UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

SCHOOL-BASED HEARING SCREENING AND DIAGNOSIS USING AUTOMATED AND MOBILE HEALTH TECHNOLOGIES

by

FAHEEMA MAHOMED-ASMAIL

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

D. Phil (Communication Pathology)

In the Department of Speech-language Pathology & Audiology

University of Pretoria
Faculty of Humanities

SUPERVISOR:
Professor De Wet Swanepoel

CO-SUPERVISOR:
Professor Robert Eikelboom

October 2015

Faheema Mahomed-Asmail
Department of Speech-Language Pathology and Audiology
University of Pretoria
Pretoria
South Africa

Faheema.mahomed@up.ac.za

ACKNOWLEDGEMENTS

'Bismillah ir-Rahman ir-Rahim

In the name of Allah, most gracious, most compassionate.'

Firstly, I am grateful to my creator for good health, wellbeing, strength and the willpower that were necessary to complete this thesis.

To my academic colleagues,

Professor Swanepoel, you have been a tremendous mentor to me. I would like to express my sincere gratitude to you for your patience, motivation, and immense knowledge. Your continuous guidance helped me throughout this research project. Your advice on both research as well as on my career have been invaluable. I cannot imagine having a better supervisor and mentor.

Professor Robert Eikelboom, for your insightful comments and encouragement, but also for your perceptive questions which incented me to widen my research from various perspectives. Thank-you for your assistance, guidance and support throughout this process.

The hearScreen™ team, Prof Swanepoel, Dr Herman Myburgh and David Howe, for your development and continued assistance with the hearScreen™ application.

Professor Vinck, for creating a culture of research at the Department ensuring that we always set aside time to focus on our research.

Leigh, thank-you for always being willing to take the time to go through all my references, it has been a tremendous help and I am very grateful for your assistance.

To the audiology students, I would like to thank you for assisting me with the data collection for this project.

National Research Foundation (NRF), for the financial assistance towards this research. Opinions expressed, and conclusions arrived at, are those of the authors and are not necessarily to be attributed to the NRF.

To my family and friends,

To my wonderful parents, for being proud of me and always believing in me. Thank-you for sharing in both my joyful and gloomy moments throughout this process. Words cannot express how grateful I am to you for your continuous encouragement and support.

To my amazing husband, Muhammed, who encouraged me to strive towards my goal. Thank you for always being there for me and always making sure you proof read every manuscript before I submitted. Your interest and enthusiasm gave me even more reason to ensure I achieve this milestone.

To my friends and extended family, thank you for always enquiring how my research was going and always lending a listening ear when I needed one.

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PUBLICATIONS AND RESEARCH OUTPUTS

The thesis is based on the following original articles:

1. **Mahomed-Asmail, F.,** Swanepoel, D.W., & Eikelboom, R. H. (2016). Referral criteria for school-based hearing screening in South Africa: considerations for resource-limited contexts. *Health SA: Gesondheid, 21*, 96-102.
2. **Mahomed-Asmail, F.,** Swanepoel, D.W., Eikelboom, R. H., MyBurgh, H. C., & Hall, J. (2016). Clinical validity of hearScreen™ smartphone hearing screening for school children. *Ear and Hearing, 37,* 11-17.
3. **Mahomed-Asmail, F.,** Swanepoel, D.W., & Eikelboom, R. H. (2016). Diagnostic hearing assessment in schools: validity and time-efficiency of automated audiometry. *Journal of American Academy of Audiology, 27,* 42-48.
4. **Mahomed-Asmail, F.,** Swanepoel, D.W., & Eikelboom, R. H. (2016). Hearing loss in urban South African school children (grade 1 to 3). *International Journal of Paediatric Otorhinolaryngology*, *84*, 27-31

Parts of this thesis has been presented at the following scientific conference:

1. **Mahomed-Asmail, F.,** Swanepoel, D.W., Eikelboom, R. H., MyBurgh, H. C., & Hall, J. (2015). Clinical validity of hearScreen™ smartphone hearing screening for school children. *Paper presented at the annual Coalition for Global Hearing Healthcare Conference Podium Presentations in Washington, DC, October 2015*

ABSTRACT

Title: School-based hearing screening and diagnosis using automated and mobile health technologies

Name: Faheema Mahomed-Asmail

Supervisor: Prof. De Wet Swanepoel

Co-supervisor: Prof. Robert Eikelboom

Department: Speech-language Pathology and Audiology

Degree: D.Phil Communication Pathology

Any loss in hearing sensitivity constitutes a major and if unidentified, an insurmountable barrier to effective learning. Current school-entry hearing screening in South Africa is unavailable to majority of children due to several challenges. This study aimed to provide research-based recommendations for clinical practice of school-based hearing screening. More explicitly, this study investigated the effect of hearing screening intensity (loudness) levels and the use of an immediate rescreen in reducing the referral rate in resource-limited contexts like South Africa. Furthermore, it investigated the use of a low-cost mobile smartphone application for calibrated hearing screening in schools. It also investigated the feasibility of conducting an automated diagnostic hearing evaluation on children in a school environment immediately after a refer rescreen result is obtained. Lastly, this study reported on the prevalence and nature of hearing loss in a representative urban school-aged population.

A within-subject study was conducted to investigate the use of referral criteria in terms of screening intensity level and the use of a rescreen. It was found that the referral

rate is reduced to 6.7% from 17% when using 25 dB HL as opposed to 20 dB HL screening intensity. Furthermore, there was a significant difference between the referral rates obtained at 20 and 25 dB HL and 20 and 30 dB HL (McNemar, $p<0.01$), but no significant differences between the referral rates at intensity levels 25 and 30 dB HL. In addition, an immediate rescreen also reduced the overall referral rate by more than one-third resulting in less referrals needing follow-up intervention. The use of 25 dB HL as a screening intensity together with an immediate rescreen is recommended as it reduces the referral rate significantly and will limit the burden of a screening programme on the health care resources.

1070 school-aged children in grade 1 to 3 (mean age 8 ±1.1 years) were recruited from five public schools to investigate the feasibility of a smartphone mobile application, hearScreen™. No statistically significant difference in performance was obtained, with smartphone screening demonstrating equivalent sensitivity (75.0%) and specificity (98.5%) to conventional screening audiometry. Whilst referral rates were lower with the smartphone screening (3.2 vs. 4.6%) it was not significantly different ($p>0.05$). Smartphone screening (hearScreen™) was 12.3% faster than conventional screening ($p<0.001$).

Sixty-two (mean age 8 ±0.9 years) of the 1070 participants were recruited to investigate the validity and time-efficiency of automated diagnostic air- and bone-conduction audiometry for children in a natural school environment. With regards to the feasibility of automated diagnostic audiometry, 85.7% of air-conduction thresholds and 44.6% of bone-conduction thresholds corresponded within the normal range (15 dB HL) for manual and automated diagnostic audiometry. Both manual and automated

diagnostic audiometry air- and bone-conduction thresholds exceeded 15 dB HL in 9.9% and 34.0% of thresholds respectively. For these thresholds average absolute differences for air- and bone-conduction thresholds were 6.3 dB (8.3 SD) and 2.2 dB (3.6 SD) and they corresponded within 10 dB across frequencies in 87.7% and 100.0%, respectively. There was no significant difference between manual and automated air- and bone-conduction across frequencies for these thresholds.

The overall prevalence rate of hearing loss across the 1070 participants was 2.2%, with hearing loss being more prevalent in the Caucasian group (5.1%). A total of 24 children (12 male, 12 female) were diagnosed with a hearing loss (54.3% conductive, 25.7% mixed and 20.0% sensorineural). Furthermore, otoscopic examinations revealed that 6.6% of the children had cerumen and 7.4% presented with type B tympanograms which is indicative of middle ear effusion.

Mobile technology together with automated diagnostic audiometry may be a feasible solution to overcome many of the prohibitive challenges faced by school-based hearing screening programs. Furthermore, prevalence data suggests that many children (2.2%) are in need of some form of follow-up service, most for medical intervention and a smaller number for audiological intervention. These findings provide valuable baseline data for realistic planning and appropriate implementation of hearing health services to ensure school-based hearing screening is employed sustainably across South Africa.

KEYWORDS

School- based hearing screening

Childhood hearing loss

Screening protocol

Referral rate

Cost-effectiveness

On-site testing

Smartphone hearing screening application

hearScreen™

Validation

Automated diagnostic audiometry

Prevalence

Developing countries

South Africa

ABBREVIATIONS

dB	Decibel
Hz	Hertz
SD	Standard Deviation
SLM	Sound Level Metre
ESHL	Educationally Significant Hearing Loss
SNHL	Sensorineural Hearing Loss
JCIH	Joint Committee of Infant Hearing
NHS	Newborn Hearing Screening
LoLT	Language of Learning and Teaching
MPANL	Maximum Permissible Ambient Noise Level
ETSPL	Equivalent Threshold Sound Pressure Level
RETSPL	Reference Equivalent Threshold Sound Pressure Level

CHAPTER 1

INTRODUCTION

1.1. Background

Hearing loss is the most prevalent chronic disability with over 5% of the global population presenting with a hearing loss of a mild or greater degree (World Health Organisation, 2013a). Most children with a congenital hearing loss have a hearing impairment at birth and are potentially identifiable by newborn and infant hearing screening (Cunningham & Cox, 2003). The presence of progressive and acquired hearing loss results in a significant increase in prevalence from the first year of life through to six years of age (Swanepoel, Olusanya, & Mars, 2010).

