HEARING LOSS AT PRIMARY HEALTH CARE CLINICS IN SOUTH AFRICA: NOVEL SCREENING APPROACHES AND PREVALENCE

by

CHRISTINE LOUW

A thesis submitted in partial fulfilment of the requirement for the degree

D.Phil (Communication Pathology)

In the Department of Speech-Language Pathology & Audiology

University of Pretoria

Faculty of Humanities

SUPERVISOR:

PROFESSOR DE WET SWANEPOEL

CO-SUPERVISOR:

PROFESSOR ROBERT EIKELBOOM

AUGUST 2018

Christine Louw
Department of Speech-Language Pathology and Audiology
University of Pretoria
Pretoria
South Africa

Christine.louw@up.ac.za

ACKNOWLEDGEMENTS

Great is Lord Jesus! You are most worthy of praise!

Professor De Wet Swanepoel – thank you for your invaluable guidance throughout this project. Thank you for your never-ending patience, enthusiasm, timely revisions of all the manuscripts and for teaching me to use SPSS. You are an inspiration, not only as a brilliant academic, but also as a remarkable person.

Professor Rob Eikelboom – thank you for being the “the pair of fresh eyes”! Thank you for your assistance and guidance throughout this project. Your insightful comments and detailed feedback made a unique contribution.

Faheema – my dear friend and colleague - we have been on many roads together. Thank you for your friendship, advice and all the laughs we have in our office!

My family, in particular my mom – thank you for raising me the way you did. Thank you for always being proud of me and for believing in me. Thank you for looking after the boys so that I can complete this project.

My dear husband, Charl – you are solid in every way. Thank you for being my best friend and for supporting me in everything I do. Thank you for looking after Charlie and Christian when I have to work. I love you.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

PUBLICATIONS AND RESEARCH OUTPUTS

The thesis is based on the following original articles:

1. **Louw, C**., Swanepoel, D., Eikelboom, R., & Myburgh, H. (2017). Smartphone-based hearing screening at primary health care clinics. *Ear and Hearing*, 38(2), 93–100.
2. **Louw, C.**, Swanepoel, D., Eikelboom, R.H., Hugo, J. (2018). Prevalence of hearing loss at primary health care clinics in South Africa. *African Health Sciences.* 18(2), 313-320.
3. **Louw, C**., Swanepoel, D., Eikelboom, R.H. (2018). Self-report of hearing loss and pure tone audiometry for screening at primary health care clinics. *Journal of Primary Care and Community Health*. 9(Dec-Jan).

Part of this thesis presented at the following scientific conference:

Louw, C., Swanepoel, D., Eikelboom, R.H., Myburgh, H. & Hugo, J. (2018). Hearing loss at primary health care clinics in underserved communities in South Africa: Prevalence and novel detection approach. *Paper to be presented at the 34th World Congress of Audiology in Cape Town, October 2018.*

ABSTRACT

Title: Hearing loss at primary health care clinics in South Africa: novel screening approaches and prevalence

Name: Christine Louw

Supervisor: Prof. De Wet Swanepoel

Co-supervisor: Prof. Robert Eikelboom

Department: Speech-language Pathology and Audiology

Degree: D.Phil Communication Pathology

Hearing loss is a serious disability that not only affects the individual and the family but also places a heavy burden on resources of communities and countries. Access to hearing care is unfortunately limited and services are often reserved for tertiary and secondary hospitals, universities and practices in the private sector. This project aimed to determine approaches that could be used to detect hearing loss accurately and affordably in primary health care clinics. More specifically, the project evaluated the performance of low-cost, smartphone-based hearing screening at primary health care clinics. The project also investigated the performance of hearing screening using self-reported hearing loss and pure tone audiometry in primary health care clinics. Furthermore, the project aimed to determine the prevalence of hearing disorders in patients three years of age and older, as well as the nature and characteristics of hearing disorders found at primary health care clinics. The project aimed to provide research-based recommendations for clinical practice of hearing detection at primary health care clinics.

Nonprobability purposive sampling was used at both primary health care clinics to evaluate the performance of low-cost, smartphone-based hearing screening. 1236

participants were included in the final analysis and participants were screened using the hearScreen™ application following a two-step screening protocol and diagnostic pure tone audiometry to confirm hearing status. Sensitivity and specificity for smartphone screening was 81.7% and 83.1% respectively. Gender [$\chi^2(1, N=126)= .304$, $p>.05$] and race [$\chi^2(1, N=126) = .169$, $p>.05$)] had no significant effect on screening outcome for children whilst for adults age ($p<0.01$; $\beta=.04$) and gender ($p=0.02$; $\beta=-.53$) had a significant effect on screening outcomes with males more likely to fail. Initial screening test times were less than a minute (48.8s ± 20.8 SD) for adults and slightly more than a minute for children (73.9s ± 44.5 SD). The hearScreen™ smartphone application provides time-efficient identification of hearing loss with adequate sensitivity and specificity for accurate testing at primary health care settings.

To evaluate the performance of self-reported hearing loss in isolation, and a combination of self-reported hearing loss and pure tone audiometry screenings in primary health care clinics in South Africa, nonprobability purposive sampling was used at both primary health care clinics and 1084 participants were included. It was found that 40.2% self-reported a hearing loss with no significant association with gender or race. Self-reported hearing loss increased significantly with increasing age. A hundred and thirty six participants (12.5%) self-reported hearing loss and failed audiometry screening (35 dB HL at 1, 2 and 4 kHz). Combining self-report with a second stage audiometry screening revealed a high test accuracy (81.0%) for hearing loss, was the most accurate procedure (86.1%) for the identification of high frequency hearing loss.

Whilst self-report of hearing loss is an easy and time-efficient screening method to use at primary health care clinics, its accuracy may be limited when used in isolation and it may not be sufficiently sensitive to detect hearing loss. Combining a simple audiometry screening as a second-stage screen can significantly improve overall performance and efficiency of the screening protocol.

To determine the prevalence of hearing disorders, a cross-sectional design was used in patients three years of age and older attending two primary health care clinics. Nonprobability purposive sampling was used and 1236 participants were screened. It was found that the hearing loss prevalence was 17.5% across both clinics. Furthermore, most hearing losses were bilateral (70.0%) and were of a sensorineural nature (84.2%). Participants 40 years and older were at significantly higher risk for hearing loss.

Decentralizing hearing services to primary health care clinics could alleviate negative effects and high expenses usually experienced due to hearing loss. Using self-reported hearing loss in combination with smartphone technology provides the possibility to expand and decentralize hearing care services to primary health care level. Furthermore, prevalence data suggests that 17.5% of people present with some form of hearing loss. These findings provide valuable baseline data to motivate for the inclusion of hearing care at primary health care clinics. Furthermore, these findings provide baseline data to plan and identify specific program goals and specification of care pathways to support implementation of sustainable hearing services across primary health care clinics in South Africa.

KEYWORDS

Primary health care

Developing countries

Low and middle income countries

South Africa

Hearing loss

Screening protocol

Referral rate

Cost-effectiveness

Smartphone hearing screening application

hearScreen™

Performance

Self-reported hearing loss

Second-stage audiometry screen

Second-stage self-reported hearing loss

Automated diagnostic audiometry

Prevalence

ABBREVIATIONS

CHWs	Community health workers
PHC	Primary health care
LMIC	Low and middle income countries
COPC	Community orientated primary care
dB	Decibel
dB HL	Decibel hearing level
Hz	Hertz
MPANL	Maximum permissible ambient noise level
SD	Standard deviation
WHO	World Health Organization
VRA	Visual response audiometry
SNHL	Sensorineural hearing loss
SR	Self-reported hearing loss
4FA	Four frequency average
HFA	High frequency average

CHAPTER 1

INTRODUCTION

1.1 Background

The faculty of hearing is central to the development and utilization of spoken communication (Swanepoel, Clark, et al., 2010). The absence, or abnormal functioning of this sense has far-reaching effects for adults and children in terms of speech, language, cognition and social abilities (Arlinger, 2003; Dalton et al., 2003; Yoshinaga-itano, Sedey, Coulter, & Mehl, 2013). The consequences of hearing loss are extensive, yet this disorder is often neglected (Arlinger, 2003; Olusanya, Luxon, & Wirz, 2006).

Hearing loss is the most prevalent chronic condition globally (Vos et al., 2016). Disabling hearing loss (> 40 dB HL) estimates have increased from 280 million to 360 million in four years (WHO, 2012; WHO, 2013a). In addition to its high prevalence, it has been ranked as one of the leading contributors to the global burden of disease (Vos et al., 2016). Furthermore, hearing loss currently ranks fifth on the global causes of years lived with disability index - higher than other chronic diseases such as diabetes and dementia (Vos et al., 2016).

Hearing loss is a serious disability that not only affects the individual and the family, but also places a heavy burden on the resources of communities and countries (WHO, 2013a). The majority of people with a disabling hearing loss live in middle or low income countries (WHO, 2012). The high prevalence of hearing loss in these countries is due to the high prevalence of exposure to environmental risks such as limited access to health care, infectious disease outbreaks, limited awareness of

prevention and unhygienic living conditions (Goulios & Patuzzi, 2008; Olusanya et al., 2006; WHO, 2012).

1.2 Primary health and hearing care services

The majority of the South African population (84.0%) depends on public health care (Naidoo, 2012). To strengthen the public health system in terms of accessibility and equitability for the larger population, a primary health care (PHC) approach was adopted by the Department of Health (DOH) in 1994 (Kinkel, Marcus, Memon, Bam, & Hugo, 2013). However, PHC was severely challenged due to emerging epidemics and a predominately hospital-centric health system, which resulted in ineffective primary health care as hospitals were over-burdened (Bam, Marcus, Hugo, & Kinkel, 2013). Parallel to the World Health Organization (WHO) advocating reviving PHC, the DOH of South Africa developed a plan to transform the health system (Naledi, Barron, & Schneider, 2011).

Central to the plan for revitalization of the health system is re-engineering of the PHC (Kinkel et al., 2013; Naledi et al., 2011). The philosophy behind PHC is that genetic proclivity and the social environment may determine the people's health (Bam et al., 2013; Dookie & Singh, 2012). Thus, the PHC approach includes services that promote healthy living, prevention of diseases, early identification as well as management of diseases and rehabilitation; these services are delivered through district specialist teams, school health teams and municipal ward outreach teams (Kinkel et al., 2013).

Municipal ward outreach services is also referred to as community orientated primary care (COPC) (Kinkel et al., 2013). COPC is characterized by a multi-disciplinary team approach where individual health needs are addressed within the greater

context of the family and the community (Bam et al., 2013; Kinkel et al., 2013). Within the framework of COPC, individuals with a prominent condition or disease, such as human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS), tuberculosis, malaria, diabetes or hypertension, need to be managed holistically by health care providers. As a chronic non-communicable condition, hearing loss is not included as a major disease that needs to be managed at PHC facilities, despite it being linked to priority conditions such as HIV/AIDS, tuberculosis, malaria, diabetes and hypertension (Agrawal, Platz, & Niparko, 2009; Ettehad, Schaaf, Seddon, Cooke, & Ford, 2012; Kakarlapudi, Sawyer, & Staecker, 2003; Seddon et al., 2012; Van der Westhuizen, Swanepoel, Heinze, & Hofmeyr, 2013). Currently, hearing loss is not typically targeted and managed at PHC level, which is in contrast to the WHO's vision to integrate ear and hearing care services at PHC facilities (WHO, 2012).

Integration of ear and hearing care services in the PHC context can be beneficial to people with, or at risk of, ear disease, and hearing loss can be supported in a timely manner (WHO, 2012). Barriers such as transport and distance can be eliminated, since people do not have to travel to a tertiary hospital. Other barriers could also be eliminated, such as specialist personnel requirements and the prohibitive cost of traditional audiological equipment and sound-treated test environments, along with their characteristically stationary nature. The implementation of such a service in a PHC context would, however, require consideration of innovative solutions to address the aforementioned barriers.

1.3 New solutions for access to primary health care hearing detection

Automated, user-friendly mHealth solutions

Innovative solutions may assist in expanding ear and hearing services at a PHC level, such as incorporating automation and more cost-effective audiological equipment, such as mobile phones (Clark & Swanepoel, 2014; Khoza-Shangase & Kassner, 2013; Louw, Swanepoel, Eikelboom, & Myburgh, 2017; Swanepoel, Myburgh, Howe, Mahomed, & Eikelboom, 2014). Research on hearing assessments being done using a computer, tablet or mobile phone has emerged in recent years (Kam et al., 2013; Louw et al., 2017; Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, & Hall, 2016; Peer & Fagan, 2015; Sandström, Swanepoel, Myburgh, & Laurent, 2016; Swanepoel et al., 2014; Thompson, Sladen, Borst, & Still, 2015; Van der Aerschot, Swanepoel, Mahomed-Asmail, Myburgh, & Eikelboom, 2016; Yousuf Hussein et al., 2016). One reason for this increased popularity is the widespread availability of mobile phones and the increased cellular network coverage - not only in developed areas, but also in under-served regions in the world (Kelly & Minges, 2012).

A mobile health (mHealth) application for hearing screening on an Android platform was recently patented. This allows use on smartphones that are low-cost and more widely available in developing countries (Swanepoel et al., 2014). The hearScreen™ application creates an inexpensive alternative to conventional screening audiometry (Mahomed-Asmail et al., 2016). This application implements valid acoustic calibration according to prescribed standards and environmental noise monitoring with no statistically significant difference between test results for conventional and smartphone-based hearing screening (Swanepoel et al., 2014). Personnel with no or

limited health care training, such as community health workers (CHW), can screen participants for disabling hearing loss, as this application has recommended pre-programmed screening protocols and is automated (Yousuf Hussein et al., 2016).

Automation is considered appropriate for clinical audiometry due to the methodological nature of the procedures involved (Mahomed, Swanepoel, Eikelboom, & Soer, 2013; Margolis et al. 2010; Margolis & Morgan, 2008; Swanepoel, Mngemane et al., 2010). Evidence demonstrates the reliability and accuracy of automated audiometry, making it an applicable method to use (Mahomed et al., 2013). This method can be employed without an audiologist being present, suggesting that it could address the shortage of hearing health care personnel (Mahomed et al., 2013; Swanepoel et al., 2010) Thus, CHW could be trained to facilitate screening and diagnostic hearing tests at a PHC facility and in the community itself through outreach and home-based services (Yousuf Hussein et al., 2016).

Automated hearing tests could assist in extending the hearing services provided at a PHC facility. However, the environment in which the hearing tests are being conducted needs to be considered. A pre-requisite for hearing tests is a controlled environment with a low level of ambient noise, i.e. sound-treated room (Maclennan-Smith, Swanepoel, & Hall, 2013). Sound-treated rooms are not available at PHC clinics, due to their immobility, size and expense (Maclennan-Smith et al., 2013). Novel audiometers with attenuating headphones and real-time noise monitoring have, however, become available. Research reports concluded that valid air and bone conduction audiometry can be conducted without the use of a sound-treated booth when using technology that provides sufficient attenuation and that provides a

way to monitor noise compliance (Maclennan-Smith et al., 2013; Margolis & Morgan, 2008; Swanepoel, Mngemane et al., 2010; Storey et al., 2014).

The audiological technology evolution is additionally complemented by the growth in internet connectivity globally (Swanepoel, Clark, et al., 2010; Kelly & Minges, 2012). Internet connectivity in developing countries is increasing, which creates opportunities that were not previously available (Internet World Stats, 2014). In terms of hearing health care, asynchronous and synchronous hearing tests are now possible. Whilst asynchronous testing refers to automated hearing test results that are stored and forwarded to an audiologist for interpretation and management, synchronous testing refers to an audiologist conducting a "real-time" manual hearing test on a participant remotely (Krumm, Ribera, & Klich, 2007; Swanepoel, Koekemoer et al., 2010). Thus, the implication for using connectivity together with novel automated audiometers is that there is now a link between participants and health care providers who might otherwise be separated by various barriers, e.g. geographical, weather, economical, distance and location (Swanepoel, Clark, et al., 2010).

Self-reported hearing loss at primary health care clinics

Self-reported hearing loss is an alternative screening method that could create a way to determine early hearing detection and timely referral to audiological services in a PHC setting, if it is linked to a clear and efficient referral pathway (Swanepoel, Eikelboom et al., 2013). This method has been proposed as being affordable and time-efficient, and it can be used by any health care worker (Ramkissoon, 2011; Swanepoel, Eikelboom et al., 2013). The use of a single hearing screen question or a questionnaire on hearing functioning could be considered as a valid self-reported screening method (Ferrite, Santana, & Marshall, 2011; Nondahl et al., 1998;

Ramkissoon, 2011; Salonen et al., 2011). Using a single question is beneficial, as it is quick and easy to administer and may also overcome language and cultural barriers, making it a valuable tool in a PHC setting (Salonen et al., 2011; Swanepoel, Eikelboom et al., 2013; Torre, Moyer, & Haro, 2006).

Using self-reported hearing loss as a single hearing screen question or a questionnaire on hearing functioning have both been proposed as valid screening methods (Ferrite et al., 2011; Nondahl, Cruickshanks, Wiley, Tweed, Klein, & Klein, 1998; Ramkissoon, 2011; Salonen, Johansson, Karjalainen, Vahlberg, & Isoaho, 2011; Sindhusake et al., 2001; Swanepoel et al., 2013; Torre et al., 2006; Vermiglio, Soli, & Fang, 2018). The Hearing Handicap Inventory for the Elderly-Shortened (HHIE-S), for example, is a screening questionnaire consisting of ten questions evaluating the perceived social-situational and emotional effects of hearing loss in the elderly (Nondahl et al.,1998). Although the HHIE-S was standardized for individuals over 65 years of age, Nondahl et al. (1998) found that it demonstrated lower sensitivity and accuracy in older individuals (65 – 92 years) compared to younger individuals (48 – 64 years. Contrary, using a single question such as “do you feel you have a hearing loss?” showed sufficient accuracy in young and older individuals in various reports (Nondahl et al., 1998; Sindhusake et al., 2001; Salonen et al., 2011; Swanepoel et al., 2013). Using a single question to screen for self-perceived hearing loss has also the advantage that it is easy to administer and may also be used in cases where individuals present with poor sight or minor cognitive impairment (Salonen et al., 2011; Swanepoel et al., 2013).

Using a single question to screen for hearing loss may be particularly accurate in cases where there is a moderate or severe hearing loss, in cases where individuals are 60 years and older, in cases where individuals have a high frequency hearing loss (4 kHz and 8 kHz), and also in individuals who experience speech-recognition-in-noise difficulties (Brennan-Jones et al., 2016; Hannula, Bloigu, Majamaa, Sorri, & Mäki-Torkko, 2011; Nondahl, et al., 1998; Salonen et al., 2011; Sindhusake et al., 2001; Vermiglio et al., 2018). Hence, it shows the potential value of using a self-report of hearing loss in a PHC clinic (Swanepoel et al., 2013). However, self-report of hearing loss it is not regarded as a standard or recommended protocol to identify hearing loss (Vermiglio et al., 2018). Although its use in combination with an audiometric screening has been proposed (Brennan-Jones et al., 2016; Kiely, Gopinath, Mitchell, Browning, & Anstey, 2012), it requires further investigation, particularly in PHC settings to investigate the performance of this technique in isolation or with a second-stage audiometry screen. Using second stage audiometry screen may be beneficial as it may provide more accurate results (Brennan-Jones et al., 2016).

1.4 Rationale

PHC is widely promoted by the WHO and has been accepted by South Africa's DOH as the approach of choice (Bam et al., 2013; Kinkel et al., 2013; WHO, 2012). Integrating hearing services into a community-based health care programme ensures accessibility of these services (WHO, 2012).

The need for increased availability of hearing services is necessitated by the high prevalence of hearing loss and the excellent outcomes of early identification and

management of this disorder. The limited amount of hearing health care personnel, however, requires consideration of novel ways to render ear and hearing services. Hearing screening using self-reported hearing loss, as well as smartphone-based technology and diagnostic hearing testing employing automated, noise-attenuating and real-time monitoring audiometers, opens up new possibilities to extend hearing services in communities (Brennan-Jones et al., 2016; Maclennan-Smith et al., 2013; Yousuf Hussein et al., 2016). By integrating ear and hearing services into a community-based health care programme, these services become accessible to the community (WHO, 2012). Consequently, essential hearing services, such as identification, diagnosis and intervention for hearing loss and ear disorders, may be established or enhanced in under-served communities at PHC level (WHO, 2012). In light of the need to expand ear and hearing care services to under-served communities, the research question for the current study is: *What approaches could be used to detect hearing loss accurately and affordably in primary health care clinics and what is the prevalence of hearing loss?*

CHAPTER 2

METHOD

2.1 Research objectives

The study evaluated different approaches to detect hearing loss at PHC clinics in Tshwane. Three research objectives were proposed each constituting a research study for submission as an article to an accredited peer-reviewed journal upon completion. The three studies are summarised in Table 2.1 according to proposed titles, objectives, and journal for submission.

Table 2.1 Summary of studies I tot III displaying article title, objectives, journal and thesis chapter

Study	I	II	III
Title	Smartphone-based hearing screening at primary health care clinics	Self-report hearing loss and pure tone audiometry for screening at primary health care clinics	Prevalence of hearing loss at primary health care clinics in South Africa
Objectives	To evaluate the performance of smartphone-based hearing screening with the hearScreen™ application in terms of sensitivity, specificity, referral rates and time efficiency at two primary health care clinics.	To evaluate the performance of self-reported hearing loss alone and in combination with pure tone audiometry screening in primary health care clinics in South Africa.	To determine (i) the prevalence of hearing disorders in patients ≥3 years of age attending two primary health care clinics, and (ii) the nature and characteristics of hearing disorders at these primary health care clinics.
Journal	Ear & Hearing (published)	Journal of Primary Care and Community Health (published)	African Health Science (published)
Chapter in thesis	**3**	**4**	**5**

2.2 Research design and methods

A cross-sectional, descriptive study design using quantitative data was used for studies I – III (Table 2.2).

2.3 Research context

Research was conducted at two PHC clinics in Tshwane as part of the larger COPC project currently running in Gauteng (Tshwane) province (Appendix A and Appendix B). One clinic is situated in Pretoria-West and the other PHC clinic is in the Mamelodi-region. No or limited hearing health care services have been provided in the past at these primary health care clinics. Figure 2.1 illustrates the model followed to collect data at both clinics. The hearing service at the clinic in Pretoria-West was conducted from 08:00 to 12:00 on a Monday and Thursday, whilst services were delivered at the Mamelodi-region clinic on a Tuesday, Wednesday and Friday, also 08:00 to 12:00.

Diagnostic hearing assessments followed when the screening results indicated a fail (refer). Based on the outcome of the results of the diagnostic assessments, the participant was referred for a) medical intervention to the General Practitioner (GP) at the PHC clinic or b) audiology intervention at the nearest tertiary hospital. Figure 2.2 and Figure 2.3 depict the decision tree for audiological referrals for adults (participants 16 years and older) and children (participants 3 – 15 years) respectively and was followed by the audiology students delivering the services.

2.4 Research participants

The research project included 1236 participants aged 3 years and older. Table 2.2 provides a detailed summery of the participant selection criteria, participant sampling method and sample size for each of the three studies completed.

