Smartphone hearing screening in mHealth assisted community-based primary care

By

Shouneez Yousuf Hussein

(28121262)

A dissertation submitted in fulfillment of the requirements for the degree M.Communication Pathology in the Department of Communication Pathology at the University of Pretoria, Faculty of Humanities.

SUPERVISOR: Prof. De Wet Swanepoel

CO-SUPERVISOR: Dr. Leigh Biagio de Jager

2015

ACKNOWLEDGEMENTS

- First and foremost, I would like to thank my Creator for guiding me.
- To Professor De Wet Swanepoel, a special thank you for your constant guidance, support and encouragement throughout this process. You have broadened my abilities to conduct research, exposed me to writing for journals as well as the opportunity to present at conferences.
- To Dr Leigh Biago, thank you for all your assistance and attention to the finer details.
- To Dr Herman Myburgh, thank you for your patience and support with my data analysis.
- I would also like to thank Prof Jannie Hugo, as well as the team leaders and CHWs of Mamelodi who assisted me with me with my data collection.
- Thank you to my loving husband and family for your support and encouragement when I needed it the most.

TABLE OF CONTENTS

TABLES

LIST OF ABBREVIATIONS

CHW – Community health worker

COPC – Community-orientated primary care

MPANLs – Maximum permissible ambient noise levels

mHealth – Mobile health

FORMATTING

APA referencing style was utilized in this dissertation.

ABSTRACT

Available ear and hearing health care services are not sufficient to meet the burden of disabling hearing loss, particularly within developing countries such as South Africa. Attempts to meet the needs of underserved populations may require a move towards community-based primary care along with the integration of recent mHealth approaches whereby primary health care personnel facilitate ear and hearing health care. The objective of this study was to determine the clinical utility of a community-based program for identification of hearing loss, using smartphone hearing screening (hearScreen^{TM}) operated by community health care workers (CHWs), in a developing South African community and to survey experiences of the CHWs.

An exploratory, descriptive cross-sectional research design was used. The study comprised two phases. During phase one, 24 CHWs were trained to conduct hearing screening in the underserved community of Mamelodi using automated test protocols (sweep performed at 1, 2 and 4kHz bilaterally at an intensity of 25dB HL for children and 35dB HL for adults), employed by the hearScreen^{TM} mHealth solution operating on low cost Android phones using calibrated headphones (Sennheiser HD202 II). A total of 820 community members were screened for hearing loss over a 12-week period. The results were analyzed in terms of referral rates of the hearing screening program, compliance of test environment noise during screening, and time proficiency of the screenings. During phase 2, CHWs completed a questionnaire regarding their perceptions and experiences of the hearing screening program.

Data analysis was conducted on 108 children (2-15 years) and 598 adults (16-85 years) screened. Referral rates for children and adults were 12% and 6.5% respectively. Noise levels only had a significant effect on referral results at low intensities of 25dB HL at 1KHz ($p<0.05$). Age effects were significant for adult referral rates ($p<0.05$) demonstrating a significantly lower referral rate in younger (below 45 years) as opposed to older (45 years and above) adults (4.3% compared to 13.2%). Majority of CHWs responded positively regarding their involvement and experiences using the hearScreen^{TM} tool in terms of usability, need for services, value to community members and time efficiency.

Results of this study indicated that community-based hearing screening programs can be successfully integrated into underserved contexts by CHWs using an mHealth solution. The hearScreen™ smartphone application offers benefits such as automated test protocols and interpretation, integrated noise monitoring, data capturing and data sharing. Appointment of a program coordinator, as well as the integration of informational counseling and minor software changes were recommended towards an effective and sustainable program.

Keywords: mHealth, community-based, smartphone, hearing screening, community health care workers, automated, cost effective, developing countries.

1. INTRODUCTION

Hearing disability is one of the most frequently occurring sensory deficits affecting individuals as well as communities and societies. According to the World Health Organization (WHO, 2013), there are 360 million persons worldwide (i.e. 5.3% of the global population) who live with a permanent disabling hearing loss, the majority of which could be prevented or treated. If left untreated, hearing diability can result many negative consequences including inability to interpret speech sounds, often producing a reduced ability to communicate, delay in language acquisition, economic and educational disadvantage, social isolation and stigmatization (Mathers, Smith, & Concha, 2000; WHO, 2014).

Majority of persons affected by hearing disability are found to have limited knowledge as well as access to good quality hearing health care (WHO, 2006, 2013). Developing low- and middle-income countries are most affected, accounting for more than 80% of those affected by hearing disability globally (Fagan & Jacobs, 2009; WHO, 2013). South Africa is regarded as a middle-income country consisting of pockets of developed contexts within an overall developing context (World Bank, 2008). The health care system of South Africa consists of public and private health care sectors with the public sector serving approximately 85% of the population (National Treasury Department: Republic of South Africa, 2005).

South Africa offers a relatively well developed health care infrastructure as opposed to other countries within the sub-Saharan African region, however, it has been shown to be unequal in hearing health care depending on socioeconomic conditions, thus posing a challenge to the development and delivery of good quality and timely hearing health care services (Swanepoel, Störbeck, & Friedland, 2009; WHO, 2013). Audiology services require technologies for accurate assessment of hearing acuity and for interventions. Whilst private health sectors may be able to afford state of the art medical services, primarily to those with a higher socioeconomic status, those with a lower socioeconomic status rely on a public health sector with severely constrained resources (Swanepoel et al., 2009).

A major challenge to the delivery of quality audiological services is due to a shortage of hearing health care providers such as audiologists. According to a recent study conducted by WHO (2014), the availability of human resources for hearing care was found to be lowest in the Africa region. Also, the most common reason cited for absence of hearing care programs was attributed to other health care priorities and lack of financial and human resources (WHO, 2014). A survey conducted by Fagan and Jacobs (2009) indicated an alarming situation in Africa of under-resourced, understaffed and outdated ENT and speech and hearing services as well as a shortage of training facilities. For every million people in sub-Saharan Africa there is an average estimate of one audiologist (Fagan & Jacobs, 2009). Furthermore, within the large continent of Africa, tertiary qualifications in audiology have traditionally only been offered in 2 countries (Swanepoel, 2010)

Apart from the shortage there is also an unequal distribution of audiologists in South Africa between the public and private health care sector, with the majority of audiologists entering the private sector for a more lucrative career (Swanepoel, 2006). This puts a further strain on the public health sector to provide hearing health care services with an insufficient number of audiologists available to meet the needs of majority of the population.

Within the public health care system; hearing health care services are mostly provided at tertiary level, and occasionally at secondary healthcare facilities, such as provincial and regional hospitals, whilst primary health care has typically omitted hearing health services (Swanepoel, 2006). This may be attributed to a shortage of audiologists, particularly in the public health sector, as well as due to the costs associated with audiological equipment (Clark & Swanepoel, 2014; Swanepoel, Clark, Koekemoer, Hall, Krumm & Ferrari, 2010) to provide hearing health care. As such conventional methods of providing hearing healthcare have proved insufficient to reach communities.

A proposed solution to South Africa's access to health care difficulties relating to prevention has been to move towards community-based primary care in an attempt re-engineer the primary health care system (Kinkel, Marcus, Memon, Bam, & Hugo, 2012). A policy paper released by the National Department of Health (2011) called for a renewed emphasis on health promotion and prevention care and also indicated that services should include community health care workers (CHWs) involved in community outreach and home-based services. Implementing primary health care within the South African healthcare system provides individuals and communities, who previously did not have access to hearing healthcare services, an opportunity to benefit from the system (van der Linde & Kritzinger, 2013).

Furthermore, for hearing health care services to be successfully implemented at a primary health care level, cost effective techniques, as well as research and training of generalist health care personnel, need to be fostered into the field of hearing health care (Fagan & Jacobs, 2009; Howe, Mash, & Hugo, 2013). The rapid development of mobile communications and technologies has brought about the field of mHealth or mobile health, often seen as a subset of eHealth, as a novel and powerful means of providing and supporting health care (Martínez-Pérez, de la Torre-Díez, & López-Coronado, 2013). mHealth can be defined as *"any use of mobile technology to address health care challenges such as access, quality, affordability, matching of resources, and behavioral norms [through] the exchange of information"* (Qiang, Yamamichi, Hausman, Miller & Altman, 2012, p.11). mHealth is demonstrating promise to transform health care systems, particularly in low-income countries because it is cost effective, can be carried out with fairly limited resources and increases access (Friederici, Hullin, & Yamamichi, 2012).

Currently, there are more than 1.08 billion smartphones of a total of 5 billion mobile phones around the world, with 80% of the population worldwide already having a mobile phone (Martínez-Pérez et al., 2013). This means that these devices have widespread penetration. If utilized for health care purposes such as ear and hearing health prevention it could serve to increase access for patients in areas where ear and hearing health services has been unavailable.

A number of mHealth applications have already been developed and have shown promising results for ear and hearing health care. An example of such an application is the uHear^{TM} (Unitron) application on iOS devices that allows for self-assessment of air conduction thresholds. A recent study revealed an accuracy level of 90% in a sound proof room when using the uHear^{TM} application to screen for a moderate or worse hearing loss (PTA>40dB HL) (Peer & Fagan, 2014). However, low frequencies thresholds were less accurately measured in comparison to mid- to high frequencies (Peer & Fagan, 2014). Furthermore, another study conducted on school children (8 to 10 years) revealed inaccurate elevated hearing thresholds (Khoza-Shangase & Kassner, 2013). Another example of such an application is the EarTrumpet application, also based on iOS devices, which provides automated hearing evaluations. A study by Foulad, Bui and Djalilian (2013) revealed that 96% of the threshold values obtained using the EarTrumpet application in a sound booth were within 10 dB of the corresponding threshold values obtained using conventional audiometry. Although this devise does show great potential, it also has limitations. One of these limitations is that it does not allow for calibration according to the prescribed standards (ISO, SANS etc.). Furthermore, iOS based devices are expensive premium products with poor penetration in developing contexts.

An mHealth application for hearing screening allowing the use of smartphones for screening audiometry with devices that are low-cost and more widely available in developing countries was recently reported (Swanepoel, Myburgh, Howe, Mahomed, & Eikelboom, 2014). The hearScreen^{TM} application creates an inexpensive alternative to conventional screening audiometry, showing valid acoustic calibration according to prescribed standards and environmental noise monitoring with no significant difference between test results for conventional and smartphone-based hearing screening (Swanepoel et al., 2014). The fact that it is automated, with recommended screening protocols pre-programmed, means personnel with no or limited health care training can operate the device to screen patients for disabling hearing loss. This technology is currently being field tested for school and primary health care clinic based screening. As part of the community-based primary care initiative in the City of Tshwane, CHWs are using smartphones to collect patient-specific information in communities. The hearScreen™ technology has been integrated with this initiative to allow CHWs to screen hearing in communities for a pilot phase. This study therefore aimed to describe a community-based prevention program for hearing loss using a low-cost smartphone-based hearing screening test operated by CHWs.

The research question was therefore: *What is the clinical utility and perceived value of a community-based primary care hearing screening program conducted by CHWs?*

2. METHODOLOGY

2.1 Research Aims

Research aim:

To describe the clinical utility and perceived value of a community-oriented primary care hearing screening program conducted by CHWs.

Secondary objectives:

1. To describe the clinical utility of smartphone-based hearing screening conducted by CHWs in terms of referral rate, compliance of test environment and time proficiency.