Nine or ten in every 1000 school-aged children will potentially have a hearing loss (White, 2010). As a result these children will have difficulties in perceiving speech clearly in the educational contexts which will contribute to difficulties with attention and learning (Bess, Dodd-Murphy, & Parker, 1998; Davis, Elfenbein, Schum, & Bentler, 1986; McKay, Gravel, & Tharpe, 2008; WHO, 2013b). In addition, a hearing loss can also result in dysfunction in areas such as behaviour, energy, stress, social support, self-esteem and socio-emotional aspects (Bess et al., 1998; McKay et al., 2008).

The Integrated School Health Policy (ISHP) (2012a) for South Africa, which was drawn up to strengthen the country's school health services, acknowledges the importance of hearing screening by including it as part of all health phases. The ISHP's (2012b) training manual specifies that hearing screening is to be conducted

using a calibrated audiometer by school health nurses with a screening intensity criteria of 20 dB HL across 1, 2 and 4 kHz in accordance with current international guidelines (American Academy of Audiology (AAA), 2011; American Speech-Language-Hearing Association (ASHA), 1997). Although school-based hearing screening has been acknowledged and guidelines stipulated, current school-entry screening in South Africa is not available to the majority of children due to several challenges.

1.2. Challenges with implementation of school-based screening

The pure tone audiometric sweep test has been considered the gold standard and is the most widely used and recommended screening method for school-based hearing screening (AAA, 2011; ASHA, 1997; Bamford et al., 2007). Although it is easy to administer, successful implementation is often hindered by a number of intrinsic and extrinsic factors. One of these intrinsic factors includes the identification of the target disorder. For school-based hearing screening the target disorder is often referred to as an educationally significant hearing loss (ESHL) (AAA, 2011; ASHA, 1997). ESHL is considered a hearing loss that interferes with a learner's academic performance (AAA, 2011). This may include permanent sensorineural, conductive and mixed hearing losses, but may also include transient conductive losses. However, the severity of a hearing loss that constitutes ESHL is not always clearly defined.

Guidelines specify a screening level of 20 dB HL across 1, 2 or 4 kHz in order to identify an ESHL (AAA, 2011; ASHA, 1997). Despite these guidelines, screening programmes have used various criteria to identify ESHL. This can be seen in reports of studies from developed and developing countries, where screening intensity levels

of 25, 30 and even 40 dB HL have typically been employed (Al-Rowaily, AlFayez, AlJomiey, AlBadr, & Abolfotouh, 2012; AAA, 2011; ASHA, 1997; Bottasso, Sanches, Bento & Samelli, 2015; Kam et al., 2013; Lo & Mcpherson, 2013; Lü et al., 2011; Wu et al., 2014). A higher screening intensity level is sometimes used due to the presence of adverse background noise levels that are present in the test environment (Counter, 1986; Kam et al., 2013; McPherson, Law, & Wong, 2010). In turn, the selected criterion for screening has an effect on the referral rates, sensitivity and specificity of a screening programmes (Dodd-Murphy, Murphy & Bess, 2014). Ultimately these factors also determine the cost-effectiveness and feasibility of hearing screening programmes.

An immediate rescreen is an additional factor to consider for the purposes of reducing the referral rate. The referral rate is an essential consideration when determining the cost-effectiveness of a programme (Bottasso, Sanches, Bento & Samelli, 2015). As referral rates increase (as a result of a low screening intensity level) more follow-up diagnostic evaluations are required. An excessive referral rate will be prohibitive to the sustainability of screening programmes, especially in developing countries or under-resourced environments like those in the public school environment of South Africa.

Variable and high referral rates, alongside poor follow-up, pose a significant threat to the feasibility of pre-school and school-based hearing screening programs (Swanepoel, Maclennan-Smith, & Hall III, 2013). High referral rates cause families to incur unnecessary costs for follow-up and may undermine the integrity of the screening process (AAA, 2011).

The lack of follow-up services are compounded further by the absence and inaccessibility of referral services (Shung-King, 2013). Globally there is an increasing gap in demand and capacity of audiologic services (Goulios & Patuzzi, 2008; WHO, 2013c) with availability of audiologists associated with income level (WHO, 2013b). Upper-middle and high-income countries typically report one audiologist per 110 000 people whereas low income regions such as Africa and Asia have reported between 0.5 and 3.4 million people per ENT surgeon with access to even smaller numbers of audiologists. Several countries (including Bangladesh, Indonesia, and Laos) reported having no audiologists and minimal provision of hearing health care (Goulios & Patuzzi, 2008). In order to ensure availability of referral services careful inspection and planning of school-based screening needs to be conducted (Shung-King, 2013). The first step to achieve this would be to determine the prevalence of hearing loss in this population in order to assist with planning a program that will ensure availability of future hearing health services.

Additional challenges in implementing school-based hearing screening include the cost of hearing screening equipment which can be prohibitive due to the expense of audiometric equipment and the requirement for trained personnel to conduct the screening (Swanepoel, Clark et al., 2010; Swanepoel, Mngemane et al., 2010; Swanepoel, Myburgh et al., 2014). Furthermore, school-based hearing screening usually takes place in an enclosed, unoccupied, furnished room where ambient noise levels often exceed permissible levels (Bamford et al., 2007; FitzZaland & Zink, 1984; Lo & Mcpherson, 2013). Test operators usually have no feedback on the compliance of ambient noise levels during testing. As a consequence, false-positive findings occur

when ambient noise masks the test signal resulting in unnecessary and costly referrals requiring diagnostic assessments (Lo & McPherson, 2013).

1.3. Mobile and automated health technology in hearing evolution

Utilising innovations in technology and the growth in connectivity may offer new ways of services through technological models, such as automated procedures and mobile health technology (Swanepoel, Olusanya, & Mars, 2010). Mobile technologies are a means of providing individual level support to health care consumers. Technological advances and improved computer processing power mean that a single mobile devices, such as smart phones, are increasingly capable of high level performance. The features of mobile technologies that may make them particularly appropriate for providing individual level support to health care consumers relate to their popularity, their mobility, and their technological capabilities (Free, Phillips, Felix, Galli, & Watson, 2013).

Mobile technology presents with many advantages which can be utilized in the field of audiology by coupling mobile technology applications with automated programs (Swanepoel, Clark et al., 2010). An example of such an application is the Apple iOS-based automated hearing testing application which was investigated by Foulad, Bui, and Djalilian (2013). This Apple iOS-based automated hearing testing application was compared to conventional audiometry to determine its accuracy. Results indicated that the Apple iOS-based devices provides a platform for automated air-conduction audiometry without requiring extra equipment and yield hearing test results that approach those of conventional audiometry (Foulad et al., 2013). However, the

technology is currently restricted to air-conduction audiometry, and thus comprehensive diagnostic evaluation may be limited.

The recently reported smartphone-based hearing screening application, hearScreen™, using an entry-level smartphone with calibrated supra-aural headphones running Android™ OS is another example (Swanepoel, Myburgh et al., 2014). The hearScreen™ software application integrates noise monitoring referenced to Maximum Permissible Ambient Noise Levels (MPANL) during testing. This provides screening operators with real-time feedback on ambient noise levels and allows frequencies to be retested where noise levels exceeds MPANLs and patients do not respond (Swanepoel, Myburgh et al., 2014). The hearScreen™ application has demonstrated promise as reported by Swanepoel, Myburgh et al. (2014), however, the study was conducted with a modest sample size and test sensitivity and specificity was not determined.

In addition to mobile audiometry, automated audiometry can be utilized to assist with the screening process. Automated or asynchronous healthcare services refers to a procedure or intervention conducted without requiring the necessary healthcare professional to be present (Margolis & Morgan, 2008). Automated audiology involves automating certain audiological procedures involved in a basic hearing test battery, such as tones presented at predetermined levels (Margolis & Morgan, 2008). This is ideal for pure-tone threshold searches as a sequence of steps need to be used to obtain a threshold which can be implemented using a software-based testing system (Margolis & Morgan, 2008).

A meta-analysis conducted on automated audiometry revealed that automated threshold audiometry provides an accurate measure of hearing threshold compared to conventional manual threshold audiometry (Mahomed, Swanepoel, Eikelboom, & Soer, 2013). Automated audiometry thresholds were within typical test–retest and inter-tester variability of manual thresholds in adults (Eikelboom, Swanepoel, Motakef, & Upson, 2013; Ho, Hildreth, & Lindsey, 2009; Margolis, & Moore, 2011; Margolis, Frisina, & Walton, 2011; Swanepoel, Mngemane, & Tutshini, 2010). Furthermore, this review found only five validation studies on automated audiometry in children, of which thresholds obtained with automated audiometry were comparable to those obtained with manual audiometry (Almqvist & Aursnes, 1978; Hartly & Siengenthalar, 1964; Margolis, & Moore, 2011; Picard, Ilecki, & Baxter, 1993; Wood, Wittich, & Mahaffey, 1973). Only two of these studies included bone-conduction (Picard et al., 1993; Wood et al., 1973). Of these air- and bone-conduction studies only one included testing in a more natural environment without a sound-treated room (Picard et al., 1993). The literature review recommended further investigation for automated audiometry in children.

Conducting diagnostic pure tone audiometry immediately after a fail result could reduce the characteristically poor follow-up rates (Swanepoel et al., 2013) by eliminating false positive screen results and identifying those who require audiological and/or medical intervention. However, the lack of compliant, sound-treated environments in typical school settings has traditionally precluded the administration of diagnostic air- and bone-conduction audiometry in a school setting (Swanepoel et al., 2013). Recent studies validated a mobile audiometer (KUDUwave, eMoyoDotNet, Pretoria, South Africa) to conduct manual diagnostic air- and bone-conduction

audiometry outside a booth environment (Maclennan-Smith, Swanepoel, & Hall III, 2013; Storey, Mu, Nelson, Larsen, & White, 2014; Swanepoel et al., 2013). Testing in a school environment without a sound booth demonstrated that valid diagnostic pure-tone audiometry could be performed for children by an audiologist (Swanepoel et al., 2013).