Table 2.2 Research design and methods summary for studies I to III

Study	I	II	III
Title	Smartphone-based hearing screening at primary health care clinics	Self-report hearing loss and pure tone audiometry for screening at primary health care clinics	Prevalence of hearing loss at primary health care clinics in South Africa
Study design	Cross-sectional, descriptive study (Leedy & Ormrod, 2005)	Cross-sectional, descriptive study (Leedy & Ormrod, 2005)	Cross-sectional, descriptive study of disease prevalence (Leedy & Ormrod, 2005)
Participant selection criteria	• Participants had to be registered at the specific PHC clinic • Male and female participants were included • Participants (>18 years) had to provide informed consent • Participants 3 years or older were included • For children 18 years or younger, and participants with mental or cognitive impairments, informed consent was first obtained from the parent/caregiver and then verbal assent was obtained from the participant.	• Participants had to be registered at the specific PHC clinic • Male and female participants were included • Participants (>16 years) had to provide informed consent • Participants 16 years and older were included	• Participants had to be registered at the specific PHC clinic • Male and female participants were included • Participants (>18 years) had to provide informed consent • Participants 3 years or older were included • For children 18 years or younger, and participants with mental or cognitive impairments, informed consent was first obtained from the parent/caregiver and then verbal assent was obtained from the participant.
	• All participants who obtained a refer result were referred for a diagnostic assessment • Diagnostic testing was also performed on a group of participants who passed the screening to allow determination of screening specificity.	• All participants who provided signed consent and who completed the screening protocol (i.e. self-reported hearing loss and audiometric hearing screening) were included in the study • All participants who failed audiometry screening were referred for a diagnostic assessment • Diagnostic testing was also performed on a group of participants who passed the screening to allow determination of screening specificity.	• Participants who failed the hearing screening in one or both ears and who underwent diagnostic testing were included
Participant sampling	Non-probability purposive sampling (Leedy & Ormrod, 2005). Nonprobability purposive sampling was used to screen participants as it was a clinical, non-experimental set-up and results would therefore be representative of the clinic population. At PHC clinic 1, universal screening took place by offering all individuals who visited the clinic a hearing screening free of charge. At PHC clinic 2 all individuals		

	who were available during the time that the services were delivered and who wanted their hearing tested were screened free of charge.		
	• A convenient sampling strategy was used to select participants with normal hearing. One to two participants per day, who passed the hearing screening, were selected based on their time and clinic constraints		
Sample size	Screening was conducted on 1236 participants. Diagnostic testing was performed on 111 participants who passed the hearing screening.	Self-reported measures and audiometry screening were conducted on 1084 participants. Diagnostic testing was performed on 81 participants who passed, and 114 who failed the audiometry screening.	Screening was conducted on 1236 participants. Diagnostic testing was performed on 138 participants who referred on the screening.

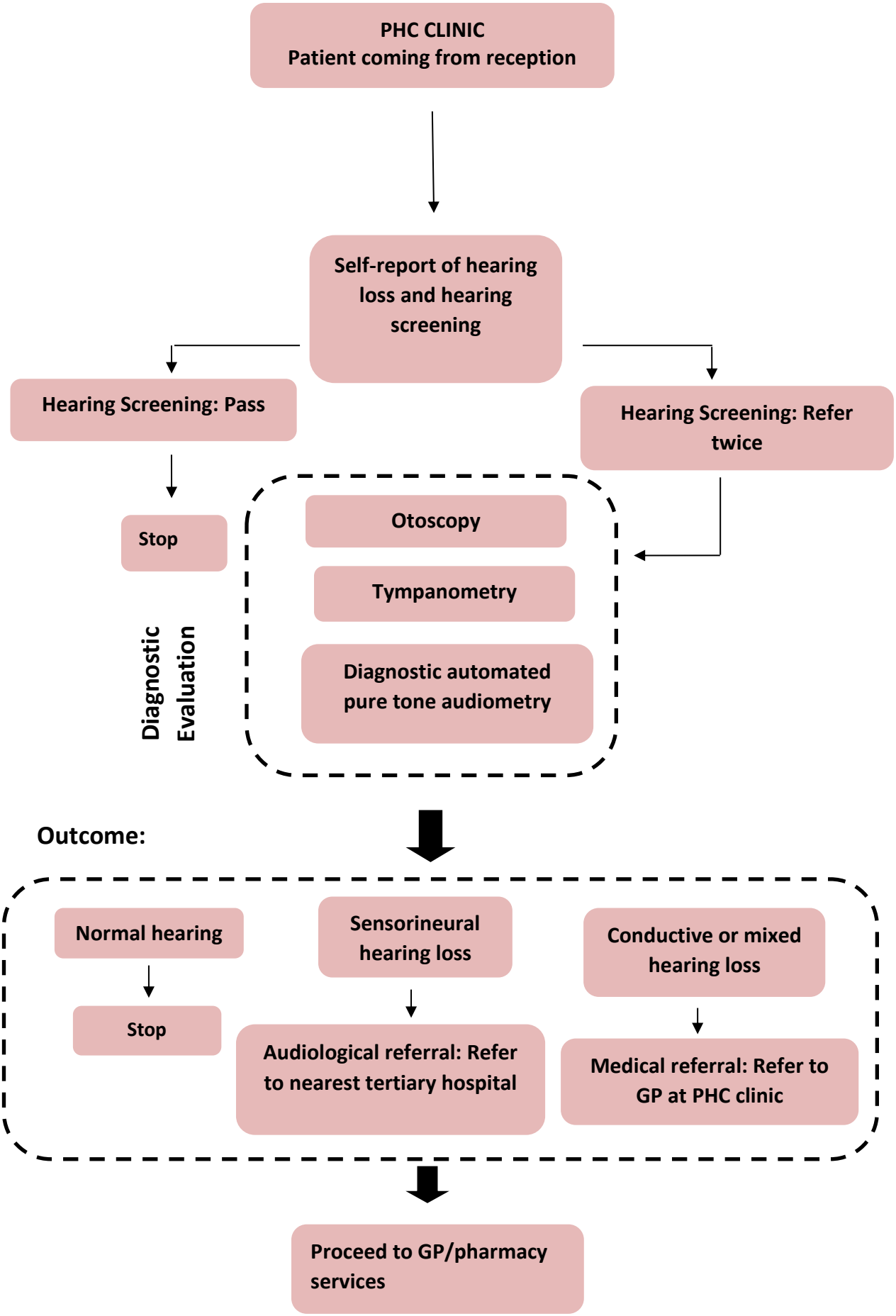

Figure 2.1 Model followed for data collection at primary health care clinics

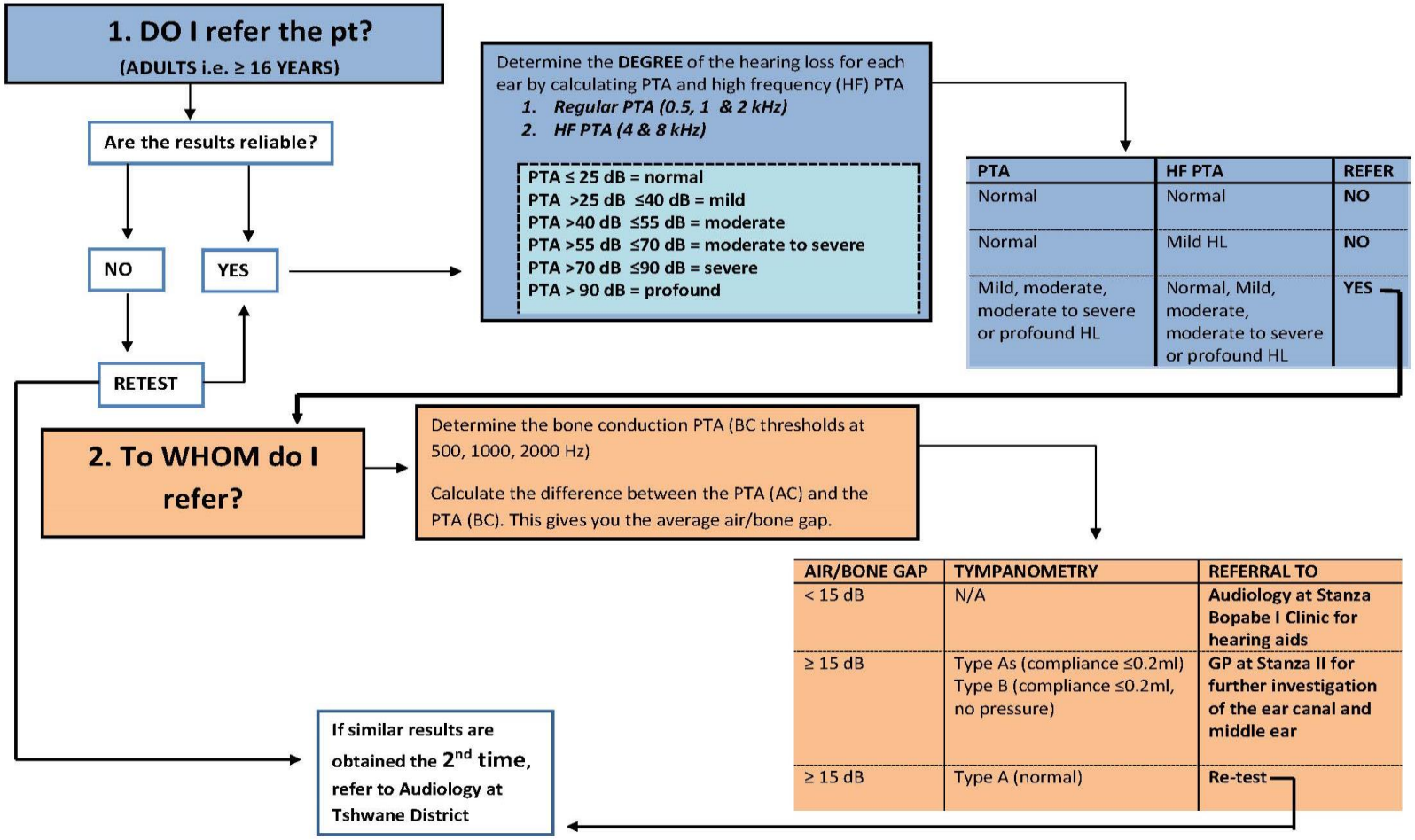

Figure 2.2 Decision tree audiological referrals at primary health care clinics: adults (16 years and older)

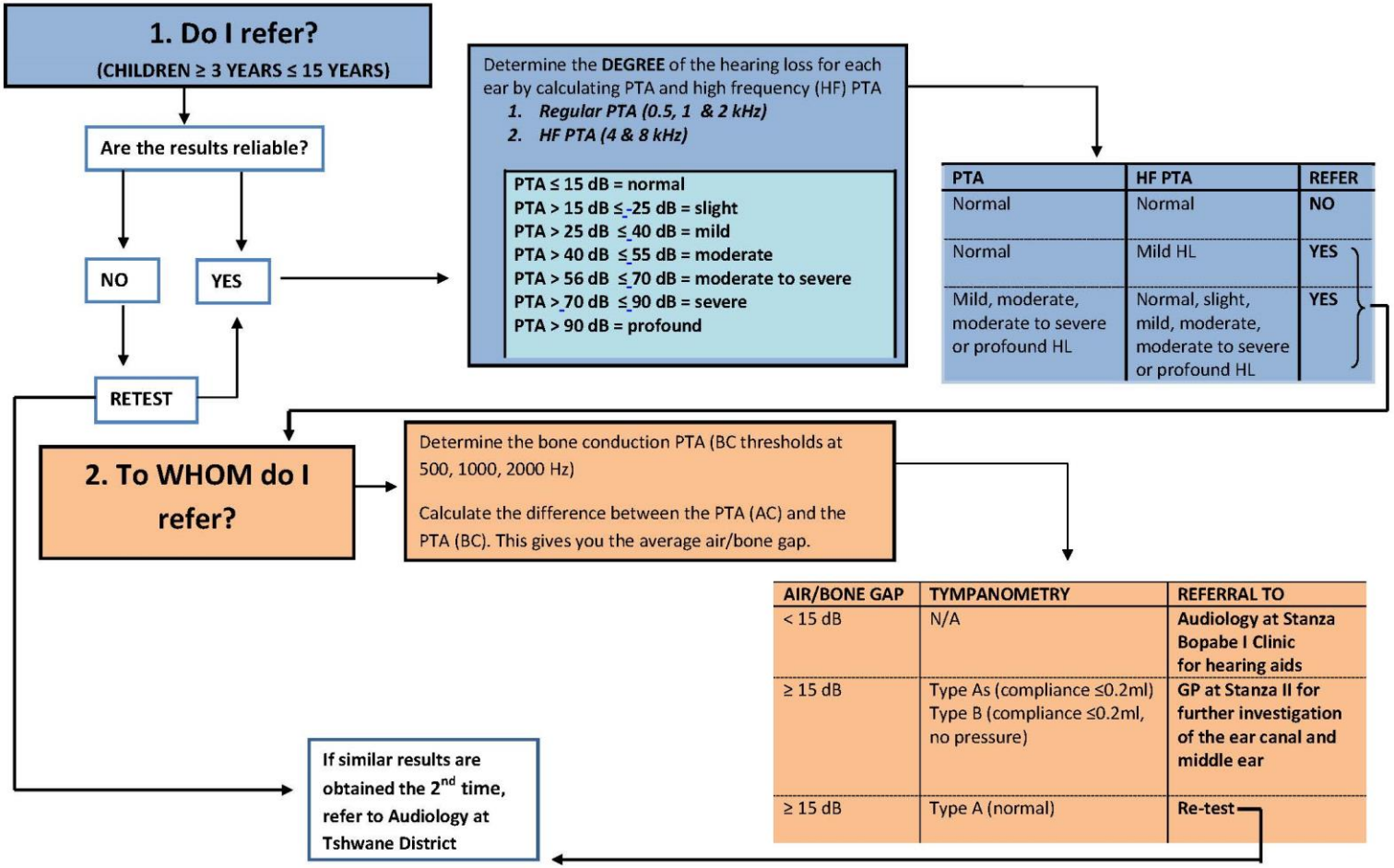

Figure 2.3 Decision tree for audiological referrals at primary health care clinics: children (3 -15 years)

2.5 Research Equipment

Table 2.3 provides a detailed summary of the equipment that was used across the various studies.

Table 2.3 Summary of equipment

Equipment	Description
Heine mini 3000 (Heine, Germany) andWelch Allyn (Welch Allyn, South Africa, Pty,Ltd) otoscope with reusable specula	The otoscope was used to visualize and identify and obvious abnormalities of the outer ear canal and tympanic membrane
Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark)	Tympanometry was conducted with this device by placing a probe in the participant's ear and measuring the middle ear pressure, compliance and ear canal volume.
hearScreen™ application running on a Samsung Galaxy Pocket Plus S5301 with supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany)	A mobile smartphone calibrated into a screening audiometer (according to national and international standards i.e. ANSI) for conducting hearing screening using commercially available headphones (HD 202 II). The software utilizes pre-specified screening protocols to assess hearing using automated sequences by presenting a tone at 25 dB HL (3 – 15 years) and 35 dB HL (≥ 16 years (WHO, 2012) at 1, 2 and 4 kHz. Additionally the software monitored the environmental noise using the device microphone to ensure environmental compliance during testing.
KUDUwave (eMoyoDotNet, Pretoria, South Africa) Type 2 Clinical Audiometer (OEC 60645-1/2)	The KUDUwave is a computer-based audiometer with circumaural ear cups which was placed over insert earphones.

2.6 Ethical Considerations

The research project was approved by the Postgraduate Committee of the Faculty of Humanities of the University of Pretoria on 26 September 2014 (Appendix C). The current study was also part of a larger research project registered under Professor J.F.M Hugo, Head of Department of Family Medicine, Faculty of Health Sciences, under the protocol title "*Researching the Development, Application and Implementation of Community Orientated Primary Care (COPC): a study in Gauteng*

(Tshwane) and Mpumalanga Province" (protocol number: 102/2011). The protocol was approved on the 22nd of June 2011 (Appendix A). An addendum to include hearing services as part of this protocol was approved by the Ethical Committee of Health Sciences on the 3rd of August 2014 (Appendix B).

The South African National Health Act (2007) states that medical and health care research is subject to ethical standards that promote respect for all human beings and protect their health and rights. In keeping with this statement, the current study was initiated and conducted within the framework of the ethical guidelines set out in the Guidelines of Practice in the Conduct of Clinical Trials in Human Subjects in South Africa (South African Department of Health, 2000) and in the South African National Health Act (2007). The individual principles presented in these documents are listed and discussed below in Table 2.4.

2.7 Research Procedures

The data was collected by third and fourth year audiology students from the Department of Speech-Language Pathology and Audiology students under supervision of the researcher (Christine Louw, M.Communication Pathology, STA 0024996). A training session was held prior to commencing data collection during which students were provided with adequate information regarding ear and hearing health care and its importance. The audiology students also received training and sufficient practice to manage the hearScreen™ application as well as the KUDUwave audiometer during this session. The training sessions were also under supervision of the researcher (Christine Louw).

2.7.1 Research procedures

Once informed consent (Appendix D) and verbal assent (Appendix E) (in case of a child under 18 years) were obtained, the student wrote the participant's name, surname and date of birth on the data collection form (Appendix F). The student then enquired if the participant felt he/she had a hearing problem and if he/she experienced any tinnitus. The participant's responses were noted on the assessment form. In the case of a child being tested, the student asked the parent/caregiver if the child presented with a hearing problem. Hearing screening was performed using the hearScreen™ smartphone application. Screening was conducted at 1, 2 and 4 kHz as prescribed by current guidelines (AAA, 2011; ASHA, 1997). The application had two protocols – a child protocol (used for participants 3 – 15 years) with an intensity level of 25 dB HL and an adult protocol (used for participants ≥ 16 years) with an intensity level of 35 dB HL.

Table 2.4 Ethical principles applied to formulation of research design, participant selection and recruitment procedures, and data collection and analysis procedures (South African Department of Health, 2000; South African National Health Act, 2007)

Principle	Application to study
The right, safety and wellbeing of the participants are the most important considerations and should prevail over interest of science and society. Foreseeable risks and inconveniences should be weighed against the anticipated benefit for participants and society. A study should only be initiated and continued if the anticipated benefits justify the risks.	There were no risks involved for the participants of this study. The only inconvenience was being the extra time spent for participants who referred the initial hearing screening test. The benefit for the population in question was verification of the accuracy and cost efficiency of a novel service delivery model. Cost effectiveness is one of the cornerstones of the South African National Health Act (2007). The participants were not exposed to unusual stress, embarrassment or loss of self-esteem.
Research or experimentation on an individual may only be conducted after the participant has been informed of the objectives of the research or experimentation and any possible positive or negative consequences on his or her health.	There were no direct benefit to the participants but also no risks involved. When the hearScreen™ application was opened, it requested that informed consent was obtained from the participant prior to commencing the test. The participant was made aware of the nature of the service being provided and that the data collected would be used for research purposes. Only once informed consent was obtained, screening commenced.
Freely given informed consent should be obtained from every participant prior to clinical trial participation.	Freely given informed consent was obtained from every participant before hearing screening was conducted. The participant signed an informed consent letter after the nature of the test was explained to him/her. In case of a child or mentally challenged person, the caregiver/parent signed an informed consent letter whilst verbal assent was obtained from the child.
The participant should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.	This principle is stated in the informed consent form of the COPC protocol (Appendix A) and was reiterated verbally prior to commencement of the assessment session.
The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).	Participant confidentiality was ensured as behavioural pure tone threshold information for each individual was reported using an alphanumeric code. The identity of the participant represented by this code was known only to the researcher.
A preliminary study should be conducted in compliance with the protocol that has received prior institutional review board / independent ethics committee approval.	The research was approved by the Research Ethics Committee of the Faculty of Humanities of the University of Pretoria as well as the Ethical Committee of Health Sciences.
Participants have the right to know their health status and researchers are obligated to disseminate results in a timely and competent manner.	The student facilitator and researcher conveyed the results of hearing assessment to participants directly after completion of audiometry. The student was trained on how to convey the information and on what information to provide.

A fail (also referred to as “refer”) at any frequency in either ear constituted an initial referral. A rescreen was done immediately following a refer result. A diagnostic assessment was performed if the results reflected a fail for a second time. The diagnostic assessment included otoscopy, tympanometry and automated pure tone audiometry. Air conduction audiometry was conducted first followed by bone conduction audiometry. Bone conduction audiometry was conducted when air conduction thresholds exceeded 20 dB HL (> 20 dB HL). Air conduction threshold differences between the test and non-test ear of 75 dB or greater at low frequencies (<1 kHz) and 50 dB at high frequencies (> 1 kHz) were masked. A narrowband noise masking level of 30 dB above the air conduction threshold of the non-test ear was used. Bone conduction thresholds were determined with a continuous masking level of 20 dB above the air conduction threshold of the non-test ear (ASHA, 2005). Participants who presented with a mixed or conductive hearing loss were referred to the clinics’ general practitioner for further medical intervention. Participants who presented with a sensorineural hearing loss were referred to the nearest district hospital for a hearing aid fitting evaluation. Instructions were provided in English or Afrikaans. Written instructions in Sepedi were used by a non-Sepedi speaking test operator if participants did not understand English or Afrikaans (Appendix F).

Self-report of hearing loss

One question was asked to the participant: “Do you have a hearing problem? Yes/No”. Using a single question demonstrated sufficient accuracy in various reports (Nondahl et al., 1998; Salonen et al., 2011; Sindhusake et al., 2001; Swanepoel et al., 2013). The participant’s response was recorded on the data collection form (Appendix F).

Smartphone hearing screening

The participant's name, surname and date of birth were entered in the hearScreen™ application. If the participant was between the ages of 3 and 15 years, the child protocol was selected, whilst the adult protocol was selected if the participant was 16 years or older (WHO, 2012). The screening intensity for the child protocol was 25 dB HL whilst the screening intensity for the adult protocol was 35 dB HL. The participant was instructed to raise their hand when a tone was heard. Sennheiser HD 202 II headphones were placed over the participant's ears. The initial presentation level at 1 kHz was raised 10 dB above the screening level for conditioning purposes after which the screening continued on the test intensity. A 1, 2, and 4 kHz sweep was then performed at 35 dB HL for adults and 25 dB HL for children (ASHA, 1997). Stimulus presentation was repeated once if the participant did not respond at a specific intensity level. Left ears were tested first, followed by testing of right ears in the same way. Participants who responded to all the frequencies on both ears passed the screening. A two-step hearing screening protocol was followed; thus when a participant failed to respond to one or more frequencies in either ear, the results constituted an initial fail and an immediate rescreen was initiated. This standard practice is in accordance with screening guidelines (AAA, 2011; ASHA, 1997) recommending an immediate rescreen, which represents the final screening outcome (AAA, 2011). The two-step protocol was followed to minimize over-referrals. All test results were uploaded from the smartphones to the cloud-based server from where data were exported for analysis and interpretation. A diagnostic hearing test was conducted on the same day if participants failed the screening for a second consecutive time. In the case of children between the age of 3 and 4 years, the

procedure was adapted to a play-based method i.e. the student conditioned the child to respond to the stimulus through a play activity such as dropping a block in a bucket when the sound was heard.

Otoscopy

Otoscopy was used to visually inspect the participant's ear canal to identify any obvious pathology of the outer ear canal or tympanic membrane. If pathology was identified, the participant was referred to the general practitioner at the PHC clinic.

Tympanometry

Tympanometry was conducted to obtain information regarding the participant's middle ear status as part of the diagnostic hearing assessments. Results were recorded in terms of middle ear pressure, static compliance and ear canal volume and classified based on the modified Jerger classification (Zielhuis, Heuvelmans-Heinen, Rach, Van den Broek, 1989).

Automated pure tone audiometry

Insert earphones were placed deep in the ear canal and circumaural headphones were placed over the ears to improve attenuation of ambient noise, and to minimize the occlusion effect. Air conduction audiometry was conducted for 0.25 kHz to 8 kHz. An automated threshold-seeking paradigm was utilized with a similar threshold-seeking method used in manual test configuration i.e. the modified Hughson-Westlake method. Participants were instructed to press the response button every time they heard a sound. Air conduction threshold differences between the test and non-test ear of 75 dB or greater at low frequencies (<1 kHz) and 50 dB at high

frequencies (> 1 kHz) were masked. A narrowband noise masking level of 30 dB above the air conduction threshold of the non-test ear was used. Bone conduction thresholds were determined with a continuous masking level of 20 dB above the air conduction threshold of the non-test ear (ASHA, 2005). The KUDUwave software actively monitored ambient noise levels across octave bands throughout the test procedures in both clinics. The results were saved on the eMoyo software and exported to an excel sheet.

