepoel, 2023; Van Wyk et al., 2022; Yousuf Hussein et al., 2016). This could dramatically expand reach and access to ear and hearing care. This approach aligns with global initiatives like the WHO hearing aid service delivery approaches for low-income settings (WHO, 2023), enabling scalable, cost-effective, and decentralised care that brings essential services directly to the communities most in need.

4.2. CLINICAL IMPLICATIONS

Community-based models play an important role in addressing hearing care needs in LMICs. This study identified a high prevalence of hearing loss and ear conditions like cerumen impaction in older adults, highlighting an increasing need for audiological services at a community level, where access is generally challenging. Offering ear and hearing care services in community settings

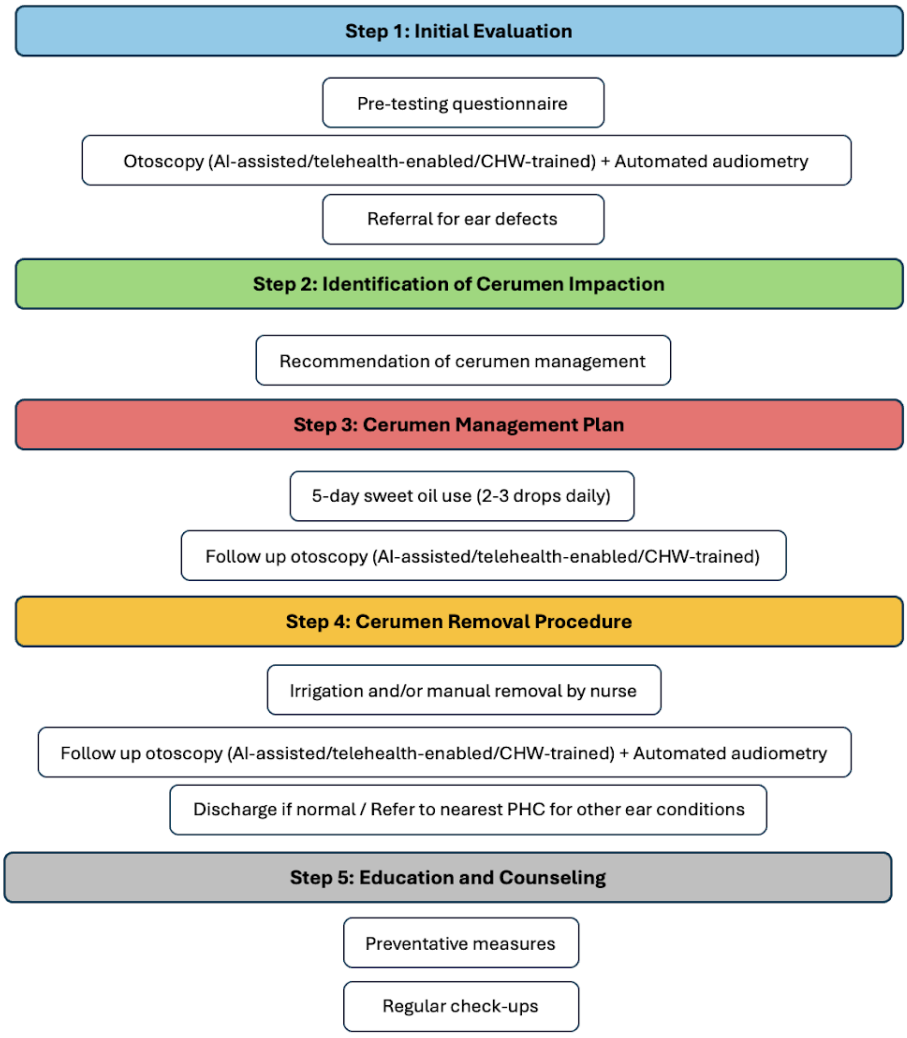
represents a successful model of care reorientation, which effectively mitigates accessibility challenges by bringing these services closer to people's homes (WHO, 2021). Additionally, the referral procedure followed in this study for participants who required further management provides a well-structured pathway toward advanced care at secondary or even tertiary healthcare levels whenever necessary. These findings advocate for adopting similar models in community or PHC sectors worldwide, especially in resource-scarce areas.