Although this may be a possible solution, the shortage of available human resources does not make it practical to employ audiologists for diagnostic testing in schools (Goulios & Patuzzi, 2008; WHO, 2013a). Automated audiometry, that can integrate with an asynchronous telehealth service model, may assist in making audiological services available in a school setting by allowing procedures to be conducted without a hearing healthcare professional present onsite (Swanepoel, Clark et al., 2010).

In situations where specialist healthcare personnel are limited or unavailable, the use of mobile technology coupled with automated audiological programs may ensure that services and healthcare resources are optimized (Swanepoel, Mngemane et al., 2010). Furthermore, by reducing the amount of time spent on each individual the number of individuals assessed will increase, thus reducing the cost of testing.

1.4. Rationale

Any loss in hearing sensitivity constitutes a major, and if unidentified an insurmountable, barrier to effective learning as all formal learning activities in typical school environments are mediated through the sense of hearing (Hatcher et al., 1995; Sarafraz & Ahmadi, 2009). Thus, school-entry hearing screening is an important public health care endeavour. Hearing screening programs should be initiated and obligatory

for all pre-school and school-age children, as these programs would help to assure equal educational opportunities for school-aged children who suffer from hearing loss (Skarżyński & Piotrowska, 2012). Therefore this study aimed to provide research-based recommendations for clinical practice of school-based screening.

CHAPTER 2

PROPOSED METHODOLOGY

2.1. Research objectives

This study evaluated the effect of screening intensity levels and an immediate rescreen as well as the validity of a smartphone-based screening application, and automated audiometry for hearing screening and diagnosis in school children. Four research objectives were proposed each constituting a research study for submission as an article to an accredited[1] peer-reviewed journal upon completion. The four studies are summarised in Table 2.1 according to proposed titles, objectives, and journal which they have been published in.

[1]Institute for Scientific Information (ISI) or Department of Higher Education and Training (DHET) accreditation list

Table 2.1. Summary of studies I to IV displaying article title, objectives, journal and thesis chapter

Study	I	II	III	IV
Title	Referral criteria for school-based hearing screening in South Africa: Considerations for resource-limited contexts	Clinical validity of hearScreen™ smartphone hearing screening for school children	Diagnostic hearing assessment in schools: Validity and time-efficiency of automated audiometry	Hearing loss in school children (grade 1 to 3) in a South African population
Objectives	To investigate the effect of screening intensity levels on the referral rate and to establish the effect of an immediate rescreen in reducing the referral rate. a) Phase 1-To compare the referral rate in a counterbalanced sequence at screening levels of 20 dB HL, 25 dB HL and 30 dB HL across 1, 2 and 4 kHz. b) Phase 2-To determine the effect of an immediate rescreen on referral rate at 25 dB HL.	To determine the performance of the smartphone-based screening application. a) To compare the sensitivity of the smartphone-based screener by conducting manual diagnostic audiometry on all participants that obtain a refer result on either screening tool. b) To determine the specificity of the smartphone-based screener by conducting manual diagnostic audiometry on 5% of participants who pass on both screens. c) To compare the time taken to complete the smartphone-based screening versus conventional hearing screening.	To investigate the validity and time-efficiency of automated diagnostic air- and bone-conduction audiometry for children in a natural school environment following hearing screening. a) To determine the accuracy of automated diagnostic audiometry by comparing it to manual diagnostic audiometry. b) To compare the time taken for automated diagnostic audiometry versus manual diagnostic audiometry.	To describe the prevalence and nature of hearing loss among school-aged children from grade one to three in a South African population. a) To describe the prevalence of hearing loss in a sample of school-aged children by utilizing a hearing screening program. b) To describe the nature of hearing loss in school-aged children.
Journal	Health SA Gesondheid	Ear and Hearing	Journal of American Academy of Audiology	International Journal of Paediatric Otorhinolaryngology
Chapter in thesis	3	4	5	6

2.2. Research design

A Quasi-experimental within subject comparative research design using quantitative data (Leedy & Ormrod, 2001) was used for Studies I, II and III. A cross-sectional research design using quantitative data (Kaplan, 1987) was used for Study IV (Table 2.2).

2.3. Research context

The research was conducted at government funded schools in the Tshwane District, Gauteng Province. Seven schools were identified as they had previously obtained services by students from the Department of Speech-Language Pathology and Audiology, University of Pretoria.

2.4. Research participants

The research project included 1542 children from grade 1 to grade 3. Table 2.2 provides a detailed summary of the participant selection criteria, participant sampling method, sample size, equipment and data collection material for each of the four studies completed.

Table 2.2. Research design and methods summary for studies I - IV

Study	I	II	III	IV
Title	Referral criteria for school-based hearing screening in South Africa: Considerations for resource-limited contexts	Clinical validity of hearScreen™ smartphone hearing screening for school children	Diagnostic hearing assessment in schools: Validity and time-efficiency of automated audiometry	Hearing loss in school children (grade 1 to 3) in a South African population
Study design	Quasi-experimental within subject comparative research design using quantitative data (Baldwin & Berkeljon, 2010; Leedy & Ormrod, 2001)			Cross sectional research design using quantitative data (Kaplan, 1987)
Participant selection criteria	▪ Participants included only children in Grade 1 to Grade 3, ▪ Participants had normal hearing or a hearing loss. ▪ Informed consent had to be obtained by the caregivers/ parent of the participant. ▪ Participant had to provide informed assent. ▪ Participants had to be enrolled in the specific school. ▪ Both male and female participants were included.			
		▪ 5% of participants who passed the screen were selected by using random sampling (Leedy & Ormrod, 2001) for manual diagnostic audiometry. ▪ All participants who obtained a refer result were tested diagnostically.	5% of participants who underwent the manual diagnostic audiometry were selected for this study.	
Participant sampling	Non-probability purposive sampling (Leedy & Ormrod, 2001)			
Sample size	Phase 1- screening was conducted on 135 participants (270 ears) Phase 2- screening was conducted on 337 participants (674 ears)	Screening was conducted on 1070 participants, 2140 ears	Participants included 32 participants who passed on both screeners (64 ears) and 30 participants who failed (11 failed on conventional screening, 6 failed smartphone-based screening, 13 failed on both screens)	Screening was conducted on 1070 participants (2140 ears)

2.5. Research equipment

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

Table 2.3. Summary of Equipment and intended use

Equipment	Description
Heine mini 3000 (Heine, Germany) and Welch Allyn (Welch Allyn, South Africa, Pty, Ltd) otoscope with reusable spectula	A tool used to visually inspect the outer ear and ear canal.
GSI Auto Tymp (Grayson Stadler, Eden Prairie, MN, USA) or Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using TDH 39P headphones (Telephonics, Huntington, N.Y)	A pure tone conventional screening device that is used to determine a pass/refer threshold by manually adjusting the intensity and frequency of the stimulus. Tympanometry was also conducted with this device by placing a probe in the participant's ear and measuring the middle ear pressure, compliance and volume of the middle ear.
hearScreen™ application running on a Samsung Galaxy Pocket Plus S5301 with supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany)	A mobile smartphone calibrated into a screening audiometer (according to national and international standards e.g. SANAS, ANSI, ISO) for conducting hearing screening using commercially available headsets (HD 201). The software utilizes pre-specified screening protocols to assess hearing using automated sequences by presenting a tone at 25 dB HL at 1, 2 and 4 kHz. Additionally the software monitored the environmental noise using the device microphone to ensure environmental compliance during testing.
RION (NA-24, Japan, Tokyo)	A sound level meter was utilized to determine the noise present in the testing environment. Furthermore it was used to ensure that the test environment for diagnostic testing was in accordance to those indicated in the validation study (Swanepoel et al., 2013)
KUDUwave (eMoyoDotNet, Pretoria, South Africa) Type 2 Clinical Audiometer (OEC 60645-1/2)	A computer-based device with circumaural ear cups which was placed over insert earphones.

2.6. Ethical considerations

The research project was approved by the Postgraduate Committee of the Faculty of Humanities of the University of Pretoria on 10th of April 2014 (Appendix A) and by the Gauteng Department of Education on the 8th of April 2014 (Appendix B).

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

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

Principle	Application to study
The right to safety and wellbeing of the participants are the most important considerations and should prevail over interest of science and society. Foreseeable risks and inconveniences should be weighed against the anticipated benefit for participants and society. A study should only be initiated and continued if the anticipated benefits justify the risks.	There were no medical risks associated with the procedures of this study. All participants were informed of their rights before data collection commenced.
Research or experimentation on an individual may only be conducted after the participant has been informed of the objectives of the research or experimentation and any possible positive or negative consequences on his or her health.	There was no risk involved with the study and no financial gain was obtained by the participants. Before data collection commenced, the principal of each school received a letter (Appendix C) requesting permission to conduct the study at their school together with informed consent letters that was handed out to caregivers/parents of potential participants (Appendix D). Furthermore, each child, whose caregiver/parent provided informed consent, received verbal information regarding the study and were required to provide assent (Appendix E).
Freely given informed consent should be obtained from every participant prior to clinical trial participation.	Freely given informed consent was obtained from a caregiver/parent of every participant as well as assent provided by every participant through the use of the informed consent and assent forms as presented in Appendix D and E. This enabled the researcher to acquire written consent/assent from each parent/caregiver and participant prior to the assessment.
The healthcare provider must also, where possible, inform the individual in a language that the individual understands, and in a manner which takes into account the individual's level of literacy.	Only participants whose language of learning and teaching (LoLT) was English were utilized in this study thus all informed consent and assent letters were provided in English. The participants were also encouraged to ask questions regarding the study and the outcomes at any time during the data collection process.
The participant should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.	The informed consent/assent forms (Appendix D and E) clearly stated that the participants do have the right to withdraw from the study at any time without any negative consequences.
The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).	All records will be treated as confidential. All participants were given an individual participation number. The identity of the participant represented by the participant number was known only to the researcher. Access to online

	data folders was also restricted to the researcher and two research supervisors.
Participants have the right to know their health status and researchers are obligated to disseminate results in a timely and competent manner.	The researcher conveyed the results of the hearing screening to participants directly after completion of the screening. All participants who passed the screen were provided with letters for their caregivers/parents indicating that they passed (Appendix F). Those participant who referred and required further investigation/or intervention were provided with a referral letter (Appendix G) and a copy of the diagnostic audiometry results. Furthermore, the principal of each school received a list of all participants who were referred for further investigation and/or intervention.