2. To describe the perceptions of CHWs regarding community-oriented primary care hearing screening.

2.2 Research Design

This study employed an exploratory, descriptive cross-sectional research design. Exploratory research is used when research is in a preliminary stage and definitive conclusions arising from it are rare (Maxwell & Satake, 2006). This research design is exploratory in nature, aimed at investigating a community-based approach to hearing health care using an mHealth application for which there is a lack of research.

Descriptive research is a non-experimental design, which is aimed at identifying characteristics of an observed occurrence in a clinical or natural setting, and can also involve acquiring information about people's attitudes or opinions by asking questions and tabulating the response (Leedy & Ormrod, 2005; Maxwell & Satake, 2006). In order to achieve the first objective, quantitative descriptive data was collected cross-sectionally by CHWs who conducted hearing screenings on members of the community as part of their home-based visits. Those who failed the hearing screening were referred to their closest clinic for a diagnostic test.

To achieve the secondary objective of the study, a cross-sectional quantitative survey was used to describe the perceptions of the CHWs regarding the perceived benefit of the study.

2.3 Ethical Considerations

It is imperative for ethical considerations to be addressed in order to protect the rights and welfare of the participants involved in the study (Leedy & Ormrod, 2010).

Confidentiality and Anonymity:
A researcher must respect the privacy of the participants by keeping the nature and quality of the participants' performance strictly confidential (Leedy & Ormrod, 2010). For the first phase of the study, each participant screened was provided with a coded number that was used for data processing purposes thus ensuring anonymity. This was explained verbally and was also stated in a participant information leaflet where applicable.

For the second phase of the study, all CHW feedback was reported anonymously when answering the questionnaire. This ensured that the participants were able to voice their true opinions. This was explained verbally and was stated in a participant information leaflet where applicable.

Protection from harm:
According to Leedy and Omrod (2010), the risk involved in participating in a study should not be greater than the normal risks of day to day living. Participants were informed of what the testing would entail, and were ensured that there were no medical risks or discomforts associated with this study.

Permission:

Prior to data collection, ethical clearance was obtained from the Research Ethics Committee of the Faculty of Humanities (Appendix A) and the Research Ethics Committee of the Faculty of Health Sciences of the University of Pretoria (Appendix B). Phase one of this study fell under the COPC initiative of the Department of Family Medicine. Therefore, In order to obtain ethical clearance from the Faculty of Health Sciences, permission to conduct this study was applied for as an addendum to an existing protocol, Researching the Development, Application and Implementation of community-orientated primary care (COPC).

Informed consent:

Informed consent is an imperative ethical consideration that must be obtained from all participants. Participants should be informed of nature of the study as well as their level of involvement in the study (Leedy & Omrod, 2010). Since phase one of this study fell under the COPC initiative of the Department of Family Medicine, it involved the CHWs who were already involved with the implementation of COPC. A participant information leaflet and informed consent form was provided to all participants in the community prior to testing (Appendix C). Only once informed consent was obtained did testing commence. All participants were made aware that their participation was voluntary and that they had the right to withdraw from the study at any time.

For the second phase of the study, a participant information leaflet and informed consent form (Appendix D) was provided to the CHWs before administering the questionnaires. Only once informed consent was obtained did data collection take place.

2.4 Phases of the study

In order to achieve the sub-aims, this study was carried out in two phases. During the first phase, CHWs used the hearing screening application (after a training session) to screen members of the community who wished to participate in the study. Data collected was then analyzed in terms of the referral rate based on the hearing screening, the compliance of the test environment during hearing screening and the time proficiency of the hearing screening.

During the second phase of the study, CHWs were required to complete a questionnaire regarding the hearing screenings that they conducted. This study phase aimed to describe the perceived value of a community-based primary care hearing screening program as reported by the CHWs.

2.4.1 Phase 1 – Clinical utility of smartphone hearing screening

Materials and apparatus for data collection

Data was collected by CHWs using the Samsung Trend Plus (S5301) smartphones (Android OS, 4.0). The hearScreen™ application developed by the University of Pretoria was installed on 24 of these phones, in conjunction to the AITA Health™ software (to collect and manage health status assessment data care), to include hearing screening as an additional service. Supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany) were supplied for each phone. The hearScreen™ calibration function was used to calibrate the headphones according to prescribed standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Swanepoel et al., 2014). Calibration was performed using an IEC 60318-1 G.R.A.S. ear stimulator connected to a Type 1 SLM (Rion NL-52). The hearScreen™ solution has been validated to monitor noise accurately within 1 and 1.5dB HL depending on the test frequency (Swanepoel et al., 2014). Data collected was documented by the smartphone and was then uploaded via a WIFI network to a secure cloud-based server and stored electronically.

Participants

Convenience sampling was used to enroll all community members that were seen by CHWs and who agreed to participate as participants along with the CHWs who provided the service. For this phase of the study the participants comprised two groups:

- 24 CHWs of an identified clinic in Mamelodi, City of Tshwane, who were trained to conduct hearing screenings on children and adults during the daily home-based visits to the community. These CHWs were already part of the COPC initiative of the Department of Family Medicine.
- All surrounding community members of the identified clinic in Mamelodi, including children (of the age of 4 years or older) and adults, to whom these CHWs offer their services were invited to participate in this study by having a hearing screening done for them. Hearing screenings were conducted over a three-month period during which 820 participants were screened.

Procedure for data collection

Hearing screenings were conducted as part of an existing COPC initiative aimed at collecting and managing health status assessment data (Bam, Marcus, Hugo, & Kinkel, 2013). Community members were recruited as CHWs to carry out primary health care within the COPC service (Marcus, 2014). The procedure for data collection comprised the following:

- CHWs involved in this study had no formal training in ear and hearing health care. A 4 hour training session was be held prior to commencing data collection during which CHWs were provided with adequate information regarding ear and hearing health care and its importance. CHWs also received training and sufficient hands-on practice to manage the hearing screening application during this session.
- During the CHWs' visits to the community of Mamelodi, individuals, parents or caregivers were offered hearing screening as an additional assessment and were asked if they were willing to participate in the study.
- Hearing screening was conducted in the participant's home in an environment that was as quiet as possible, as environmental noise may

affect the reliability of the results.

- A participant information leaflet and informed consent letter (Appendix C) was provided to each individual. The participant was made aware of the nature of the service being provided and that the data collected will be used for research purposes. Only once the participant read through the information leaflet and informed consent was obtained did testing commence.
- The CHW provided clear instructions of what the testing comprised of. The participant was instructed to raise their hand whenever they heard the tone presented.
- The hearing screening application required the CHW to enter the participant's name, surname, date of birth and gender. He/she also had to select the child (4-15 years of age) or adult (>15 years of age) protocol.
- The CHW thereafter placed the headphones on the participant and stood behind the participant before beginning the test.
- The hearing screening application employs automated test protocols. A sweep is performed at the test frequencies of 1, 2 and 4kHz bilaterally. The screening intensity is 25dB HL for the "child protocol" and 35dB HL for the "adult protocol".
- The smartphone microphone measured noise levels in the environment and employed a smart noise-monitoring algorithm that only initiates a rescreen if noise levels exceeded maximum permissible ambient noise levels (MPANLs) when there was a no response from a patient. In such cases CHWs received a warning on the software and could move to a quieter room or reduce background noise as much as possible before continuing the test. Testing would be completed on the second trial even if noise levels could not be reduced sufficiently. Noise levels were automatically recorded by the hearScreen™ application during the test.
- Screening began at 10dB HL above the initial pass or fail test intensity at 1kHz to condition the child/adult. Depending on the response from the child/adult, the CHW selected the "yes" or "no" option provided by the smartphone application. The hearing screening application will then

automatically move to the next test intensity and frequency.

- The stimulus was repeated once if the child/adult did not respond at any frequency and intensity level.
- The participant needed to respond to all tones in order to pass the hearing screening. Failure to hear a tone at any frequency in either ear constituted an overall 'refer' result after which an immediate second screen was initiated by the software. The second screening followed the same procedure. Each participant who referred the immediate second screen was referred to his/her closest primary health care clinic for comprehensive diagnostic testing.
- This clinic was scheduled three times a week when students from the University of Pretoria offered audiology services.
- Test results were shared with the researcher by uploading the data from the phones to a secured cloud-based server via a WIFI connection.

2.4.2 Phase 2 – CHW perceptions of community-based smartphone hearing screening

Materials and apparatus for data collection

A questionnaire using a 5-point rating scale, also known as the Likert-type scale (Leedy & Ormrod, 2010) were provided to the CHWs to elicit their perceptions of community-based primary care hearing screening regarding aspects such as usability, need for services, value to community members, time efficiency and perceptions regarding their involvement in this service delivery after the 12 week pilot study (Appendix E).

Participants

The participants of phase two of the study included the 24 CHWs who conducted hearing screenings during the first phase of the study.

Pilot study

Before the questionnaires were provided to the CHWs, a pilot study will be conducted in order to ensure the validity and reliability of this newly developed questionnaire. A pilot study aids in ensuring that accurate data is obtained and also increases the precision of the research method (De Vos, Strydom, Fouchè, & Delport, 2005). The questionnaire was provided to five second-year audiology students from the University of Pretoria who had sufficient experience in using the smartphone hearing screening application at Daspoort Clinic. The same procedure for data collection was used for this pilot study. Feedback was thereafter obtained from the students so that necessary changes could be made to the questionnaire.

Procedure for Data Collection

The procedure for data collection will comprise of the following:

- A participant information leaflet and informed consent form (Appendix D) was provided to the CHWs. This indicated that during household visits; CHWs will be required to offer to screen the hearing of family members, and only once the CHWs have obtained sufficient experience in using the hearing screening application, will a questionnaire need to be completed.
- Only once informed consent was obtained did data collection commence.
- The participants completed the questionnaire anonymously.
- The participants were required to provide an answer of 1 to 5 for ten questions, 1 representing that they strongly agree and 5 indicating that they strongly disagree with the question.
- An open-ended question was included for any additional comments regarding the hearing screenings conducted.
- Participants were requested to return the questionnaire within 5 working days of receiving it.

2.5 Data processing procedure

Data processing involves the integration of the data collected from diverse sources and the presentation of the data in a logical manner (Babbie & Mouton, 2001). Data preparation requires the researcher to code the data, enter the data and clean the data set (Terre Blanche, Durrheim, & Painter, 2006). For phase one of the study, data was extracted from the hearData cloud-based server to an MS Excel (2011) sheet for statistical analysis. For phase two of the study responses from the self-administered questionnaires were also coded into quantitative data in MS Excel (2011) for statistical analysis.

2.6 Data analysis procedure

Data collected during both phases was analyzed using a statistical software package, SPSS v22 (Chicago, Illinois). Within phase one of the study, descriptive statistical measures were employed to describe and synthesize the quantitative data collected (Irwin, Pannbacker, & Lass, 2008). Descriptive statistical measures were used to analyze referral rates and test times. An independent samples t-test was used to determine if age had an effect on screening results. Results of adults were divided into younger (below 45 years) and older adults (45 years and above) in order to conduct a Chi-square test to compare the effect of aging in referral rates. A Chi-square test was also used to determine gender effects on screening results. Frequency distributions and cross-tabulations were used to investigate screening outcomes where MPANLs were exceeded.

Within phase two of the study, descriptive statistical measures were used to analyze the responses from the questionnaire in terms of frequency distributions. Additional comments provided by CHWs were analyzed using thematic analysis where comments were considered carefully and coded for themes to meaningfully organize responses.