Participants who presented with a mixed or conductive hearing loss were referred to the clinics' general practitioner for further medical intervention. Participants who presented with a sensorineural hearing loss were referred to the nearest district hospital for a hearing aid fitting evaluation (Appendix G).

2.8 Data processing and analysis

The research project was made up of three studies thus different statistical analysis and data processing was utilized for each. Table 2.5 provides an overview of the types of statistical analysis that was conducted.

Table 2.5 Statistical analysis and data processing

Study	I	II	III
Title	Smartphone-based hearing screening at primary health care clinics	Self-report of hearing loss and pure tone audiometry for screening in primary health care clinics	Prevalence of hearing loss at primary health care clinics in South Africa
Study design	Cross-sectional, descriptive study (Leedy & Ormrod, 2005)	Cross-sectional, descriptive study (Leedy & Ormrod, 2005)	Cross-sectional, descriptive study of disease prevalence (Leedy & Ormrod, 2005)
Statistical analysis	• Descriptive statistical measures were used to determine overall referral rates and recording times • A Chi-square test ($p<.05$ indicated a significant effect) was used to determine if gender, race and age had an effect on the screening outcome in children. • A binary logistic regression model was used to determine the effect of age (as a continuous variable) gender, race and clinic on referral rate in adults ($p<.05$ indicated significance). • Recording time differences between adults and children who passed and failed the initial screening were determined with an independent sample t-test. • Recording time differences between initial and rescreens were determined with a paired sample t-test. • Sensitivity and specificity were calculated for smartphone hearing screening with reference to diagnostic test results. A hearing loss, indicated by the screening test, was confirmed by the diagnostic hearing test if the air conduction threshold at 0.5, 1, 2 or 4 kHz was greater than 25 dB for children or greater than 35 dB for adults. • Sensitivity and specificity were calculated for smartphone hearing screening with	• Self-reported hearing loss data was obtained from questionnaire whilst audiometry screening data was extracted from the cloud-based data management system (mHealth Studio, hearX group, South Africa • Data was reported according to three groups: screening group, assessment group and diagnosed group (Figure 4.1). The screening group included all participants and descriptive statistical measures were used to determine how many participants self-reported hearing loss, failed audiometry screening and both self-reported hearing loss and failed audiometry screening. • A binary logistic regression model was used to determine the effect of age (as a continuous variable), gender and race on self-reported hearing loss ($p<.05$ indicated significance). Participants were divided into three age groups (16 – 39 years, 40 – 59 years, and 60 years and greater) to determine the effect of increasing age on self-reported hearing loss. • In the assessment group, all participants who failed audiometry screening, and who attended for diagnostic assessments (including 81 participants who passed the audiometric screening) were included in the	• Diagnostic testing confirming a hearing loss informed the prevalence rate for this population. • Demographic data, screening and diagnostic results were analysed and presented using descriptive statistics • A one way ANOVA analysis was performed to evaluate the effect of age, gender and race on the presence of a hearing loss in the sample, with $p < .05$ indicating a significant association. • The presence of a hearing loss was defined as a pure tone threshold average (0.5, 1, 2 or 4 kHz) greater than 25 dB HL in one or both ears. A hearing loss was classified as conductive when the average difference between the pure tone air conduction and bone conduction thresholds (0.5 kHz – 4 kHz) was 15 dB HL or greater with normal air conduction thresholds. A hearing loss was classified as a sensorineural hearing loss (SNHL) when the pure tone air and bone conduction thresholds (0.5 kHz – 4 kHz) were abnormal (> 25 dB HL) with an average air-bone gap less than 15 dB HL. The classification of a mixed hearing loss (conductive and sensorineural) entailed abnormal air and bone conduction thresholds with an average air-bone gap of

	reference to diagnostic test results. A hearing loss, indicated by the screening test, was confirmed by the diagnostic hearing test if the air conduction threshold at 0.5, 1, 2 or 4 kHz was greater than 25 dB for children or greater than 35 dB for adults.	analysis to evaluate the performance of self-reported hearing loss in isolation, and a combination of self-reported hearing loss and pure tone audiometric screening. Descriptive statistical measures were used to determine how many participants self-reported hearing loss, and how many self-reported hearing loss and failed audiometry screening. Descriptive statistical measures were used to report how many participants were diagnosed with mid-frequency hearing loss ([4FA] 0.5 – 4 kHz and high frequency average [HFA] 4 and 8 kHz) resulting in the diagnosed group. The performance (sensitivity, specificity, positive predictive and negative predictive values as well as overall test accuracy) of the different protocols (self-reported hearing loss and self-reported hearing loss with second stage pure tone audiometry screening) was calculated in reference to diagnostic audiometry results (4FA and HFA). A high frequency loss was confirmed if the HFA was ≥ 25 dB HL.	15 dB HL or greater. Another hearing loss category (“other”) was added in the current study to include participants with different types of hearing losses in the two ears i.e. a SNHL and conductive hearing loss. • The degree of the hearing loss was classified as mild (> 25 dB HL and ≤ 40 dB HL), moderate (> 40 dB HL and ≤ 55 dB HL), moderate to severe (> 55 dB HL and ≤ 70 dB HL) and severe to profound (> 70 dB HL. • A unilateral hearing loss was obtained when one ear had normal hearing with a hearing loss in the other ear. A bilateral hearing loss indicated a hearing loss present in both ears.

CHAPTER 3

SMARTPHONE-BASED HEARING SCREENING AT PRIMARY HEALTH CARE CLINICS

Authors:

Christine Louw, De Wet Swanepoel, Robert H. Eikelboom, Hermanus C. Myburgh

Journal: Ear and Hearing

Submitted: February 2016

Status: Published (Louw C, Swanepoel DW, Eikelboom RH, Myburgh HC. Smartphone-Based Hearing Screening at Primary Health Care Clinics. 2017. *Ear & Hearing,* 93–100)

Note: This manuscript was edited in accordance with editorial specifications of the journal and may differ from the editorial style of the rest of this dissertation.

3.1 Abstract

Objective

To evaluate the performance of smartphone-based hearing screening with the hearScreen™ application in terms of sensitivity, specificity, referral rates and time efficiency at two primary health care clinics.

Design

Nonprobability purposive sampling was used at both clinics. 1236 participants (mean age: 37.8 ± SD 17.9 and range 3 – 97 years; 71.3% female) were included in the final analysis. Participants were screened using the hearScreen™ application following a two-step screening protocol and diagnostic pure tone audiometry to confirm hearing status.

Results

Sensitivity and specificity for smartphone screening was 81.7% and 83.1% respectively, with a positive and negative predictive value of 87.6% and 75.6% respectively. Gender [$\chi^2(1, N=126)= .304$, $p>.05$] and race [$\chi^2(1, N=126) = .169$, $p>.05$)] had no significant effect on screening outcome for children whilst for adults age ($p<0.01$; $\beta=.04$) and gender ($p=0.02$; $\beta=-.53$) had a significant effect on screening outcomes with males more likely to fail. Overall referral rate across clinics was 17.5%. Initial screening test times were less than a minute (48.8s ± 20.8 SD) for adults and slightly more than a minute for children (73.9s ± 44.5 SD).

Conclusion

The hearScreen™ smartphone application provides time-efficient identification of hearing loss with adequate sensitivity and specificity for accurate testing at primary health care settings.

3.2 Introduction

Hearing loss is one of the most prevalent chronic disabilities globally (WHO, 2008). It is estimated that 538 million people older than five years of age have disabling hearing loss (Stevens et al., 2011). The incidence rises to more than a billion people when including milder degrees of hearing loss (Global Burden of Disease Study 2013 Collaborators, 2015). It is unsurprising therefore that hearing loss is a leading contributor to the global burden of disease (Global Burden of Disease Study 2013 Collaborators, 2015).

The burden of hearing loss is the greatest in developing world regions such as sub-Saharan Africa, South-east Asia and Asia Pacific where more than 80.0% of people with hearing loss reside (Fagan & Jacobs, 2009; WHO, 2012, 2013b). Unfortunately, hearing care services are either very limited, or totally absent in these regions (WHO, 2006; Fagan & Jacobs, 2009). Inadequate hearing care services are in large part due to the limited number of trained hearing care personnel worldwide (Goulios & Patuzzi 2008; Fagan & Jacobs, 2009). A recent survey showed that there is approximately one hearing health care worker for half a million people in sub-Saharan Africa (WHO, 2013b). Additionally, hearing services in developing countries are not prioritised by health systems overwhelmed by life-threatening diseases as opposed to non-life-threatening conditions (such as hearing loss), limited resources, poor public and professional awareness as well as geographical barriers such as distance (Swanepoel et al., 2010).

The inequality between the lack of hearing services and the growing burden of hearing loss in developing world regions is significant and current hearing care

efforts to reach the majority of underserved communities are inadequate (Swanepoel et al., 2010). Thus, approaches to expand and decentralise hearing services to contexts such as primary health care (PHC) clinics should be explored as a means of increasing access to care. In many developing countries PHC continues to be the only effective gateway to some form of health care (Tanser et al., 2006). This implies that if ear and hearing services are not available at PHC level, many communities in developing countries may not have any access to these services. Providing basic ear and hearing care services at a PHC clinic could increase equitable access to prevention, management, support programmes and services for hard-to-reach populations (WHO, 2013a). Including ear and hearing care in a community based rehabilitation programme and PHC clinics have also been advocated by the World Health Organisation (WHO) (WHO, 2006, 2013a).

The WHO emphasis is to provide hearing care services through PHC workers who receive basic training in ear mopping/wicking, syringing of ear wax and prescribing treatment for common middle ear problems (WHO, 2006). A low technology approach such as performing the voice test has typically been recommended to screen hearing because audiometers are mostly unavailable at PHC clinics (WHO, 2006). The aforementioned are cost-effective interventions and can have a major impact on the burden of ear disease and hearing loss; however, using the voice test as a screening tool must be approached with caution. The voice test can yield unreliable results due to poor inter-observer variability and test-retest reliability, and is not recommended to be included in a screening programme (ASHA, 1997; Bogardus et al., 2003).

Pure tone audiometry is still recommended as the primary part of a hearing screening protocol to identify a hearing loss in children (> 5 years) and adults (ASHA, 1997; AAA, 2011). Requirements for pure tone hearing screening test entail appropriately qualified hearing health care personnel, low ambient noise levels during testing, calibrated audiometers and daily biologic checks of the audiometers to rule out distortion and intermittency (ASHA, 1997). Using these requirements as the gold standard, performing audiometry screening at PHC clinics is a challenge. There are limited numbers of qualified hearing care professionals available to perform conventional hearing screening and daily biologic checks on the audiometer. Furthermore, traditional audiological equipment and sound-treated test environments are expensive with a characteristically fixed location (Maclennan-Smith et al., 2013). The lack of controlled test environments with low levels of ambient noise can impede accurate hearing test results.

Novel telehealth approaches such as mobile health (mHealth) have, however, become available that could address some of these issues and could make identification of a hearing loss at PHC level feasible (Clark & Swanepoel, 2014; Swanepoel et al., 2014; Peer & Fagan 2015; Yousuf Hussein et al., 2016). Smartphone applications for basic hearing assessments create opportunities to provide low-cost point of care diagnostics at PHC level (Kelly & Minges, 2012; Thompson et al., 2015).

The hearScreen™ application is one such technology that was developed as a low cost alternative to conventional hearing screening (Mahomed-Asmail et al., 2016). A recent report demonstrated no significant difference for sensitivity and specificity

using the hearScreen™ application compared to conventional screening audiometry with more efficient testing (Mahomed-Asmail et al., 2016). hearScreen™ uses an entry-level smartphone running Android™ OS and inexpensive supra-aural headphones (Swanepoel et al., 2014). The low-cost headphones can be acoustically calibrated according to international standards allowing the inexpensive smartphone to be used as a screening audiometer (Swanepoel et al., 2014). A user-friendly interface employs pre-programmed automated test sequences with a forced-choice paradigm (Swanepoel et al., 2014). An operator with limited training can place headphones on the patient, capture demographic data, provide the onscreen instructions during the test and act on the screening outcome (Mahomed-Asmail et al., 2016). In terms of environmental noise levels, the hearScreen™ software integrates noise monitoring referenced to maximum permissible ambient noise levels (MPANLs) during testing (Swanepoel et al., 2014). Data capturing and uploading to the centralised cloud-based server, hearData, allows for remote monitoring. This creates unique opportunity to be integrated with current community-orientated primary care (COPC) initiatives.

Integrating hearing screening at PHC clinics may allow universal and equal access to ear and hearing services (WHO, 2013a). Low-cost and user-friendly solutions for hearing screening such as smartphones offer the potential to aid prevention, early identification and management of hearing loss in underserved communities (Swanepoel et al., 2014). hearScreen™ has been investigated with success for use in schools and by community health workers (CHWs) in community-based testing (Kinkel et al., 2013; Yousuf Hussein et al., 2016; Mahomed-Asmail et al., 2016). This study aimed to evaluate the performance of smartphone hearing screening in terms

of sensitivity, specificity, time efficiency and referral rates at two different PHC clinics in South Africa.

3.3 Materials and method

This research project was approved by the Institutional Research Board of the University of Pretoria, South Africa.

3.3.1 Participants

The current project was part of a larger COPC project currently underway in Gauteng (Tshwane) province (Kinkel et al., 2013). Data was collected at two PHC clinics (PHC clinic 1 and PHC clinic 2) in underserved communities in the Tshwane area where there were no prior audiology services. Data was collected during a 13-month and 6-month period at PHC clinic 1 and PHC clinic 2 respectively. PHC clinic 1 is situated in the Pretoria West area and PHC clinic 2 is situated in the Mamelodi region. Hearing tests were conducted once a week at each clinic.

1236 participants (PHC clinic 1 = 603; PHC clinic 2 = 633) were recruited with an average age of 37.8 years (±17.9; range 3 to 97 years of age) of whom 73.6% were female and 68.2% African (Table 3.1). Only participants who provided signed consent (children had to provide assent along with a signed consent letter from their parent/caregiver) and who completed the screening protocol (i.e. completed a rescreen upon referral of initial screen) were included in the study.

Table 3.1 Demographic details of participants (PHC – Primary Health Care)

	Overall	PHC Clinic 1	PHC Clinic 2
ADULTS			
N	1110	498	612
Male	26.4% (n=293)	28.7% (n=143)	24.5% (n=150)
Female	73.6% (n=817)	71.3% (n=355)	75.5% (n=462)
Ave Age (SD)	41.2 years (SD 15.5)	43.0 years (SD 16.8)	39.7 (SD 14.2)
Age range	16 – 97 years	16 - 89 years	16 - 97 years
Race	68.2% African (n=757)	29.1% African (n=145)	100% African (n=612)
	31.8% Caucasian (n=353)	70.9% Caucasian (n=353)	
CHILDREN			
N	126	105	21
Male	49.2% (n=62)	49.5% (n=52)	47.6% (n=10)
Female	50.8% (n=64)	50.5% (n=53)	52.4% (n=11)
Ave age (SD)	7.5 (SD 2.9)	7.3 (SD 3.0)	8.5 (SD 2.5)
Age range	3 – 15 years	3 – 15 years	5 – 15 years
Race	31% African (n=39)	17.1% African (n=18)	100% African (n=21)
	69% Caucasian (n=87)	82.9% Caucasian (n=87)	

Nonprobability purposive sampling was used to screen participants at both health care clinics. At PHC clinic 1, universal screening took place by offering all individuals who visited the clinic a hearing screening free of charge. At PHC clinic 2 all individuals who were available during the time that the services were delivered and who wanted their hearing tested were screened free of charge.

Diagnostic testing was available for confirmation of hearing loss on participants failing the screening. Diagnostic testing was also performed on a group of 111 participants who passed the screening to allow determination of screening specificity. A convenience sampling strategy was used to select these participants.

One to two participants per day, who passed the hearing screening, were selected based on their availability and clinic time constraints.

3.3.2 Equipment

Smartphone hearing screening

Hearing screening was conducted using the hearScreen™ application (Android OS) on two smartphones (Samsung Pocket Plus S5301) connected to Sennheiser HD 202 II (Sennheiser, Wedemark, Germany) supra-aural headphones. Headphones were calibrated on the hearScreen™ calibration function according to prescribed standards (ANSI/ASA S3.6-2010; ISO 389-1, 1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Van der Aerschot et al. submitted). Calibration was performed using an IEC 60318-1 G.R.A.S. Ear stimulator connected to a Type 1 sound level meter (Rion NL-52). hearScreen™ utilized an automated test sequence with a forced-choice paradigm to minimize operator influence and ensure ease of use (Swanepoel et al., 2014). Screening was conducted using current recommended protocols (ASHA, 1997; AAA, 2011) with the exception that the intensity was raised to 35 dB HL for adults (>15 years of age) and 25 dB HL was used for children (3 to 15 years of age) (Swanepoel et al., 2014). These screening intensities were to identify disabling hearing loss in children (>30 dB) and adults (>40 dB) (WHO, 2012). Furthermore, typical criteria of 20 dB HL for children and 25 dB HL for adults may not be appropriate for resource-limited countries (Wenjin et al. 2014; Mahomed-Asmail et al., 2016). Lower screening intensities may result in over referral, which can overburden the health system and, in PHC contexts, may be vulnerable to false positives due to excessive ambient noise levels. In addition, studies conducted in developed and developing countries have used various screening intensity levels including 25, 30 and even 40

dB HL (AAA, 2011; Al-Rowaily et al., 2012; Kam et al., 2013; Lo & McPherson, 2013; Wenjin et al., 2014).

The smartphone hearing screening application monitored and recorded noise levels during data collection for each participant. Noise monitoring using the hearScreen™ application on these smartphones has been reported to be accurate within 1 to 1.5 dB, depending on frequency (Swanepoel et al., 2014). Recorded noise levels consisted of the averaged ambient noise recorded by the smartphone during pure-tone presentation (1.2 seconds duration) in the octave band corresponding to the test frequency (Swanepoel et al., 2014). Smartphones were connected to a 3G cellular or WiFi network whereby screening results were uploaded at the end of each session to the secure cloud-based server (hearData).

Diagnostic audiometry

The KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2) was used to conduct diagnostic pure tone audiometry on participants who failed the hearing screening. The audiometer hardware was contained within the circumaural ear cups and connected to a notebook (Dell Inspiron running Microsoft Windows 7) via USB cables. Circumaural ear cups were placed over the insert earphones for additional attenuation to make hearing tests in a non-optimal environment outside a soundproof booth possible (Maclennan-Smith et al., 2013). A B-71 bone oscillator (Kimmetrics, Smithsburg, USA) was placed on the forehead with a standard adjustable spring head-band held in place on the centre of the circumaural headband with a screw fitting. The circumaural ear cups had two microphones that provided constant monitoring of environmental noise in octave bands during testing. An electronic response was connected to the headset software

interface (eMoyo) that controlled the KUDUwave audiometer. The audiometer was calibrated prior to commencement of the study using a Type 1 sound level meter (Larson Davis System 824, Larson Davis, Provo, Utah) with a G.R.A.S. (Holte, Denmark) IEC 711 coupler for insert earphones and an AMC493 Artificial Mastoid on an AEC101 coupler (Larson Davis) with 2559 ½ inch microphone for the Radioear B-71 bone oscillator. Insert earphones and the bone oscillator were calibrated in accordance with ISO 389-2:1994 and ISO 389-3:1994 standards respectively.

3.3.3 Procedures

Testing was conducted in an examination room without sound isolation. Due to the busy nature of the clinics at times more than one participant was examined at the same time in the room. Hearing screening and diagnostic hearing tests were facilitated by third and fourth year undergraduate audiology students from the University of Pretoria, under supervision of an experienced audiologist (first author). The audiology students had basic experience in hearing screening and were trained in the use of smartphone hearing screening and to facilitate automated pure tone air and bone conduction audiometry during a two hour practical session prior to performing services.

Instructions were provided in English or Afrikaans. Written instructions in Sepedi were used by a non-Sepedi speaking test operator if participants did not understand English or Afrikaans. After capturing demographic information on hearScreen™, the student placed the headphones on the participant. The forced-choice paradigm required the student to indicate if the participant responded to the sound with a Yes/No response after the sound was presented (Figure 3.1).

The student stood behind the participant with the participant instructed to raise a hand upon hearing the tone. The initial presentation level at 1 kHz was raised 10 dB above the screening level for conditioning purposes after which the screening continued on the test intensity. A 1, 2, and 4 kHz sweep was then performed at 35 dB HL for adults and 25 dB HL for children (ASHA, 1997). Stimulus presentation was repeated once if the participant did not respond at a specific intensity level. Left ears were tested first, followed by testing of right ears in the same way. Participants who responded to all the frequencies on both ears passed the screening. A two-step hearing screening protocol was followed; thus when a participant failed to respond to one or more frequencies in either ear, the results constituted an initial fail and an immediate rescreen was initiated. This standard practice is in accordance with screening guidelines (AAA, 2011; ASHA, 1997) recommending an immediate rescreen, which represents the final screening outcome (AAA, 2011).

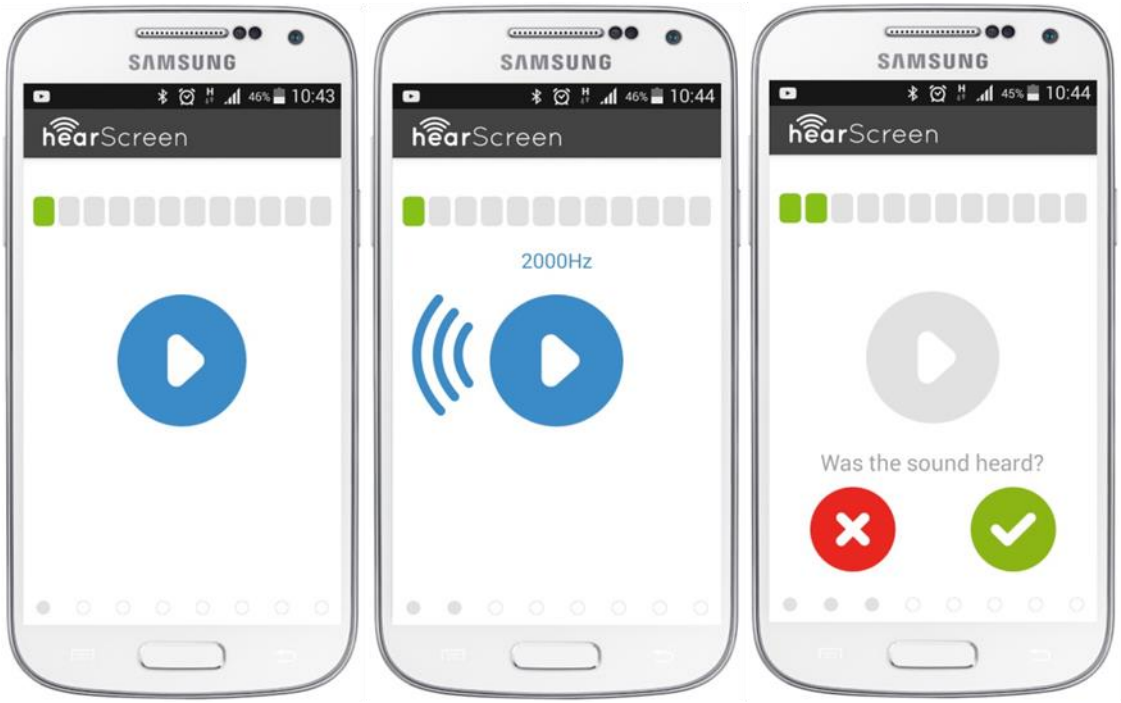

Figure 3.1 hearScreen ™interface. Forced-choice paradigm requires the test operator to select yes/no based on the response of the participant

The two-step protocol was followed to minimize over-referrals. All test results were uploaded from the smartphones to the cloud-based server from where data were exported for analysis and interpretation. A diagnostic hearing test was conducted on the same day if participants failed the screening for a second consecutive time. In the case of children between the age of 3 and 4 years, the procedure was adapted to a play-based method i.e. the student conditioned the child to respond to the stimulus through a play activity such as dropping a block in a bucket when the sound was heard.