2.7. Research procedures

Once ethical clearance was granted by the Humanities faculty (Appendix A) and permission obtained from Gauteng Department of Education (Appendix B). The principals of the identified schools were contacted and informed about the study (Appendix C). Once permission was granted by the principals, parent/caregiver informed consent forms were distributed at the identified schools (Appendix D). Only students who had obtained informed consent from their caregivers/parents and provided assent (Appendix E) were used as participants in the study.

The data was then collected by audiology students, who received training in the specific procedures of the research studies, under supervision of the researcher (Faheema Mahomed-Asmail, MCommunication Pathology, HPCSA no. STA00317958).

2.7.1. Research procedures for Study I

Study one consisted of two phases. In phase one, only conventional screening was conducted on each participant using the GSI Auto Tymp (Grayson Stadler, Eden Prairie, MN, USA) or Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using Telephonics TDH 39P headphones. Each participant received three hearing screenings at different screening intensity levels of 20, 25 and 30 dB HL respectively. The three screening levels were counterbalanced to minimize an order effect. Screening was conducted at 1, 2 and 4 kHz as prescribed by current guidelines (AAA, 2011; ASHA, 1997). If a student did not respond to the sound at a

specific frequency it was repeated once to confirm a no-response and then recorded as a refer result. A refer at any frequency in either ear constituted an overall referral.

In phase two, the same screeners were used as in phase one on a different group of students. Screening procedures were conducted at a screening intensity level of 25 dB HL at 1, 2 and 4 kHz. A refer at any frequency in either ear constituted an initial referral. A rescreen was done immediately following a refer result. This was done by removing the headphones and re-instructing the child. The screening audiometer on which the initial refer was recorded was used to conduct the rescreen. Manual diagnostic audiometry was then conducted on children who referred on the rescreen.

2.7.2. Research procedures for study II to IV

Figure 2.1 illustrates the data collection process that was followed for study II, III and IV.

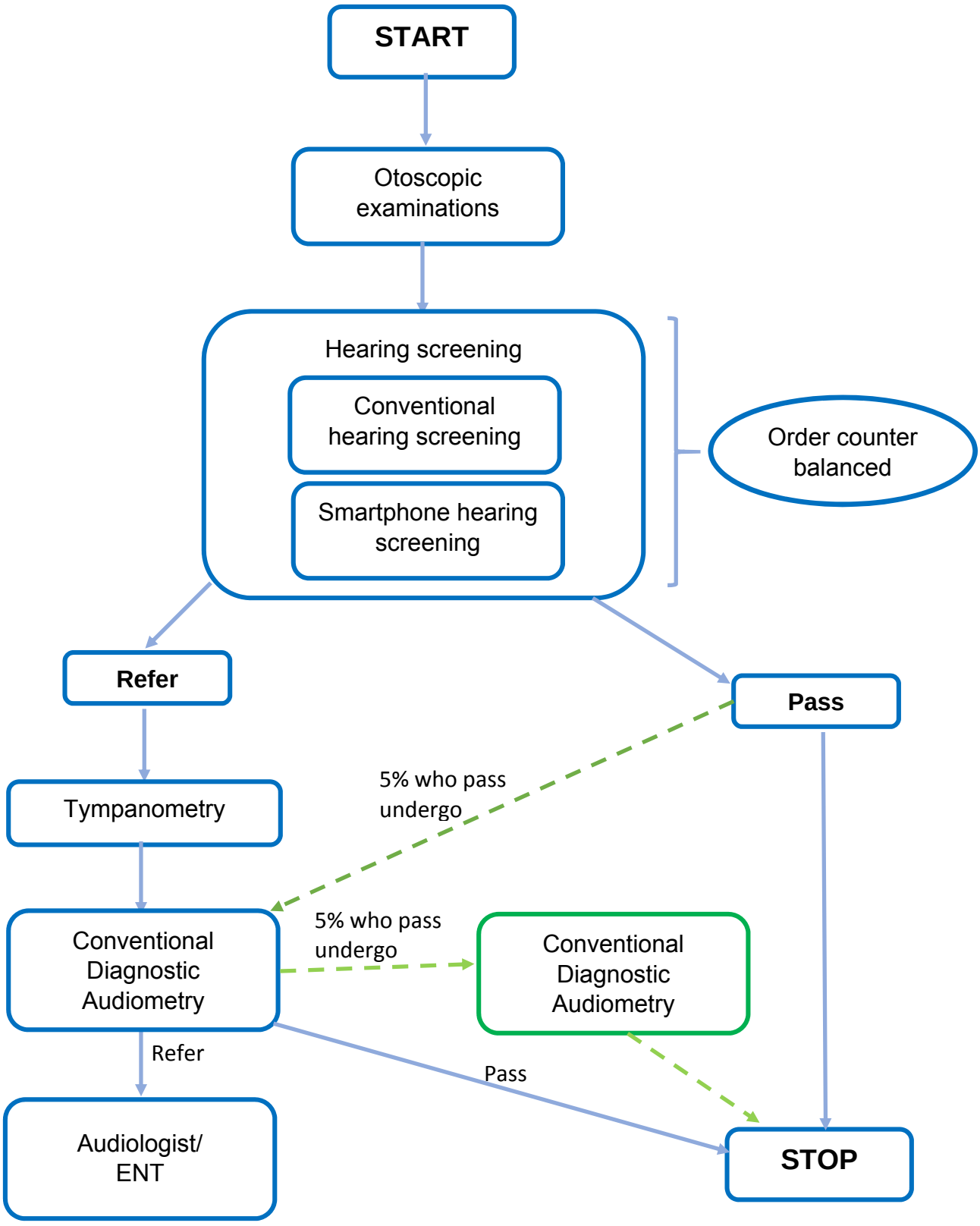

Figure 2.1. Data collection process

*blue – indicates procedure followed for studies II and IV.
*green- indicates procedures followed for study III.

Otoscopy

The participant's ear canal and outer ear was visually inspected in order to rule out any obvious pathology such as a discharge, or excessive wax build-up. If a pathology was detected, the participant was referred for appropriate medical services, such as to a General Practitioner or Ear, Nose and Throat specialist (Appendix G).

Conventional hearing screening

Conventional hearing screening was conducted with either a GSI Auto Tymp (Grayson Stadler, Eden Prairie, MN, USA) or Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using TDH 39P headphones (Telephonics, Huntington, N.Y). The TDH-39 headphones were placed of over the participant's ears and the participant was instructed to raise their hand every time a tone/beep was heard. A sweep test of hearing screening was conducted whereby the preselected frequencies 1, 2 and 4 kHz were presented at a predetermined level of 25 dB HL. Results were considered a pass if the participants response was judged to be clinically reliable at least two times at 25 dB HL at each frequency in each ear, a refer result was obtained if the participant did not respond twice at 25 dB HL at each frequency in each ear (ASHA, 1997). Participants who obtained a refer result at any frequency were rescreened immediately. Results were recorded on the participant worksheet 1 (Appendix H).

Ambient noise during testing is an important contributor to higher false positive referral rates since screening is commonly conducted in less than ideal surroundings (Bamford et al. 2007). The American Academy of Audiology (2011) screening guidelines have indicated, based on a screening level of 20 dB HL, the ambient noise levels should

not exceed 50, 58, and 76 dB SPL respectively for 1000, 2000, and 4000 Hz. In order to monitor the ambient noise levels a sound level meter (RION, NA-24) was utilized to determine the noise present in the testing environment. Three measurements were taken during the day; prior to testings, during testing and after testing was conducted.

Smartphone hearing screening

The smartphone hearing screening device, hearScreen™, was utilized. Testing procedures were conducted in the same manner as conventional screening utilizing the same pass and refer criteria. Results were recorded on the participant worksheet 1 (Appendix H).

Tympanometry

Tympanometry was conducted to obtain information regarding the participant's middle ear status as secondary process as part of the hearing screening process. Tympanometry provided information that allowed transient middle ear pathologies that may create a temporary or fluctuating conductive hearing loss, to be ruled out. Results were recorded in terms of middle ear pressure, static compliance and ear canal volume and classified based on the modified Jerger classification (Zielhuis, Heuvelmans-Heinen, Rach, van den Broek, 1989).

Participants were referred to a general practitioner or Ear, Nose and Throat specialist if any middle ear pathologies were observed (Appendix G).