The successful task-shifting to CHWs and nurses, empowered by mHealth technologies (video otoscopy with an integrated AI tool and automated audiometry) and community resources, underscores the practicality and success of straightforward community-based assessment and treatment. These innovative strategies can enhance the cost-effectiveness and accessibility of ear and hearing care in LMICs. By leveraging user-friendly, validated smartphone screening with automated testing and quality control measures, trained CHWs can effectively conduct ear and hearing evaluation and facilitate access to hearing aids and other interventions (Dawood et al., 2020; Frisby at al., 2022b; WHO, 2021). Training non-specialist personnel such as CHWs and nurses to handle basic ear care tasks, including assessment and cerumen removal, can alleviate the burden on specialised healthcare providers and make ear care services more accessible to the community, as demonstrated in this study (Bright et al., 2019; Dawood et al., 2020; Frisby et al., 2022a; Mulwafu et al., 2016; Munro et al., 2023; WHO, 2021; Yousuf Hussein et al., 2016).

Studies have highlighted an unmet need for cerumen management, particularly in the PHC sector (Gabriel, 2015; Munro et al., 2023). The effectiveness of the community-based cerumen management plan in restoring outer ear canal integrity is evidence of the value of such interventions. Figure 3 demonstrates the simple five-step community-based cerumen management protocol followed in this study, utilising task-shifting and mHealth solutions. The

development and implementation of the five-step cerumen management protocol provide a structured, effective, and scalable approach to addressing this common yet often neglected condition. This protocol can therefore be effectively contextualised and implemented in other low-income community contexts.

Figure 3: Five-step cerumen management protocol for community-based settings.



The five-step community-based cerumen management protocol is discussed below.

Step 1: Initial evaluation begins with administering a brief pre-testing questionnaire, which can either be given to the patient to fill in or completed by the CHW as they interview the patient to gather information about their hearing abilities. This is followed by conducting otoscopy using one of the following methods: i) AI-assisted video otoscopy; ii) Telehealth-enabled otoscopy (e.g., synchronous or asynchronous connection between an ear healthcare professional and CHW); OR iii) CHW-performed otoscopy, following their training to identify basic otoscopy categories. An otoscopic evaluation would be conducted to check for outer and/or middle ear defects and automated pure tone audiometry would be conducted to assess hearing thresholds. Patients with ear defects other than cerumen impaction (e.g., discharge, ear infection, perforated tympanic membrane) are referred for appropriate medical attention.

Step 2: Identification of cerumen impaction focuses on recommending cerumen management to patients identified with cerumen impaction.

Step 3: Cerumen management plan involves instructing patients to use a cerumenolytic agent, such as sweet oil, by placing 2-3 drops into the affected ear(s) daily for five days. A follow-up appointment is scheduled with the CHW at the community centre after five days, whereby a follow-up otoscopy is conducted to assess the status of the outer ear canal.

Step 4: Cerumen removal procedure includes assessing the condition of cerumen post sweet oil use. Nurse-administered syringing or manual removal is performed if the cerumen is still impacted. If the cerumen is not sufficiently softened, another five days of sweet oil use is recommended. Removal techniques include irrigation with warm water to flush out cerumen and manual removal using appropriate medical instruments, such as lighted curettes. Further follow-

up includes another otoscopy and pure tone audiometry re-assessment following cerumen removal to check for possible improvement in ear and hearing health. Post-removal, those with normal otoscopy and normal hearing are discharged. In contrast, those with other outer/middle ear conditions and/or hearing loss are referred to the nearest PHC facility for further management (e.g., ear infection treatment and hearing aid fitting).

Step 5: Education and counselling encompass educating patients on preventive measures to avoid future cerumen impaction and providing guidance on maintaining ear hygiene. Regular hearing check-ups and ear examinations are encouraged, especially for individuals with recurrent cerumen issues.