For diagnostic testing, insert earphones were placed deep in the ear canal with circumaural headphones placed over the ears to improve attenuation of ambient noise, and to minimize the occlusion effect. Air conduction audiometry was conducted for 0.25 kHz to 8 kHz. An automated threshold-seeking paradigm was utilized with a similar threshold-seeking method used in manual test configuration i.e. the modified Hughson-Westlake method. Participants were instructed to press the response button every time they heard a sound. Air conduction threshold differences between the test and non-test ear of 75 dB or greater at low frequencies (<1 kHz) and 50 dB at high frequencies (> 1 kHz) were masked. A narrowband noise masking level of 30 dB above the air conduction threshold of the non-test ear was used. Bone conduction thresholds were determined with a continuous masking level of 20 dB above the air conduction threshold of the non-test ear (ASHA, 2005). The KUDUwave software actively monitored ambient noise levels across octave bands throughout the test procedures in both clinics. The participant's results were saved in the form of an audiogram on the

Participants who presented with a mixed or conductive hearing loss were referred to the clinics' general practitioner for further medical intervention. Participants who

presented with a sensorineural hearing loss were referred to the nearest district hospital for a hearing aid fitting evaluation.

3.4 Data analysis

Data was extracted from hearData and analysed using SPSS v23 (Chicago, Illinois). To evaluate the performance of the smartphone hearing screening, descriptive statistical measures were used to determine overall referral rates and recording times. Overall referral rates were obtained based on overall results following an immediate rescreen. A Chi-square test ($p<.05$ indicated a significant effect) was used to determine if gender, race and age had an effect on the screening outcome in children. A binary logistic regression model was used to determine the effect of age (as a continuous variable) gender, race and clinic on referral rate in adults ($p<.05$ indicated significance). Recording time differences between adults and children who passed and failed the initial screening was determined with an independent sample t-test. Recording time differences between initial and rescreens was determined with a paired sample t-test.

Sensitivity and specificity were calculated for smartphone hearing screening with reference to diagnostic test results. A hearing loss, indicated by the screening test, was confirmed by the diagnostic hearing test if the air conduction threshold at 0.5, 1, 2 or 4 kHz was greater than 25 dB for children or greater than 35 dB for adults. Frequency distributions and cross-tabulations were used to investigate screening outcomes where MPANLs were exceeded.

3.5 Results

Twenty six participants (22 adults, 4 children) at PHC clinic 1 and 2 participants (2 adults) at PHC clinic 2 were excluded from the study because the screening protocol was not completed due an operator error. Two other participants were omitted from the study group at PHC clinic 2 because their date of birth was not captured. A total of 1236 participants were included in the final analysis.

The overall referral rate across clinics was 17.5% (adults 194/1110; children 22/126) (Table 3.2 and 3.3). Gender or race did not have a significant effect on screening outcomes for children [gender: $\chi^2(1, N=126)=.304$, p>.05; race: $\chi^2(1, N=126) = .169$, p>.05); Chi square]. Whilst race did not have a significant effect on the screening outcome for adults (p=0.66; $\beta=$-.55; binary logistic regression), the screening outcome was significantly affected by gender (p=0.02; $\beta=$-.53; binary logistic regression) as more male participants failed the screening. Referral rate increased significantly with age (p<0.01; $\beta=$.04; binary logistic regression). More adults referred at PHC clinic 1 (20.5%) than at PHC clinic 2 (15.0%) although this difference was not significant (p=0.41; β=-0.23; binary logistic regression).

Table 3.2 Referral rates for adults using smartphone hearing screening in primary health care clinics (PHC – Primary Health Care)

	Overall (n)	PHC Clinic 1 (n)	PHC Clinic 2 (n)
Overall referral	17.5% (194/1110)	20.5% (102/498)	15.0% (92/612)
Initial screen	20.7% (230/1110)	21.5% (107/498)	20.1% (123/612)
Rescreen	84.3% (194/230)	93.6% (102/107)	74.8% (92/123)
Gender			
Male	25.3% (74/293)	31.5% (45/143)	19.3% (29/150)
Female	14.7% (120/817)	16.1% (57/355)	13.6% (63/462)
Age			
16-39 years	9.8% (55/562)	*9.6% (22/228)	*9.9% (33/334)
≥40 years	25.4% (139/548)	*29.6% (80/270)	*21.2% (59/278)
Ears			
Left	15.9% (177/1110)	18.1% (90/498)	14.2% (87/612)
Right	14.6% (162/1110)	16.1% (80/498)	13.4% (82/612)
Frequencies			
1 kHz left	8.0% (89/1110)	7.6% (38/498)	8.3% (51/612)
2 kHz left	9.3% (103/1110)	9.2% (46/498)	9.3% (57/612)
4 kHz left	10.8% (120/1110)	14.1% (70/498)	8.2% (50/612)
1 kHz right	7.7% (86/1110)	7.4% (37/498)	8.0% (49/612)
2 kHz right	8.7% (97/1110)	8.6% (43/498)	8.8% (54/612)
4 kHz right	11.4% (126/1110)	13.5% (67/498)	9.6% (59/612)

Table 3.3 Referral rates for children using smartphone hearing screening in primary health care clinics (PHC – Primary Health Care)

	Overall (n)	PHC Clinic 1 (n)	PHC Clinic 2 (n)
Overall referral	17.5% (22/126)	16.2% (17/105)	23.8% (5/21)
Initial screen	25.4% (32/126)	24.8% (26/105)	28.6% (6/21)
Rescreen	68.7% (22/32)	65.4% (17/26)	83.3% (5/6)
Gender			
Male	19.4% (12/62)	19.2% (10/52)	20% (2/10)
Female	15.6% (10/64)	13.2% (7/53)	27.3% (3/11)
Ears			
Left	22.2% (28/126)	21.0% (22/105)	28.6% (6/21)
Right	16.7% (21/126)	16.2% (17/105)	19.0% (4/21)
Frequencies			
1 kHz left	15.9% (20/126)	14.3% (15/105)	23.8% (5/21)
2 kHz left	15.1% (19/126)	13.3% (14/105)	23.8% (5/21)
4 kHz left	15.1% (19/126)	14.3% (15/105)	19.0% (4/21)
1 kHz right	12.7% (16/126)	11.4% (12/105)	19.0% (4/21)
2 kHz right	13.5% (17/126)	13.3% (14/105)	14.3% (3/21)
4 kHz right	10.3% (13/126)	10.5% (11/105)	9.5% (2/21)

Initial recording time was significantly shorter (44.0s ± 15.0 SD) for adults who passed the screening compared to adults who referred [67.3s ± 27.0 SD; $t(1108)= -16.9$, $p<.05$; Independent t-test]. In children there was also a significant difference between the initial screening times for those who passed (62.8s ± 38.8 SD) and those who referred [106.4s ± 44.5 SD; $t(124)= -5.3$, $p<.05$; Independent t-test]. Initial screening test times were significantly shorter for adults (48.8s ± 20.8 SD) compared to children [73.9s ± 44.5 SD; $t(1234)= -10.9$, $p<.05$; Independent t-test] (Table 3.4). Rescreen test time was significantly longer (82.6 ± 49.9 SD) compared to initial test time [67.3s ± 27.0 SD; $t(231)= -4.9$, $p<.05$; Paired t-test] for adult participants. There was no significant difference between initial (106.4s ± 44.5 SD) and rescreen [123.9s ± 80.0 SD; $t(31)= -1.6$, $p>.05$; Paired t-test] times for children.

Table 3.4 Mean test duration using hearScreen™ at both primary health care clinics

	Adults	Children
Initial screen		
Mean test time (±SD)	48.8s (±20.8)	73.9s (±44.5)
Range	24 -192s	27 – 241s
Rescreen		
Mean test time (±SD)	82.6s (±49.9)	123.9s (±80.0)
Range	26 – 382s	30 – 320s

Diagnostic evaluations were performed on 63.8% (138/194) of the participants (4 children and 134 adults) who referred. Fifty-six participants were not tested diagnostically, mostly due to logistical reasons at the PHC clinics. In the group tested diagnostically, the average age was 48.5 years (±19.7; range 7 to 97 years), 56.1% female and 56.9% African. Of the 138 participants tested diagnostically, 87.6% (121/138; 4 children, 117 adults) presented with a confirmed hearing loss. Diagnostic evaluations were also performed on 10.8% (111/1020) of participants who passed the screening. These had an average age of 38.0 years (±14.9; range 6 to 70 years), 78.2% female, and 77.2% African. Sensitivity and specificity for the screening was 81.7% and 83.1% respectively (Table 3.5). False positive and false negative results accounted for 10.8% (27/249) and 6.8% (17/249) of cases respectively.

Smartphone noise levels only exceeded MPANLs in 2.4% (left ear) and 6.3% (right ear) of thresholds tested at 1 kHz in children and only one instance at 2 kHz. In the adult population noise levels only exceeded MPANLs in 0.2% (left ear) and 0.1% (right ear) of instances tested at 1 kHz.

Table 3.5 Test performance for hearScreen™ at primary health care clinics (n=249). Participants' hearing status was confirmed by diagnostic testing (PHC – Primary Health Care)

	Overall (n=249; 44.5% pass; 55.4% refer)	95% Confidence intervals	PHC Clinic 1 (n=99)	PHC Clinic 2 (n=150)
Sensitivity	81.7%	74.3 - 87.4	88.8%	75.0%
Specificity	83.1%	74.1 - 89.6	77.7%	85.1%
Positive likelihood ratio	4.86%	3.13 – 7.54	4.0%	5.0%
Negative likelihood ratio	0.22%	0.15 – 0.31	0.14%	0.29%
Positive predicative value	87.6%	81.0 – 92.6	91.4%	83.8%
Negative predicative value	75.6%	66.6 – 83.3	72.4%	76.8%

3.6 Discussion

This study evaluated the performance of smartphone-based hearing screening following a two-step screening protocol with hearScreen™ at two PHC clinics in South Africa. The performance of a screening test depends on the sensitivity and specificity of the technique. Sensitivity and specificity across adults and children for hearScreen™ at PHC clinics was 81.7% and 83.1% respectively. These are the first results of smartphone hearing screening at PHC clinics reported to date. While sensitivity is somewhat better to a recent reported sensitivity of 75.0% using the same software for smartphone hearing screening in a school-based context (Mahomed-Asmail et al., 2016), the specificity (98.5%) of the recent study was considerably higher than the current study. The variation in specificity values between the two studies can be attributed to differences in the populations and disease prevalence. Mahomed-Asmail's et al. (2016) study focused on young children (mean age 8 years ± 1.1; range 6 to 12 years) with an overall referral rate of

only 3.2%. In contrast, the current study population comprised mostly (89.8%) adults (mean age 37.8 ±17.9; range 3 to 97 years) and had an overall referral rate of 17.5%. Previous studies performed in PHC contexts using a hand-held combination otoscope and audiometer demonstrated lower specificity (60% - 80%) and slightly higher sensitivity (94%) compared to current study findings (Lichtenstein et al., 1988; Ciurlia-Guy et al., 1993; McBride et al., 1994). These studies differed however in terms of screening protocol (500 – 4000 Hz vs. 1000– 4000 Hz), screening level (40 dB HL vs. 35 dB HL) and different population ages. A number of the studies (Lichtenstein et al., 1988; Ciurlia -Guy et al., 1993; McBride et al., 1994) included elderly persons (above 60 years) whilst the average age in the current study was 41.2 years (15.5 SD).

Increasing age had a significant impact on referral rate in the adult population. These results reflect the familiar patterns of nonlinear increase of hearing loss with age and compare well to other epidemiology studies (Cruickshanks et al., 1998; Cruickshanks et al., 2003; Lin et al., 2011; Roth et al., 2011). These results are also comparable to a recent study performed in a community setting indicating that 25.0% of adults older than 45 years failed the hearing screening (Yousuf Hussein et al., 2016).

The majority of referrals in children occurred at 1 kHz. In contrast, the majority of referrals in adults were seen at 2 kHz and 4 kHz. This suggests a sloping pattern of loss and is typical of age-related hearing loss (Cruickshanks et al., 1998; Lin et al., 2011). In addition to age, environment factors (e.g. noise exposure, ototoxic medication, socio-economic status) and health co-morbidities (e.g. cardiovascular disease) could also have predisposed a higher referral rate in this selected population (Agrawal et al., 2009; Lin et al., 2011). Many of the individuals screened visited the PHC clinic for management of prominent diseases and conditions such as

diabetes, tuberculosis, HIV/AIDS, hypertension and malaria, all from which hearing loss can arise (Araújo et al., 2012; Seddon et al., 2012; Assuiti et al., 2013; Van der Westhuizen et al., 2013). It was, however, beyond the scope of this study to establish relationships between the abovementioned risk factors and hearing loss at PHC level.

More adult females (73.6%) than males (26.4%) were screened. This could be expected as South African women are more likely to visit a health care worker/ clinic than men (Statistics South Africa, 2013). Male participants were, however, more likely to fail the screening. These results compare well to other epidemiology studies that show men have a greater risk of hearing loss (Cruickshanks et al., 1998).

A leading cause for increased referral rates in community-based hearing tests is environmental noise. The hearScreen™ application provides a quality control feature which monitors noise levels during testing. In the current study ambient noise levels did not demonstrate a significant effect on screening outcome. Previous studies using the same application showed that recorded noise levels exceeded MPANLs mostly at 1 kHz for 25 dB HL, which is the screening intensity for the child protocol (Yousuf Hussein et al., 2016; Mahomed-Asmail et al., 2016). The 1 kHz stimulus is typically more susceptible to ambient noise than 2 and 4 kHz whilst the 25 dB HL screening level is more susceptible than the 35 dB HL screening level employed for adults in this study.

Average test time for the initial smartphone hearing screening, excluding time taken for instructions and capturing demographic information, was less than a minute for adults (48.8s ± 20.8 SD) and just over a minute for children (73.9s ± 44.5 SD). This compares well with recent hearScreen™ studies performed in a community context

and in a school-based context (Yousuf Hussein et al., 2016; Mahomed-Asmail et al., 2016). These average test times are shorter than conventional hearing screening (Sideris & Glattke, 2006; Wenjin et al., 2014; Mahomed-Asmail et al., 2016). Shorter test times could facilitate more efficient hearing screening at PHC level.

The high referral rate (17.0%) in this study demonstrates the need for hearing services at PHC clinics. Smartphone hearing screening by minimally trained personnel could be seen as the initial phase in the attempt to increase access to early detection of hearing loss at a PHC level. A limitation of the current study, however, was that screening was performed by audiology students with basic experience in hearing screening and not by minimally trained community members or clinic staff. A recent study, however, has demonstrated that CHW's can be trained to successfully perform hearing screening using this smartpone technology at primary care level (Yousuf Hussein et al., 2016). The current study revealed some operator errors which reduced the data available to the study. Upgrades to the software that insist that the date of birth be entered, and not allowing the operator to exit the software if a rescreen is indicated, are recommended.

The burden of hearing loss is a global dilemma, particularly in developing world regions where the majority of hearing-impaired persons reside. The growing burden of hearing loss and the lack of hearing services are particularly significant in underserved communities worldwide where there is a pervasive shortage of hearing care personnel. Mobile technology is a gateway to expand and decentralize hearing services to PHC level where persons with minimal training could perform hearing screening. PHC detection could be followed by air conduction threshold testing using similar technology, as recently demonstrated, which could reduce false-positive referrals (Van Tonder et al., 2016; Sandstrom et al., 2017). Additionally, smartphone

audiometry opens the door for new possibilities at PHC such as monitoring programmes for ototoxicity in treatment for tuberculosis. Using smartphone technology in conjuction with automated tympanometry or tympanic membrane image-analysis to detect otitis media or ear canal obstructions may further optimise the referral system in resourced-constrained communities (Myburgh et al., 2016). Integrating smartphone technology could therefore increase access to PHC hearing care in terms of decentralised detection and point-of-care diagnostics whilst future opportunities may also extend to interventions i.e. self-fitting, or preset hearing aids (WHO, 2013; Keidser & Convery, 2016).The current study demonstrates that, as a step towards increased access in underserved areas, smartphone-based hearing tests using calibrated headphones at PHC clinics can provide simple, time-efficient screening with adequate sensitivity and specificity for children and adults.

CHAPTER 4

SELF-REPORTED HEARING LOSS AND PURE TONE AUDIOMETRY FOR SCREENING AT PRIMARY HEALTH CARE CLINICS

Authors:

Christine Louw, De Wet Swanepoel, Robert H Eikelboom

Journal: Journal of Primary Care and Community Health

Submitted: July 2018

Status: Published (Louw, C., Swanepoel, D. W., & Eikelboom, R. H. (2018). Self-reported hearing loss and pure tone audiometry for screening in primary health care clinics. *Journal of Primary Care & Community Health*.(https://doi.org/10.1177/2150132718803156)

Note: This manuscript was edited in accordance with editorial specifications of the journal and may differ from the editorial style of the rest of this dissertation.

4.1 Abstract

Objective

To evaluate the performance of self-reported hearing loss alone and in combination with pure tone audiometry screening in primary health care clinics in South Africa.

Design

Nonprobability purposive sampling was used at two primary health care clinics. 1084 participants (mean age: 41.2 years; SD 15.5 years; range 16 – 97 years, 74.0% female) were screened using self-report and audiometry screening. Those failing audiometric screening and a sample of those who passed audiometric screening were also assessed by diagnostic pure time audiometry, to confirm or negate the finding of a hearing loss.

Results

Four hundred and thirty-six participants (40.2%) self-reported a hearing loss with no significant association with gender or race. Hundred and thirty six participant (12.5%) self-reported hearing loss and failed audiometry screening (35 dB HL at 1, 2 and 4 kHz). Combining self-report with a second stage audiometry screening revealed a high test accuracy (81.0%) for hearing loss, which was the most accurate procedure (86.1%) for the identification of high-frequency hearing loss.

Conclusion

Whilst self-report of hearing loss is an easy and time-efficient screening method to use at primary health care clinics, its accuracy may be limited when used in isolation and it may not be sufficiently sensitive to detect hearing loss. Combining a simple audiometry screening as a second-stage screen can significantly improve overall performance and efficiency of the screening protocol.

4.2 Introduction

Hearing loss is one of the most prevalent chronic disabilities affecting more than 1.33 billion people globally (Vos et al., 2016). Unaddressed hearing loss has a devastating impact on the individual and family, but also on the global economy. A recent report from the World Health Organization (WHO) estimated the annual cost of unaddressed hearing loss to be approximately 750 billion USD (WHO, 2017a). The high costs of hearing loss and widespread prevalence draws attention to the importance of access to care (Ramkissoon, 2011). Early access to timely diagnosis and management can reduce the adverse effects of hearing loss and, ultimately, can minimize the burden of disease (WHO, 2013). Unfortunately, accessible hearing care is not a reality in many developing world regions like sub-Saharan Africa where, ironically, the majority of people with hearing loss reside (Mulwafu, Ensink, Kuper, & Fagan, 2017).

In many low and middle income countries primary health care (PHC) remains the only effective gateway to some form of health care (Tanser, Gijsbertsen, & Herbst, 2006). Thus, expanding and decentralizing ear and hearing care to a PHC clinic may increase equitable access for early diagnosis and management (Louw, Swanepoel, Eikelboom, & Myburgh, 2017; WHO, 2013). Providing hearing care at PHC may, however, be challenging due to equipment costs and insufficient numbers of hearing care providers with one audiologist to every million people or more in developing world regions (Fagan & Jacobs, 2009; Swanepoel et al., 2010). To address these challenges at a PHC level, the traditional model of audiological service delivery needs to be approached in a different way (Clark & Swanepoel, 2014).

Self-reported hearing loss is a simple screening method that can facilitate early hearing detection and timely referral to audiological services in a PHC setting if linked to a clear and efficient referral pathway (Swanepoel, Eikelboom, Hunter, Friedland, & Atlas, 2013). This method has been proposed to be affordable, time-efficient and can be administered by any health care worker (Ramkissoon, 2011; Swanepoel et al., 2013). The use of a single question may also overcome language and cultural barriers (Ferrite, Santana, & Marshall, 2011; Swanepoel, Maclenan-smith, Hall, & Koekemoer, 2012; Swanepoel et al., 2013; Torre, Moyer, & Haro, 2006) which is considered an important factor in multi-cultural and multi-lingual settings like South Africa.

Using self-reported hearing loss as a single hearing screen question or a questionnaire on hearing functioning have both been proposed as valid screening methods (Ferrite et al., 2011; Nondahl, Cruickshanks, Wiley, Tweed, Klein, & Klein, 1998; Ramkissoon, 2011; Salonen, Johansson, Karjalainen, Vahlberg, & Isoaho, 2011; Sindhusake et al., 2001; Swanepoel et al., 2013; Torre et al., 2006; Vermiglio, Soli, & Fang, 2018). The Hearing Handicap Inventory for the Elderly-Shortened (HHIE-S), for example, is a screening questionnaire consisting of ten questions evaluating the perceived social-situational and emotional effects of hearing loss in the elderly (Nondahl et al.,1998). Although the HHIE-S was standardized for individuals over 65 years of age, Nondahl et al. (1998) found that it demonstrated lower sensitivity and accuracy in older individuals (65 – 92 years) compared to younger individuals (48 – 64 years. Contrary, using a single question such as “do you feel you have a hearing loss?” showed sufficient accuracy in young and older individuals in various reports (Nondahl et al., 1998; Salonen et al., 2011; Swanepoel et al., 2013). Using a single question to screen for self-perceived hearing loss has

also the advantage that it is to administer and may also be used in cases where individuals present with poor sight or minor cognitive impairment (Salonen et al., 2011; Swanepoel et al., 2013).

Using a single question to screen for hearing loss may be particularly accurate in cases where there is a moderate or severe hearing loss, in cases where individuals are 60 years and older, in cases where individuals have a high frequency hearing loss (4 kHz and 8 kHz), and also in individuals who experience speech-recognition-in-noise difficulties (Brennan-Jones et al., 2016; Hannula, Bloigu, Majamaa, Sorri, & Mäki-Torkko, 2011; Nondahl, et al., 1998; Salonen et al., 2011; Sindhusake et al., 2001; Vermiglio et al., 2018). Hence, it shows the potential value of using a self-report of hearing loss in a PHC clinic (Swanepoel et al., 2013). However, self-report of hearing loss it is not regarded as a standard or recommended protocol to identify hearing loss (Vermiglio et al., 2018). Although its use in combination with an audiometric screening has been proposed (Brennan-Jones et al., 2016; Kiely, Gopinath, Mitchell, Browning, & Anstey, 2012), it requires further investigation, particularly in PHC settings to investigate the performance of this technique in isolation or with a second-stage audiometry screen. Using second stage audiometry screen may be beneficial as it may provide more accurate results (Brennan-Jones et al., 2016). The current study therefore evaluated the performance of self-reported hearing loss in isolation and in combination with pure tone audiometry screening in PHC clinics in South Africa.

4.3 Methods

This research project was approved by the Institutional Research Board of the University of Pretoria, South Africa and was part of a larger community-oriented primary care (COPC) project in Gauteng (Tshwane) province (Kinkel, Marcus, Memon, Bam, & Hugo, 2013) (protocol number:102/2011).

4.3.1 Selection and description of participants

A cross-sectional design was used at two PHC clinics (PHC clinic 1 and PHC clinic 2) situated in underserved communities in Tshwane, both having limitations in human resources for hearing care and a lack of appropriate equipment. Nonprobability purposive sampling was used to recruit participants at both clinics. At PHC clinic 1, all individuals who visited the clinic were offered a hearing screening. At PHC clinic 2, all individuals who were available during the time that the services were delivered and who wanted their hearing tested were recruited for the study. Only those sixteen years and older, who provided signed consent and who completed the screening protocol (i.e. self-reported hearing loss and audiometric hearing screening) were invited to participate in the study.

Participants who presented with a mixed or conductive hearing loss were referred to the clinics' general practitioner for further medical examination and intervention. Participants who presented with a sensorineural hearing loss (SNHL) were referred to the nearest district hospital for a hearing aid fitting evaluation.