2.7 Reliability and Validity

The validity of a measurement instrument is the extent to which the instrument measures what it is supposed to measure (Leedy & Ormrod, 2010), whereas the reliability refers to the accuracy and consistency of measures (Bryman & Bell, 2007). Reliability and validity will be ensured in both phase one and two of the study.

Phase one:

- The newly developed hearScreen^{TM} smartphone application selected to conduct hearing screenings during phase one of the test is a valid and accurate tool. This was substantiated by a recent studies which revealed that this application shows valid acoustic calibration for audiometry according to prescribed standards and environmental noise monitoring, as well as comparable test results for conventional and smartphone-based hearing screening (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, & Hall, In Press; Swanepoel et al., 2014).
- Furthermore, equipment was calibrated monthly in order to ensure accurate and consistent results.
- All participants required to conduct hearing screenings were provided with adequate information and training prior to data collection during a training session.
- The test-retest method was used in order to ensure accurate results.

Phase two:

- After extensive research, a questionnaire was developed to address areas regarding the application used and community-based hearing screening for which there is a lack of information.
- A pilot study was conducted to ensure the reliability and validity of the questionnaire developed. This aided in predicting any inaccuracies or flaws in the questionnaire, which were altered before data collection took place.
- Furthermore, participants required to answer questionnaires were given anonymity in order to ensure that their true opinions were voiced.

3. SMARTPHONE HEARING SCREENING IN mHEALTH ASSISTED COMMUNITY-BASED PRIMARY CARE

Authors: Shouneez Yousuf Hussein, De Wet Swanepoel, Leigh Biagio de Jager, Hermanus C Myburgh, Robert H Eikelboom, Jannie Hugo

Journal: Journal of Telemedicine and Telecare
Accepted: 16 September 2015

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

3.1 Abstract

Introduction: Access to ear and hearing health is a challenge in developing countries where the burden of disabling hearing loss is greatest. This study investigated community-based identification of hearing loss using smartphone hearing screening (hearScreen™) operated by community health care workers (CHWs) in terms of clinical utility and reported experiences of CHW's.

Method: The study comprised two phases. During phase one 24 CHW's did community-based hearing screening as part of their regular home visits over 12 weeks in an underserved community using automated test protocols employed by the hearScreen™ smartphone application operating on low cost smartphones with calibrated headphones. During phase two CHWs completed a questionnaire regarding their perceptions and experiences of the community-based screening program.

Results: Data analysis was conducted on the results of 108 children (2-15 years) and 598 adults (16-85 years). Referral rates for children and adults were 12% and 6.5% respectively. Noise exceeding permissible levels had a significant effect on screen results at 25dB HL at 1kHz ($p<0.05$). Age significantly affected adult referral rates ($p<0.05$) demonstrating a lower rate (4.3%) in younger as opposed to older adults (13.2%). CHWs were positive regarding the hearScreen™ solution in terms of usability, need for services, value to community members and time efficiency.

Conclusion: Smartphone-based hearing screening allows CHWs to bring hearing health care to underserved communities at a primary care level. Active noise monitoring and data management features allow for quality control and remote monitoring for surveillance and follow-up.

3. 2 Introduction

Hearing loss is one of the most frequently occurring sensory deficits affecting individuals, communities and societies. There are 360 million people worldwide (5.3% of the global population) who live with a permanent disabling hearing loss, the majority of which could be prevented or treated (WHO, 2013). Hearing loss ranks third on the list of non-fatal disabling conditions (WHO, 2014). It is a silent and invisible condition associated with various deleterious consequences, including higher unemployment rates, poor health, social isolation, depression, dementia and increased mortality (Archbold, Lamb, O' Neill, & Atkins, 2014; Olusanya, Neumann, & Saunders, 2014).

The burden of disabling hearing loss is greatest in developing world regions, such as sub-Saharan Africa, where access to good quality ear and hearing health care is a major challenge (Fagan & Jacobs, 2009; WHO, 2012b, 2013). A greater concentration of human resources for ear and hearing health care is found in high- and upper-middle-income countries, while low- and middle-income countries account for more than 80% of individuals with hearing loss globally (Fagan & Jacobs, 2009; WHO, 2013). The WHO estimates that there is only one audiologist per 0.5 million to 6.25 million people in the developing world, with countries in sub-Saharan Africa typically presenting with less than one audiologist for every million people (Fagan & Jacobs, 2009; WHO, 2013).

The significant burden of hearing loss, and limited access to ear and hearing health services in developing countries require new methods of providing access to ear and hearing health care. Evidence suggests that primary health care visits may be the first and, in some instances, the only access to screening and treatment that individuals affected by disabling hearing loss may receive (Bogardus, Yueh, & Shekelle, 2003). Implementing ear and hearing health care services within primary health care, particularly within developing contexts, could provide individuals and communities who previously did not have access to ear and hearing health care, an opportunity to benefit from these services (Van der Linde & Kritzinger, 2013).

Unfortunately, many barriers exist to providing ear and hearing health care in primary health care settings. One obvious barrier is the high cost associated with screening and diagnostic equipment, which poses a serious challenge to the availability of ear and hearing care services in low- and middle-income countries (Clark & Swanepoel, 2014; Swanepoel et al., 2010). Self-report of hearing loss in primary health care settings may be quick and cost effective to identify hearing loss in adults. However, there is no way to ensure that persons with a hearing loss will not be missed (Swanepoel, Eikelboom, Hunter, Friedland, & Atlas, 2013). Furthermore, children are usually unable to self-report a hearing loss, and the use of questionnaires and checklists for identification in children may not always be accurate (Harlor & Bower, 2009). This is especially true of the more common mild hearing losses which may also lead to educational, social, and behavioral challenges (Harlor & Bower, 2009).

Novel approaches and service delivery models are required to increase access, for both adults and children, to ear and hearing health care services at a primary health care level. Studies have reported the use of health care personnel within primary health care settings, such as primary health care workers, nurses and community health care workers (CHWs), to successfully improve access of health care services within developing as well as developed countries (Horrocks, Anderson, & Salisbury, 2002; Maher, Smeeth, & Sekajugo, 2010; McCullagh & Frank, 2013; Stein, Lewin, & Fairall, 2007). The use of generalist health care workers may be extended to meet the ear and hearing health needs of a larger segment of the population (Howe et al., 2013). WHO primary ear and hearing care training manuals have been recommended for training primary health care workers and CHWs in developing countries in order to stimulate and encourage greater prioritization of prevention, identification and treatment of ear and hearing health care needs (WHO, 2006). This in turn may reduce the demand placed on already limited professional ear and hearing health human resources in developing countries.

In conjunction with generalist health personnel, innovative technological developments could be harnessed to overcome barriers to accessing ear and hearing health care, such as mobile health (mHealth) using smartphones, tablets, computers and other portable devices (Clark & Swanepoel, 2014; Davis & Smith, 2013). These new developments offer the potential to provide point of care diagnostics, allowing primary ear and hearing care services to be integrated with community-based programs, thereby enhancing access at grass-root levels and in homes to those in need (WHO, 2012a). mHealth applications can be linked to a network allowing the immediate sharing and management of patient specific data collected within the field.

A recent study reported the use of a smartphone-based hearing screening application (hearScreen™, hearScreen Pty, Pretoria, South Africa) for community-based services. By utilizing smartphones and off-the-shelf headphones, clinical screening outcomes showed no significant difference from conventional hearing screening (Mahomed-Asmail, et. al., In Press; Swanepoel et al., 2014). This type of screener offers an inexpensive alternative to conventional screening audiometry whilst adhering to required acoustic calibration standards and integrating quality control features like environmental noise monitoring and data management (Clark & Swanepoel, 2014; Swanepoel et al., 2014). Since recommended screening protocols are automated, screening personnel with no or limited health care training can operate the device to screen patients for disabling hearing loss. These advantages allow for asynchronous hearing assessments to be conducted within communities after which patient specific data and results collected on the smartphone application can be uploaded to a centralized cloud-based server through cellular networks for data management. This can be integrated with current community-based mHealth initiatives such as using smartphones to collect and manage data and care in community-based primary care (Bam et al., 2013; Howe et al., 2013).

Integrating low-cost, quick and user-friendly asynchronous smartphone-based hearing screening into novel contexts such as community-based primary health care initiatives, and empowering non-specialist personnel such as CHWs, could aid in prevention, early identification and treatment of disabling hearing loss in underserved regions. The current study therefore investigated a tele-assisted community-based program for identification of hearing loss using a smartphone-based hearing screener operated by generalist health workers (i.e. CHWs).

3.3 Method

Institutional review board clearance was obtained for this study before any data collection commenced. The study included two phases. The first phase evaluated the clinical utility of smartphone-based community hearing screening of children and adults by CHWs, and the second phase evaluated the experiences of CHWs conducting community-based hearing screening.

3.3.1 Phase 1: Clinical utility of smartphone hearing screening

Equipment

Samsung Trend Plus (S5301) smartphones (Android OS, 4.0), used by CHWs in the City of Tshwane, to collect and manage health status assessment data and care (using AITA Health™ software) were utilized for this study. The hearScreen™ application was installed on 24 of these phones to include hearing screening as an additional service, and supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany) were supplied for each phone. The application was developed at the University of Pretoria who provided the application ($120), headphones ($35) and calibration service ($80) for this study. A private company (hearScreen Pty; www.hearscreen.co.za) has since licensed it from the University of Pretoria. The hearScreen™ calibration function was used to calibrate the headphones according to prescribed standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Swanepoel et al., 2014). Calibration was performed using an IEC 60318-1 G.R.A.S. Ear stimulator connected to a Type 1 SLM (Rion NL-52). The hearScreen™ solution has been validated to monitor noise accurately within 1 and 1.5dB HL depending on the test frequency (Swanepoel et al., 2014). Noise levels are recorded and stored by the smartphone application during each screening conducted and a smart noise monitoring algorithm will repeat tests where a patient did not respond and noise levels exceeded maximum permissible ambient noise levels (MPANL).

Participants

Participants were selected from the community of Mamelodi, City of Tshwane, Gauteng Province, South Africa. Convenience sampling was used to invite all community members, including children four years of age and older, and adults that were seen by CHWs during home-based visits to participate in this study. The CHWs who served this community were also participants in the study. Twenty-four CHWs conducted behavioral pure tone hearing screenings over a period of three months.

Setting and procedures

Hearing screenings were conducted as part of an existing COPC (community-orientated primary care) initiative aimed at collecting and managing health status assessment data (Bam et al., 2013). Community members were recruited as CHWs to carry out primary health care within the COPC service (Marcus, 2014). The implementation of COPC assists in meeting the health needs of communities for whom the classical institution-based model of care is inaccessible (Marcus, 2014). Health posts are located within communities and consist of a health post manager and approximately 20 to 40 CHWs who are each assigned to approximately 150 to 200 households (Bam et al., 2013). CHWs offered hearing screenings to community members during home-based visits congruently to the collection and management of health status assessment data.

CHWs involved in this study had no formal training in ear and hearing health care. Prior to implementation of the first phase, a four-hour training session was held during which CHWs were provided with information regarding ear and hearing health care, and its importance, as well as training and hands-on practice with the hearing screening smartphone application.

The hearScreen™ application employs automated test protocols. A sweep was performed at the test frequencies of 1, 2 and 4kHz bilaterally. A screening intensity of 25dB HL for the "child protocol" (4 to 15 years) and 35dB HL for the "adult protocol" (16 years and above) was used. The smartphone microphone measured noise levels in the environment and employed a smart noise-monitoring algorithm that only initiates a rescreen if noise levels exceeded MPANLs when there was a no response from a patient. In such cases CHWs received a warning on the software and could move to a quieter room or reduce background noise as much as possible before continuing the test. Testing would be completed on the second trial even if noise levels could not be reduced sufficiently. Noise levels were automatically recorded by the hearScreen™ application during the test.