Given that ear and hearing care encompasses more than just cerumen management, our participants were referred for further treatment as needed. The importance of access to hearing care services is underscored by the high prevalence of hearing loss found in our study, which contributes significantly to global hearing loss estimates, particularly in African LMIC literature. This widespread prevalence greatly affects individuals' daily communication and functioning. The severity of hearing loss is crucial in determining its impact on quality of life. The higher the severity, the more adverse the impact (WHO, 2021). In our study, mild hearing loss was the most prevalent among the adult cohort from both communities. Mild hearing loss, although minimal in severity, is linked to conditions like cognitive impairment and depression in older adults (Chern & Golub, 2019; Grewal et al., 2022). Providing treatment for mild hearing loss is as important as for other severities because it can effectively reduce psychosocial effects (Cox et al., 2014; Grewal et al., 2022; Johnson et al., 2016; Mukadam et al., 2019; WHO, 2021). Therefore, addressing mild hearing loss in older adults should be prioritised similarly to children (Ferguson, 2021; Grewal et al., 2022).

4.3. CRITICAL EVALUATION: STRENGTHS AND LIMITATIONS OF THE CURRENT STUDY

4.3.1. Strengths of the study

This study exhibited multiple strengths that highlight its contributions to community-based healthcare. One of the key strengths is the **community-based model** it successfully demonstrated. This model has shown great potential to be both scalable and sustainable, which is particularly significant in low-income settings where access to healthcare resources is often limited. By leveraging local infrastructure and CHWs, the study provides a possible blueprint for extending hearing care services to underserved populations.

This study was **conducted in a real-world** setting, which enhances the ecological validity of the findings. By implementing the cerumen management plan and mHealth technologies within actual community settings, the study demonstrates the feasibility and effectiveness of these interventions in everyday practice rather than in a controlled, experimental environment.

An **innovative approach** involving the integration of mHealth technologies and AI for otoscopic classification represents a method that significantly enhances the accuracy and efficiency of ear care. These technological advancements not only improve diagnostic capabilities but also make the process more accessible and cost-effective. Alternative options like a rapid telehealth cross-check by program managers could also support such community-based services.

The study also showcased the potential of **task-shifting** in healthcare. By training CHWs to perform basic ear care tasks, the study demonstrated that task-shifting could make healthcare delivery more efficient and could address the shortage of specialised healthcare professionals in low-resource settings. This approach empowers CHWs, enhances their skill set, and improves the overall healthcare system's capacity.

Furthermore, the study developed and successfully implemented an effective **community-based cerumen management protocol**. This protocol provides a structured and practical method for addressing cerumen impaction, a common but often neglected issue within the community. Moreover, our study ensured that all participants received appropriate **management and referrals** after completing their hearing assessments. This comprehensive approach ensured that each participant received the necessary treatment or referral for further medical attention, thereby enhancing the overall effectiveness and impact of the study.

4.3.2. Limitations of the study

The study faced several limitations that may affect the robustness and applicability of its findings. **Selection bias** may have emerged due to the self-referred nature of the participant cohort in this study. This implies that the individuals who chose to participate might have different characteristics or motivations compared to the broader population, thereby limiting the generalisability of the results.

The **limited sample size**, **female-to-male ratio** (more female participants), and the **specific community settings** in which the study was conducted also present potential constraints. The low number of male participants in this study may be attributed to the nature of the selected community centres, which offered activities such as knitting and beading that cater more to females than males. These factors may limit the study's ability to accurately reflect the diverse demographics of other regions, making it difficult to generalise the findings to broader populations.

Additionally, the study encountered **technical issues** that resulted in the exclusion of some participants. These technical difficulties, particularly with the otoscopic system not operating sometimes, may have compromised the study’s completeness and introduced an element of data

loss that could affect the outcomes. These excluded cases might have had unique characteristics or results that, if included, could potentially alter the study's final outcomes.