4.3.2 Procedures

Hearing screening included a self-report of hearing loss as well as audiometry screening for all participants. Participants who failed the audiometry hearing screening were invited to undertake diagnostic audiometry to confirm that there was

a hearing loss. Diagnostic testing was also performed on a group of 81 participants who passed the screening test to allow determination of screening specificity (Figure 1). A convenience sampling strategy was used to select these participants. One to two participants per day who passed the hearing screening, were selected based on their availability and clinic time constraints. Instructions were provided in English or Afrikaans. Written instructions in Sepedi were used if participants did not understand English or Afrikaans. If participants were unable to understand one of these three languages, a health care nurse who was available at the specific time, was asked to translate the information.

Self-reported hearing loss

The key question utilized in the current study was “Do you have a hearing problem? “Yes/No” (Swanepoel et al., 2013). Using a single question demonstrated sufficient accuracy in various reports (Nondahl et al., 1998; Salonen et al., 2011; Sindhusake et al., 2001; Swanepoel et al., 2013). The participant’s response was recorded on the data collection form.

Pure tone audiometry screening

Pure tone audiometry screening was conducted on all participants regardless of their self-reported hearing loss response. Pure tone audiometry screening was conducted by audiology students from the University of Pretoria under supervision of an experienced audiologist (first author). Testing was conducted in an examination room without sound isolation. Due to time and facility constraints at clinics more than one participant was examined at the same time in a room in some instances. Each ear was assessed. Audiometry screening was performed with the validated hearScreen™ Android OS application (hearX group, Pretoria, South Africa) on a

Samsung Galaxy Pocket Plus S5301 phone with calibrated supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany) (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, & Hall, 2016; D. W. Swanepoel, Myburgh, Howe, Mahomed, & Eikelboom, 2014). Screening audiometry was conducted according to recommended guidelines (ASHA, 1997) with a failure to respond to 35 dB HL at any of the test frequencies in either ear indicating immediate rescreening of both ears using the same protocol (Swanepoel et al., 2014). The hearing screening application monitored and recorded noise levels during data collection for each participant. Noise monitoring using the hearScreen™ application on these smartphones has been reported to be accurate within 1 to 1.5 dB, depending on frequency (D. W. Swanepoel et al., 2014). Recorded noise levels consisted of mean ambient noise recorded by the smartphone during pure tone presentation (1.2 seconds duration) in the octave band corresponding to the test frequency (Swanepoel et al., 2014).

Pure tone diagnostic testing

Diagnostic testing was utilised for confirmation of a hearing loss on participants failing the screening for a second time on either ear. The procedure was performed on the same day, and in the same examination room as the screening tests. Automated pure tone audiometry (air- and bone-conduction) was performed for both ears at 0.5, 1, 2, 4, 8 kHz using a Type 2 Clinical Audiometer (KUDUwave, eMoyo, South Africa). Insert earphones were placed deep in the ear canals with circumaural headphones placed over the ears to improve attenuation of ambient noise, and to minimize the occlusion effect. An automated threshold-seeking paradigm was utilized with a similar threshold-seeking method used in a manual test configuration i.e. the modified Hughson-Westlake method. Air and bone conduction thresholds

were determined with masking of the non-test ear when indicated. A hearing loss in an ear was confirmed by diagnostic audiometry if the four frequency average (4FA) was ≥ 25 dB HL (clinically significant hearing loss). The software actively monitored ambient noise levels across octave bands throughout the test procedures in both clinics. Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold, the test operator could pause the automated testing and wait for the transient noise to subside before continuing the test.

4.4 Data analysis

Self-reported hearing loss data was obtained from the data collection form whilst audiometric screening data was extracted from the cloud-based data management system (mHealth Studio, hearX group, South Africa). Participant confidentiality was ensured as behavioural pure tone threshold information for each individual was reported using an alphanumeric code. The identity of the participant represented by this code was known only to the first author.

Data was analysed using SPSS v24 (IBM Corp., Armonk, New York). Data was reported according to three groups: screening group, assessment group and diagnosed group (Figure 4.1). The screening group included all participants and descriptive statistical measures were used to determine how many participants self-reported hearing loss, failed audiometry screening and both self-reported hearing loss and failed audiometry screening. A binary logistic regression model was used to determine the effect of age (as a continuous variable), gender and race on self-reported hearing loss ($p<.05$ indicated significance). Participants were divided into three age groups (16 – 39 years, 40 – 59 years, and 60 years and greater) to

determine the effect of increasing age on self-reported hearing loss. In the assessment group, all participants who failed audiometry screening, and who attended for diagnostic assessments (including 81 participants who passed the audiometric screening) were included in the analysis to evaluate the performance of self-reported hearing loss in isolation, and a combination of self-reported hearing loss and pure tone audiometric screening. Descriptive statistical measures were used to determine how many participants self-reported hearing loss, and how many self-reported hearing loss and failed audiometry screening. Descriptive statistical measures were used to report how many participants were diagnosed with mid-frequency hearing loss ([4FA] 0.5 – 4 kHz and high frequency average [HFA] 4 and 8 kHz) resulting in the diagnosed group. The performance (sensitivity, specificity, positive predictive and negative predictive values as well as overall test accuracy) of the different protocols (self-reported hearing loss and self-reported hearing loss with second stage pure tone audiometry screening) was calculated in reference to diagnostic audiometry results (4FA and HFA). A high frequency loss was confirmed if the HFA was ≥ 25 dB HL.

4.5 Results

A total of 1084 participants, 16 years and older were included in the study; 55.6% were from PHC 1, 74.0% were female, and 69.0% and 31.0% of the sample was African and Caucasian respectively. The mean age was 41.2 years (SD 15.5 years; range 16 – 97 years). Four hundred and thirty-six participants (40.2%) self-reported a hearing loss whilst 189 participants (17.4%) failed the pure tone audiometry screening. Hundred and thirty six participants (12.5%) both self-reported hearing loss and failed pure tone audiometry screening (Figure 4.1).

The mean age of those who self-reported hearing loss was 44.2 years (SD 15.8 years; range 16 – 97 years), and the majority were female (72.4%; n=316). Gender and race did not have a significant association with self-reported hearing loss (p=.498; p>.05; Binary logistic regression). Self-reported hearing loss increased significantly with increasing age (p<.05; Binary logistic regression) (Table 4.1).

Table 4.1 Distribution of self-reported hearing loss across age and gender categories (n=1084).

	All age groups		16-39 years		40-59 years		≥60 years	
	N	%	n	%	N	%	n	%
Male	120/283	42.4	50/129	39.0	42/98	42.8	28/56	50.0
Female	316/801	39.5	132/419	32.0	129/284	45.4	55/98	56.1
Total	436/1084	40.2	182/548	33.2	171/382	44.8	83/154	50.6

The highest sensitivity for self-reported hearing loss compared to failed audiometry screening was found in the 60 years and older age group (Table 4.2). Specificity was highest for the younger age group (16 – 39 years).

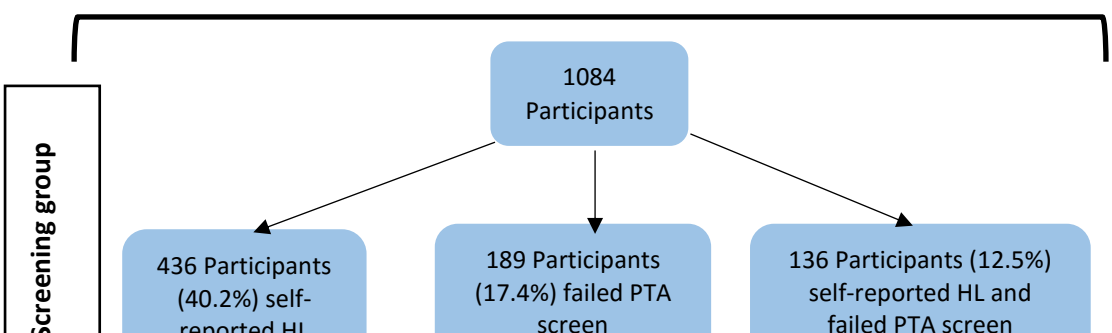

Figure 4.1 Flow diagram of how results are presented in the current study

Table 4.2 Sensitivity and specificity for detecting significant hearing loss (4FA ≥ 25 dB HL by diagnostic audiometry) for those who self-reported hearing loss according to different age groups (n=436).

	All age groups (95% CI)	16 – 39 years (95% CI)	40-59 years (95% CI)	≥60 years (95% CI)
Sensitivity	71.9% (64.8 - 78.1%)	72.2% (58.1 - 83.1%)	67.6% (55.3 - 77.9%)	76.5% (64.0 - 85.8%)
Specificity	66.4% (63.2 - 69.5%)	71.0% (66.7 - 74.9%)	60.4% (54.7 - 65.8%)	62.2% (51.3 - 72.0%)
Positive predictive value	40.2% (37.2 - 43.2%)	21.4% (15.5 - 28.2%)	28.0% (21.6 - 35.5%)	59.0% (47.6 - 69.5%)
Negative predictive value	91.8% (89.3 - 93.7%)	95.9% (93.1 - 97.6%)	89.0% (83.9 - 92.8%)	78.8% (67.2 - 87.3%)

To compare the test accuracy of self-reported hearing loss alone and in combination with second-stage pure tone audiometry screening, the assessment group included 195 participants who attended diagnostic assessments (Figure 4.1). The mean age of the assessment group was 45.6 years (SD 17.9 years; range 16 – 97 years; 65.1% female, 66.2% and 33.8% African and Caucasian respectively). Of these 195 participants, 69.7% self-reported a hearing loss, and 49.7% both self-reported hearing loss and failed the hearing screening test (Figure 4.1).

Of the 195 participants that were tested diagnostically, 131 (67.2%) were identified with a mid-frequency hearing loss (4FA ≥ 25 dB HL) (Table 4.3). Using HFA ≥ 25 dB HL as cut-off, all participants who were identified with hearing loss using 4FA were identified with an additional three participants who did not have a 4FA ≥ 25 dB HL.

Table 4.3 Descriptive comparison of participants diagnosed with hearing loss using an audiometric cut-off 4 FA ≥ 25 dB HL and 4FA and HFA ≥ 25 dB HL. SR HL – self reported hearing loss; PTA screen – audiometry screening

Hearing status	Total	Mean age	Gender (n)	Race (n)	SR HL	Fail PTA

							(n)	screen (n)
			Male	Female	African	Caucasian		
Mid-frequency HL (4FA ≥25 dB HL)	131	50.0±18.4	41.2% (54)	58.8% (77)	58.0% (76)	42.0% (55)	85.5% (112)	86.3% (113)
Mid-and high frequency HL (4FA≥25 dB HL and HFA ≥25 dB HL)	134	49.7±18.3	41.0% (55)	59.0% (79)	59.0% (79)	41.0% (55)	84.3% (113)	85.1% (114)

Combining self-report with second stage audiometry screening revealed a higher test accuracy (81.0% and 86.1%, depending on the audiometry cut-off) compared to self-report hearing loss alone (Table 4.4). Using the combined test protocol also revealed higher specificity (100%) in comparison to self-report measures alone (62.3%). The combination of self-report and an audiometry screening was more sensitive in detecting those with a high frequency hearing loss (81.1%) than those with mid-frequency hearing loss (72.8%). However, self-report alone was more sensitive to detecting a mid-frequency than a high-frequency hearing loss.

Table 4.4 Sensitivity and specificity (with 95% confidence intervals) of different screening protocols used in primary health care clinics using a 4FA ≥ 25 dB HL and HFA ≥ 25 dB HL cut-off in assessment group (n=195). SR HL – self-report of hearing loss, 4FA – four frequency average 0.5 – 4 kHz, HFA – high frequency average 4 – 8 kHz.

Test protocol	Audiometric cut-off	Test performance				
		Sensitivity	Specificity	Positive predictive	Negative predictive	Accuracy
SR HL	*4FA≥25 dB HL*	84.3% (±77.0 – 90.0%)	62.3 % (±48.9 – 74.3%)	83.0% (±77.9 – 87.2%)	64.4% (±53.8 – 73.7%)	77.4% (±70.0 – 83.1%)
	HFA ≥25 dB HL	81.1% (±73.7 – 87.1%)	62.0% (±47.0 – 74.7%)	85.2% (±80.3 – 89.1%)	54.2% (±44.2 – 63.9%)	76.0% (±69.2 – 81.7%)
SR HL and 2nd stage audiometric screening	*4FA≥25 dB HL*	72.4% (±64.0 – 79.9%)	100.0% (±94.1 – 100.0%)	100.0% (100.0%)	62.2% (±55.6 – 68.4%)	81.0% (±74.8 – 86.2%)
	HFA ≥25 dB HL	81.1% (±73.7 – 87.1%)	100.0% (±93.1 – 100.0%)	100.0% (100.0%)	65.8% (±57.8 – 73.0%)	86.1% (±80.5 – 90.6%)

4.6 Discussion

The burden of chronic diseases such as hearing loss is increasing in low and middle income countries (Mulwafu et al., 2017). In the midst of the growing burden of hearing loss, hearing care services are still scare in these regions (Mulwafu et al., 2017). As PHC continues to be the only effective gateway to some form of health care in many low and middle income countries, decentralizing hearing care at PHC levels for early detection and treatment has been promoted by the WHO (Tanser et al., 2006; WHO, 2012). The current study therefore evaluated the performance of self-reported hearing loss in isolation, and in combination with second stage pure tone audiometry screening in PHC clinics in South Africa.

Results of the current study demonstrate that the number of people who self-reported hearing loss increased significantly with increasing age. The highest sensitivity, compared to the number of people who failed audiometry screening, found to be most common in the 60 years and older age category. This is in agreement with previous studies indicating a significantly higher prevalence of self-reported hearing loss for older age samples, probably due to the increasing prevalence of presbycusis with age (Nondahl et al., 1998; Salonen et al., 2011; Sindhusake et al., 2001; Swanepoel et al., 2013; Torre et al., 2006). Nondahl et al. (1998) also found that older individuals are more likely to self-report hearing loss as they are more accepting of hearing impairment as they consider it a typical aspect of ageing. Contrary to this, Kamil et al. (2015) reported an increasing rate of subjective underestimation of hearing loss in adults 70 years and above. The authors further noted that different perceptions of hearing loss in younger versus older adults (e.g. older adults may consider hearing loss to be normal and do not report it), which may contribute to an underestimation of hearing loss in older adults (Kamil et al., 2015).

Apart from different perceptions of hearing loss related to age, stress, anxiety, the presence of middle ear infection and tinnitus can also influence accurate self-report measures resulting in over- or under-estimation of hearing loss (Lindblad, Rosenhall, Olofsson, & Hagerman, 2014; Moon et al., 2015; Sindhusake et al., 2003). As such, using self-report measures may not be sufficiently sensitive to identify hearing loss and may require a combined approach that includes a test in combination with self-report or as a second-stage screen (Kiely et al., 2012).

The study findings showed a high specificity (100%) for a combined screening method. This is an important finding for the efficiency of a screening program particularly in a PHC setting as unnecessary referrals will most likely be excluded (Akbari et al., 2014). In addition, a combined screening method had a higher test accuracy (86.1% and 81.0%) than self-report measures in isolation (77.4% and 76.0%) when compared to a 4FA and HFA ≥ 25 dB HL audiometric protocol when used as the gold standard. This indicates that using self-perceived hearing loss and a second stage audiometry screen has greater benefit for timely diagnostic audiology referrals compared to self-reported measures in isolation. Previous studies also indicated the need to combine both self-report measures with a hearing assessment for a more accurate identification of hearing loss (Brennan-Jones et al., 2016; Kiely et al., 2012).

This study has shown that a screening strategy of a self-report plus an audiometry screen will better identify those with a high-frequency than those with a mid-frequency hearing loss. This is despite the fact that the screening frequencies do not include 8 kHz. A large percentage of speech cues are found between 4 and 8 kHz, and therefore it is possible that participants are reflecting deficits in high frequency

speech perception when self-reporting hearing loss (Swanepoel et al., 2013). Utilizing this screening strategy may also be appropriate to detect high frequency hearing loss in conditions such as presbycusis and ototoxicity from HIV and tuberculosis treatment (Peer & Fagan, 2015) in PHC clinics where conditions such as HIV and tuberculosis are being treated at primary level, at least in the South African context (Naidoo et al., 2017).

One of the basic challenges for PHC hearing care is finding a screening tool that is affordable, simple and efficient. Self-reported hearing loss is a simple procedure that can be a strong predictor of quality of life and well-being, it can play a role in determining the social burden of hearing loss and it can also be used to evaluate the need for audiological rehabilitation (Kiely et al., 2012; Salonen et al., 2011). Using a single question has demonstrated performance results similar to the HHIE-S (Nondahl et al.,1998; Salonen et al., 2011; Sindhusake et al., 2001); thus it may be a useful initial screen to facilitate timely referrals (Salonen et al., 2011; Swanepoel et al., 2013) particularly in a PHC context.

The findings of the current study, however, demonstrated that, when used in isolation, however, self-report measures may not be sufficiently sensitive to detect hearing loss in a PHC context. A single question on self-perceived hearing loss may also not always be an accurate screening method in a PHC setting with the risk of being interpreted differently by some participants(Swanepoel et al., 2013). Thus, future research should investigate if the use of a questionnaire such as the HHIE-S may be more appropriate in a PHC context.

Findings from the current study showed that combing self-report measures with a user-friendly, affordable second stage audiometry screening tool, has the potential to accurately detect in particular high frequency hearing loss. The results of the study furthermore indicated that a simple high frequency audiometry screening as a second-stage screen may significantly improve overall performance and efficiency of the screening protocol. This implies that the screening protocol becomes optimised in terms of time and resource requirements as only those who self-report hearing loss are screened. Using this affordable, simple and efficient hearing screening strategy may improve access to hearing care at PHC clinics in resource-starved countries. Future studies may investigate whether the inclusion of 8 kHz in the audiometry screening is appropriate for PHC contexts to improve management of hearing loss resulting from ototoxic treatments.

CHAPTER 5

PREVALENCE OF HEARING LOSS AT PRIMARY HEALTH CARE CLINICS IN SOUTH AFRICA

Authors:

Christine Louw, De Wet Swanepoel, Robert H Eikelboom, Jannie Hugo

Journal: African Health Sciences

Submitted: August 2017

Status: Published (Louw, C., Swanepoel, D., Eikelboom, R.H., Hugo, J. Prevalence of hearing loss at primary health care clinics in South Africa. *African Heath Sciences*. 2018; 18(2), 313-320.

Note: This manuscript was edited in accordance with editorial specifications of the journal and may differ from the editorial style of the rest of this dissertation.

5.1 Abstract

Background

Hearing loss prevalence data in South Africa is scarce, especially within primary health care settings.

Objectives

To determine (i) the prevalence of hearing disorders in patients ≥3 years of age attending two primary health care clinics, and (ii) the nature and characteristics of hearing disorders at these primary health care clinics.

Method

A cross-sectional design was used at two primary health care clinics. Nonprobability purposive sampling was used to screen participants at clinics for hearing loss with pure tone audiometry. A total of 1236 participants were screened (mean age 37.8 ±17.9 years). Diagnostic testing was available for confirmation of hearing loss on participants who failed the screening.

Results

Hearing loss prevalence was 17.5% across both clinics. Most hearing losses were bilateral (70.0%) and were of a sensorineural nature (84.2%).

Conclusion

Hearing loss prevalence was comparable at both primary health care clinics. Participants 40 years and older were at significantly higher risk for hearing loss. The current study is the first attempt to establish hearing loss prevalence for primary health care clinics in South Africa.

5.2 Introduction

Hearing loss is a major public health concern affecting more than 1.33 billion people globally in 2015 (Vos et al. 2016). As one of the leading contributors to the global burden of disease, it currently ranks fifth on the global causes of years lived with disability index, higher than other chronic diseases such as diabetes or dementia (Vos et al., 2016). A combination of factors is responsible for the upward trend in the global hearing loss epidemic. These include increased life expectancy leading to the number one cause of hearing loss, aging. The widespread use of ototoxic treatments for diseases such as cancer and tuberculosis, and occupational and recreational noise exposure without appropriate protection are other major contributors to the global burden of hearing loss (WHO, 2015).

Hearing loss has a devastating effect on the individual with some of the resulting sequelae including academic failure, higher unemployment, poorer general health, social isolation and an increased incidence of depression (Arlinger, 2003; WHO, 2013a). In addition to its individual effects, hearing loss puts an immense financial burden on society. Health care costs, excluding rehabilitation services such as hearing devices and cochlear implants, are estimated to be in the range of US 67 - 107 billion annually (WHO, 2017b). The financial burden of unaddressed hearing loss, however, is far worse for developing countries that are challenged by pre-existing poverty, environmental risk factors and life-threatening diseases (WHO, 2017b).

Sub-Saharan Africa is one of the developing world regions with substantially higher hearing loss prevalence compared to developed countries (Stevens et al., 2013; WHO, 2013a). Available reports indicate an estimated prevalence of 11.5 to 20.3%

for adults (≥ 15 years) and 1.2 to 3.0% for children (5 – 14 years) in SSA compared to 4.0 to 6.4% (adults ≥ 15 years) and 0.3 to 0.6% (children 5 – 14 years) in high-income countries (Stevens et al. 2013). Hearing loss prevalence in sub-Saharan Africa may however be underestimated as population-based studies are limited (Mulwafu, Kuper, & Ensink, 2015).

Apart from a preliminary population-based study conducted in the Cape Town metropolitan area (Ramma & Sebothoma, 2016), limited hearing loss data is available also in South Africa. Similarly hearing loss prevalence in South African communities and those attending primary health care (PHC) facilities is unknown. It is an important priority to obtain local data for hearing loss prevalence at PHC level where communicable (i.e. tuberculosis) and non-communicable diseases (i.e. diabetes), which are associated with acquired hearing losses, are being treated (Assuiti et al., 2013; Seddon et al., 2012). Considering that an estimated 50% of the burden of hearing loss could be prevented (WHO, 2006), implementing hearing care services such as prevention, management and intervention are needed at PHC level. Determining the prevalence of hearing loss is required for adequate health planning to increase access to hearing care services within communities. This study describes the prevalence and nature of hearing loss of those attending two South African PHC clinics.

5.3 Materials and methods

This research project was approved by the Institutional Research Board of the University of Pretoria, South Africa and was part of a larger community oriented primary care (COPC) project in Gauteng province in the City of Tshwane (Kinkel et al., 2013).

5.3.1 Selection and description of participants

A cross-sectional design was used at two PHC clinics (PHC clinic 1 and PHC clinic 2) situated in different underserved communities in Tshwane. Nonprobability purposive sampling was used to screen participants as it was a clinical, non-experimental set-up and results would therefore be representative of the clinic population. At PHC clinic 1, universal screening took place by offering all individuals who visited the clinic a hearing screening free of charge. At PHC clinic 2 all individuals who were available during the time that the services were delivered and who wanted their hearing tested were screened free of charge. Only individuals visiting the clinic as a patient were selected as a participant. Diagnostic testing was available for confirmation of hearing loss on participants who failed the screening. Participants aged three years and older were included in the study. This criterion was included as the preferred method of testing children younger than 3 years of age is visual response audiometry (VRA) which was not available at the clinics. Only participants who provided signed consent (children had to provide assent along with a signed consent letter from their parent/caregiver) and who completed the screening protocol (i.e. completed a rescreen upon referral of initial screen) were included in the study. Instructions were provided in English or Afrikaans. Written instructions in Sepedi were used if participants did not understand English or Afrikaans. If participants were unable to understand one of these three languages, a

health care nurse who was available at the specific time, was asked to translate the information. Participants who presented with a mixed or conductive hearing loss were referred to the clinics' general practitioner for further medical examination and intervention. Participants who presented with a sensorineural hearing loss (SNHL) were referred to the nearest district hospital for a hearing aid fitting evaluation (Appendix H).