At the end of the testing week data, including patient identifiers and test results, were uploaded from phones to the hearScreen™ cloud-based server by a secure 256-bit encrypted SSL link via a WIFI connection. The cloud-based service is owned by the University of Pretoria and hosted by a local hosting service. For this study, the hearScreen™ application and server front end was a research version. For commercial purposes, users will be required to subscribe to the data management service. Patient identifiers captured included participant's gender and national identity numbers from which their date of birth was extracted. Audiometric screening employs clearly defined referral algorithms based on the test results that allow CHWs immediate and automated interpretations. All data collected was exported from the hearScreen™ cloud-based server to an MS Excel spreadsheet for data analysis. The server allows for text messages to be sent directly to the patient or their caregiver with test results and contact details of the closest hearing health providers based on the geo-location.

A CHW, seated behind each participant, instructed participants to raise their hand when they heard the tone presented through the calibrated headphones. Screening commenced in the left ear 10dB HL above the initial pass or fail test intensity at 1kHz to condition the child/adult. The screener, depending on the response given by the participant, indicated "yes" or "no" to whether a behavioral response to the stimulus was observed. The hearing screening application automatically moved to the next test intensity and frequency. The stimulus was repeated once if the child/adult did not respond at any frequency and intensity level. Failure to hear a tone at any frequency in either ear constituted an overall 'refer' result after which an immediate resecond screen was initiated by the software. Once testing was completed, the hearScreen™ application immediately calculated and displayed the results at each frequency and an overall 'pass' or 'refer' result to the CHW.

If a participant obtained a 'refer' result on the immediate rescreen, he/she was referred to the closest primary health care clinic for diagnostic testing. This clinic was scheduled three times a week when fourth year audiology students from the University of Pretoria offered screening and diagnostic audiology services. Diagnostic testing comprised of otoscopy, immittance testing and pure tone (air and bone conduction) audiometry. Once diagnostic testing was completed, participants were referred to their closest secondary or tertiary hospital that offered the required services.

Data analysis

Data were extracted from the hearData cloud-based server to an MS Excel sheet and analyzed using SPSS v22 (Chicago, Illinois). Descriptive statistical measures were used to analyze referral rates and test times. An independent samples t-test was used to determine if age had an effect on screening results. Results of adults were divided into younger (below 45 years) and older adults (45 years and above) in order to conduct a Chi-square test to compare the effect of aging in referral rates with $p<0.05$ used to indicate a significant effect. A Chi-square test was also used to determine gender effects on screening results. Frequency distributions and cross-tabulations were used to investigate screening outcomes where MPANLs were exceeded.

3.3.2 Phase 2: CHW perceptions of community-based smartphone hearing screening

Participants

The 24 CHWs who conducted hearing screenings during the first phase of the study were asked to indicate their experiences and perceptions of the community-based smartphone hearing screening in terms of usability, need for services, value to community members, time efficiency and their involvement in ear and hearing health care service delivery after the 12 week pilot study.

Procedures

CHWs were required to complete a questionnaire consisting of 10 questions (Appendix E) regarding their experiences with the hearing screenings they conducted. The questionnaire was completed at the end of the study. The questionnaire consisted of 10 questions to be answered using a five-point Likert rating scale (1-indicating strong agreement; 5-indicating strong disagreement). An open-ended question was included at the end of the questionnaire for CHWs to write any additional comments regarding the hearing screenings conducted. Participants completed the questionnaires anonymously.

Data analysis

Responses from the self-administered questionnaires were also coded into quantitative data in MS Excel 2011, and then analyzed using SPSS v22 (Chicago, Illinois). Descriptive statistical measures were used to analyze the data in terms of frequency distributions. The researcher analyzed additional comments provided by CHWs by using thematic analysis. This is a method for identifying, analyzing and coding themes within data collected in order to meaningfully organize the responses (Braun & Clarke, 2006). Data were read carefully to identify and code significant comments after which these were arranged in potential themes along with all relevant data to each potential theme.

3.4 Results

3.4.1 Phase 1: Clinical utility of smartphone hearing screening

A total of 820 participants including children and adults underwent hearing screening. All data were successfully uploaded to the hearScreen™ cloud-based sever on the first attempt from where it was exported to an MS excel spreadsheet. Each CHW screened an average of 32 participants (range 7-63; SD 16.6). Of these, 78 participants were excluded from the study, as their date of birth could not be accurately ascertained. An incorrect screening protocol (adult vs. child) was selected for 3.6% of children and 5.1% of adults. These participants were excluded from the study as well. A total of 108 children (2-15 years) and 598 adults (16-85 years) were included for data analysis.

Initial screen referral rates were 20.4% for children (n=108 participants) and 13.7% for adults (n=598 participants; Table 1). There was no significant difference between the initial referral rates in adults and children for left ears compared to right ears ($p>0.05$; Chi-Square). Immediately following a 'refer' result from the initial screening, a rescreen was initiated automatically. A total of 20 children and 69 adults were rescreened. Fifteen participants (2 children; 13 adults) failed to complete the rescreening due to a CHW inadvertently electing to skip this process. The overall screen referral rates were 12% for children and 6.5% for adults.

Age had a significant effect on the initial screening referral rate for adults ($p<0.05$; independent samples t-test) with average age for referring adults (46.2 years, SD 11.4) higher than for those who passed (35.6 years, SD 13.2). Furthermore, significantly fewer adults younger than 45 years of age failed the final screening test (4.3%), compared to adults aged 45 years and older (13.2%; $p<0.05$; Pearson Chi-Square). More females (n=422) than males (n=176) were screened. Although more females (14.5%) than males (11.9%) failed the initial screen, the difference was not significant ($p>0.05$; Pearson Chi-Square).

MPANLs were exceeded during some hearing screenings in children and adults at 1, 2 and 4kHz (Table 2). In children, a significant effect of exceeded MPANLs on passing or failing a screening was evident at 1kHz ($p<0.05$, Chi-square test), but not at 2 or 4kHz ($p>0.05$, Chi-square test). Noise levels demonstrated no significant effect on initial screen outcomes in adults at any frequency ($p>0.05$, Chi-square test).

Mean test duration recorded for children was 47.4 seconds (SD 20.0), with a rescreen mean duration of 50.0 seconds (SD 21.6). Adults displayed slightly lower average initial screen duration of 47.0 seconds (SD 28.8) and rescreen duration of 46.2 seconds (SD 19.6).

Table 1. Referral rates for screening in children and adults using the hearScreen™ smartphone application.

	Children		Adults	
	(n)	Refer (%)	(n)	Refer (%)
Initial Screen	108	20	598	14
Left	108	19	598	11
Right	108	12	598	7
Immediate Rescreen	20	55	69	28
Left	20	55	69	28
Right	20	55	69	28
Overall	108	12	598	7
Initial Screen				
Left 1kHz	108	13	598	7
Left 2kHz	108	13	598	6
Left 4kHz	108	8	598	6
Right 1kHz	108	8	598	5
Right 2kHz	108	7	598	6
Right 4kHz	108	6	598	5
Immediate Rescreen				
Left 1kHz	20	30	69	23
Left 2kHz	20	30	69	20
Left 4kHz	20	35	69	16
Right 1kHz	20	20	69	19
Right 2kHz	20	25	69	19
Right 4kHz	20	35	69	20

Table 2. Distribution of noise levels above maximum permissible ambient noise levels (MPANL's) for adults (screening level 35 dB HL) and children (screening level 25 dB HL).

Frequencies	Adults (%) (n=598)	Children (%) (n=108)
Left 1kHz	13	52
Right 1kHz	13	50
Left 2kHz	5	22
Right 2kHz	1	18
Left 4kHz	1	5
Right 4kHz	0	0

Phase 2: CHW perceptions of community-based smartphone hearing screening

Two thirds of CHWs (67%) indicated that hearing screening was easy to administer in children compared to 100% who agreed it was quick and easy to administer in adults (Table 3). The majority of CHWs were of the opinion that members of the community needed hearing health care services (87.5%) and that community members were positive about receiving this service (83.3%). CHW all agreed and strongly agreed that they would like to continue to provide hearing screenings as part of their services. Table 4 summarizes the central themes and illustrative quotes identified from the thematic analysis of CHWs comments.

Table 3. Distribution of CHW responses (%) on usability of smartphone screener, value of hearing screening to community and perceptions on involvement in hearing screening (n=24).

Questions	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. ***Instructions straightforward***	88	8	4	-	-
2. ***Administration easy (adults)***	75	25	-	-	-
3. ***Administration easy (children)***	33	33	17	13	4
4. ***Administration easy (quick)***	67	33	-	-	-
5. ***CHW trust results***	54	33	13	-	-
6. ***Important for community***	38	46	13	4	-
7. ***Community needs hearing health***	38	38	25	-	-
8. ***Community positive***	46	25	29	-	-
9. ***Community trust results***	67	25	8	-	-
10. ***Would continue service***	63	38	-	-	-

Table 4: Thematic analysis of CHW's comments regarding hearing screening.

Central Themes	Illustrative Quotes
Community need and satisfaction	- *"Community members are happy with the hearing screenings because they need to know about their ears"* - *"Community members want hearing screenings for toddlers."* - *"Community members want the audiologist to follow up on hearing screenings through home visits."*
Need for community education	- *"Most community members welcome the hearing screening but others do not understand the need for the screenings."*

	- *"Some community members do not want their hearing screened because they are afraid to be consulted."*
CHWs' commitment to provide services	- *"Hearing screening is important for the community to detect hearing problems and we need to know more about hearing."* - *"Hearing screenings should go out into the community in the form of a campaign so that a large number can be screened"* - *"Hearing screening is important for the community to detect hearing problems at an early stage."*

3.5 Discussion

Empowering CHWs through the use of mHealth applications is a novel approach to improve the range and access of primary care services such as ear and hearing health in both developing and developed contexts (Braun, Catalani, Wimbush, & Israelski, 2013; Shaw, 2015). However, the use of mHealth applications by CHWs to improve health care still requires expansion and evaluation in areas such as accessibility, productivity, quality and sustainability over time (Braun et al., 2013). To date, there has been a shortage of research evidence for community-based hearing loss detection programs, particularly in developing countries such as those in sub-Saharan Africa. In order to promote awareness of and access to ear and hearing health care in underserved populations, contextual evidence and guidelines are necessary for effective CHW programs. This study provides the first report on the clinical utility of a community-based hearing screening program in a developing country, using an mHealth screening solution (Swanepoel et al., 2014).

Twenty-four CHWs screened the hearing of 820 community members within a period of three months in addition to their regular workload. Results of 706 participants were used for data analysis since some exclusions were necessary because ages could not be determined from incorrect date of birth selections and wrong screening protocols selected (adult vs. child). The majority of adults screened (70.6%) were female, which is likely due to the fact that households were visited during the week within work hours.