4.4. RECOMMENDATIONS FOR FUTURE RESEARCH

Larger samples in multiple contexts

The study's findings highlight several key areas for future research to build upon its successes and address its limitations. The expansion of the sample size across more diverse community settings is a crucial area to consider in future research. It is recommended that a larger and more diverse participant pool be included to improve the generalisability of the findings. A broader sample would ensure that the results are more representative of different demographics and can be applied to a wider population.

Long-term outcomes of community-based care models

Longitudinal studies are recommended to evaluate community-based ear care models' sustainability and long-term outcomes. For instance, conducting longitudinal studies to assess the sustainability and durability of the benefits observed with the five-step cerumen management protocol over time. Such studies would provide more insights into the effectiveness of these models over extended periods and help understand their potential for enduring benefits in low-income settings.

Scalability of the intervention

Research should investigate how the protocol can be adapted and implemented in diverse settings, including various geographic regions and different healthcare systems (beyond ear/hearing care). This includes examining the feasibility of scaling up the protocol in low-resource

settings and evaluating the necessary modifications to ensure it remains effective and accessible in larger populations. Factors such as cost, resource availability, and the training requirements for CHWs should be considered when developing a scalable model. Furthermore, this model can be expanded to other population groups, such as children, people with disabilities who might have unique ear care needs, and others.

Advancement of innovative tools

mHealth technology advancement may be beneficial in enhancing accuracy, reliability, and applicability, making them more effective tools in the delivery of ear care services. Further development and validation of mHealth and AI technologies are essential for broader use in various healthcare settings. The usability, user-friendly design, and overall user experience of these tools are crucial for ensuring digital inclusivity.

Exploration of cerumenolytic agents

The effectiveness of the initial cerumen management plan (Figure 3) involving a 5-day sweet oil use can be evaluated by exploring various cerumenolytic agents. Studies could focus on identifying agents that work faster, are more effective, and are still safe to use.

Comparative studies

Comparative studies are an important area of research. By comparing different models of ear care delivery, future research can focus on identifying the most effective and efficient approaches. This comparative analysis can help determine best practices and optimise ear care protocols. Additionally, for low-income settings with accessibility and affordability challenges, future research could focus on comparing our five-step cerumen management protocol with other protocols or approaches to identify best practices. Future research can build on the current study's

findings by addressing these areas, leading to more effective, adaptable, and sustainable cerumen management practices.

Education and training of personnel

Understanding the most effective methods for training CHWs and other healthcare providers in ear care can enhance the implementation of community-based models. Research in this area can lead to the development of comprehensive training programs that ensure high-quality care and improve overall healthcare outcomes.

4.5. CONCLUSION

Apart from identifying an increasing prevalence of adult hearing loss rooted in low-income settings, this study reinforces the critical need for innovative ear and hearing care services that are both effective and accessible. The community-based ear and hearing care protocol, supported by digital otoscopy with AI classification and task-shifting strategies, presents a promising avenue for addressing hearing loss and the prevalent issue of cerumen impaction. The cerumen management plan effectively restored outer ear canal integrity and improved hearing thresholds for some participants. Integrating community resources and innovative service delivery models offers a promising, cost-effective solution for enhancing ear and hearing care in resource-constrained settings. It is imperative that such models be integrated into international health policies to ensure the provision of comprehensive ear health care, particularly for the most vulnerable populations in LMICs. The journey towards better hearing health is ongoing, and this study serves as a catalyst for future endeavours in this field.

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APPENDICES

Appendix A: Ethical Approval Letter for Broader Study

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100. Since 1919

05 December 2022

Dear Prof DCDW Swanepoel

Project Title:	Hearing care for adults in low-income communities using mHealth and hearing aid technologies
Researcher:	Prof DCDW Swanepoel
Supervisor(s):	
Department:	Speech Language Pathology and Audiology
Reference number:	02606623 (HUM011/0822)
Degree:	Staff Research / Non Degree

I have pleasure in informing you that the above application was **approved** by the Research Ethics Committee on 05 December 2022. Please note that before research can commence all other approvals must have been received.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely,