Manual diagnostic audiometry

All participants who referred on either one of the screening procedures as well as 5% of participants who passed the screen underwent manual diagnostic audiometry. Diagnostic audiometry was performed with a KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2). Testing was only conducted down to 15 dB HL as hearing of children is considered normal if all thresholds are at or below 15 dB HL (Clark, 1981; Smith, Bale, & White, 2005). Diagnostic air- and bone-conduction was determined across 0.5, 1, 2, 4 kHz. Air-conduction pure tones were delivered via deeply inserted insert foam tips covered by circumaural earcups with forehead placement bone-conduction audiometry conducted with both ears occluded by the deep insertion of the insert earphones. Results were recorded on the participant worksheet 2 (Appendix I).

Automated diagnostic audiometry

5% of participants who underwent the manual diagnostic audiometry were selected in a randomized controlled manner for this procedure in order to reach the objectives of study III. Testing was conducted in the same manner as for manual diagnostic audiometry utilizing the KuduWave's (MoyoDotNet, Johannesburg, South Africa) automated function.

The AMCLASS™ classification system (Margolis & Saly, 2007) was used to classify audiograms. If a hearing loss was present the participant was referred to an Audiologist for possible hearing aid fitting and intervention (Appendix G) by addressing a letter to the parents. If the participant passes the screen a letter was sent to the

parents indicating that currently the participants hearing abilities appear within normal range (Appendix F).

2.8. Data processing and analysis

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

Table 2.5. Statistical analysis and data processing

Study	I	II	III	IV
Title	Referral criteria for school-based hearing screening in South Africa: Considerations for resource-limited contexts	Clinical validity of hearScreen™ smartphone hearing screening for school children	Diagnostic hearing assessment in schools: Validity and time-efficiency of automated audiometry	Hearing loss in school children (grade 1 to 3) in a South African population
Study design	Quasi-experimental within subject comparative research design using quantitative data (Baldwin & Berkeljon, 2010; Leedy & Ormrod, 2001).			Cross-sectional research design using quantitative data (Kaplan, 1987) .
Statistical analysis	▪ Cross-tabulations of referral rates at 20, 25 and 30 dB HL across 1, 2 and 4 kHz as well as overall cross tabulations for each ear at the above mentioned intensities were used. ▪ The McNemar test was performed to determine if there was a significant difference between referral rates amongst the three screening intensities (Statistical significance was noted as $p<0.01$). ▪ Data analyses included cross-tabulation of initial screening outcomes obtained at 25 dB HL compared to refer results obtained during the rescreen.	▪ Overall referral rates (two consecutive fail results) with the smartphone and conventional screening were compared using cross-tabulations of test outcomes for each child. ▪ A Chi-square test was used to assess differences across testing with a level of $p<0.05$ set as significant. ▪ Sensitivity and specificity were calculated separately for each screening technique with reference to conventional diagnostic test results for each child. ▪ Sensitivity and specificity results obtained for smartphone screening were compared to those obtained for conventional screening. ▪ Noise level measurements recorded with hearScreen™ were averaged and compared to maximum permissible	▪ Threshold data for air- and bone-conduction manual and automated audiometry were analyzed descriptively, with average differences, average absolute differences and respective distributions. ▪ To evaluate results without the possible influence of a floor-effect, a comparative analysis between thresholds (manual vs automated audiometry) was done where thresholds of 15 dB HL in either manual or automated test conditions were excluded. ▪ Corresponding thresholds between manual and automated audiometry, expressed as a percentage of cases within 5, within 10 dB and differing more than 15 dB were determined.	▪ Demographic data, otological status, tympanometric findings and screening results was analysed and presented using descriptive statistics. ▪ The prevalence of hearing loss was determined by obtaining the number of participants that had a hearing loss over the total number of participants. ▪ A binary logistic regression was performed to evaluate the effect of age, gender and race on presence of a hearing loss on the sample ($p<0.01$). ▪ The AMCLASS™ system was used to classify audiograms in terms of the nature of the hearing loss (Margolis & Saly, 2007).

	ambient noise levels (MPANL's) for the specified headphones screening level of 25 dB HL. ▪ Average test time between methods, excluding instructions and preparation time, was also determined with the paired sample t-test.	▪ The Wilcoxon signed ranked test was used to compare hearing thresholds between manual and automated test modes ($p \leq 0.05$). ▪ The paired samples t-test was used to compare test time, the statistical significance was set as $p \leq 0.05$. ▪ The AMCLASS™ system was used to classify audiograms in terms of the nature of the hearing loss (Margolis & Saly, 2007).	

CHAPTER 3

REFERRAL CRITERIA FOR SCHOOL-BASED HEARING SCREENING IN SOUTH AFRICA: CONSIDERATIONS FOR RESOURCE-LIMITED CONTEXTS

Authors: Mahomed-Asmail, F., Swanepoel, D.W., & Eikelboom, R. H.

Journal: Health SA: Gesondheid

Accepted: 2/11/2015

Proof of acceptance: Appendix J

Publication: 2016, Vol 21, pp.96-102

3.1. Abstract

Background

School-based hearing screening is likely to be the first opportunity to identify childhood hearing loss in South Africa. Criteria for school-based hearing screening requires balancing the targeted degree of hearing loss while ensuring that referral rates are sufficiently low for a cost-effective and sustainable programme. The study aim was to investigate the effect of screening intensity (loudness) levels on the referral rate and to establish the effect of an immediate rescreen in reducing the referral rate.

Methods

A within-subject study was conducted in two phases. Phase 1: compared the referral rate in a counterbalanced sequence at screening levels of 20 dB HL, 25 dB HL and 30 dB HL across 1, 2 and 4 kHz for 135 children. Phase 2: determined the effect of an

immediate rescreen on referral rate for 337 children screened at 25 dB HL. If a further referral was obtained on rescreen, diagnostic audiometry was subsequently conducted.

Results

Referral rate was reduced to 6.7% from 17% when using 25 dB HL as opposed to 20 dB HL as screening intensity. Referral rate was reduced to 4.4% when employing 30 dB HL as screening intensity. An immediate rescreen reduced the overall referral rate by more than one-third. Diagnostic audiometry confirmed that almost half (47%) of the referred children had a hearing loss.

Conclusion

A screening intensity of 25 dB HL and immediate rescreen reduces the referral rate significantly and will limit the burden of the screening programme on health care resources.

3.2. Introduction

Hearing loss is the most common developmental disorder which is identifiable at birth, with an increase in prevalence throughout school-age due to the additions of late-onset, late identified and acquired hearing loss (Fortnum, 2003; Lopez, Mathers, Ezzati, Jamison, & Murray, 2006; Smith et al., 2005; WHO, 2013a). Newborn hearing screening has made early identification of congenital and early-onset hearing loss possible to allow for optimal outcomes through early intervention (Cunningham & Cox, 2003; Muse et al., 2013). Beyond the newborn period, close to 20% of permanent, moderate or greater bilateral, mild bilateral and unilateral impairments remain to be identified around the time of school entry due to progressive or delayed-onset hearing loss (AAA, 2011; Bamford et al., 2007; Grote, 2000).

Nine or ten in every 1000 school-aged children (White, 2010) will potentially have a hearing loss and as a result these students will have difficulties in perceiving speech clearly in social and educational contexts which will contribute to difficulties with attention, learning and social functioning (Bess et al., 1998; Davis et al., 1986; McKay et al., 2008; WHO, 2013a). Minimal and unilateral permanent hearing losses may also result in poorer educational test performance, higher incidence of failed grades and greater dysfunction in areas such as behaviour, energy, stress, social support, self-esteem and socio-emotional aspects (Bess et al., 1998; McKay et al., 2008; Tharpe, 2008).

3.2.1. Definition of key concepts

School-based hearing screening is used to identify children with late-onset or progressive hearing impairments (Meyer, Swanepoel, Van Der Linda, & Le Roux,

2012; Theunissen & Swanepoel, 2008). School-based hearing screening is widely recommended (ASHA, 1997; Skarżyński & Piotrowska, 2012) with clear guidelines in terms of implementation. The universal goal of hearing screening is to identify all children with a significant hearing loss in order to allow for further diagnosis and appropriate intervention (AAA, 2011; ASHA, 1997; Skarzynski, Henryk, Piotrowska, 2012; Kam et al., 2013; Theunissen & Swanepoel, 2008).

School-based hearing screening is of particular importance in countries like South Africa where no legislation or health care mandate is in place to conduct hearing screening on newborns and infants for hearing loss (Meyer et al., 2012; Theunissen & Swanepoel, 2008). As a result, school-based screening may be the first point of access for detection of hearing loss. The recently launched Integrated School Health Policy (ISHP, 2012a) for South Africa acknowledges the importance of hearing screening by including it as part of all the health phases with priority on the foundational phase (Grade R–3). The Integrated School Health Policy (2012b) specifies that hearing screening is to be conducted by school health nurses with an audiometer using a screen criteria of 20 dB HL intensity at 1, 2 and 4 kHz in accordance with current international guidelines (AAA, 2011; ASHA, 1997).

The pure tone audiometric sweep test has been considered the gold standard and is the most widely used and recommended screening method for school-based hearing screening (AAA, 2011; ASHA, 1997; Bamford et al., 2007). A pure tone signal is presented across different frequencies at a specific screening intensity level; responses to the signals typically include a hand raise or a conditioned response (e.g. dropping a block in a bucket). Although it is easy to administer, successful

implementation is often hindered by a number of intrinsic and extrinsic factors. One of these intrinsic factors is to identify the target disorder. For school-based hearing screening the target disorder is often referred to as an educationally significant hearing loss (ESHL) (AAA, 2011; ASHA, 1997).