The referral rate found in children (2-15 years) using the hearScreen™ application was 12%. A higher screen referral rate of 21.5% in children (±2-6 years) was found using conventional pure tone audiometry at a stimulus intensity of 5dB lower than the current study's child protocol (20dB HL)(Sideris & Glattke, 2006). Recent studies reported hearScreen™ smartphone referral rate of 4.3% for children aged 5 to 7 and 3.2% for children aged 6 to 12 (Mahomed-Asmail et al., In Press; Swanepoel et al., 2014). Higher referral rates in the current study are likely due to the effects of environmental noise. The MPANLs, as measured by the smartphone microphone, were exceeded in more than 50% of instances at 1kHz when screening children at an intensity of 25dB HL (left ears: 52% cases; right ears: 50% cases) and demonstrated a significant effect on referral rates at this frequency. Environmental noise poses a challenge to the successful implementation of hearing screening programs in uncontrolled environments such as schools, and in the case of the present study, during home-visits in underserved communities (American Academy of Audiology [AAA], 2011; Dodd-Murphy, Murphy, & Bess, 2014). Recent studies using smartphone applications have also reported effects of environmental noise on screening results, particularly at lower frequencies (Peer & Fagan, 2014; Swanepoel et al., 2014). This effect may be minimized in the future by considering increasing screening intensities to 30 or 35dB HL at 1kHz. MPANLs were only exceeded in approximately 12.5% of cases when screening at an intensity of 35dB HL at 1kHz.

The referral rate in adults was 6.5%. Age had a significant effect on referral rates with approximately 1 in 7 adults (13.2%) older than 45 failing the screen, in line with the effects of age-related hearing loss demonstrated in epidemiology studies (Nash, Cruickshanks, Klein, Klein, Nieto, & Huang et al., 2011; Stevens, Flaxman, Brunskill, Mascarenhas, Mathers, & Finucane et al., 2011). For example, overall prevalence of hearing loss in the Beaver Dam Offspring Study (pure tone average [PTA] > 25dB HL) increased from 2.9% in persons aged 21 to 34 years, to 10.9% in persons aged 45 to 54 years, and to 42.7% in those aged 65 to 84 years (Nash et al., 2011).

Rescreens have been recommended directly after initial screening refers in order to minimize the number of false positive results, and has proven to reduce the number of failures in children by half (AAA, 2011). Referral rates in children and adults dropped by 8.4% (from 20.4%) and by 7.2% (from 13.7%) respectively after the immediate rescreen.

Counter-intuitively pass rates were higher for children and adults when noise levels exceeded MPANLs. This is likely related to the way that the screening application records noise levels. If a child or adult failed the initial screen, CHWs were prompted by the application to reduce noise levels before rescreening. The hearScreen^{TM} application would only record new noise levels for the rescreen if they exceeded the initial screening noise levels. Therefore, when participants passed the rescreen, recorded noise levels represented the loudest noise levels recorded during the initial and rescreen.

Average test time for the smartphone hearing screening, excluding test setup and instructions, was less than a minute (children: 47.4s, SD 20.0s; adults: 47.0s, SD 28.8). In comparison, other studies reported average testing time for conventional hearing screening of more than two minutes for children (Sideris & Glattke, 2006; Wu et al., 2014). The short testing time and minor investment in additional resources (viz. application and headphones) allows for smartphone hearing screening to be integrated in COPC initiatives facilitated by CHWs with additional primary health care duties.

All CHWs indicated that the hearScreen^{TM} application was easy to administer in adults, whilst 16.7% reported that testing children was difficult. CHWs may require more information and experience to ensure better competency and confidence in testing children. CHWs also expressed the need for community education regarding the necessity and importance of ear and hearing health care. mHealth tools have shown to be useful in supporting education of CHWs (Braun et al., 2013). CHWs can be trained to successfully screen for hearing loss within their communities using smartphone technology. This supports the notion that non-specialist hearing health care personnel could implement community-based health services which could in turn ease the demand placed on already limited professionals (Fagan & Jacobs, 2009; McCullagh & Frank, 2013; Olusanya, Wirz, & Luxon, 2008; WHO, 2006).

Some problems were identified with the CHW community-based screening. Firstly, the test protocol for adults and children was incorrectly selected for 3.6% of children and 5.1% of adults in the sample. A secondary problem was that fifteen participants who referred on the initial screening did not undergo a rescreening. This was because CHWs inadvertently exited the smartphone application before the rescreen commenced or before the rescreen could be completed. Changes in the software should be made to automatically select adult/child protocols based on date of birth to avoid any possible error, as well as to disable the option of canceling a rescreen or exiting the application during a rescreen.

The current study would have benefitted from information on what transpired following the referral for diagnostic assessment. Follow-up rates could not be established however, due to record keeping errors for identification numbers and/or birth dates and the limited monitoring period at primary health care clinics post screening. Diagnostic hearing testing at the primary health care clinic was terminated at the end of the data-collection period due to end of year exams commencing for students. Recent studies indicated that although individuals are screened for hearing loss, the actual follow-up rate to seek further assessment after failing a hearing screen was low (Amlani, 2015; Thodi et al., 2013). The integration of informational counseling could provide CHWs with clear guidelines and prompts to assist them in explaining screening results, and to educate and motivate those who referred to pursue follow-up services. Integrating a system for sending reminders directly to patients by means of text messages, for example, may also increase follow-up return rates and direct them to the nearest clinic offering relevant services (Leong et al., 2006; Liew et al., 2009; Perron et al., 2010).

3.6 Conclusion

Generalist CHWs can successfully screen the hearing of both children and adults during home-based visits as part of a tele-assisted community-based primary care program. An mHealth hearing screening application with automated test sequences, integrated noise monitoring, data capturing and data sharing makes asynchronous hearing assessments possible. Furthermore, centralized data management allows for immediate and automated interpretations of results obtained through asynchronous hearing screenings by CHWs. The hearScreen™ adult protocol allows for hearing screenings to be conducted on community members during home-based visits within the community. However, environmental noise poses a challenge when screening at the lower frequencies (viz. ≤1kHz) when using a 25dB HL level intended for children. Improvements in the data collection process were also recommended to better record keeping of patient details. CHWs displayed a positive attitude towards smartphone hearing screenings and wanted to continue providing the service. Screening hearing in children was identified by CHWs as an area in which they required additional experience. CHWs showed commitment to improving the hearing health status within their community and were motivated to continue this mHealth hearing screening service.

4. DISCUSSION AND CONCLUSION

4.1 Discussion of Results

Training of generalist health care personnel, such as CHWs, to employ mHealth applications particularly within community and primary health care settings may be vital to improve access to hearing health care within South Africa (Braun et al., 2013; Howe et al., 2013; Shaw, 2015). However, the use of mHealth applications by CHWs to improve health care still requires expansion and evaluation in areas such as accessibility, productivity, quality and sustainability over time (Braun et al., 2013). Primary ear and hearing care training manuals have been recommended for training primary health care workers and CHWs by the WHO in order to improve the prevention, identification and treatment of ear and hearing health care needs (WHO, 2006). However, there is a lack of research and contextually based evidence to successfully implement community-based hearing screening programs especially in developing contexts, as South Africa, where the incidence of hearing loss is greatest (WHO, 2014). This study was conceptualised as a first phase to implement and determine the clinical utility of a community-based hearing screening program within the developing context of South Africa through the use of an mHealth solution facilitated by CHWs.

4.1.1 Phase one: Clinical utility of smartphone hearing screening

Community-based hearing screenings were conducted over a period of 12 weeks during which 820 participants including children and adults were screened. The results of 78 participants was excluded from the study as their correct date of birth could not be determined. Results of 3.6% of children and 5.1% of adults were also excluded as an incorrect screening protocol (adult vs. child) was selected. A total of 706 participants (108 children and 598 adults) were included for data analysis. The study findings are presented in the following sub-sections.

Referral rate

Referral rates were analyzed and compared to other studies in order to compare the clinical utility of a community-based hearing screening program. A referral rate of 12% was found in children (2-15 years) using the hearScreen™ application. A higher screen referral rate of 21.5% in children (2-6 years) was found using conventional pure tone audiometry, however a stimulus intensity of 5dB lower than the current study's child protocol (20 vs 25dB HL) was used (Sideris & Glattke, 2006). Recent studies reported hearScreen™ smartphone referral rates of 4.3% for children aged 5 to 7 and 3.2% for children aged 6 to 12 (Mahomed-Asmail et al., In Press; Swanepoel et al., 2014). The effects of environmental noise at 1kHz may explain the higher referral rate obtained in the current study as discussed in the sections below.

Referral rate in adults was 6.5%, with the average age for referring adults (46.2 years, SD 11.4) higher than for those who passed (35.6 years, SD 13.2). Furthermore, a lower percentage of 4.3% adults younger than 45 years of age failed the screening test compared to 13.2% of adults aged 45 years and older. This corresponds with the expected effect of presbyacusis reported in other epidemiology studies (Nash et al., 2011; Stevens et al., 2011). Presbyacusis is the loss of hearing related to the aging process which results in reduced hearing sensitivity and speech understanding in noisy environments, slowed central processing of acoustic information and impaired localization of sound sources (Gates & Mills, 2005; Thodi et al., 2013). For example, overall prevalence of hearing loss in the Beaver Dam Offspring Study (pure tone average [PTA] > 25dB HL) increased from 2.9% in persons aged 21 to 34 years, to 10.9% in persons aged 45 to 54 years, and to 42.7% in those aged 65 to 84 years (Nash et al., 2011). Gender effects on referral rates were not significant.

Rescreens have been recommended directly after initial screening refers in order to minimize the number of false positive results, and has proven to reduce the number of failures in children by half (AAA, 2011). Referral rates in children and adults dropped by 8.4% (from 20.4%) and by 7.2% (from 13.7%) respectively after the immediate rescreen.

Compliance of test environment during screening

MPANLs were exceeded at the frequencies of 1, 2 and 4kHz when testing both children and adults, however significant effects of exceeded noise levels on referral rates were only evident when testing children at a lower intensity of 25dB HL at 1kHz. The MPANLs, as measured by the smartphone microphone, were exceeded in more than 50% of instances (left ears: 52% cases; right ears: 50% cases) and demonstrated a significant effect on referral rates at this frequency. This finding was consistent with recent studies using smartphone applications that also reported effects of environmental noise on screening results, particularly at lower frequencies (Peer & Fagan, 2014; Swanepoel et al., 2014).

Time proficiency of the hearing screening

Studies have reported average testing time for conventional hearing screening of more than two minutes for children (Sideris & Glattke, 2006; Wu et al., 2014). In comparison, smartphone hearing screening proved to be more time effective. Smartphone hearing screenings, excluding test set up and instructions, was conducted in an average of 47.4s (SD 20.0s) in children and 47.0s (SD 28.8S) in adults. This short test time allows for a greater number of the community to be screened within the test day, while still allowing CHWs to conduct additional primary health care duties.

4.1.2 Phase two: CHW perceptions of community-based smartphone hearing screening

Majority of CHWs responded positively regarding smartphone hearing screenings in terms of usability, need for services, value to community members, time efficiency and perceptions regarding their involvement in this service delivery. However, 16.7% reported that testing children was difficult. CHWs may require more information and experience to ensure better competency and confidence in testing children.

Thematic analysis of the CHWs comments revealed three central theme, viz. community need for and satisfaction with ear and hearing care services, CHW's commitment to continue to provide ear and hearing care services and a need for community education regarding the necessity and importance of ear and hearing health care. mHealth tools have shown to be useful and can be used further to support the education needs of CHWs and in turn of the communities which they serve (Braun et al., 2013).

4.2 Clinical implications and recommendations

Results of this study demonstrate that integration of mHealth screening initiatives by CHWs within a community-based setting can be a provide a way of providing access to cost effective and time efficient hearing evaluations at grass root levels to persons whom hearing services are not readily accessible. Findings from this study can be analyzed and improved in order to optimize such services. These are described below.