Prof Karen Harris
Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

Room 7-27, Humanities Building, University of Pretoria, Private Bag X20, Hatfield 0028, South Africa
Tel +27 (0)12 420 4853| Fax +27 (0)12 420 4501|Email pghumanities@up.ac.za | www.up.ac.za/faculty-of-humanities

Appendix B: Ethical Approval Letter for Current Study

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100. Since 1919

2 June 2023

Dear Mr SM Manganye

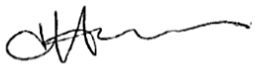
Project Title:	Adult hearing loss in a low-income African community: Incidence, nature, and outcomes of an initial primary ear and hearing care treatment program
Researcher:	Mr SM Manganye
Supervisor(s):	Prof DCDW Swanepoel
Department:	Speech Language Pathology and Audiology
Reference number:	19151285 (HUM032/0523)
Degree:	Masters

I have pleasure in informing you that the above application was **approved** by the Research Ethics Committee on 4 May 2023. Please note that before research can commence all other approvals must have been received.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely,



Prof Karen Harris
Chair: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

Appendix C: HearX Foundation Collaboration Letter

1 August 2022

De Wet Swanepoel, PhD
Professor | Dept of Speech-Language Pathology and Audiology, University of Pretoria, South Africa

Dear Prof De Wet Swanepoel,

I write on behalf of the hearX Foundation in enthusiastic support of our collaboration regarding the community project titled "Hearing care for adults in low-income communities using mHealth and hearing aid technologies." This project aims to reduce hearing healthcare disparities in low- and middle-income countries, where services are scarce and exceedingly expensive, by providing an end-to-end solution leveraging mHealth technology.

The hearX Foundation NPC has led several projects in low-income communities using mobile technology to enhance access to ear and hearing care. This aligns with our vision to provide "healthy hearing for everyone, everywhere." Our direct impact community-based projects in South Africa have reached more than 40 000 children and adults, while many more have been reached via third-party projects implemented by partners across various LMICs. Our work in low-income communities is focused on developing innovative service delivery models that can enhance access to and the affordability of hearing health services. Core to our approach is the use of community health workers (CHWs) equipped with mHealth technology that delivers the services in low-resource settings. We believe that our extensive experience in the training and deployment of CHWs uniquely positions us to make a valuable contribution to this project.

Through this letter, we acknowledge that through this collaboration, we will have specific roles and responsibilities to fulfill, including:

The hearX Foundation will assist with the field-based validation studies, developing training materials for community healthcare workers, and piloting the specific training materials. The Foundation will be significantly involved in implementing the model and executing the feasibility study in the community using our existing networks.
We look forward to working with you to eliminate hearing heath disparities in our community and achieve health equity.

Sincerely,

Tersia de Kock
hearX Foundation Executive Director

Appendix D: Participant Informed Consent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

November 2022

INVITATION TO RECEIVE A HEARING CHECK

The hearX Foundation, in partnership with the University of Pretoria, will be providing a hearing service in communities. Many people suffer from hearing loss, and this project aims to identify community members with hearing loss and demonstrate the potential benefit of hearing aids.

What will I need to do if I agree to receive the hearing check?

All tests will be non-invasive, free of charge, and results will be made available to you. All testing should take about 35 minutes to complete. Should you agree to receive the hearing check, the following procedures will be followed:

- Questionnaire about your hearing (5 minutes)

Before your hearing is checked, you will be asked a few questions about your hearing as well as how you feel about hearing aids.

- Looking in your ear with a camera [Video-otoscopy] (5 minutes)

For this test, you will be required to be seated upright while your ear canal is visually inspected using an otoscope (ear-light).

- Hearing check (15 minutes)

For this check, you will wear earphones on your ears. You will be asked to respond to a soft sound (at different pitches) by raising your hand or pressing a button. This will measure how sensitive your hearing is.

- Demonstration of listening with hearing aids (10 minutes)

After the hearing check, and if the video-otoscopy indicates your ear canal is clear and no abnormalities were detected, you will get the opportunity to experience listening with hearing aids if you are interested. After the demonstration, you will be asked a few questions about the sound quality and your attitude toward hearing aids.