5.3.2 Procedures

Hearing screening

Hearing screening was facilitated by undergraduate audiology students from the University of Pretoria under supervision of an experienced audiologist (first author). Otoscopy was performed with a handheld Welch Allyn otoscope (Welch Allyn, South Africa) as a pre-screen to determine any obvious abnormalities of the external ear canal or tympanic membrane. Any obvious abnormalities of the external ear canal or tympanic membrane were noted. Testing was conducted in an examination room without sound isolation. Due to time and facility constraints at clinics more than one participant was examined at the same time in a room in some instances. In these instances, more than one student audiologist was available to evaluate participants. Smartphone hearing screening was performed using two sets of Samsung Galaxy Pocket Plus S5301 phones running the validated hearScreen™ Android OS application with calibrated supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany) (Mahomed-Asmail et al. 2016; Swanepoel et al. 2014). The application's integrated real-time monitoring of ambient noise levels provided a measure of quality control (Swanepoel et al., 2014). Screening audiometry was conducted, according to recommended guidelines (AAA, 2011) using a 1, 2 and 4 kHz sweep with screening levels of 25 dB HL or 35 dB HL for

participants younger than 15 years and 15 years and older respectively (Swanepoel et al., 2014). These age cut-offs are in line with the World Health Organization (WHO, 2012). Immediately following a fail result, the participant was rescreened. Only those who failed both screenings were considered to have failed the hearing screening test. Findings from previous studies indicate that hearScreen™ can be used as a reliable screening tool, also in PHC settings (Louw et al., 2017; Swanepoel et al., 2014). To determine screening specificity in the current study, diagnostic testing was performed on a group of 111 participants who passed the screening (Louw et al., 2017).

Diagnostic testing

To determine the prevalence and nature of hearing loss, pure tone audiometry was performed on the same day on participants who failed the screening for a second consecutive time. Automated pure tone audiometry (air- and bone conduction) was performed at 0.5, 1, 2, 4 kHz using a Type 2 Clinical Audiometer (KUDUwave, eMoyo, South Africa). Insert earphones were placed deep in the ear canal with circumaural headphones placed over the ears to improve attenuation of ambient noise, and to minimize the occlusion effect. An automated threshold-seeking paradigm was utilized with a similar threshold-seeking method used in manual test configuration i.e. the modified Hughson-Westlake method. Air and bone conduction thresholds were determined with masking of the non-test ear when indicated. The software actively monitored ambient noise levels across octave bands throughout the test procedures in both clinics. Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold, the test operator waited for the transient noise to subside.

5.4 Data analysis

Diagnostic testing confirming a hearing loss informed the prevalence rate for this population. The presence of a hearing loss was defined as a pure tone threshold average (0.5, 1, 2 or 4 kHz) greater than 25 dB HL in one or both ears (Cruickshanks et al., 1998). A hearing loss was classified as conductive when the average difference between the pure tone air conduction and bone conduction thresholds (0.5 kHz – 4 kHz) was 15 dB HL or greater with normal air conduction thresholds (Cruickshanks et al., 1998). A hearing loss was classified as a sensorineural hearing loss (SNHL) when the pure tone air and bone conduction thresholds (0.5 kHz – 4 kHz) were abnormal (> 25 dB HL) with an average air-bone gap less than 15 dB HL. The classification of a mixed hearing loss (conductive and sensorineural) entailed abnormal air and bone conduction thresholds with an average air-bone gap of 15 dB HL or greater. Another hearing loss category ("other") was added in the current study to include participants with different types of hearing losses in the two ears i.e. a SNHL and conductive hearing loss. The degree of the hearing loss was classified as mild (> 25 dB HL and ≤ 40 dB HL), moderate (> 40 dB HL and ≤ 55 dB HL), moderate to severe (> 55 dB HL and ≤ 70 dB HL) and severe to profound (> 70 dB HL) (Cruickshanks et al., 1998). A unilateral hearing loss was obtained when one ear had normal hearing with a hearing loss in the other ear. A bilateral hearing loss indicated a hearing loss present in both ears. Data analysis was performed using SPSS v23 (Armonk, New York; 2015). Demographic data, screening and diagnostic results were analysed and presented using descriptive statistics. A one way ANOVA analysis was performed to evaluate the effect of age, gender and race on the presence of a hearing loss in the sample, with $p < .05$ indicating a significant association.

5.5 Results

A total of 1236 participants were included in the study (PHC 1: n=633; PHC: n=603) (Table 5.1). The mean age was 37.8 years (±17.9 years, range 3 – 97 years). Twenty six participants (22 adults, four children) at PHC clinic 1 and two participants (2 adults) at PHC clinic 2 were excluded from the study because the screening protocol was not completed due to operator error. Two other participants were omitted from the study group at PHC clinic 2 because their date of birth was not captured. Two hundred and sixteen (17.5%) participants failed the hearing screening (PHC 1 = 18.8%, PHC 2 = 16.1%). 4.8% participants failed in the 3-14 years category, whilst 10.5% and 25.4% failed in the 15 – 39 years and > 40 years categories respectively. Of the 216 participants failed, 138 participants were tested diagnostically whilst 78 did not attend the diagnostic assessment.

Table 5.1 Demographic categories across the study population (n=1236)

Characteristics	Combined sample (n=1236)	PHC 1 (n=633)	PHC 2 (n=603)
Race			
Black	64.4% (796)	100.0% (633)	27.0% (163)
White	35.6% (440)	-	73.0% (440)
Gender			
Male	28.7% (355)	25.3% (160)	32.3% (195)
Female	71.3% (881)	74.7% (473)	67.7% (408)
Age			
3 – 14 years	10.2% (126)	3.3% (21)	17.4% (105)
15 – 39 years	45.5% (562)	52.8% (334)	37.8% (228)
≥40 years	44.3% (548)	43.1% (278)	44.7% (270)

One hundred and twenty (9.7%) of the participants (mean age 49.8±19.8 years) presented with a confirmed hearing loss (PHC 1=9.3%; PHC 2=10.1%) (Table 5.2). When the 78 participants who failed the screening, but who did not attend for diagnostic testing, are included, the prevalence is 17.5% across both clinics. The majority of persons with hearing loss presented with a bilateral loss (70.0%, n=84). SNHL (uni- and bilateral) was the most common type of hearing loss (84.2%, n=101)

followed by conductive (3.3%, n=4) and mixed hearing loss (1.7%, n=2). Sixty seven adults and two children presented with a bilateral sensorineural hearing loss (Table 2). Thirteen participants (10.8%) were diagnosed with combinations of SNHL, conductive or mixed losses in respective ears (Table 5.3). Nineteen participants (9 participants with conductive hearing loss, 10 participants with mixed hearing loss) were referred for further medical investigation. The majority of the hearing impaired (38.0%) participants presented with a moderate degree of hearing loss (Table 5.4). Race and gender did not have a significant effect on hearing loss ($p>.05$; ANOVA) but age had a significant affect ($p< .05$) with hearing sensitivity decreasing by 3.4 dB (95% CI: 0.25 – 0.45) for every additional year.

Table 5.2 Nature of hearing loss in adults and children (n=120)

	Conductive hearing loss	**Mixed hearing loss**	**SNHL**	**Other (SNHL & mixed, SNHL & conductive, conductive & mixed)**
≥ 15 years	1.7% (2)	1.7% (2)	81.0% (97)	9.2% (11)
3-14 years	1.7% (2)	-	3.3% (4)	1.7% (2)

Table 5.3 Prevalence and nature of hearing loss (n=120)

	Total (n=1236)	**PHC 1 (n=633)**	**PHC 2 (n=603)**
All	9.7% (120)	9.3% (59)	10.1% (61)
3-14 years	4.8% (6)	9.5% (2)	3.8% (4)
15 – 39 years	5.7% (32)	6.0% (20)	5.3% (12)
≥40 years	15.0% (82)	13.3% (37)	16.7% (45)
Unilateral			
SNHL	2.6% (32)	3.8.% (24)	1.3% (8)
Conductive	0.2% (2)	0.2% (1)	0.2% (1)
Mixed	0.2% (2)	-	0.3% (2)
Bilateral			
SNHL	5.6% (69)	4.1% (26)	7.1% (43)
Conductive	0.2% (2)	0.3% (2)	-
Mixed	-	-	-
Other			
SNHL & Mixed	0.6% (7)	0.3% (2)	0.8% (5)
SNHL & Conductive	0.4% (5)	0.6% (4)	0.1% (1)
Conductive &Mixed	0.1% (1)	-	0.1% (1)

Table 5.4 Degree of hearing loss (based on the worst ear pure tone average) (n=120)

Degree	Total (n=120)	PHC 1 (n=59)	PHC 2 (n=61)
Mild	29.2% (35)	32.2% (19)	26.2% (16)
Moderate	38.0% (45)	31.0% (18)	44.2% (27)
Moderate to severe	11.7% (14)	8.5% (5)	14.8.% (9)
Severe to profound	21.7% (26)	28.8% (17)	14.8% (9)

5.6 Discussion

Hearing loss prevalence data in Africa varies greatly. The current study revealed a hearing loss prevalence of 17.5% at two PHC clinics in underserved communities in the Tshwane area. This is slightly higher than the 12.35% prevalence reported in the Cape Town metropolitan area (Ramma & Sebothoma, 2016) whilst it is very similar to an estimated range of 11.4% - 20.3% for sub-Saharan Africa (Stevens et al., 2013). Different contexts such as school settings or population-based contribute to the prevalence variation. The current study investigated hearing loss prevalence at PHC clinics. Different hearing test techniques employed also contribute to the variation. Also, in studies where pure tone audiometry was used as the screening method, there was also a wide variation in the intensity cut-off criteria i.e. 25 dB HL, 30 dB HL, 35 dB HL (Mulwafu et al., 2015). Using a stricter screen intensity such as 25 dB HL will identify milder hearing losses, and will produce a higher prevalence whilst a pure tone cut off at 40 dB HL will result in a lower prevalence as only moderate and severe losses will be included. The cut off criteria in the current study was of 25 dB HL (children) and 35 dB HL (adults). These intensities were selected to identify disabling hearing loss in children (>30 dB HL) and adults (>40 dB HL) (WHO, 2012); however there may have been a small percentage of adults with slight hearing loss (> 25 dB < 35 dB) that may have passed the hearing screening.

There is an upward trend in hearing loss prevalence with increasing age (Cruickshanks et al., 1998). The age differences in age groups also contribute to the prevalence discrepancy in Africa. Of the hearing loss participants was a significant factor in the current study with 15.0% of the participants 40 years or older presenting with a hearing loss Cruickshanks et al. (Cruickshanks et al., 1998) showed that the risk of hearing loss, specifically SNHL increased by almost 90% for every five years of age. In the US, approximately two thirds of adults age 70 years and older present with a hearing loss (Cruickshanks et al., 1998; Lin, Niparko, & Ferrucci, 2014). In the same age group in Europe at least 30% of men and 20% of women are affected by a hearing loss (Roth et al. 2011). Only limited age-related prevalence evidence is available for sub-Saharan Africa. A study conducted in Nigeria indicated 6.1% of people aged 65 years and older self-reported hearing impairment (Lasisi, Abiona, & Gureje, 2010). Self-report of hearing loss is a quick and inexpensive way to determine hearing handicap, though the use of it in prevalence studies is limited if not validated against pure tone audiometry as the severity and site of lesion cannot be determined (Sindhusake et al., 2001; Stevens et al., 2013). Two recent community-based studies conducted in PHC settings also in the Tshwane area showed increasing age had an impact on audiometric screening referral rate (Louw et al., 2017; Yousuf Hussein et al., 2016). Both studies indicated that 25% of adults older than 40 years (Louw et al., 2017) and 45 years (Yousuf Hussein et al., 2016) were at risk hearing loss. In the current study SNHL was the most common type of hearing loss observed among the hearing impaired participants who attended the diagnostic follow-up (n=120). Uni- and bilateral SNHL was observed in 2.6% and 5.6% of the participants respectively with 1.0% of the participants presenting with a bilateral loss which is sensorineural in nature in at least one ear. Conductive hearing

loss, which refers to a middle ear pathology resulting in a loss of audibility, was observed in 0.2% of the hearing impaired participants with 0.5% of the hearing impaired presenting with a bilateral hearing loss which is conductive in nature in at least one ear. A recent systematic review demonstrated that middle ear disease, that could ultimately lead to conductive hearing loss, is the most common cause not onl in the school-aged population, but also in the general population (Mulwafu et al., 2015). The screening cut off criteria was not aimed to identify mild conductive hearing losses, hence the low prevalence in the current study.

With the great variation in hearing loss prevalence due to different contexts, screening techniques and different age groups, it is imperative to recognize the lack of population-based studies in Africa. Hearing loss is a significant public concern being a highly prevalent and chronic condition. Individuals and communities are challenged by a variety of adverse effects as well as high costs. The negative effects and expenses in communities could be alleviated by implementing hearing care at PHC level. Implementing ear and hearing services at PHC level will require careful planning and identification of specific program goals and specification of care pathways. The current study is the first attempt in establishing hearing loss prevalence baselines and descriptions at PHC clinics. Novel hearing detection solutions, capitalizing on advances in technology and connectivity, which were used in the current study, provide the possibility to expand and decentralize hearing care services to PHC level.

5.7 Study limitations

A limitation of the study was that participants younger than three years of age were not included. Furthermore, the population was sampled purposively and not

randomly taking into consideration power and precision. This was mainly due to the clinical time and human resource constraints of the research setting.

CHAPTER 6

DISCUSSION, CLINICAL IMPLICATIONS AND CONCLUSION

Hearing loss is a public health concern that is estimated to have affected 1.33 billion people globally in 2015 (Vos et al., 2016; WHO, 2017a). Whilst unaddressed hearing loss has a devastating impact on the individual and the family, a recent analysis shows that it also adds considerable cost to health care systems worldwide, which affects the global economy (WHO, 2017b). Recently, a report developed by the WHO suggested that the annual cost of unaddressed hearing loss worldwide is approximately 750 billion USD (WHO, 2017b).

A survey done by the WHO reported that some countries - mainly high-income countries - have developed strategies to address the high prevalence of hearing loss (WHO, 2013b). However, access to ear and hearing care service remains very limited in low and middle income countries (LMIC), where hearing loss prevalence is highest (Fagan & Jacobs, 2009; Mulwafu et al., 2017; WHO, 2013b). Early access to timely diagnosis and management is pivotal to minimizing hearing loss consequences and, ultimately, the burden of disease (WHO, 2013a).

Expanding and decentralizing ear and hearing care to a PHC model could increase equitable access for early diagnosis and management (WHO, 2013a), as PHC remains the only effective gateway to some form of health care in many developing countries (Tanser et al., 2006). By capitalizing on innovations in technology, there is scope to change the traditional audiological service delivery methods to accommodate challenges such as the limited number of hearing care personnel and the high cost of equipment at PHC clinics. Automated procedures and mobile health

technology could assist in alleviating these challenges (Swanepoel & Clark, 2014). The current project therefore investigated different hearing detection approaches in a PHC clinic-setting, taking into account the distinct demands of a LMIC such as South Africa. The project aimed to provide research-based recommendations for clinical practice hearing screening at a PHC clinic, using novel approaches.

6.1 Summary of findings

A smartphone application for basic hearing assessments was proposed as a way to create opportunities for low-cost point of care diagnostics at PHC level (Thompson et al., 2015). The current project aimed to determine approaches that could be used to detect hearing loss accurately and affordably at PHC clinics. Furthermore, the project aimed to determine the prevalence of hearing loss reported by PHC clinics.

Study I aimed to evaluate the performance of smartphone hearing screening applications in terms of sensitivity, specificity, time efficiency and referral rates, at two different PHC clinics. The findings of Study I indicated that sensitivity and specificity for smartphone screening using the hearScreen™ application was 81.7% and 83.1% respectively. Neither gender nor race had an effect on screening outcome for children ($p>.05$; Chi-Square) and adults ($p> .05$; binary logistic regression). Furthermore, the overall referral rate across clinics was 17.5%, but this increased significantly with age ($p<.05$; binary logistic regression).

Study II aimed to evaluate the performance of self-reported hearing loss in isolation, and a combination of self-reported hearing loss and pure tone audiometry screening done at PHC clinics in South Africa. The findings of this study showed that 436 participants (40.2%) self-reported a hearing loss, with no significant difference across gender and race, but with a significant increase with age. Of those who self-

reported hearing loss, 1 in 3 (31.1%) also referred on audiometry screening. The highest sensitivity (76.5%) was found in participants aged 60 years and above, and the highest specificity (95.9%) was found in participants between 16 and 39 years of age. Combining self-reporting with second stage audiometry screening revealed a high test accuracy rate of 81.0% for hearing loss was the most accurate (86.1%) in identifying high-frequency hearing loss.

Study III described the prevalence and nature of hearing loss of individuals who attended the two PHC clinics. Study II found that hearing loss prevalence was 17.5% at both clinics. The majority of the cases of hearing loss were bilateral (70.0%) and of a sensorineural nature (84.2%). Furthermore, participants 40 year and older were at significantly higher risk for hearing loss. This study was the first attempt to establish hearing loss prevalence at PHC clinics in South Africa.

6.2 Clinical implications

In light of the high prevalence of hearing loss, particularly in LMICs, integrating hearing screening at PHC clinics may improve universal and equal access to ear and hearing services (WHO, 2013a). Thus, low-cost and easy-to-use solutions for increasing access to early detection of hearing loss in under-served populations are an important priority. Furthermore, self-reported hearing loss is a simple procedure that could play a role in determining the social burden of hearing loss, and it could also be used to evaluate the need for audiological rehabilitation (Kiely et al., 2012; Salonen et al., 2011). When used in isolation, however, self-report measures may not be sufficiently sensitive to detect hearing loss. The results from Study II showed that combining self-report measures with a user-friendly, affordable, second stage audiometry screening tool, could have the potential to accurately detect hearing loss.

Furthermore, results from Study II showed that self-reported hearing loss could, in particular, correctly detect high frequency hearing loss. Furthermore, the results of this study indicated that a simple audiometry screening, done as a second-stage screen, may significantly improve the overall performance and efficiency of the screening protocol. This implies that the screening protocol becomes optimised in terms of time and resource requirements, as only those who self-report hearing loss are screened.

Using low-cost smartphone-based hearing screening with calibrated headphones can facilitate accurate and time-efficient hearing screening at PHC clinics for children and adults (Louw et al., 2017; Mahomed-Asmail et al., 2016; Sandström et al., 2016; Yousuf Hussein et al., 2016). Including quality control features such as ambient noise monitoring and automated test sequences can ensure high sensitivity and specificity to identify hearing loss (Swanepoel et al., 2014). Using this affordable, simple and efficient hearing screening approach may improve access to hearing detection at PHC clinics in resource-starved countries (Louw et al., 2017; Yousuf Hussein et al., 2016; Swanepoel et al. 2014).

6.3 A model for hearing detection at primary health care clinics

As PHC continues to be the only effective gateway to some form of health care in many LMIC, decentralizing hearing care at PHC levels for early detection and treatment has been promoted by the WHO (Tanser et al., 2006; WHO, 2012). The conclusions drawn from studies I, II and III were utilised to develop and propose a model for hearing detection at a PHC clinic using low-cost and user-friendly hearing

screening tools. Figure 6.1 depicts the proposed model for hearing detection at PHC clinics.

The proposed service delivery model suggests that the hearing service starts at the vitals station where a PHC nurse can ask the patient if he/she has a hearing problem (self-reported hearing loss). Only if the patient indicates that he/she does have a hearing problem, will they be referred for a second stage hearing screening. Findings of study III revealed high specificity when combining self-reported hearing loss with a second stage audiometry screen. This is an important finding for the efficiency of a PHC screening program as unnecessary referrals, which can overburden the system, will most likely be excluded (Akbari et al., 2014). Also, following this route can also assist to evaluate the need for audiological rehabilitation and focus on those patients who indicate a hearing problem (Swanepoel et al., 2013). Those patients who do not consider his/her hearing to be impaired would be less motivated for further audiological rehabilitation (Salonen et al., 2011).

Depending on the patient's response on a self-reported hearing loss, he/she would be referred to the next level of treatment. Should the patient self-report a hearing problem, a second stage audiometry screen should be performed. The findings from Study I indicate that smartphone screening can provide time-efficient identification of hearing loss at primary health care settings, if there is adequate sensitivity and specificity for accurate testing. Second stage smartphone screening can be performed by the PHC nurse or a community health worker (CHW).

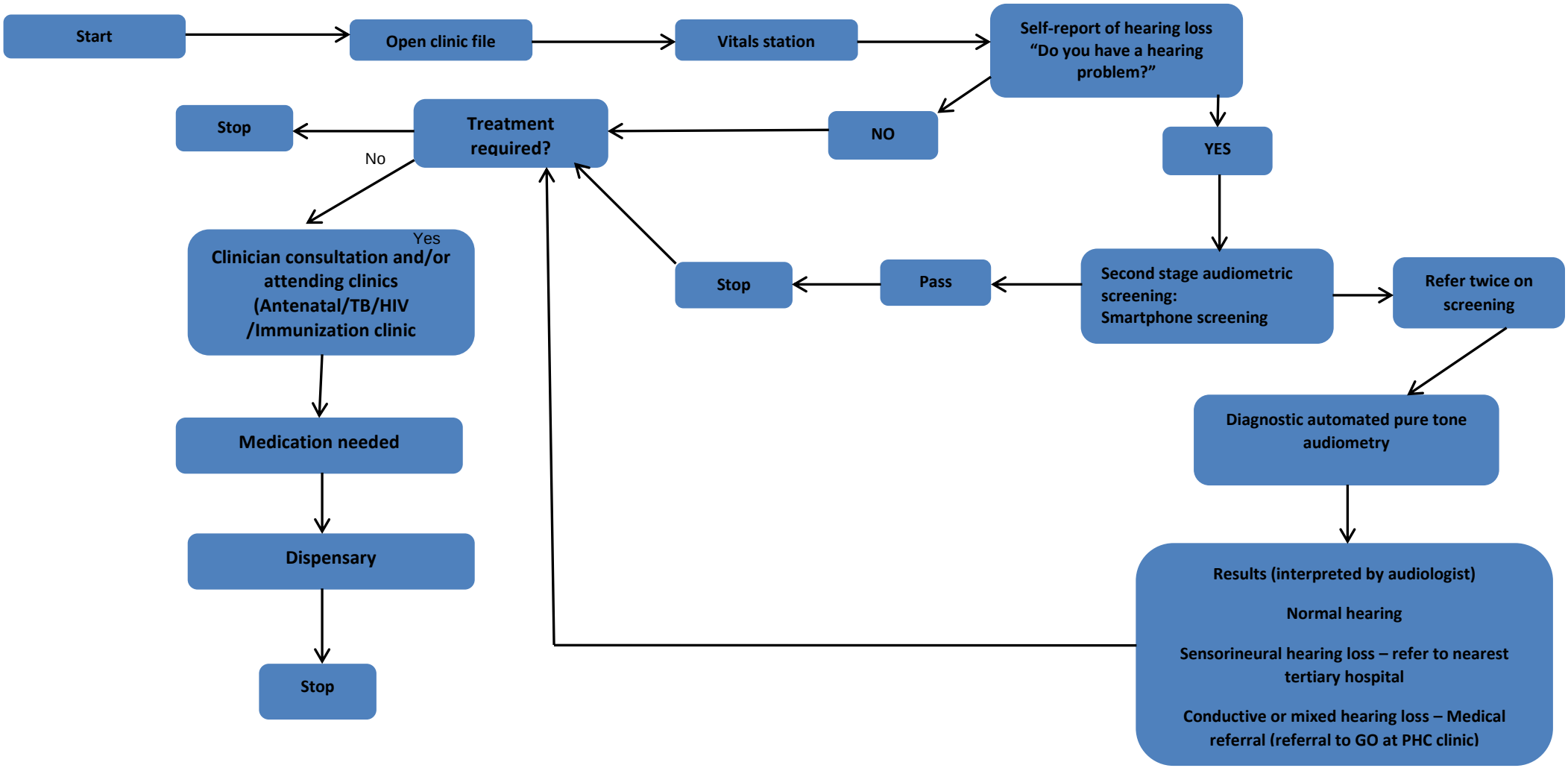

Figure 6.1 Proposed model for hearing detection at primary health care clinics

Yousuf et al.'s study (2016) demonstrated that CHWs can be trained to successfully perform hearing screening at primary care level using the same smartpone technology that was used in the current study. Smartphone hearing screening by minimally trained personnel could be seen as the initial phase of an attempt to increase access to early detection of hearing loss at a PHC level. The PHC nurse / CHW should conduct the pure tone screen test using a device that is light, battery-operated and includes quality control and data management. The pure tone screen test should be conducted at 25 dB HL across 1, 2 and 4 kHz for children between the ages of 3 and 15 years. The pure tone screening test should be conducted at 35 dB HL across 1, 2 and 4 kHz for individuals 16 years and older. If the individual passes the pure tone screening, no further investigation is needed. If an individual refers at any frequency, a rescreen test should be conducted (AAA, 2011). If a refer result is obtained on the rescreen test, the individual could receive automated diagnostic audiometry.