ESHL is considered a hearing loss that interferes with a learner's academic performance (AAA, 2011). This may include permanent sensorineural, conductive and mixed hearing losses, but may also include transient conductive losses. However, the severity of a hearing loss that constitutes ESHL is not always clearly defined. According to the World Health Organisation (2014) a disabling childhood hearing loss constitutes an average hearing threshold in the better ear across the frequencies 0.5, 1, 2, 4 kHz to be >30 dB HL. Despite some variability in the frequencies employed for screening, current recommendations generally agree that 1, 2 and 4 kHz should be screened bilaterally (AAA, 2011; ASHA, 1997; ISHP, 2012b; Kam et al., 2013; Wu et al., 2014). However, there is less consistency with regards to the screening intensity level that should be used to appropriately identify children with ESHL.

Guidelines specify a screening level of 20 dB HL across 1, 2 or 4 kHz in order to identify an ESHL (ASHA, 1997; AAA, 2011; ISHP, 2012b). Despite these guidelines, screening programmes have used various criteria to identify ESHL. For example, Lü et al. (2011) defined a possible hearing loss as an average of >40 dB HL across frequencies (0.5 to 4 kHz) and Kam et al., (2013) use a screening level of >25 dB HL at 1, 2, and 4 kHz . Furthermore, in some developed and developing countries screening intensity levels of 25, 30 and even 40 dB HL have typically been employed (Al-Rowaily, et al., 2012; AAA, 2011; Kam et al., 2013; Lo & McPherson, 2013; Wu et

al., 2014). A higher screening intensity level is sometimes used due to the presence of adverse background noise levels that are present in the test environment (Counter, 1986; Kam et al., 2013; McPherson et al., 2010). The selected criterion for screening in turn has an effect on the referral rates, sensitivity and specificity of a screening programmes (Dodd-Murphy, Murphy, & Bess, 2014). Ultimately these factors also determine the cost-effectiveness and feasibility of hearing screening programmes.

An immediate rescreen is an additional factor to consider for the purposes of reducing the referral rate. Screening is seen as a subjective test which requires the child to respond, thus external factors may influence the way a child may initially respond. Some of these external factors include the child's attention or understanding of instructions as well as the presence of environmental noise or distractions (AAA, 2011, ASHA, 1997). American Speech-Language-Hearing Association (1997) and American Academy of Audiology (2011) guidelines indicate that an immediate rescreen should be conducted which includes removing the headphones from the child's head, repeating the instructions and carefully replacing the headphones over the ears. However, immediate rescreen results are often not reported in studies as a rescreen may not have been included (Kam et al., 2013; McPherson et al., 2010; Wu et al., 2014).

3.2.2. Problem statement

Referral rate is an essential consideration when determining the cost-effectiveness of a programme. As referral rates increase (as a result of a low screening intensity level) more follow-up diagnostic evaluations are required. An excessive referral rate will be prohibitive to the sustainability of screening programmes, especially in developing

countries or under-resourced environments like those in the public school environment of South Africa. A higher screening intensity level can reduce the number of referrals, but may compromise the identification of milder hearing losses. This may be a trade-off that must be established by the constraints inherent to various contexts.

Less resourced contexts may require slightly higher hearing screening intensity levels to avoid overburdening health care systems that are already limited. In contrast more resourced countries may have lower screening intensity levels with higher referral rates with better sensitivity for identifying milder losses. Deciding on the appropriate screening intensity with regard to what the expected referral rate for school children will be, may assist in planning school-based programmes in different settings (McPherson & Olusanya, 2008).

3.2.3. Objectives

This study, therefore aims to firstly to investigate the effect of screening intensity level and secondly the effect of an immediate rescreen on the referral rate in a school-based hearing screening programme.

3.3. Material and methods

3.3.1. Design

A within-subject study was conducted which consists of two phases. Phase one compared the referral rate at different screening intensity levels (20, 25 and 30 dB HL) whilst phase two determined the effect of an immediate rescreen in reducing the referral rate.

3.3.2. Participants

3.3.2.1. Phase 1

One hundred and thirty-five school-aged children between the ages of 5 to 9 years (6.7 mean; 0.7 SD) participated in this phase of the study. The medium of instruction was English as all children's language of learning and teaching (LoLT) was English.

3.3.2.2. Phase 2

Three hundred and thirty-seven school-aged children between the ages of 5 to 10 years (6.7 mean ± 1.09 SD) participated in Phase 2 of the study. The medium of instruction was also English since all the children's LoLT was English.

3.3.3. Context

Ethical clearance for the study was obtained from the University of Pretoria Institutional Review Board and the Gauteng Department of Education. Children were recruited from two local public schools in Tshwane, South Africa, with children from one school participating in Phase one and children from the other in Phase two. All students, via their parents, in grade 1 to 3 in both schools were invited to participate. Only those children who provided signed assent along with a signed consent from their parent/caregiver participated in the study.

3.3.4. Data collection procedures

3.3.4.1. Phase 1

Screening was conducted over three days in a quiet room, provided by the local school. Ambient noise measurements could not be measured as the equipment was unavailable. An alternate approach, biologic noise level check, was conducted prior to

the commencement of hearing screening. This has been defined as the ability to establish hearing thresholds at 10 dB HL below the screening level at all frequencies for a person with known normal hearing. If these thresholds could not be established, the area was not used (AAA, 2011). Audiology students from the University of Pretoria conducted the screenings under direct supervision.

Each subject received three hearing screenings at different screening intensity levels of 20, 25 and 30 dB HL respectively. The three screening levels were counterbalanced to minimize an order effect. Screening was conducted at 1, 2 and 4 kHz as prescribed by current guidelines (AAA, 2011; ASHA, 1997). Left ears were tested first with an initial presentation at 1 kHz, 10 dB HL above the chosen screening level as a conditioning presentation. Test order was 1, 2 and then 4 kHz.

Children were instructed to raise their hand if they heard the sound with the screener sitting behind them (Figure 3.1) administering the test. If a student did not respond to the sound at a specific frequency it was repeated once to confirm a no-response and then recorded as a refer result. A refer at any frequency in either ear constituted an overall referral.

Figure 3.1. Screener administering hearing screening by sitting behind the patient.

3.3.4.2. Phase 2

Screening was conducted over five days with the same environmental conditions as used in Phase one. Screening procedures where conducted at a screening intensity level of 25 dB HL at 1, 2 and 4 kHz. A refer at any frequency in either ear constituted an initial referral. A rescreen was done immediately following a refer result. This was done by removing the headphones and re-instructing the child. The screening audiometer on which the initial refer was recorded was used to conduct the rescreen. Diagnostic audiometry was then conducted on children who referred on the rescreen. The school principal received hearing screening reports for all children tested. Based on the screening and diagnostic findings parents were provided with hearing screening reports and in the case of a referral, recommendations regarding follow-up assessments and interventions were made.

3.3.5. Equipment

3.3.5.1. Phase 1

Screening was conducted with one of two screening audiometers, a GSI Auto Tymp (Grayson Stadler, Eden Prairie, MN, USA) or an Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using Telephonics TDH 39P headphones. Both instruments were calibrated according to ISO 389-1 specifications.

3.3.5.2. Phase 2

Screening was conducted with the same screening audiometers used in phase one. Diagnostic pure tone air- and bone-conduction audiometry was conducted using the KUDUwave 5000 (GeoAxon, Pretoria, South Africa). This audiometer has been validated in a school-setting and previously described by Swanepoel, Maclennan-Smith, Hall (2013). The KUDUwave is a Type 2 Clinical Audiometer (IEC 60645-1/2) controlled by software on a computer (Acer Travelmate 2492). The audiometer hardware is encased in circumaural earcups and powered by a USB cable plugged into the notebook. The transducers include embedded, custom insert earphones, which were covered by the circumaural cups after insertion. A response button was connected to the KUDUwave device to record patient responses to stimuli. The audiometer was calibrated prior to commencement of the study, insert earphones were calibrated in accordance with ISO 389-2 and the bone oscillator according to ISO 389-3.

3.4. Calculation/data analysis

3.4.1. Phase 1

Data analyses included cross-tabulations of referral rates at 20, 25 and 30 dB HL across 1, 2 and 4 kHz as well as overall cross tabulations for each ear at the above mentioned intensities. The McNemar test was performed to determine if there was a significant difference between referral rates amongst the three screening intensities (Statistical significance was noted as $p<0.01$). Data was analysed using SPSS (v22. Chicago, Illinois).

3.4.2. Phase 2

Data analyses included cross-tabulation of initial screening outcomes obtained at 25 dB HL compared to refer results obtained during the rescreen. Data was analysed using SPSSv22 (Chicago, Illinois).

3.5. Results

3.5.1. Phase 1

One hundred and thirty-five children were tested at the respective screening intensities. At 20 dB HL, ear specific referrals were most common at 2 kHz (9.3%) whilst at 25 and 30 dB HL referrals was at its highest at 4 kHz (3.3% and 1.9%) (Table 3.1). The referral rates obtained increased as the screening intensity level decreased across the frequencies 1, 2, 4 kHz.

Table 3.1. Distribution of referrals across frequencies and different screening intensity levels (n=270 ears)

	20 dB HL	25 dB HL	30 dB HL
1kHz	5.9%	1.5%	1.5%
2kHz	9.3%	1.9%	0.7%
4kHz	6.3%	3.3%	1.9%
Referral rate per ear*	11.5%	5.1%	2.2%

*Number of referrals obtained for each ear (n=270 ears) across frequencies

A total of 23 children referred at 20 dB HL, more than half (14/23) of which passed at 25 dB HL, whilst only six (6/14) referred at 30 dB HL. There was a significant difference between the referral rates obtained at screening intensity levels of 20 and 25 dB HL and 20 and 30 dB HL (McNemar, $p<0.01$), but no significant differences between the referral rates at intensity levels 25 and 30 dB HL (Table 3.2).