Are there any risks or benefits for me if I participate in this study?

Participants will not be exposed to any risk or experience any discomfort during this test. Information obtained from this project will assist in increasing the effectiveness of smartphone technologies in hearing loss detection and access to hearing aids. Participants that are not eligible for hearing aids, or that require additional follow-up services will be referred to public health facility offering hearing aids or Ear, Nose, and Throat specialist services.

What are your rights as a participant?

Your participation in this project is entirely voluntary. You may decline to participate or stop at any time during the examination. This will not affect any current services you are receiving. You can consent if you wish to have your results used as part of any potential research based on this service. You can decline to have your results included in any potential research based on this service with no effect on any current services you are receiving. You can provide your contact details should you be interested in participating in potential future research. You can decline participation in potential future research or request that your contact details be removed with no effect on any current services you are receiving.

COVID-19 Protocols

The hearing screeners will bring in hand sanitiser, and all participants, hearing screeners, and researchers will be required to sanitize their hands frequently. All equipment will be sanitized before and after each participant's tests. If the participant, hearing screeners, or researcher feels unwell on the day scheduled for testing, the testing will be postponed to a later date.

Confidentiality

All your information will be kept confidential. Once your results have been captured, a number will be allocated to your results. All data will be analysed using the alphanumerical code assigned to you. Your name will not appear on any documents.

Should you consent to have your results used for research purposes, research articles in scientific journals will not include any information that could identify you. All the data collection sheets from this project will be stored for a period of 15 years in both hard copies and scanned electronic versions.

Before agreeing to participate, you should fully understand what is involved. Please do not hesitate to ask your hearing screener if you have any questions that this letter does not fully explain. Alternatively, you can contact us at info@hearxfoundation.org or send a *please call me* to 068 192 2413 (Mbekweni) or 084 393 0717 (Khayelitsha).

CONSENT TO RECEIVING A HEARING ASSESSMENT

I, _____, hereby consent to:

	I consent to receiving the hearing assessment.
	I consent that my results be used anonymously for any possible research publications on this project.
	I consent that my contact details be stored and that I can be contacted for any potential future services or research.
	I consent that photos be taken during the hearing assessment and hearing aid demonstration.

I have read or been explained the content of the consent letter verbally. I understood the consent letter and have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I will not be reimbursed for participating in this project. I know that I may withdraw from the project at any time, should I wish to do so. I understand that every effort will be made to ensure that I am not harmed while receiving the hearing check.

Signature: _____ **Date:** _____

Phone number: _____

Appendix E: Community Healthcare Worker Informed Consent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Community healthcare worker informed consent

October 2022

INVITATION TO PARTICIPATE IN A COMMUNITY PROJECT

The hearX Foundation, in partnership with University of Pretoria, will be providing a hearing service in the communities. Many people suffer from hearing loss. This project aims to identify community members with hearing loss, demonstrate the potential benefit of hearing aids, and fit adults with suitable hearing loss with hearing aids. Furthermore, this study aims to determine the benefit of hearing aids once fitted bilaterally.

What will I need to do if I agree to participate?

You will be trained as a lay community health worker. You will be required to facilitate tests that will be non-invasive on a set of participants from the community. Should you agree to participate in this community project, you will receive training on the following procedures, and you will perform them on the participants. This includes video-otoscopy and a hearing test. You will also receive further training on providing feedback and demonstrating hearing aid use. You will be expected to keep all community members' information confidential. You will be required to send the participants WhatsApp messages/pictures/voice notes or SMSs for a period of 45 days and make three phone calls to each participant during this period. The messages you need to send will be in Xhosa. You will also have to conduct two follow-up visits, 45 days and six months after the hearing aid fitting, to ask the participants various questions. You will also be asked to complete a questionnaire six months after the hearing aid fitting. This questionnaire will aim to get your opinion on any challenges or the success of the project and on any improvements that can be made for future projects.

Are there any risks or benefits for me if I participate in this study?