CHWs to improve service delivery

Empowering CHWs to meet health care needs through the use of mHealth applications is a new concept evolving not only in developing but also developed contexts (Braun et al., 2013; Shaw, 2015). Generalist health workers, such as CHWs, may be key in addressing the shortage of ear and health care professionals as well as to aid communities in reaching health care centers (Howe et al., 2013). Results from the screening as well as the questionnaires indicated that CHWs could successfully screen for hearing loss using the hearScreen™ application, thus supporting the notion that generalist hearing healthcare personnel could implement community-based health services (Fagan & Jacobs, 2009; McCullagh & Frank, 2013; Olusanya et al., 2008; WHO, 2006).

mHealth tools

Results including referral rates, environmental noise monitoring, time proficiency of the hearScreen™ smartphone application and the perceptions of CHWs, indicate that an mHealth solution can be utilized to improve the prevention and identification of hearing loss with minor adaptions for integration into a community-based setting. Environmental noise poses a challenge to the successful implementation of hearing screening programs in uncontrolled environments such as schools, and in the case of the present study, during home-visits in underserved communities (AAA, 2011; Dodd-Murphy et al., 2014). This effect may be minimized in the future by considering an increase in screening intensities at 1kHz from to 30 or 35dB HL. MPANLs were only exceeded in approximately 12.5% of cases when screening at an intensity of 35dB HL at 1kHz. This in turn may lower the high referral rate obtained in children in comparison to other studies.

An added benefit of using mHealth tools for hearing screening is that it allows for data-capturing and data sharing on site. This means that screening results can be immediately shared with an audiologist, allowing remote management when CHWs are testing in the field. Smartphones present with a geotag feature that can easily be used to identify the closest referral center that offers audiological services. This furthermore provides the option of directly conveying results and referral centers (geotagged) to the mobile devices of those who referred or their caregivers.

mHealth tools have shown to be useful and can be used further to support the education needs of CHWs and in turn of the communities which they serve (Braun et al., 2013). Guidelines and informational counseling may be integrated into the hearScreen™ application in order to better equip CHWs when seeing more difficult to test individuals, as well as to provide readily available and relevant information that may be needed when testing in the field.

Program Coordinator

The need for a program coordinator was demonstrated by the inability to detect follow-up rates at the primary health care clinic. Furthermore, ongoing support and training of the CHWs may have reduced errors such as selection of the incorrect screening protocol and incorrect recoding of client information. A recent study demonstrated the importance of a program coordinator to monitor quality and provide on-going support and training (Friderichs, Swanepoel, & Hall, 2012). Within the scope of practice of audiology, is a responsibility to promote hearing wellness through community hearing conservation and identification programs (American Speech-Language-Hearing Association [ASHA], 2004). Audiologists should therefore serve as a program coordinator thereby ensuring an effective screening program. The role of these audiologists may include training of CHWs, ongoing support and education of CHWs, regular calibration of equipment, follow-up diagnostic testing of individuals who fail community-based screenings, as well as intervention or appropriate referral of individuals.

4.3 Proposed community-based hearing screening program

A proposed model for community-based hearing screening program is indicated in Figure 1 below:

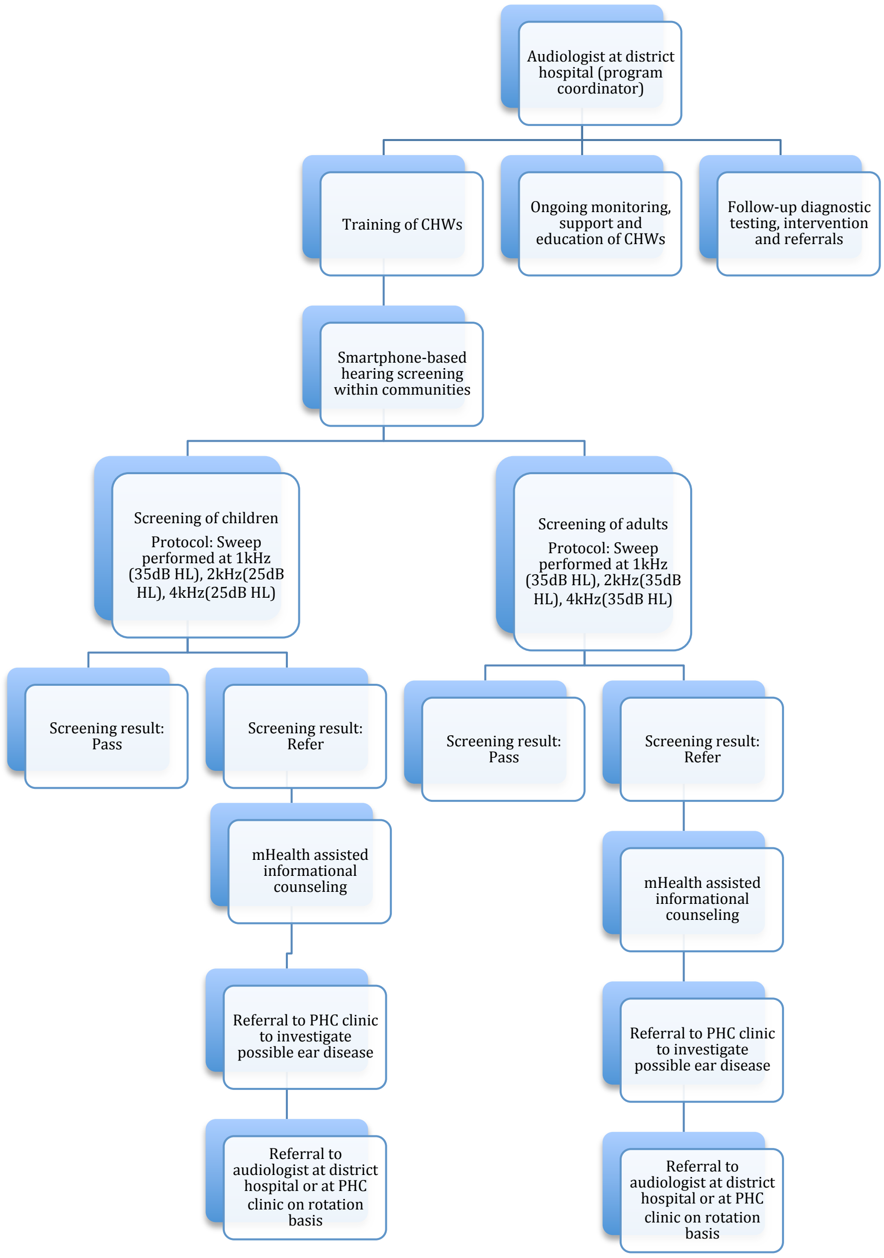

Figure 1: Conceptual Model for Community-Based Hearing Screening

The above model was designed from the clinical implications and recommendations in mind. The implementation of COPC aids in meeting the health needs of communities for whom the classical institution-based model of care is inaccessible (Marcus, 2014). Health posts are typically located within communities and consist of a health post manager and approximately 20 to 40 CHWs who are each assigned to approximately 150 to 200 households (Bam et al., 2013). CHWs will offer hearing screenings to community members during home-based visits congruently to other health care duties.

The smartphone screening protocol for children is proposed to be changed to 35dB HL at 1kHz to compensate for the effects of environmental noise. Automated mHealth assisted informational counseling should also be integrated into the smartphone application when community members refer on screenings, in order to guide CHWs on conveying results, making appropriate referrals and motivating community members to attend follow-up appointments.

Since audiologists are rarely based at primary health care clinics, an audiologist based at a district hospital could serve as a program coordinator. The main duties of the audiologist will be to train CHWs and to provide ongoing monitoring, support and education of CHWs. Monthly meetings should take place at each health post to ensure a sustainable and effective program. If audiological services are not available to community members at their closest primary health care clinic, the audiologist based as the district hospital will also have the responsibility to conduct follow-up diagnostic testing, intervention and make appropriate referrals.

4.4 Critical evaluation

A critical evaluation of the research project is crucial in order to interpret the findings of the research within the framework of its strengths and limitations. These are highlighted below:

Strengths of study

This study was the first to investigate a community-based hearing screening program facilitated by CHWs through the use of an mHealth hearing screening solution. Thus it provided a baseline regarding the clinical utility of community-based hearing screening programs. Firstly, this study emphasized the potential of CHWs to act as hearing screening personnel. Secondly, it demonstrated the benefits of integrating an mHealth smartphone hearing screening solution as opposed to conventional screening methods. Lastly, this study provided information upon which to build future community-based hearing programs and assisted in identifying the limitations that need to be addressed for a sustainable and effective program.

Limitations of study:

The greatest limitation of this study was that the follow-up rate and in turn diagnostic outcomes of the screenings could not be determined. This was attributed to record keeping errors for identification numbers and/or birth dates and the limited monitoring period at primary health care clinics post screening. Secondly, the sensitivity and specificity of the hearing screenings could not be dertmined. Thirdly, results of 3.6% of children and 5.1% had to be excluded as the incorrect screening protocol was selected. Fourthly, fifteen participants who referred on the initial screening did not undergo a rescreening.

4.5. Future research

Results from this study created a potential for future research regarding a number of aspects. Changes in the hearScreen™ smartphone software should be made to automatically select adult/child protocols based on date of birth to avoid any possible error, as well as to disable the option of canceling a rescreen or exiting the application during a rescreen, thereby ensuring an efficient screening tool. Additional pilot studies should be conducted in order to determine if follow-up rates increase with improved recording keeping and if sufficient time is provided for follow-up testing at primary health care clinics. Furthermore, education of communities regarding the importance and necessity of ear and hearing health care may be necessary in order to ensure that they understand and are motivated to have their hearing screened as well as attend follow-up appointments. Recent studies indicated that although individuals are screened for hearing loss, the actual follow-up rate to seek further assessment after failing a hearing screen was low (Amlani, 2015; Thodi et al., 2013). The integration of guidelines and informational counseling into the hearScreen™ appliaction could assist CHWs in explaining the importance of hearing screening, what hearing screening results mean, as well as to educate and motivate those who referred to pursue follow-up services. Integrating a system for sending reminders directly to patients by means of text messages, for example, may also increase follow-up return rates and direct them to the nearest clinic offering relevant services (Leong et al., 2006; Liew et al., 2009; Perron et al., 2010).

4.6. Conclusion

The integration of a mHealth hearing solution into community-based hearing screening programs is a novel approach to improving ear and hearing health care needs which was explored for the first time within the South African context. The study highlighted that CHWs are motivated to and can competently screen for hearing loss within a community-based primary health care program, thereby lessening the burden placed on limited professionals for ear and hearing health care. Smartphone hearing screenings offer advantages such as automated test protocols, integrated noise monitoring, data capturing and data sharing, thus allowing hearing screenings to be conducted at grass-root levels and in homes. Integrating mHealth hearing solutions into community-based hearing screening programs may allow a larger portion of the population within developing countries, to whom ear and hearing health care would have been inaccessible, to be reached.

5. References:

American Academy of Audiology (AAA). (2011). American academy of audiology childhood hearing screening guidelines. Retrieved 01 May 2015 from www.cdc.gov/ncbddd/hearingloss/documents/aaa_childhood-hearing-guidelines_2011.pdf

Amlani, A. M. (2015). Improving patient compliance to hearing healthcare services and treatment through self-efficacy and smartphone applications. *Hearing Review*, *21*(2).

Archbold, S., Lamb, B., O' Neill, C., & Atkins, J. (2014). The real cost of adult hearing loss: Reducing its impact by increasing access to the latest hearing technologies. *Retreived 30 April 2014 from* www.earfoundation.org.uk/files/download/869

American Speech-Language-Hearing Association (ASHA). (2004). Scope of practice in audiology. Retrieved 21 July 2015 from www.asha.org/policy.