Table 3.2. Distribution of referrals at ear-specific screening intensity levels (n=135 participants)

	20 dB HL	25 dB HL	30 dB HL
Right ear	11.9%	3.7%	2.2%
Left ear	11.1%	6.7%	2.2%
Referral rate per subject*	17%	6.7%	4.4%

*Number of referrals obtained across participants (n=135) and frequencies

3.5.2. Phase 2

The initial referral rate in this sample was 7.7% (Figure 3.2) which reduced by one-third (2.7%) with an immediate rescreen. Diagnostic audiometry conducted on all 17 students who failed the rescreen indicated that eight (47%) were true positives presenting with a hearing loss in the referred ear/s. One of the 17 children was difficult to test and reliable results could not be obtained. Of these eight children, two presented with a unilateral mild-to-moderate conductive hearing loss, two with a

unilateral moderate-to-profound mixed hearing loss, two with a bilateral mild-to-moderate sensorineural hearing loss, one with a bilateral profound sensorineural hearing loss and one with a bilateral asymmetrical moderate-to-profound mixed hearing loss in the right ear and a mild conductive hearing loss in the left ear.

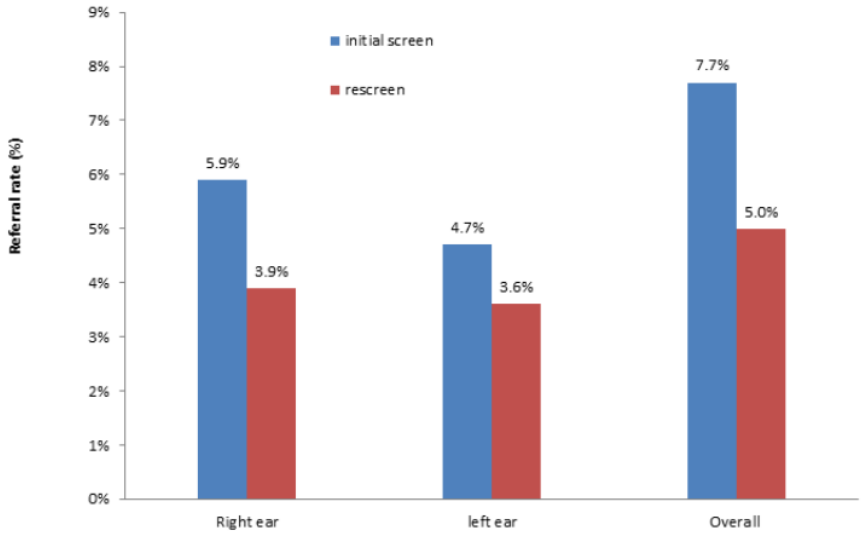

Figure 3.2. Distribution of referrals for initial screen and rescreen with screening intensity level at 25 dB HL across 1, 2 and 4 kHz (n=337 children)

3.6. Discussion

3.6.1. Outline of results

Despite widespread use of screening programmes to detect hearing loss, the recommended criterion for referral may not be ideal for resource-limited countries like South Africa (Kam et al., 2013). It has been proposed that the best screening programme is useless without definitive criterion for referral (AAA, 2011; ASHA, 1997). Programmes may be inappropriate or even unethical if there is not a sufficient audiological or medical infrastructure to cope with the possible cases of hearing loss identified through screening programmes (WHO, 1998, WHO, 2013b). As a result

implementing a school-based hearing screening programme could become problematic if a large number or referrals could not be managed by a limited amount of follow-up resources, as is often is the case in developing countries (McPherson & Olusanya, 2008).

A referral rate of 17% was obtained at 20 dB HL in the current study which means close to 1 in 5 children require following up services. These results were similar to the referral rate of 21.5% obtained by Sideris and Glattke (2006) who used the same referral criterion on a younger cohort of children between the ages of 2 and 5 years. These referral rates seem excessively high in comparison to those obtained at 25 and 30 dB HL (6.7% and 4.4% respectively). Dodd-Murphy, Murphy & Bess (2014) report similar findings using screening levels of 20 and 25 dB HL, on grade 2 learners, with referral rates of 17.8% and 7.6% respectively. Dodd-Murphy, Murphy & Bess (2014) confirmed that 20 dB HL is better suited to identify mild hearing losses but with referral rates 2.5 times higher. An excessive referral rate could be prohibitive to the sustainability of screening programmes, especially in developing countries or under-resourced environments like South Africa. The use of a higher screening intensity level will reduce the number of referrals but will have less sensitivity for milder hearing losses. The ISHP (2012b) specifies the use of 20 dB HL as the screening intensity level, however, a trade-off exists where less resourced countries like South Africa may require slightly higher screening intensity levels (e.g. 25 dB HL) to avoid overburdening health care systems that are already constrained. More resourced contexts that can deal with higher referral rates may however, opt for lower screening intensities (e.g. 20 dB HL) to improve identification of milder losses.

A screening intensity level of 25 dB HL was used in Phase 2 to determine the effect of an immediate rescreen on referral rates. The American Academy of Audiology (2011) and American Speech-Language-Hearing Association (1997) recommend a rescreen, but limited information has been reported on the effect of conducting an immediate rescreen (Lo & McPherson, 2013; Szudek, Ostevik, Dziegielewski, Robinson-Anagor, & Gomaa, 2012). Findings from the current study demonstrated that an immediate rescreen reduced the number of referrals initially obtained by 35%. Furthermore it was noted that from the participants who referred the rescreen, nearly half (47%) tested positive for some type of hearing loss after diagnostic testing.

3.6.2. Practical implications

As a result of the variability in the way school-based screening has been conducted there is no clear guideline on what the referral rate should ideally be. For newborn hearing screening (NHS) programmes, however, the recommended referral rate has been clearly prescribed to be less than 4% (Joint Committee on Infant Hearing, 2007). Referral rates obtained in this study at 25 and 30 dB HL were closer to these recommended rates from NHS programmes than the high referral rate obtained at 20 dB HL. Since no significant difference in referral rate was evident between 25 and 30 dB HL but a significant difference noted between 20 and 25 dB HL, a 25 dB HL screening intensity level may be most appropriate for resource-limited contexts. Employing 25 dB HL provides lower referral rates and is likely to have better sensitivity for milder hearing losses than a screening level of 30 dB HL. Furthermore, an immediate rescreen should be conducted on all children who refer an initial screening to reduce the number of excessive referrals, so as to minimize the burden faced by follow-up services.

3.6.3. Limitations of the study

A limitation of the current study included the omission of an immediate rescreen during the first phase of the study to determine the reduction in referral rate at 20 and 30 dB HL. However, if a rescreen was conducted each child would receive more than six screens in total. This would have extended test time opening up the possibility of fatigue and a possible order effect. Additionally, all participants undertook three screening tests at different screening intensity levels which could have influenced the overall referral rates. The test sequence was however, counterbalanced to limit this effect. An additional limitation was that true sensitivity and the specificity of results could not be determined in either phases of the study because diagnostic testing was only conducted in the second phase for those children referring the screening. Furthermore, the study did not make use of acoustic immittance testing as a secondary screening (AAA, 2011) to identify or rule out the presence of any middle ear pathologies. However, diagnostic testing was conducted which determined the presence of conductive or mixed hearing losses on the children who did refer on the rescreen in phase 2 of the study.

3.7. Recommendations and conclusion

In resource-limited contexts, a screen intensity level of 25 dB HL with an immediate rescreen at recommended frequencies (1, 2 and 4 kHz) can significantly reduce the overall referral rate to avoid overburdening health care resources. Of those children referred for follow-up services using this protocol close to half may be expected to present with hearing loss. It is recommended that a follow-up study be conducted to evaluate the follow-up services and the referral pathways available in resource-limited countries like South Africa.

CHAPTER 4

CLINICAL VALIDITY OF hearScreen™ SMARTPHONE HEARING SCREENING FOR SCHOOL CHILDREN

Authors: Mahomed-Asmail, F.; Swanepoel, D.W.; Eikelboom, R. H.; MyBurgh, H. C. & Hall III, J.

Journal: Ear and Hearing

Accepted: 22/07/2015

Proof acceptance: Appendix J

Publication: 2016, Vol. 37, pp. 11-17

4.1. Abstract

Objectives

The study aimed to determine the validity of a smartphone hearing screening technology (hearScreen™) compared to conventional screening audiometry in terms of (1) sensitivity and specificity, (2) referral rate and (3) test time.

Design

One thousand and seventy school-aged children in grade 1 to 3 (8 ±1.1 average years) were recruited from five public schools. Children were screened twice, once using conventional audiometry and once with the smartphone hearing screening. Screening was conducted in a counterbalanced sequence, alternating initial screen between conventional or smartphone hearing screening.

Results

No statistically significant difference in performance between techniques was noted, with smartphone screening demonstrating equivalent sensitivity (75.0%) and specificity (98.5%) to conventional screening audiometry. Whilst referral rates were lower with the smartphone screening (3.2 vs. 4.6%) it was not significantly different ($p>0.05$). Smartphone screening (hearScreen™) was 12.3% faster than conventional screening.

Conclusion

Smartphone hearing screening using the hearScreen™ application is accurate and time-efficient.