Participants will not be exposed to any risk or experience any discomfort during this project. There are no direct benefits of participating in this study, and no reimbursements will be given to participants. However, information obtained from this study will assist in increasing the effectiveness of smartphone technologies in hearing loss detection, support, and intervention.

What are your rights as a participant?

Your participation in this study is entirely voluntary. You may decline to participate or stop at any time during the community project.

COVID-19 Protocols

The community health workers will bring in hand sanitiser, and all participants, community health workers, and researchers will be required to sanitize their hands frequently. All equipment will be sanitized before and after each participant's tests. If the participant, community health worker, or researcher feels unwell on the day scheduled for testing, the testing will be postponed to a later date.

CONFIDENTIALITY

All your information will be kept confidential. An alphanumerical number will be allocated to your name. All data will be analysed using the alphanumerical code assigned to you. Your name will not appear on any documents.

Should you consent to have your results used for research purposes, research articles in scientific journals will not include any information that could identify you. All the data collection sheets from this project will be stored for a period of 15 years in both hard copies and scanned electronic versions.

Before you agree to take part, you should fully understand what is involved. Please do not hesitate to ask if you have any questions that this letter does not fully explain. Alternatively, you can contact us at info@hearxfoundation.org.

CONSENT TO PARTICIPATE IN A COMMUNITY PROJECT

I, _____, hereby consent to:

	I consent to participate in the community project.
	I consent that my data be used anonymously for any possible research publications on this project.
	I consent that my contact details be stored and that I can be contacted for any potential future services or research.
	I consent that photos be taken during the community project.

I have read the content of the consent letter. I understood the consent letter and have been allowed to ask questions, and I am satisfied that they have been answered satisfactorily. I know I may withdraw from the project should I wish to do so. I understand that every effort will be made to ensure I am not harmed during the community project.

Signature: _____ **Date:** _____

Phone number: _____

Faculty of Humanities
Department of Speech-Language Pathology and Audiology
Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

Appendix F: Pre-Testing Questionnaire

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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Participant number:	
Date completed:	
Field worker number:	
Participant contact number:	
Participant contact number: (Alternative)	

Pretesting questionnaire (for all participants)

1. Which of the following cases (sentences/statements) best describe *how you feel about your hearing* at the moment?

	I do not think I have a hearing problem.
	I think I have a hearing problem. However, I am not yet ready to take any action to solve the problem, but I might do so in the future.
	I know I have a hearing problem, and I intend to take action to solve it soon.
	I know I have a hearing problem, and I am here to take action to solve it now.
	None of these symptoms.

2. For how long have you had a problem with your hearing? (Ask the participant to specify, i.e., 6 months, 3 years, or longer than 10 years)

_____

_____

_____

3. Do you have any of the following symptoms?

	Sudden hearing loss: You woke up one morning and suddenly could not hear as well as you could the day before
	You hear a ringing (shh shh sounds) in your ears that is very loud and sounds like a heartbeat.
	Hearing loss in one ear only.
	You often feel dizzy.
	None of these symptoms.

4. Do you or someone in your home have a phone that can receive WhatsApp and/or SMSs?

	WhatsApp
	SMS
	No

If SMS or WhatsApp who has a phone

	Participant themselves
	Household member

If only a household member has a phone, who is this household member? (e.g. child, sister, uncle etc.) What is their contact number? _____

5. How comfortable are you in using a phone?

	I can receive phone calls.
	I know how to make and receive calls.
	I can make and receive calls and send and receive text messages via SMS.
	I can make and receive calls and send and receive text messages via WhatsApp.
	I need someone at home to help me use the phone.

6. Have you had your hearing tested before?

	Yes
	No
	Unsure

7. If yes, can you tell us where and what the results were?

_____

_____

_____

8. Do you have a hearing aid?

	Yes
	No

If yes, do you use your hearing aid? Can you tell us why not if you do not use your hearing aid?

_____

_____

_____

9. Have you had an ear infection or discharge from the ears in the last two years?

	Yes
	No
	Unsure

If yes, did you seek treatment? Was it a once-off problem or did the infection come back a few times?