The automated diagnostic audiometry results should be interpreted by an audiologist, who will provide further recommendations. In cases where diagnostic audiometry results indicate the presence of a mixed or conductive hearing loss, a referral for medical treatment should be made. Medical treatments are usually given by a general practitioner at primary health care clinics. In cases where diagnostic audiometry results indicate a sensorineural hearing loss, a referral needs to be made to the nearest audiologist for intervention. Screening and automated diagnostic results need to be stored on a server for reference purposes and also for comparison during follow-up assessments. This is an important step towards effective management of a screening program.

A trans-disciplinary/multi-disciplinary team approach is necessary for successful implementation of hearing detection in a PHC context. The primary role players include hearing health care providers such as audiologists, screening personnel (PHC nurse, CHW) clinic managers and doctors. It would be the responsibility of the audiologist to train the screening personnel on hearing loss, the effects of hearing loss, outcome of early intervention and screening methods used. PHC nurses or the CHW should be trained to ask the simple question: “Do you have a hearing problem?” In addition to self-reported hearing loss, the PHC nurse / CHW should be trained to: perform audiometric pure tone screening using a smartphone application; and to facilitate automated diagnostic audiometry. A team manager should ensure all equipment is calibrated prior to testing, and should implement and supervise the screening program.

6.4 Study strengths and limitations

A critical evaluation of this research project was conducted, in order to evaluate its strengths and weaknesses.

6.4.1 Study strengths

The strengths of the current studies include the following:

- The age of the participants in Study I and Study III differed from the age of the participants in Study II: participants were 3 years and older were included in Study I and Study III; participants 16 years and older were included in Study II. Nevertheless, the populations targeted in all three studies were drawn from a heterogeneous population attending the PHC clinic. This ensured ecological validity to facilitate generalization of the findings to other PHC settings.

- In Study I, the performance of smartphone-based hearing screening using the hearScreen™ application at PHC clinics was investigated. The results of the study revealed that hearScreen™ provides time-efficient identification of hearing loss with adequate sensitivity and specificity for accurate testing at PHC settings.
- In Study II, the performance of self-reported hearing loss in isolation, and a combination of self-reported hearing loss and pure tone audiometric screenings at PHC clinics, was investigated. The results indicated that using self-reported hearing loss together with a second stage audiometry screen test can be beneficial to timely diagnostic audiology referral compared to the self-reported measure in isolation. Previous studies also indicated the need to combine both the self-reporting measure with a hearing assessment for more accurate identification of hearing loss (Brennan-Jones et al., 2016; Kiely et al., 2012).
- Study III was the first attempt to establish hearing loss prevalence baselines and descriptions at PHC clinics in South Africa. The results showed that novel hearing detection solutions, which capitalize on advances in technology and connectivity that were used in the current project, provide the possibility to expand and decentralize hearing care services to PHC level.

6.4.2 Study limitations

The limitations of the current study include:

- The population was sampled purposively and not randomly taking into consideration power and precision. This was mainly due to the clinical time and human resource constraints of the research setting.

- The screening was performed by trained audiology students and not by minimally trained community health care workers or clinic staff. According to the proposed model for hearing detection at PHC clinics, a PHC nurse or a CHW would have to perform the hearing screening service.
- A single level of masking (30 dB narrowband noise above the air conduction threshold of the non-test ear) was used in the current study. It might be seen as a limitation in certain instances (unilateral profound hearing losses) a hearing loss is more easily identified when increasing levels of masking are used in finding a plateau (Studebaker, 1964). However the interaural attenuation for insert earphones was used which is higher for the interaural attenuation for conventional headphones, thus it is unlikely that the single level of masking had an effect.
- Study II used pure tone audiometric screening. This may be seen as a limitation, as pure tone testing is related to the ability to recognize speech in a quiet environment, hence the results poorly reflect the presence of a speech-recognition-in-noise disorder (Vermiglio et al., 2018). According to Vermiglio et al. (2018), the ability to recognize speech must not be inferred from the audiogram, but should rather be measured directly.

6.5 Recommendations for future research

The results obtained and the conclusions drawn from this project revealed several significant aspects that require further investigation. These are presented below to provide suggestions for future research endeavours.

- An investigation should be conducted on the performance of the smartphone application, hearScreen™, when administered by PHC clinic staff or a CHW in

a PHC setting. Their attitudes and perceptions regarding their involvement in ear and hearing care should also be investigated.

- An investigation should be conducted in a PHC setting on the performance of a speech recognition-in-noise test, i.e. the validated South African digits-in-noise test (Potgieter et al., 2015). Speech-in-noise tests have become a significant asset to the diagnostic audiometry test battery, as a speech-recognition-in-noise disorder may be found in the presence of normal pure tone audiometry thresholds (Vermiglio et al., 2018). Currently, no data exists on speech-recognition-in-noise tests in a PHC setting.
- An investigation should be conducted to investigate possibilities for an optimal hearing detection programme on PHC level. The sensitivity and specificity of various screening protocols investigating different intensity levels and different frequencies should be explored.
- Future research should focus on monitoring programmes for ototoxicity in the treatment of tuberculosis at PHC clinics using smartphone audiometry.
- Large-scale longitudinal studies that utilise the recommended service delivery model at PHC clinics should be conducted, in order to determine the effectiveness and efficiency of such a model.
- Referral pathways available in resource-limited countries like South Africa should also be investigated, so as to determine the feasibility of screening programs in PHC clinics.
- An investigation should be conducted to determine if using smartphone technology in conjunction with automated tympanometry or tympanic membrane image-analysis to detect otitis media or ear canal obstructions may further optimise the referral system in resourced-constrained communities.

- Future studies should investigate whether or not the inclusion of 8 kHz in the audiometry screening is appropriate for PHC contexts, in order to improve the management of hearing loss resulting from ototoxic treatments.

6.6 Conclusion

Hearing loss is a significant public concern, as it is a highly prevalent and chronic condition. In the current project, hearing loss prevalence was comparable at both PHC clinics, with participants aged 40 years and older being at greater risk. Individuals with hearing loss and communities are challenged by a variety of adverse effects, as well as high costs. The negative effects and expense for communities could be alleviated by implementing hearing detection at PHC level.

Smartphone hearing screening is a gateway to expand and decentralize hearing services to PHC level, where staff with minimal training could perform hearing screening. The current research project showed that smartphone screening can provide time-efficient identification of hearing loss with adequate sensitivity and specificity for accurate testing in PHC settings. Furthermore, smartphone audiometry opens the door for new possibilities at PHCs, such as monitoring programmes for ototoxicity in tuberculosis treatment programmes.

Introducing self-reported hearing loss as the first line screening, followed by second stage smartphone audiometry screening, could optimise the screening protocol in terms of time and resource requirements. Introducing this model for hearing detection at PHC clinics may result in some false negatives. However, literature indicated that a person who does not considers his or her hearing to be impaired, may not be motivated to seek an audiological diagnosis and rehabilitation as yet (Salonen et al., 2011). The current project showed that using this particular service

delivery model (self-report of hearing followed by second stage smartphone audiometry screening) the screening protocol becomes optimised in terms of time and resource requirements as only those who self-report hearing loss are screened. Using this affordable, simple and efficient hearing screening strategy may improve access to hearing care at PHC clinics in resource-starved countries.

REFERENCES

Agrawal, Y., Platz, E. A., & Niparko, J. K. (2009). Risk factors for hearing loss in US adults: data from the national health and nutrition examination survey, 1999 to 2002. *Otology & Neurotology*, *30*(2), 139–145. https://doi.org/10.1097/MAO.0b013e318192483c

Akbari, A., Mayhew, A., Al-alawi, M. A., Grimshaw, J., Winkens, R., Glidewell, E., … Fraser, C. (2014). Interventions to improve outpatient referrals from primary care to secondary care. *The Cochrane Collaboration*, (1). https://doi.org/10.1002/14651858.CD005471.pub2.Interventions

Al-Rowaily, M. A., AlFayez, A. I., AlJomiey, M. S., AlBadr, A. M., & Abolfotouh, M. A. (2012). Hearing impairments among Saudi preschool children. *International Journal of Pediatric Otorhinolaryngology*, *76*(11), 1674–1677. https://doi.org/10.1016/j.ijporl.2012.08.004

American Academy of Audiology. (2011). Hearing Screening Guidelines. Retrieved from http://www.audiology.org/resources/documentlibrary/Documents/ChildhoodScreeningGuidelines.pdf.

American Speech-Language-Hearing Association. (1997). Guidelines for audiologic screening. https://doi.org/10.1044/policy.GL1997-00199

Araújo, E. D. S., Zucki, F., Corteletti, L. C. B. J., Lopes, A. C., Feniman, M. R., & Alvarenga, K. D. F. (2012). Hearing loss and acquired immune deficiency syndrome: systematic review. *Jornal Da Sociedade Brasileira de*

Fonoaudiologia, *24*(2), 188–192. https://doi.org/10.1590/S2179-64912012000200017

Arlinger, S. (2003). Negative consequences of uncorrected hearing loss--a review. *International Journal of Audiology*, *42 Suppl 2*, 2S17-2S20. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12918624

Assuiti, L. F. C., Lanzoni, G. M. D. M., dos Santos, F. C., Erdmann, A. L., & Meirelles, B. H. S. (2013). Hearing loss in people with HIV/AIDS and associated factors: an integrative review. *Brazilian Journal of Otorhinolaryngology*, *79*(2), 248–255. https://doi.org/10.5935/1808-8694.20130042

Bam, N., Marcus, T., Hugo, J., & Kinkel, H.-F. (2013). Conceptualizing community oriented primary care (COPC) – the Tshwane, South Africa, health post model. *African Journal of Primary Health Care & Family Medicine*, *5*(1), Art #423. https://doi.org/10.4102/phcfm.v5i1.423

Brennan-Jones, C. G., Taljaard, D. S., Brennan-Jones, S. E. F., Bennett, R. J., Swanepoel, D., & Eikelboom, R. H. (2016). Self-reported hearing loss and manual audiometry: A rural versus urban comparison. *Australian Journal of Rural Health*, *24*(2), 130–135. https://doi.org/10.1111/ajr.12227

Bogardus, S. T., Yueh, B. & Shekelle, P. G. (2003). Clinician's corner: screening and management of adult hearing loss in primary care clinical applications. *JAMA*, *289*(15), 1986–1990.

Clark, J. L., & Swanepoel, D. W. (2014). Technology for hearing loss - as we know it, and as we dream it. *Disability and Rehabilitation Assistive Technology*, *9*(5), 408–413. https://doi.org/10.3109/17483107.2014.905642

Cruickshanks, K. J., Tweed, T. S., Wiley, T. L., Klein, B. E. K., Klein, R., Chappell,

Dalton, D. S. (2003). The 5-year incidence and progression of hearing loss: the epidemiology of hearing loss study. *Archives of Otolaryngology--Head & Neck Surgery*, *129*(10), 1041–1046. https://doi.org/10.1001/archotol.129.10.1041

Cruickshanks, K. J., Wiley, T. L., Tweed, T. S., Klein, B. E. K., Klein, R., Mares-Perlman, J. a, & Nondahl, D. M. (1998). Prevalence of hearing loss in older adults in Beaver Dam, Wisconsin. The epidemiology of hearing loss study. *American Journal of Epidemiology*, *148*(9), 879–886. https://doi.org/10.1093/oxfordjournals.aje.a009713

Ciurlia-Guy, E., Cashman, M., Lewsen, B. (1993). Identifying hearing loss and hearing handicap among chronic care elderly people. *Gerontologist*, *33*(5), 644-649.

Dalton, D. S., Cruickshanks, K. J., Klein, B. E. K., Klein, R., Wiley, T. L., & Nondahl, D. M. (2003). The impact of hearing loss on quality of life in older adults. *The Gerontologist*, *43*(5), 661–668. https://doi.org/10.1093/geront/43.5.661

Dookie, S., & Singh, S. (2012). Primary health services at district level in South Africa: a Critique of the primary health care approach. *BMC Family Practice*, *13*(1), 67. https://doi.org/10.1186/1471-2296-13-67

Ettehad, D., Schaaf, H. S., Seddon, J. A., Cooke, G. S., & Ford, N. (2012). Treatment outcomes for children with multidrug-resistant tuberculosis: A systematic review and meta-analysis. *The Lancet Infectious Diseases*, *12*(6), 449–456. https://doi.org/10.1016/S1473-3099(12)70033-6

Fagan, J. J., & Jacobs, M. (2009). Survey of ENT services in Africa: Need for a comprehensive intervention. *Global Health Action*, *2*(1), 1–7. https://doi.org/10.3402/gha.v2i0.1932

Ferrite, S., Santana, V. S., & Marshall, S. W. (2011). Validity of self-reported hearing loss in adults: Performance of three single questions. *Revista de Saude Publica*, *45*(5), 824–830. https://doi.org/10.1590/S0034-89102011005000050

Goulios, H., & Patuzzi, R. B. (2008). Audiology education and practice from an international perspective. *International Journal of Audiology*, *47*(10), 647–664. https://doi.org/10.1080/14992020802203322

Global Burden of Disease Study 2013 Collaborators. (2015). Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet, 386*, 743-800.

Hannula, S., Bloigu, R., Majamaa, K., Sorri, M., & Mäki-Torkko, E. (2011). Self-reported hearing problems among older adults: Prevalence and comparison to measured hearing impairment. *Journal of the American Academy of Audiology*, *22*(8), 550–559. https://doi.org/10.3766/jaaa.22.8.7

International Organization for Standardization (ISO) 389-2 (1994). *Acoustics - Reference zero for the calibration of audiometric equipment. Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones.* Geneva: ISO.

International Organization for Standardization (ISO). ISO 389-3. (1994). *Acoustics - Reference zero for the calibration of audiometric equipment. Part 3: Reference equivalent threshold force levels for pure tones and bone vibrators*. Geneva: ISO.

International Standardization Organization (ISO) 389-1 (1998). *Acoustics- Reference zero for the calibration of audiometric equipment. Part1: Reference equivalent*

threshold sound pressure levels for pure tones and supra-aural earphones. Geneva: ISO.

International Organization for Standardization (ISO) 389-9 (2009). *Acoustics - Reference zero for the calibration of audiometric equipment – Part 9: Preferred test conditions for the determination of reference hearing threshold levels.* Geneva: ISO

Kakarlapudi, V., Sawyer, R., & Staecker, H. (2003). The effect of diabetes on sensorineural hearing loss. *Otology & Neurotology*, *24*(3), 382–386. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12806288

Kam, A. C. S., Gao, H., Li, L. K. C., Zhao, H., Qiu, S., & Tong, M. C. F. (2013). Automated hearing screening for children: A pilot study in China. *International Journal of Audiology*, *52*(12), 855–60. https://doi.org/10.3109/14992027.2013.832419

Kamil, R. J., Genther, D. J., & Lin, F. R. (2015). Factors associated with the accuracy of subjective assessments of hearing impairment. *Ear and Hearing*, *36*(1), 164–167. https://doi.org/10.1097/AUD.0000000000000075

Kelly T. & Minges M. (2012). *Executive summary. Maximizing Mobile.* Washington: International Bank for Reconstruction and Development/ The World Bank. Retrieved from

http://siteresources.worldbank.org/EXTINFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/Resources/IC4D-2012-Report.pdf (Accessed 19 November 2015.)

Keidser, G. & Convery, E. (2016). Self-fitting hearing aids: status quo and future

predictions. *Trends Hear, 20*, 1 - 15.

Kiely, K. M., Gopinath, B., Mitchell, P., Browning, C. J., & Anstey, K. J. (2012). Evaluating a dichotomized measure of self-reported hearing loss against gold standard audiometry: Prevalence estimates and age bias in a pooled national data set. *Journal of Aging and Health*, *24*(3), 439–458. https://doi.org/10.1177/0898264311425088

Khoza-Shangase, K., & Kassner, L. (2013). Automated screening audiometry in the digital age: exploring Uhear™ and its use in a resource-stricken developing country. *International Journal of Technology Assessment in Health Care*, *29*(01), 42–47. https://doi.org/10.1017/S0266462312000761

Kinkel, H.-F., Marcus, T., Memon, S., Bam, N., & Hugo, J. (2013). Community oriented primary care in Tshwane district, South Africa: assessing the first phase of implementation. *African Journal of Primary Health Care & Family Medicine*, *5*(1), 1–9. https://doi.org/10.4102/phcfm.v5i1.477

Krumm, M., Ribera, J., & Klich, R. (2007). Providing basic hearing tests using remote computing technology. *Journal of Telemedicine and Telecare*, *13*(8), 406–410. https://doi.org/10.1258/135763307783064395

Lasisi, A. O., Abiona, T., & Gureje, O. (2010). The prevalence and correlates of self-reported hearing impairment in the Ibadan Study of Ageing. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *104*(8), 518–523. https://doi.org/10.1016/j.trstmh.2010.03.009

Leedy, P. D., & Ormrod, J. E. (2005). *Practical Research. Planning and Design* (8th ed.). New Jersey: Pearson Education Inc.

Lichtenstein, M. J., Bess, F. H., Logan, S. A. (1988). Validation of Screening Tools for Identifying Hearing-Impaired Elderly in Primary Care. *Journal of American Medical Association, 259*(19), 2875-2878.

Lin, F. R., Niparko, J. K., & Ferrucci, L. (2014). Hearing loss prevalance in the United States. *Archives of Otolaryngology- Head and Neck Surgery*, *171*(20), 2011–2012. https://doi.org/10.1002/gps.2627.6.

Lin, F. R., Thorpe, R., Gordon-salant, S., & Ferrucci, L. (2011). Hearing loss prevalence and risk factors among older adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, *66*(5), 582–590. https://doi.org/10.1093/gerona/glr002

Lindblad, A. C., Rosenhall, U., Olofsson, Å., & Hagerman, B. (2014). Tinnitus and other auditory problems - occupational noise exposure below risk limits may cause inner ear dysfunction. *PLoS ONE*, *9*(5). https://doi.org/10.1371/journal.pone.0097377

Lo, A. H. C., & McPherson, B. (2013). Hearing screening for school children: utility of noise-cancelling headphones. *BMC Ear, Nose, and Throat Disorders*, *13*(1), 6. https://doi.org/10.1186/1472-6815-13-6

Louw, C., Swanepoel, D. W., Eikelboom, R. H., & Myburgh, H. C. (2017). Smartphone-based hearing screening at primary health care clinics. *Ear and Hearing*, *38*(2), 93–100. https://doi.org/10.1097/AUD.0000000000000378

Maclennan-Smith, F., Swanepoel, D. W., & Hall, J. W. (2013). Validity of diagnostic pure-tone audiometry without a sound-treated environment in older adults. *International Journal of Audiology*, *52*(2), 66–73. https://doi.org/10.3109/14992027.2012.736692

Mahomed-Asmail, F., Swanepoel, D. W., Eikelboom, R. H., Myburgh, H. C., & Hall, J. (2016). Clinical validity of hearScreen™ smartphone hearing screening for school children. *Ear and Hearing*, *37*(1), e11–e17. https://doi.org/10.1097/AUD.0000000000000223

Mahomed, F., Swanepoel, D. W., Eikelboom, R. H., & Soer, M. (2013). Validity of automated threshold audiometry: a systematic review and meta-analysis. *Ear and Hearing*, 745–752. https://doi.org/10.1097/AUD.0b013e3182944bdf

Margolis, Glasberg, Creeke, & Moore. (2010). AMTAS: automated method for testing auditory sensitivity: validation studies. *International Journal of Audiology*, *49*(3), 185–194. https://doi.org/10.3109/14992020903092608

Margolis, R. H., & Morgan, D. E. (2008). Automated pure-tone audiometry: an analysis of capacity, need, and benefit. *American Journal of Audiologyournal of Audiology*, *17*(2), 109–113. https://doi.org/10.1044/1059-0889(2008/07-0047).

McBride, W. S., Mulrow, C. D., Aguilar, C.,Tuley, M. R. (1994). Methods for screening for hearing loss in older adults. *American Journal of Medical Sciences, 307*(1), 40-42.

Moon, I. J., Won, J. H., Kang, H. W., Kim, D. H., An, Y.-H., & Shim, H. J. (2015). Influence of tinnitus on auditory spectral and temporal resolution and speech perception in tinnitus patients. *Journal of Neuroscience*, *35*(42), 14260–14269. https://doi.org/10.1523/JNEUROSCI.5091-14.2015

Myburgh, H. C., Van Zijl, W. H., Swanepoel, D. et al. (2016). Otitis media diagnosis for developing countries using tympanic membrane image- analysis. *EBioMedicine*, *5*, 156 - 160.

Mulwafu, W., Ensink, R., Kuper, H., & Fagan, J. (2017). Survey of ENT services in

sub-Saharan Africa: Little progress between 2009 and 2015. *Global Health Action*, *10*(1). https://doi.org/10.1080/16549716.2017.1289736

Mulwafu, W., Kuper, H., & Ensink, R. J. H. (2015). Prevalence and causes of hearing impairment in Africa. *Tropical Medicine and International Health*, *21*(2), 158–165. https://doi.org/10.1111/tmi.12640

Naidoo, S. (2012). The South African national health insurance: a Revolution in health-care delivery! *Journal of Public Health*, *34*(1), 149–150. https://doi.org/10.1093/pubmed/fds008

Naledi, T., Barron, P., & Schneider, H. (2011). Primary Health Care in South Africa since 1994 and implications of the new vision for PHC re-engineering. *South African Health Review 2011*, 17–28. https://doi.org/10.1093/heapol/czn006

Nondahl, D. M., Cruickshanks, K. J., Wiley, T. L., Tweed, T. S., Klein, R., & Klein, B. E. K. (1998). Accuracy of self-reported hearing loss. *International Journal of Audiology*, *37*(5), 295–301. https://doi.org/10.3109/00206099809072983

Olusanya, B. O., Luxon, L. M., & Wirz, S. L. (2006). Ethical issues in screening for hearing impairment in newborns in developing countries. *Journal of Medical Ethics*, *32*(10), 588–591. https://doi.org/10.1136/jme.2005.014720

Peer, S., & Fagan, J. J. (2015). Hearing loss in the developing world: evaluating the iPhone mobile device as a screening tool. *South African Medical Journal*, *105*(1), 35–39. https://doi.org/10.7196/samj.8338

Potgieter, JM, Swanepoel, DW, Myburgh, H.C., Hopper, T.C. & Smits, C. (2015). Development and validation of a smartphone-based digits-in-noise hearing test in South African English. *International Journal of Audiology, 55*(7), 405-411.