Babbie, E., Mouton, J. (2001). The practice of social research, South African edition. Cape Town: Oxford University Press Southern Africa.

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 and Family Medicine*, *5*(1), 13–15. doi:10.4102/phcfm.v5i1.423

Bogardus, S. T., Yueh, B., & Shekelle, P. G. (2003). Screening and management of adult hearing loss in primary care: Clinical applications. *The Journal of the American Medical Association*, *289*(15), 1986–1990. doi:10.1001/jama.289.15.1986

Braun, R., Catalani, C., Wimbush, J., & Israelski, D. M. (2013). Community health workers and mobile technology: A systematic review of the literature. *PloS One*, *8*(6). doi:10.1371/journal.pone.0065772

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. doi:10.1191/1478088706qp063oa

Bryman, B., Bell, E. (2007). Business research methods. New York: Oxford University Press.

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. doi:10.3109/17483107.2014.905642

Davis, A., & Smith, P. (2013). Adult hearing screening: Health policy issues- what happens next? *American Journal of Audiology*, *22*(1), 167–170. doi:10.1044/1059-0889(2013/12-0062)

De Vos, A. S., Strydom, H., Fouché, D. B., & Delport, C. S. L. (2005). *Research at Grassroots: For social sciences and human service professions (*3rd ed). Pretoria: Van Schaik Academic Publishers

Dodd-Murphy, J., Murphy, W., & Bess, F. H. (2014). Accuracy of school screenings in the identification of minimal sensorineural hearing loss. *America Journal of Audiology*, *23*, 365–373. doi:10.1044/2014

Fagan, J. J., & Jacobs, M. (2009). Survey of ENT services in Africa: Need for a comprehensive intervetion. *Global Health Action, 2*, 1932-1939. doi:103402/gha.v2i0.1932.

Foulad, A., Bui, P., & Djalilian, H. (2013). Automated audiometry using apple iOS-based application technology. *American Academy of Otolaryngology-Head and Neck Surgery*, *149*(5), 700–706. doi:10.1177/0194599813501461

Friderichs, N., Swanepoel, D., & Hall, J. W. (2012). Efficacy of a community-based infant hearing screening program utilizing existing clinic personnel in Western Cape, South Africa. *International Journal of Pediatric Otorhinolaryngology*, *76*(4), 552–559. doi:10.1016/j.ijporl.2012.01.015

Friederici, N., Hullin, C., & Yamamichi, M. (2012). mHealth. In World Bank (Ed.), 2012 Information and communications for development: Maximizing mobile (pp. 45-57). Washington, DC: World Bank.

Gates, G. A., & Mills, J. H. (2005). Presbycusis. *The Lancet*, *366*, 1111–1120. doi:10.1016/S0140-6736(05)67423-5

Harlor, A. D. B., & Bower, C. (2009). Hearing assessment in infants and children: Recommendations beyond neonatal screening. *American Academy of Pediatrics, 124*(4), 1252–1263. doi:10.1542/peds.2009-1997

Horrocks, S., Anderson, E., & Salisbury, C. (2002). Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors. *British Medical Journal (Clinical Research Edition)*, *324*, 819–823. doi:10.1136/bmj.324.7341.819

Howe, A. C., Mash, R. J., & Hugo, J. F. M. (2013). Developing generalism in the South African context. *South African Medical Journal*, *103*(12), 899–900. doi:10.7196/SAMJ.7509

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*(1), 42–47. doi:10.1017/S0266462312000761

International Standardization Organization (ISO) 389-1. (1998). Acoustics - Reference zero for the calibration of audiometric equipment. Part 1: Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones. Retrieved 30 May 2014 from www.iso.org/obp/ui/#iso:std:iso:389:-1:ed-1:v1:en

International Standardization Organization (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. Retrieved 30 May 2014 from www.iso.org/obp/ui/#iso:std:iso:389:-9:ed-1:v1:en

Irwin, D. L., Pannbacker, M., & Lass, N. J. (2008). Clinical research methods in speech-language pathology and audiology. San Diego, CA: Plural Publishing, Inc.

Kinkel, H. F., Marcus, T., Memon, S., Bam, N., & Hugo, J. (2012). Community orientated primary care in Tshwane District, South Africa: Assessing the first phase of implementation. *African Journal of Primary Health Care and Family Medicine*, *5*(1). doi:10.4102/phcfm.v5i1.477.

Leedy, P. D., & Ormrod, J. E. (2010). Practical research: Planning and Design (9th ed.). New Jersey: Pearson Education, Inc.

Leong, K. C., Chen, W. S., Leong, K. W., Mastura, I., Mimi, O., Sheikh, M. A., … Teng, C. L.(2006). The use of text messaging to improve attendance in primary care: A randomized controlled trial. *Family Practice*, *23*(6), 699–705. doi:10.1093/fampra/cml044

Liew, S., Tong, S. F., Kar, V., Lee, M., Ng, C. J., Leong, K. C., & Teng, C. L. (2009). Text messaging reminders to reduce non-attendance in chronic disease follow-up : A clinical trial. *British Journal of General Practice*, *59*, 916–920. doi:10.3399/bjgp09X472250.Conclusion

Maher, D., Smeeth, L., & Sekajugo, J. (2010). Health transition in Africa: Practical policy proposals for primary care. *Bulletin of the World Health Organization*, *88*, 943–948. doi:10.2471/BLT.10.077891

Mahomed-Asmail, F., Swanepoel, D. W., Eikelboom, R. H., Myburgh, H. C., & Hall, J. W. (In Press). Clinical validity of hearScreen™ smartphone hearing screening for school children. *Ear and Hearing*.

Marcus, T. S. (2014). Community orientated primary care: Origins and history. Pretoria: Minuteman Press Lynwood.

Martínez-Pérez, B., de la Torre-Díez, I., & López-Coronado, M. (2013). Mobile health applications for the most prevalent conditions by the World Health Organization: Review and analysis. *Journal of Medical Internet Research*, *15*(6). doi:10.2196/jmir.2600

Mathers, C., Smith, A., & Concha, M. (2000). Global burden of hearing loss in the year 2000. *World Health Organisation*. Retrieved 11 March 2014 from www.who.int/healthinfo/statistics/bod_hearingloss.pdf

Maxwell, D. L., & Satake, E. (2006). Research and statistical methods in communication sciences & disorders (1st ed.). Boston: Thomson Delmar Learning.

McCullagh, M. C., & Frank, K. (2013). Addressing adult hearing loss in primary care. *Journal of Advanced Nursing*, *69*(4), 896–904. doi:10.1111/j.1365-2648.2012.06078.x

Mouton, J. (2001). How to succeed in your master's and doctoral studies: A South African guide and research book. Pretoria: Van Schaik.

Nash, S. D., Cruickshanks, K. J., Klein, R., Klein, B. E. K., Nieto, F. J., Huang, G. H., … Tweed, T. S. (2011). The prevalence of hearing impairment and associated risk factors: the Beaver Dam Offspring Study. *Archives of Otolaryngology Head and Neck Surgery*, *137*(5), 432–439. doi:10.1001/archoto.2011.15

National Department of Health. (2011). Republic of South Africa, National Health Insurance in South Africa, Policy paper, Pretoria: Department of Health. Available from www.health-e.org.za/documents/2bcce61d2d1b8d972af41ab0e2c8a4ab.pdf.

National Treasury Department: Republic of South Africa. (2005). Provincial Budgets and Expenditure Review: 2001/02 – 2007/08. Retrieved 07 March 2014 from www.treasury.gov.za/publications/igfr/2005/prov/06.

Olusanya, B. O., Neumann, J., & Saunders, J. E. (2014). The global burden of disabling hearing impairment : A call to action. *Bulletin of the World Health Organization*, *92*, 367–373. doi:http://dx.doi.org/10.2471/BLT.13.128728

Olusanya, B. O., Wirz, S. L., & Luxon, L. M. (2008). Community-based infant hearing screening for early detection of permanent hearing loss in Lagos, Nigeria: A cross-sectional study. *Bulletin of the World Health Organization*, *86*(12), 956–963.

Peer, S., & Fagan, J. J. (2014). Hearing loss in the developing world: Evaluating the iPhone mobile device as a screening tool. *South African Medical Journal*, *105*(1), 35–39. doi:10.7196/samj.8338

Perron, N. J., Dao, M. D., Kossovsky, M. P., Miserez, V., Chuard, C., Calmy, A., & Gaspoz, J. M. (2010). Reduction of missed appointments at an urban primary care clinic: A randomised controlled study. *BMC Family Practice*, *11*(79). doi:10.1186/1471-2296-11-79

Qiang, C. Z., Yamamichi, M., Hausman, V., Miller, R., & Altman. D. (2012). Mobile applications for the health sector. ICT Sector Unit, World Bank, Washington, DC. Retrieved 07 March 2014 from www.siteresources.worldbank.org/INFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/Resources/mHealth_report.pdf

Shaw, G. (2015). Community health workers bridge gap to hearing loss treatment. *The Hearing Journal*, *68*(5), 8–10.

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

Stein, J., Lewin, S., & Fairall, L. (2007). Hope is the pillar of the universe: Health-care providers' experiences of delivering anti-retroviral therapy in primary health-care clinics in the Free State province of South Africa. *Social Science and Medicine*, *64*(4), 954–964. doi:10.1016/j.socscimed.2006.10.028

Stevens, G., Flaxman, S., Brunskill, E., Mascarenhas, M., Mathers, C. D., & Finucane, M. (2011). Global and regional hearing impairment prevalence: An analysis of 42 studies in 29 countries. *European Journal of Public Health*, *23*(1), 146–152. doi:10.1093/eurpub/ckr176

Swanepoel, D. W., Störbeck, C., & Friedland, P. (2009). Early hearing detection and intervention in South Africa. *International Journal of Pediatric Otorhinolaryngology*, *73*(6), 783–786. doi:10.1016/j.ijporl.2009.01.007

Swanepoel, D. W. (2006). Audiology in South Africa. *International Journal of Audiology*, *45*(5), 262–266. doi:10.1080/14992020500485650

Swanepoel, D. W. (2010). Tele-audiology: Providing remote hearing health care. *Audiology Today*, *22*(2), 38–45.

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. doi: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), 514–521. doi:10.3766/jaaa.24.6.7

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*, 841–849. doi:10.3109/14992027.2014.920965

Terre Blanche, M., *Durrheim*, K., & *Painter*, D. (*2006*). Research in practice: Applied methods for the social sciences. (2nd ed.). Cape Town: UCT Press.

Thodi, C., Parazzini, M., Kramer, S. E., Davis, A., Stenfelt, S., Janssen, T., … Grandori, F. (2013). Adult hearing screening: Follow-up and outcomes. *American Journal of Audiology*, *22*, 183–185. doi:10.1044/1059-0889(2013/12-0060)

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 and Family Medicine*, *5*(1). doi:10.4102/phcfm.v5i1.553

World Bank. (2008). Africa development indicators 2007. World Bank Publications. Washington, DC. Retrieved 07 March 2014 from www.siteresources.worldbank.org/INTSTATINAFR/Resources/adi2007_final.pdf

World Health Organization (WHO). (2006). Primary ear and hearing care training resource. *World Health Organisation*. Geneva: Switzerland. Retrieved on 26 February 2015 from www.who.int/pbd/deafness/activities/hearing_care/advanced.pdf

World Health Organization (WHO). (2012a). Community-based rehabilitation promoting ear and hearing care through CBR. *World Health Organisation*. Retrieved on 11 November 2014 from www.who.int/pbd/deafness/news/CBREarHearingCare.pdf

World Health Organization (WHO). (2012b). WHO global estimates on prevalence of hearing loss. *World Health Organisation*. Retrieved 15 April 2014 from www.who.int/pbd/deafness/estimates.