_____

_____

_____

Appendix G: Data Collection Form

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Data collection sheet

Participant: **Date:**

Gender: **Date of birth:**

hearScope:

Left ear: AI imaging classification

	Normal
	Abnormal
	Wax
	Chronic suppurative otitis media
	Unable to determine
	Could not be done

Right ear: AI imaging classification

	Normal
	Abnormal
	Wax
	Chronic suppurative otitis media
	Unable to determine
	Could not be done

Comments:_____
_____
_____

AC Audiometry:

Ear	500Hz	1000Hz	2000Hz	4000Hz	6000Hz	8000Hz
Left						
Right						

Comments: (Any comments or difficulties. Did the participant test themselves and push the button themselves or did they raise their hands and you had to push the button? Any reliability concerns?)

_____
_____
_____

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Appendix H: Script for Cerumen Participants

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Script for if a participant has wax

The equipment shows that you have wax in one or both of your ear canals. If you want to remove the wax, you can see the nurse.

It helps to use sweet oil to soften the wax before you see the nurse.

You can purchase sweet oil from a pharmacy, or we also have a bottle of sweet oil available if you would like to take this home.

You only put a few drops of sweet oil in your ears every day for five days, and then you can visit the nurse who will look into your ears and remove the wax if necessary.

Appendix I: Referral Letter

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Referral Letter

Date: _____

A hearing check test was conducted on _____
(name) on _____20__.

During this check, it was determined that a referral for further audiological intervention is required. Therefore, we would like to refer you to:

	Specialist		**Reason**
	Audiologist		Wax removal
	Ear Nose and Throat Specialist		Possible ear disease
	Local Clinic		

We urge you to attend to this matter as soon as possible.

Sincerely,

Tersia De Kock

De Wet Swanepoel, Ph.D.

APPENDIX J: Journal Submission Confirmation

Gmail **Sello Marven <sellomarvenmms@gmail.com>**

Submission Confirmation for Primary Health Care Research & Development

2 messages

PHCRD Editorial Office <em@editorialmanager.com> Fri, Mar 22, 2024 at 9:28 PM
Reply-To: PHCRD Editorial Office <phcrd@cambridge.org>
To: Sello Marven Manganye <sellomarvenmms@gmail.com>

You are being carbon copied ("cc:'d") on an e-mail "To" "De Wet Swanepoel" dewet.swanepoel@up.ac.za
CC: "Caitlin Frisby" caitlin.frisby@up.ac.za, "Tarryn Marisca Reddy" tarryn.reddy@up.ac.za, "Tersia de Kock" tersia@hearxfoundation.org, "Sello Marven Manganye" sello.manganye@tuks.co.za;sellomarvenmms@gmail.com, "Sello Marven Manganye" sello.manganye@tuks.co.za;sellomarvenmms@gmail.com

Dear Prof. Swanepoel,

Your submission entitled "Primary Ear Care in Low-Income Settings: Hearing Loss Characteristics and Cerumen Management Efficacy." has been received by journal Primary Health Care Research & Development.

You will be able to check on the progress of your paper by logging on to Editorial Manager as an author. The URL is https://www.editorialmanager.com/phc/.

Your manuscript will be given a reference number once an Editor has been assigned.

(A separate Copyright Form will be sent to you with your proof for approval should your paper be accepted for publication.)

Should any author of this manuscript be interested in acting as a reviewer for PHCRD in the future please contact the editorial office for further details (phcrd@cambridge.org).

Thank you for submitting your work to this journal.

Kind regards,

Editorial Office
Primary Health Care Research & Development

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/phc/login.asp?a=r). Please contact the publication office if you have any questions.

PHCRD Editorial Office <em@editorialmanager.com> Fri, Mar 22, 2024 at 9:28 PM
Reply-To: PHCRD Editorial Office <phcrd@cambridge.org>
To: Sello Marven Manganye <sellomarvenmms@gmail.com>

[Quoted text hidden]