Ramkissoon. (2011). Self-reported hearing difficulty versus audiometric screening in younger and older smokers and nonsmokers. *Journal of Clinical Medicine Research*, *3*(4), 183–190. https://doi.org/10.4021/jocmr611w

Ramma, L., & Sebothoma, B. (2016). The prevalence of hearing impairment within the Cape Town Metropolitan area. *The South African Journal of Communication Disorders*, *63*(1), e1–e10. https://doi.org/10.4102/sajcd.v63i1.105

Roth, T. N., Hanebuth, D., & Probst, R. (2011). Prevalence of age-related hearing loss in Europe: a review. *European Archives of Oto-Rhino-Laryngology*, *268*(8), 1101–1107. https://doi.org/10.1007/s00405-011-1597-8

Salonen, J., Johansson, R., Karjalainen, S., Vahlberg, T., & Isoaho, R. (2011). Relationship between self-reported hearing and measured hearing impairment in an elderly population in Finland. *International Journal of Audiology*, *50*(5), 297–302. https://doi.org/10.3109/14992027.2010.549517

Sandström, J., Swanepoel, D., Myburgh, H., & Laurent, C. (2016). Smartphone threshold audiometry in underserved primary health-care contexts. *International Journal of Audiology*, *55*(4), 232–238. https://doi.org/10.3109/14992027.2015.1124294

Seddon, J. A, Godfrey-Faussett, P., Jacobs, K., Ebrahim, A., Hesseling, A. C., & Schaaf, H. S. (2012). Hearing loss in patients on treatment for drug-resistant tuberculosis. *The European Respiratory Journal*, *40*(5), 1277–86. https://doi.org/10.1183/09031936.00044812

Sideris, I., & Glattke, T. J. (2006). A comparison of two methods of hearing screening in the preschool population. *Journal of Communication Disorders*, *39*(6), 391–401. https://doi.org/10.1016/j.jcomdis.2005.11.006

Sindhusake, D., Golding, M., Newall, P., Rubin, G., Jakobsen, K., & Mitchell, P. (2003). Risk factors for tinnitus in a population of older adults: The Blue Mountains Hearing Study. *Ear and Hearing*, *24*(6), 501–507. https://doi.org/10.1097/01.AUD.0000100204.08771.3D

Sindhusake, D., Mitchell, P., Smith, W., Golding, M., Newall, P., Hartley, D., & Rubin, G. (2001). Validation of self-reported hearing loss. The Blue Mountains Hearing Study. *International Journal of Epidemiology*, *30*(6), 1371–8. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11821349

South African Department of Health. A policy on quality in health care for South Africa, Government Gazette. (2000). Pretoria: Government Printer.

South African National Health Act, 2003. Regulations relating to research on human subjects, Government Gazette § (2007). Pretoria.

Statistics South Africa. (2013). *Gender statistics South Africa 2011*. Retrieved from http://www.statssa.gov.za/publications/Report-03-10-05/Report-03-10-052011.pdf

Stevens, G., Flaxman, S., Brunskill, E., Mascarenhas, M., Mathers, C. D., & Finucane, M. (2013). Global and regional hearing impairment prevalence: An analysis of 42 studies in 29 countries. *The European Journal of Public Health*, *23*(1), 146–152. https://doi.org/10.1093/eurpub/ckr176

Storey, K.K., Muñoz, K., Nelson, L., Larsen, J.B., & White, K. (2014). Ambient noise impact on accuracy of automated hearing assessment. *International Journal of Audiology, 53*(10), 730-736. https://doi.org 10.3109/14992027.2014.920110

Studebaker, G.A. (1964). Clinical masking of air-and bone conducted stimuli .

Journal of Speech and Hearing Disorders, *9*(1), 23-25.

Swanepoel, D. W., Clark, J. L., Koekemoer, D., Hall, J. W., Krumm, M., Ferrari, D. V, … Barajas, J. J. (2010). Telehealth in audiology: the need and potential to reach underserved communities. *International Journal of Audiology*, *49*(3), 195–202. https://doi.org/10.3109/14992020903470783

Swanepoel, D. W., Eikelboom, R. H., Hunter, M. L., Friedland, P. L., & Atlas, M. D. (2013). Self-reported hearing loss in baby boomers from the Busselton Healthy Ageing Study: Audiometric correspondence and predictive value. *Journal of the American Academy of Audiology*, *24*(6), 514–21. https://doi.org/10.3766/jaaa.24.6.7

Swanepoel, D. W., Koekemoer, D., & Clark, J. (2010). Intercontinental hearing assessment - a study in tele-audiology. *Journal of Telemedicine and Telecare*, *16*(5), 248–252. Retrieved from http://jtt.sagepub.com/content/16/5/248

Swanepoel, D. W., Mngemane, S., Molemong, S., Mkwanazi, H., & Tutshini, S. (2010). Hearing assessment-reliability, accuracy, and efficiency of automated audiometry. *Telemedicine Journal and E-Health : The Official Journal of the American Telemedicine Association*, *16*(5), 557–63. https://doi.org/10.1089/tmj.2009.0143

Swanepoel, D. W., Myburgh, H. C., Howe, D. M., Mahomed, F., & Eikelboom, R. H. (2014). Smartphone hearing screening with integrated quality control and data management. *International Journal of Audiology*, *53*(12), 841–849. https://doi.org/10.3109/14992027.2014.920965

Tanser, F., Gijsbertsen, B., & Herbst, K. (2006). Modelling and understanding primary health care accessibility and utilization in rural South Africa: An

exploration using a geographical information system. *Social Science & Medicine*, *63*(3), 691–705. https://doi.org/10.1016/j.socscimed.2006.01.015

Thompson, G. P., Sladen, D. P., Borst, B. J. H., & Still, O. L. (2015). Accuracy of a tablet audiometer for measuring behavioral hearing thresholds in a clinical population. *Otolaryngology -- Head and Neck Surgery*, *153*(5), 838–842. https://doi.org/10.1177/0194599815593737

Torre, P., Moyer, C. J., & Haro, N. R. (2006). The accuracy of self-reported hearing loss in older Latino-American adults. *International Journal of Audiology*, *45*(10), 559–562. https://doi.org/10.1080/14992020600860935

Van der Aerschot, M., Swanepoel, D. W., Mahomed-Asmail, F., Myburgh, H. C., & Eikelboom, R. H. (2016). Affordable headphones for accessible screening audiometry: An evaluation of the Sennheiser HD202 II supra-aural headphone. *International Journal of Audiology*, *55*(11). https://doi.org/10.1080/14992027.2016.1214756

Van der Linde, J., & Kritzinger, A. (2013). Perceptions of rural primary healthcare personnel about expansion of early communication intervention. *African Journal of Primary Health Care & Family Medicine*, *5*(1), 1–11. https://doi.org/10.4102/phcfm.v5i1.553

Van der Westhuizen, Y., Swanepoel, D., Heinze, B., & Hofmeyr, L. H. (2013). Auditory and otological manifestations in adults with HIV/AIDS. *International Journal of Audiology*, *52*(1), 37–43.

Van Tonder, J. Swanepoel, D., Mahomed-Asmail, F. et al. (2017). Automated smartphone threshold audiometry: validity and time-efficiency. *Journal of American Academy of Audiology.28*(3), 200-208.

Vermiglio, A. ., Soli, S. ., & Fang, X. (2018). An argument for self-report as a reference standard in audiology. *Journal of the American Academy of Audiology*, *29*(3), 2018. https://doi.org/10.3766/jaaa.16128

Vos, T., Allen, C., Arora, M., Barber, R. M., Bhutta, Z. A., Brown, A., … Murray, C. J. L. (2016). Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990 - 2015: a systematic analysis for the Global Burden of Disease Study 2015. *The Lancet*, *388*(10053), 1545–1602. https://doi.org/10.1016/S0140-6736(16)31678-6

World Health Organization. (2006). Primary ear and hearing care training resource.Geneva: Switzerland. Retrieved from www.who.int/pbd/deafness/activities/hearing_care/trainer.pdf (Accessed 2 July 2015).

World Health Organization. (2008). The global burden of disease: 2004 update.Geneva: Switzerland. Retrieved from http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.Pdf. (Accessed 16 November 2015).

World Health Organization. (2012). Global estimates on prevalence of hearing loss. Geneva: Switzerland. Retrieved from http://www.who.int/pbd/deafness/WHO_GE_HL.pdf. (Accessed 19 November 2015).

World Health Organization. (2013a). Millions of people in the world have hearing loss that can be treated or prevented. Geneva: Switzerland. Retrieved from http://www.who.int/pbd/deafness/news/Millionslivewithhearingloss.pdf (Accessed 16 November 2015).

World Health Organization. (2013b). Multi-country assessment of national capacity to

provide hearing care. Geneva: Switzerland. Retrieved from www.http://www.who.int/pbd/publications/WHOReportHearingCare_Englishweb.pdf?ua=1. (Accessed 16 November 2015).

World Health Organization. (2015). Make Listening safe.Geneva:Switzerland. Retrieved from http://www.who.int/pbd/deafness/activities/MLS_Brochure_English_lowres_for_web.pdf (Accessed 20 November 2016)

World Health Organization. (2017a). Global costs of unaddressed hearing loss and cost-effectiveness of interventions: a WHO report. Geneva: Switzerland. Retrieved from http://apps.who.int/iris/bitstream/handle/10665/254659/9789241512046-eng.pdf;jsessionid=19406967ACAAB3ABC4BA428FAA97F8A1?sequence=1doi:Licence: CC BY-NC-SA 3.0 IGO.(Accessed 4 April 2017)

World Health Organization. Action for hearing loss. (2017b). Geneva: Switzerland. Retrieved from: http://www.who.int/pbd/deafness/world-hearing-day/en/ (Accessed 4 April 2017)

Wu, W., Lü, J., Li, Y., Kam, A. C. S., Fai Tong, M. C., Huang, Z., & Wu, H. (2014). A new hearing screening system for preschool children. *International Journal of Pediatric Otorhinolaryngology*, *78*(2), 290–295. https://doi.org/10.1016/j.ijporl.2013.11.026

Yoshinaga-itano, C., Sedey, A. L., Coulter, D. K., & Mehl, A. L. (2013). http://pediatrics.aappublications.org/content/102/5/1161.full.html.

Yousuf Hussein, S., Wet Swanepoel, D., Biagio de Jager, L., Myburgh, H. C., Eikelboom, R. H., & Hugo, J. (2016). Smartphone hearing screening in mHealth

assisted community-based primary care. *Journal of Telemedicine and Telecare*, *0*(0), 405–412. https://doi.org/10.1177/1357633X15610721

Zielhuis GA, Heuvelmans-Heinen EW, Rach GH, van den Broek P. Environmental risk factors for otitis media with effusion in preschool children (1989). *Scandinavian Journal of Primary Health Care*. 7, 33–8.

APPENDICES

APPENDIX A

Approval letter for researching the development, application, and implementation of Community Orientated Primary Care (COPC): A Study In Gauteng (Tshwane) And Mpumalanga Province

---

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* FWA 00002567, Approved dd 22 May 2002 and Expires 13 Jan 2012.
* IRB 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

DATE: 27/06/2011

PROTOCOL NO.	**102/2011**
PROTOCOL TITLE	Researching the Development, Application and Implementation of Community Oriented Primary Care (COPC) a study in Gauteng (Tshwane) and Mpumulanga Province.
INVESTIGATOR	**Principal Investigator:** JFM Hugo
SUBINVESTIGATOR	None
SUPERVISOR	None
DEPARTMENT	**Dept: Phone:** 012 3542463 **Fax:** 012 3541317 **E-Mail:** jannie.hugo@up.ac.za
STUDY DEGREE	None
SPONSOR	None
MEETING DATE	**22/06/2011**

The Protocol was approved on 22/06/2011 by a properly constituted meeting of the Ethics Committee subject to the following conditions:

1. Provisionally approved pending changes.
2. The approval is valid for 5 years period [till the end of December 2016] , and
3. The approval is conditional on the receipt of 6 monthly written Progress Reports, and
4. The approval is conditional on the research being conducted as stipulated by the details of the documents submitted to and approved by the Committee. In the event that a need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

Members of the Research Ethics Committee:

Prof M J Bester	(female)BSc (Chemistry and Biochemistry); BSc (Hons)(Biochemistry); MSc(Biochemistry); PhD (Medical Biochemistry)
Prof R Delport	(female)BA et Scien, B Curationis (Hons) (Intensive care Nursing), M Sc (Physiology), PhD (Medicine), M Ed Computer Assisted Education
Prof JA Ker	MBChB; MMed(Int); MD – Vice-Dean (ex officio)
Dr NK Likibi	MBB fM – Representing Gauteng Department of Health) MPH
Dr MP Mathebula	(female)Deputy CEO: Steve Biko Academic Hospital; MBCHB, PDM, HM
Prof A Nienaber	(female) BA(Hons)(Wits); LLB; LLM; LLD(UP); PhD; Dipl.Datametrics(UNISA) – Legal advisor
Mrs MC Nzeku	(female) BSc(NUL); MSc(Biochem)(UCL, UK) – Community representative
Prof L M Ntlhe	MbChB (Natal) FCS (SA)
Snr Sr J Phatoli	(female) BCur(Eet.A); BTec(Oncology Nursing Science) – Nursing representative
Dr R Reynders	MBChB (Pret), FCPaed (CMSA) MRCPCH (Lon) Cert Med. Onc (CMSA)
Dr T Rossouw	(female) MBChB (cum laude); M.Phil (Applied Ethics) (cum laude), MPH (Biostatistics and Epidemiology (cum laude), D.Phil
Dr L Schoeman	(female) B.Pharm, BA(Hons)(Psych), PhD – Chairperson: Subcommittee for students' research
Mr Y Sikweyiya	MPH; SARETI Fellowship in Research Ethics; SARETI ERCTP; BSc(Health Promotion)Postgraduate Dip (Health Promotion) – Community representative
Dr R Sommers	(female) MBChB; MMed(Int); MPharmMed – **Deputy Chairperson**
Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path), PGCHE – School of Dentistry representative

MS: dd 2011/06/28: C:\Documents and Settings\User\Desktop\grade briewe main\94.2011.DOC

APPENDIX B

Approval letter Ethical Committee of Health Sciences, Faculty of Health Sciences, University of Pretoria

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

3/08/2014

Approval Certificate
Amendment
(to be read in conjunction with the main approval certificate)

Ethics Reference No.: 102/2011

Title: Researching the Development, Application and Implementation of Community Oriented Primary Care (COPC) a study in Gauteng (Tshwane) and Mpumulanga Province.

Dear Prof JFM Hugo

The **Amendment** as described in the documents received in June 2014 was approved by the Faculty of Health Sciences Research Ethics Committee on the 3/08/2014.

Please note the following about your ethics amendment:
- Please remember to use your protocol number (**102/2011**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics amendment is subject to the following:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

DR R SOMMERS; MBChB; MMed(Int); MPharmMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee
University of Pretoria

The Faculty of Health Sciences, Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

☎ 012 354 1677 🖷 0866516047 deepeka.behari@up.ac.za http://www.healthethics-up.co.za
✉ Private Bag X323, Arcadia, 0007 - 31 Bophelo Road, HW Snyman South Building, Level 2, Room 2.33, Gezina, Pretoria

APPENDIX C

Approval letter Postgraduate Research Committee, Faculty of Humanities, University of Pretoria

---

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

26 September 2014

Dear Prof Vinck

Project:	**Primary health care audiology: Incorporating mobile technologies, automation and connectivity**
Researcher:	**C Louw**
Supervisor:	**Prof De Wet Swanepoel**
Department:	**Speech-Language Pathology and Audiology**
Reference numbers:	**04357523**

Thank you for the application that was submitted for ethical consideration.

I am pleased to inform you that the above application was **approved** by the **Research Ethics Committee** on 25 September 2014. Data collection may therefore commence.

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.

The Committee requests you to convey this approval to the researcher.

We wish you success with the project.

Sincerely

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

APPENDIX D

Informed consent (Daspoort and Stanza II Clinics)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Participant

RE: INFORMED CONSENT TO PARTICIPATE IN AUDIOLOGY SERVICES

The Department of Speech-Language Pathology and Audiology at the University of Pretoria provide audiology services at Daspoort clinic free of charge. Audiology students provide the services under supervision. The services comprise hearing screening and diagnostic hearing assessment. The diagnostic service will be rendered should you refer on the screening test. Hearing screening takes approximately 5 minutes to complete. Diagnostic assessments take between 20 and 30 minutes and consist of the following procedures:

- Examination of the ear canals
- Assessment of the middle ear status
- Test for hearing thresholds

All procedures are non-invasive and results and recommendations from the hearing tests will be provided and explained to you.

Please note that the information obtained from the hearing screening and diagnostic procedures may be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If you want to withdraw from the project at any time, you may do so without any negative consequences to yourself. Data will be stored at the Department of Speech-Language Pathology and Audiology, University of Pretoria for research and archiving purposes.

Should you wish to make use of these services, kindly complete the form below.

Sincerely

Mrs Christine Louw	Professor De Wet Swanepoel
Postgraduate student/Audiologist	**Research Supervisor**

Consent:

Hereby I _____ (name) grant permission that audiology services may be conducted on myself and I acknowledge that the information may be used for research purposes as specified above.

Signature of participant	**Date**

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Participant

RE: INFORMED CONSENT TO PARTICIPATE IN AUDIOLOGY SERVICES

The Department of Speech-Language Pathology and Audiology at the University of Pretoria provide audiology services at Stanza II clinic free of charge. Audiology students provide the services under supervision. The services comprise hearing screening and diagnostic hearing assessment. The diagnostic service will be rendered should you refer on the screening test. Hearing screening takes approximately 5 minutes to complete. Diagnostic assessments take between 20 and 30 minutes and consist of the following procedures:

- Examination of the ear canals
- Assessment of the middle ear status
- Test for hearing thresholds

All procedures are non-invasive and results and recommendations from the hearing tests will be provided and explained to you.

Please note that the information obtained from the hearing screening and diagnostic procedures may be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If you want to withdraw from the project at any time, you may do so without any negative consequences to yourself. Data will be stored at the Department of Speech-Language Pathology and Audiology, University of Pretoria for research and archiving purposes.

Should you wish to make use of these services, kindly complete the form below.

Sincerely

Mrs Christine Louw	Professor De Wet Swanepoel
Postgraduate student/Audiologist	**Research Supervisor**

Consent:

Hereby I _____ (name) grant permission that audiology services may be conducted on myself and I acknowledge that the information may be used for research purposes as specified above.

Signature of participant	**Date**

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za

APPENDIX E

Informed consent (parents) and verbal assent (children)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Parent

RE: INFORMED CONSENT FOR YOUR CHILD TO PARTICIPATE IN AUDIOLOGY SERVICES

The Department of Speech-Language Pathology and Audiology at the University of Pretoria provide audiology services at Daspoort clinic free of charge. Audiology students provide the services under supervision. The services comprise hearing screening and diagnostic hearing assessment. The diagnostic service will be rendered should your child refer on the screening test. Hearing screening takes approximately 5 minutes to complete. Diagnostic assessments take between 20 and 30 minutes and consist of the following procedures:

- Examination of the ear canals
- Assessment of the middle ear status
- Test for hearing thresholds

All procedures are non-invasive and results and recommendations from the hearing tests will be provided and explained to you.

Please note that the information obtained from the hearing screening and diagnostic procedures may be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If your child, want to withdraw from the project at any time, he/she may do so without any negative consequences to him/herself. Data will be stored at the Department of Speech-Language Pathology and Audiology, University of Pretoria for research and archiving purposes.

Should you wish to make use of these services, kindly complete the form below.

Sincerely

Mrs Christine Louw	Professor De Wet Swanepoel
Postgraduate student/Audiologist	**Research Supervisor**

Consent:

Hereby I _____ (name) grant permission that audiology services may be conducted on my child _____ (name) and I acknowledge that the information may be used for research purposes as specified above.

Signature of parent/guardian	**Date**

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Parent

RE: INFORMED CONSENT FOR YOUR CHILD TO PARTICIPATE IN AUDIOLOGYY SERVICES

The Department of Speech-Language Pathology and Audiology at the University of Pretoria provide audiology services at Stanza II clinic free of charge. Audiology students provide the services under supervision. The services comprise hearing screening and diagnostic hearing assessment. The diagnostic service will be rendered should your child refer on the screening test. Hearing screening takes approximately 5 minutes to complete. Diagnostic assessments take between 20 and 30 minutes and consist of the following procedures:

- Examination of the ear canals
- Assessment of the middle ear status
- Test for hearing thresholds

All procedures are non-invasive and results and recommendations from the hearing tests will be provided and explained to you.

Please note that the information obtained from the hearing screening and diagnostic procedures may be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If your child, want to withdraw from the project at any time, he/she may do so without any negative consequences to him/herself. Data will be stored at the Department of Speech-Language Pathology and Audiology, University of Pretoria for research and archiving purposes.

Should you wish to make use of these services, kindly complete the form below.

Sincerely

Mrs Christine Louw	Professor De Wet Swanepoel
Postgraduate student/Audiologist	**Research Supervisor**

Consent:

Hereby I _____ (name) grant permission that audiology services may be conducted on my child _____ (name) and I acknowledge that the information may be used for research purposes as specified above.

Signature of parent/guardian	**Date**

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za

Verbal Assent Form (Both Clinics)

➡ I am going to put the headphones on your ears

➡ When you hear a beep, raise your hand.

➡ Can we proceed?

YES

NO

APPENDIX F

Data collection form (Both Clinics)

Sepedi translation

EAR AND HEARING CARE SERVICES **UNIVERSITY OF PRETORIA**

CLINIC:_____ **Student name: _____**

Patient: _____ **Date of birth: _____**
Patient file number: _____ **Tel nr: _____**

1st screening	**Follow up screening**	**Referred on screening done by CHW**

Do you have a hearing problem?/
Het jy 'n gehoorprobleem?

YES	NO

If "YES" which ear?/
Indien "JA", watter oor?

LEFT	RIGHT	BOTH

1. Hearing screening

	hearScreen: 1st screening		**hearScreen:2nd screening**	
Left ear	Pass	Refer	Pass	Refer
Right ear	Pass	Refer	Pass	Refer

If results indicate "Fail", proceed to the following procedures.

4. Otoscopy

Left ear	Normal	≥75% wax in canal	Perforation	Discharge	Other
Right ear	Normal	≥75% wax in canal	Perforation	Discharge	Other

Comments: _____

5. Tympanometry

	Compliance	**Tympanic peak pressure**	**Ear canal volume**	**Tympanic width**
Left ear				
Right ear				

6. Outcome

Normal hearing	Refer to TD Hospital for manual testing	Refer to Stanza I for hearing aids	Refer to GP at Stanza II

Sepedi Sentences used during SCREENING	
Do you have a problem with your hearing?	O na le botuata ka go utlwa?
Do you hear a sound (ringing) in your hear?	O utlwa modumo ka ditsebeng?
I put headphones on your ears, when you hear “beep” raise your hand	Ke bea headphones mo ditsebe tsa gago, ge o utlwa “beep”, emisa letsogo la gago
Sentences used during DIAGNOSTIC HEARING ASSESSMENTS	
I put headphones on your ears, when you hear “beep”, press nr 2 as quickly as possible	Ke bea headphone mo ditsebe tsa gago, ge o utlwa “beep” tobetsa nr 2 ka bonako ge go nega.
Listen only to the “beep” now. When you hear “shhhhhhh” do not listen to that. Only press nr 2 when you hear “beep”	Utlwella fela “beep” gona jaanong. Ge o utllwa “shhhh” o seke wa utlwella seo. Presa fela button nr 2 ge o utlwa “beep”

APPENDIX G

Referral letter for hearing aids (Daspoort and Stanza II Clinics)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Date: _____

Dear: _____

A diagnostic hearing assessment was conducted on _____ 20___. Based on the hearing test results you are referred to Kalafong Hospital for a hearing aid fitting.

You can contact the Audiology department of Kalafong Hospital at 012 318 6777 for an appointment.

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

Kind regards,

Mrs C Louw
Researcher / Audiologist

Professor D Swanepoel
Principal Researcher

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Date: _____

Dear: _____

A diagnostic hearing assessment was conducted on _____ 20___. Based on the hearing test results you are referred to Stanza Bopabe I Clinic for a hearing aid fitting on _____ at _____.

You can contact the Audiology department of Stanza Bopabe I Clinic (Stand no 2, Shilovane street, Mamelodi East).

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

Kind regards,

Mrs C Louw
Researcher / Audiologist

Professor D Swanepoel
Principal Researcher

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za