World Health Organization (WHO). (2013). Multi-country assessment of national capacity to provide hearing care. *World Health Organisation*. Retrieved April 30, 2014, from www.who.int/pbd/publications/WHOReportHearingCare_Englishweb.pdf

World Health Organization (WHO). (2014). Deafness and hearing loss. Retrieved 3 December 2014, from www.who.int/mediacentre/factsheets/fs300/en/

Wu, W., Lü, J., Li, Y., Kam, A. C. S., Tong, M. C. F., Huang, Z., & Wu, H. (2014). A new hearing screening system for preschool children. *International Journal of Pediatric Otorhinolaryngology*, *78*, 290–295.

6. Appendices

Appendix A:
Ethical Clearance Form: Faculty of Humanities

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

5 July 2015

Dear Prof Vinck

Project:	**Community-orientated primary care: Smartphone-based hearing screening**
Researcher:	**Yousuf Hussein S**
Supervisor:	**Prof DCD Swanepoel**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**28121262**

Thank you for the your response to the Committee's correspondence of 1 September 2014.

I have pleasure in informing you that the Research Ethics Committee formally **approved** the above study at an *ad hoc* meeting held on 5 July 2015. 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 your 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

Kindly note that your original signed approval certificate will be sent to your supervisor via the Head of Department. Please liaise with your supervisor.

Appendix B:
Ethical Clearance Form: Faculty of Health Sciences

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA 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:
Participant Information Leaflet and Informed Consent Form for Hearing Screening

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

INFORMATION LEAFLET & INFORMED CONSENT FORM FOR NON-CLINICAL RESEARCH

TITLE OF THE STUDY:

Researching the Development, Application and Implementation of Community Oriented Primary Care (COPC). A study in Gauteng (Tshwane) and Mpumalanga Province

Hearing screening

Dear Participant

1) INTRODUCTION

We invite you to participate in a research study. This information leaflet is to help you to decide if you want to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions that are not fully explained in this leaflet, please do not hesitate to ask the interviewer.

The City of Tshwane, together with the University of Pretoria, has begun to roll out proactive primary health care through Ward Base Outreach Teams (WBOT) in your area. This is being done in support of government's reengineering of primary health. As we roll out WBOT we identify issues that we need to understand better so that we can provide health care services that are community oriented.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this part of the study is to evaluate COPC ear and hearing care services in Tshwane through the use of mobile technology and automation.

University of Pretoria
PRETORIA 0002
Republic of South Africa

Tel: 012 420 4280
Fax: 012 420 3517

dewet.swanepoel@up.ac.za
www.up.ac.za

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

We plan to offer hearing services at a primary health care level. These hearing services will be offered to people in the communities through ward based outreach teams as well as at primary health care clinics. During their visits to introduce themselves and register your household, your WBOT community health worker will also offer to screen the hearing of family members. The CHW will use a headset attached to his/her cell phone to screen each person's hearing. The hearing screening is an application on the phone that tests how well you can hear. It takes about 2 minutes. Your CHW will be able to tell each person his or her result straight away. The results on this test are either "pass" or "refer". If a test shows "pass" it means that the person's hearing is fine. If the test shows "refer" the person needs to go for further testing. A follow up appointment to find out what the hearing problem is will be made by the CHW through the WBOT at the nearest primary health care clinic that has hearing diagnostic services.

At the primary health care clinics with diagnostic hearing assessments, people referred for further tests will be assessed by a trained health care worker, professional or a student of the Department of Speech-Language Pathology and Audiology. At the end of the assessment each person will be given his or her test results. They will also be given advise about what they should do if they need treatment.

4) RISK AND DISCOMFORT INVOLVED

There are no risks involved in participating in the study. The tests are pain free and should not cause discomfort.

The interview and hearing screening in your home takes approximately 5minutes of each person's time.

The follow up diagnostic hearing test at the primary health clinic takes approximately 25 minutes to do.

5) POSSIBLE BENEFITS OF THIS STUDY

By participating in this study, you will be given a free hearing service in your home and community. Anyone with a hearing problem in your home will also be referred for further testing and management of their hearing problems. The results of this study will also help your CHW and WBOT team work with you to improve health in your community. Advantages and disadvantages of COPC ear and hearing care services can be identified and improved in order to better service delivery in the future.

6) WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your decision to take part in this part of the study is entirely voluntary. You can choose to withdraw from the study at any time. Your decision will not affect your participation in community oriented primary care in any way.

7) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

The Faculty of Health Sciences Research Ethics Committee at the University of Pretoria has approved this study. A copy of the approval letter is with the facilitator if you would like to read it.

8) INFORMATION AND CONTACT PERSON

The contact persons for the study are:
Mrs Christine Louw: 012 4206801
Mrs Shouneez Yousuf Hussein: 072 634 9906
Alternatively you can contact our supervisor:
Prof De Wet Swanepoel 012 420 4280

9) CONFIDENTIALITY

The information that is collected during the hearing screening in the community and at the primary health clinic is confidential. Your name and any details that may identify you as an individual will only be available to the health care team that works with you in order to provide you with advice or services. Information from the screening and tests that is used for research will not identify you in any way. A coded number will be assigned to each participant in order to ensure this.

10) CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (information leaflet and informed consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed and presented in research reports. I am participating willingly. I have had time to ask questions and have no objection to participating in the study. I understand that I will not be penalized in any way should I wish to discontinue with the study. This decision will not influence the health care that I receive now or in the future.

I have received a signed copy of this informed consent agreement.

Participant's name ………………………………………………….. (Please print)

Participant's signature ……………….…………… Date ………………………

Investigator's name ……………………………………………….. (Please print)

Investigator's signature ……………………………. Date ……………………

Witness's name ………………………..……………………….. (Please print)

Witness's signature …………….……………….………… Date ………………………

Appendix D: Participant Information Leaflet and Informed Consent Form for Questionnaire

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

INFORMATION LEAFLET & INFORMED CONSENT FORM FOR NON-CLINICAL RESEARCH

TITLE OF THE STUDY:

Researching the Development, Application and Implementation of Community Oriented Primary Care (COPC). A study in Gauteng (Tshwane) and Mpumalanga Province

Survey: Perception of Community Health Workers regarding COPC Ear and Hearing Care Services

Dear Participant

1) INTRODUCTION

We invite you to participate in a research study. This information leaflet is to help you to decide if you want to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions that are not fully explained in this leaflet, please do not hesitate to ask the interviewer.

The City of Tshwane, together with the University of Pretoria, has began to roll out proactive primary health care through Ward Base Outreach Teams in your area. This is being done in support of government's reengineering of primary health. As we roll out WBOT we identify issues that we need to understand better so that we can provide health care services that are community oriented.

2) THE NATURE AND PURPOSE OF THIS STUDY

The aim of this part of the study is to determine the perceived value of the implementation COPC ear and hearing care services in Tshwane through the use of mobile technology and automation.

University of Pretoria
PRETORIA 0002
Republic of South Africa

Tel: 012 420 4280
Fax: 012 420 3517

dewet.swanepoel@up.ac.za
www.up.ac.za

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

We plan to offer hearing services at a primary health care level. These hearing services will be offered to people in the communities through ward based outreach teams as well as at primary health care clinics. During household visits, WBOT community health workers will be required to introduce themselves, register a household as well as offer to screen the hearing of family members. The CHW will use a headset attached to his/her cell phone to screen each person’s hearing. The hearing screening is an application on the phone that tests how well a person can hear. It takes about 2 minutes. After screening, one will be able to provide the results immediately. The results on this test are either “pass” or “refer”. If a test shows “pass” it means that the person’s hearing is fine. If the test shows “refer” the person needs to go for further testing. A follow up appointment to find out what the hearing problem is must be made by the CHW through the WBOT at the nearest primary health care clinic that has hearing diagnostic services.

Only once a community health worker has obtained sufficient experience in using the application, each participant will be required to fill in a short questionnaire regarding his or her perceptions of the hearing screening. The questionnaire will take approximately 5 minutes to complete.

All information will be treated confidentially and data will be stored for research and archiving purposes for 15 years at the University of Pretoria.

4) RISK AND DISCOMFORT INVOLVED

There are no risks involved in participating in the study.

The questionnaire should take approximately 5 minutes of your time.

5) POSSIBLE BENEFITS OF THIS STUDY

You will not directly benefit from the study. However, the results obtained will allow us to develop and improve the implementation of COPC ear and hearing services in yours and other communities in the future. Advantages and disadvantages of COPC ear and hearing care services can be identified and improved in order to better service delivery in the future.

6) WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your participation in this study is entirely voluntary. You can choose to withdraw from the study at any time. Your decision will not affect your participation in community-orientated primary care in any way.

7) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

The Faculty of Health Sciences Research Ethics Committee at the University of Pretoria has approved this study. A copy of the approval letter is with the facilitator if you would like to read it.

8) INFORMATION AND CONTACT PERSON

The contact person for the study is:

Mrs Shouneez Yousuf Hussein: 072 634 9906

Alternatively you can contact our supervisor:

Prof De Wet Swanepoel 012 420 4280

9) ANONYMITY

All participants will be requested to remain anonymous when answering the questionnaire to ensure that one feels free to voice their own opinions. Your name and any details that may identify you as a person will not be included in the results.

10) CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (information leaflet and informed consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed and presented in research reports. I am participating willingly. I have had time to ask questions and have no objection to participating in the study. I understand that I will not be penalized in any way should I wish to discontinue with the study. This decision will not influence the health care that I receive now or in the future.

I have received a signed copy of this informed consent agreement.

Participant's name ………………………………………………….. (Please print)

Participant's signature ……………….……………. Date ………………………

Investigator's name ………………………………………………….. (Please print)

Investigator's signature ……………………………… Date ……………………

Witness's name …………………………..……………………….. (Please print)

Witness's signature …………….…………….……………. Date ………………………

Appendix E: Questionnaire

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Smartphone Hearing Screening in mHealth Assisted Community-based Primary Care

Below is a list of 10 statements. Please circle an answer of 1-5, 1 indicating that you strongly agree, 2 indicating that you agree, 3 indicating that you are neutral, 4 that you disagree or 5 that you strongly disagree.

1. Instructions for conducting the hearing test are straightforward for testers.	**1 2 3 4 5**
2. The smartphone hearing test is easy to administer in adults.	1 2 3 4 5
3. The smartphone hearing test is easy to administer in children.	1 2 3 4 5
4. The smartphone hearing test is quick to administer.	1 2 3 4 5
5. I trust the results of the hearing test.	1 2 3 4 5
6. The hearing test is important for community screening.	1 2 3 4 5
7. Community members need hearing health care services.	1 2 3 4 5
8. Community members were positive about the receiving a smartphone **hearing test.**	1 2 3 4 5
9. Community members trust the results of the smartphone hearing test.	1 2 3 4 5
10. I would like to continue providing a hearing test as part of my service.	1 2 3 4 5

Any additional comments:

____
____
____
____
____

University of Pretoria
PRETORIA 0002
Republic of South Africa

Tel: 012 420 4280
Fax: 012 420 3517

dewet.swanepoel@up.ac.za
www.up.ac.za