4.2. Introduction

Unidentified hearing loss has a substantial impact on a child's speech and language development, educational attainment and socio-emotional development (JCIH, 2007; WHO, 2013b). As a result a child's risk for failure and drop-out from school is significantly greater (WHO, 2013b). Most children who present with a hearing impairment at birth are potentially identifiable by newborn and infant hearing screening (Cunningham & Cox, 2003; JCIH, 2007). In developing areas of the world, where more than 80% of persons with hearing loss reside, there are limited prospects of early detection for hearing loss (Skarżyński & Piotrowska, 2012; WHO, 2013b) due to a number of barriers. Thus close to 20% of permanent moderate or greater bilateral, mild bilateral and unilateral impairments, remain to be identified around the time of school entry (Bamford et al., 2007)

School-entry hearing screening, if available, is the first point of access for screening in most developing countries and even in some developed countries (Bamford et al., 2007; Theunissen & Swanepoel, 2008). In a country like South Africa for example, where no legislation or health care mandate is in place to conduct newborn hearing screening, the recently mandated school-based screening (ISHP, 2012a) is the first opportunity for hearing screening in most children (Theunissen & Swanepoel, 2008; Meyer et al., 2012). However, effective implementation of school-based hearing screening presents a number of significant challenges (Madriz, 2001; McPherson & Olusanya, 2008).

The cost of hearing screening can be prohibitive due to the expense of audiometric equipment and the requirement for trained personnel to conduct the screening.

Furthermore, school-based hearing screening usually takes place in an enclosed, unoccupied, furnished room where ambient noise levels often exceed permissible levels (Bamford et al., 2007; FitzZaland & Zink, 1984; Lo &McPherson, 2013). Furthermore, test operators usually have no feedback on the compliance of ambient noise levels during testing. As a consequence, false-positive findings occur when ambient noise masks the test signal resulting in unnecessary and costly diagnostic assessments (Lo & McPherson, 2013).

A recent report of smartphone based hearing screening using the hearScreen™ application has demonstrated promise to address some of the abovementioned barriers (Swanepoel, Myburgh et al., 2014). hearScreen™ is a cost-effective screening option that can be operated on an entry-level smartphone running Android™ OS. A supra-aural headphone can be acoustically calibrated according to international standards taking into consideration the procedures specified to determine equivalent threshold sound pressure levels (ETSPL) for non-audiometric headphones (American National Standards Institute/Acoustical Society America (ANSI/ASA) S3.6-2010; International Standardization Organization (ISO) 389-1, 1998) using a type 1 sound level meter and coupler. This feature creates opportunity for smartphones to be utilized as screening audiometers with headphones calibrated according to prescribed standards. Furthermore, the hearScreen™ software application integrates noise monitoring referenced to MPANLs during testing. This provides screening operators with real-time feedback on ambient noise levels and allows frequencies to be retested where noise levels exceeds MPANLs and patients do not respond (Swanepoel, Myburgh et al., 2014)

hearScreen™ can be programmed according to recommended screening protocols (AAA, 201; ASHA, 1997) utilizing automated test sequences based on a forced-choice paradigm to ensure reliability and ease of use (Swanepoel, Myburgh et al., 2014). An operator with limited training can place headphones on the patient, capture demographic data, provide the onscreen instructions during the test and act on the screening outcome. Additionally, the hearScreen™ application has a data storage feature utilising the connectivity available on the phone (GPRS/3G/HSDPA and Wi-Fi) to securely upload data to a cloud-based server for remote monitoring and management. An initial validation study showed no significant difference for screening outcomes using hearScreen™ and conventional audiometry (Swanepoel, Myburgh et al., 2014). However, the study was conducted with a modest sample size and test sensitivity and specificity was not determined.

An additional investigation is necessary to validate the smartphone hearing screening against conventional screening audiometry followed by diagnostic assessment to determine true sensitivity and specificity rates. This study therefore aimed to establish the validity of school-based hearing screening using smartphone hearing screening with the hearScreen™ application compared to conventional screening audiometry in terms of (1) sensitivity and specificity (2) referral rates and (3) test time.

4.3. Materials and methods

The research project was approved by the Research Board of the University of Pretoria, South Africa and Gauteng Department of Education, South Africa.

4.3.1. Participants

One thousand and seventy school-aged children from grade 1 to grade 3 with an average age of 8 years (±1.1 SD; Range 6 to 12 years) were recruited from five public government schools in underserved regions of the Gauteng Province, South Africa. Demographic distribution was 50.7% female and 83.5% African (16.5% Caucasian). Only children who provided assent along with a signed consent from their parent/caregiver were included in the study. A response rate of 64.2% (1070/1667) was obtained for this study. Data were collected during a 7-month period with the exception of two vacation periods.

4.3.2. Test environment and screening personnel

Screening was conducted by second year audiology students from the University of Pretoria who were trained in the use of both the smartphone hearing screening and conventional screening audiometry. As part of the practical block the audiology students, under direct supervision of the first author who conducted validation checks throughout, were required to complete five consecutive screening sessions. Diagnostic audiometry was conducted by the first author. Testing was conducted in a quiet room provided by the school were five stations were set up, two for conventional screening, two for smartphone hearing screening and one for diagnostic audiometry. Due to the limited number of screeners and testers available, small groups of four to six children were taken into the testing venue. Larger number of children can be screened based on the available resources. Sound in the test environment was measured with a sound level meter (RION, NA-24) for no less than five minutes prior to data collection and no less than five minutes twice during data collection during the session. Calibration was checked every four to six weeks thereafter using an IEC

60318-1 G.R.A.S Ear stimulator connected to a Type 1 SLM (Rion NL-52). Calibration checks on both screeners were carried out in order to rule out any variations to the presented pure tone signal, the values did not vary more than 1 dB HL across the multiple checks.

4.3.3. Equipment

4.3.3.1. Smartphone hearing screening

Data were collected with two sets of Samsung Galaxy Pocket Plus S5301 phones running the hearScreen™ Android OS application with supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany). As the hearScreen™ application (under investigation) is not intended to be an end-user application it requires objective calibration on pre-selected smartphone models standardised for testing. Thus before data collection commenced, headphones were calibrated on the hearScreen™ calibration function according to prescribed standards (ANSI/ASA S3.6-2010; ISO 389-1, 1998) for TDH 39 supra-aural headphones (see Swanepoel, Myburgh et al., 2014 for detailed description). Furthermore, the smartphone hearing screening application monitored and recorded noise levels during data collection for each child. Previously published work indicate that noise monitoring using this application on these smartphones is accurate within 1 and 1.5 dB, depending on the frequency (Swanepoel, Myburgh et al., 2014). Recorded noise levels consisted of the averaged ambient noise recorded by the smartphone during the pure-tone presentation (1.2 seconds duration) in the octave band corresponding to the test frequency (see Swanepoel, Myburgh et al., 2014). Smartphones were connected to a 3G cellular network whereby screening results were uploaded to a database at the end of each screening session.

4.3.3.2. Conventional hearing screening

Conventional hearing screening was conducted with one of two screening audiometers, a GSI Auto Tymp (Grayson Stadler, Eden Prairie, USA) or an Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using Telephonics TDH 39P headphones. Audiometers were calibrated according to ISO 389-1 (1998) standards prior to data collection.

4.3.3.3. Diagnostic audiometry

Diagnostic audiometry was performed with a KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2). The KUDUwave is operated via a notebook computer (Acer Aspire E1-532, running Microsoft Windows 8) with the audiometer hardware encased in each circumaural ear cup and powered by a USB cable plugged into the notebook. Transducers were insert earphones covered by the circumaural cups after insertion. A response button was connected to the KUDUwave device to record patient responses to stimuli. The KUDUwave had two microphones on the circumaural earcup that monitored the environmental noise in octave bands during testing and was visually represented in real-time within the software. Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold as indicated by the effective attenuation level in the KUDUwave software, the audiologist waited for the transient noise to abate and then continued the testing. The KUDUwave device has been validated for accurate air- and bone-conduction thresholds in school settings utilizing the increased attenuation (insert earphones covered by circumaural earcups) and real-time noise monitoring (Swanepoel, Maclennan-Smith & Hall, 2013). The audiometer,

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

4.3.4. Procedures

Each child was screened twice by the same tester, once with a conventional screening audiometer and once with the smartphone hearing screening device on the same day in the same room. Screening was conducted in a counterbalanced sequence, alternating initial screen between conventional and smartphone screening. The screener sat behind the child with the child instructed to raise a hand upon hearing the tone (Figure 4.1). Screening was conducted using current recommended protocols (AAA, 2011; ASHA, 1997) with the exception that the screening intensity level was raised to 25 dB HL for both methods of screening (Swanepoel, Myburgh et al., 2014). Kam et al. (2013) indicated that the recommended criterion of 20 dB HL for referral may not be ideal for resource-limited countries. Furthermore, studies conducted in some developed and developing countries such as China, India and Africa utilized screening intensity levels of 25, 30 and even 40 dB HL (Al-Rowaily et al., 2012; AAA, 2011; Kam et al., 2013; Lo & McPherson, 2013; Wu et al., 2014). As a resource-limited country with less than optimal test environments being utilized the screening level was set at an elevated level of 25 dB HL.

Conventional screening was conducted manually whereas hearScreen™ was programmed utilizing an automated test sequence with a forced choice paradigm to ensure ease of use and minimal operator influence (Swanepoel, Myburgh et al., 2014). An operator placed the headphones on the child and provided the necessary onscreen instructions after filling out the child's details (Figure 4.1). The forced-choice paradigm requires that, after the test operator presented the test signal the child will raise a hand upon hearing the tone, the tester will then have to indicate whether the child responded to the sound in a YES/NO response provided on the application. Based on the response the intensity and frequency changes automatically according to the programmed test protocol (See Swanepoel, Myburgh et al., 2014 for detailed description). Furthermore, the inter-stimulus interval of hearScreen™ is similar to conventional screening as the tester still controls when the tone should be presented allowing similar flexibility as conventional screening.

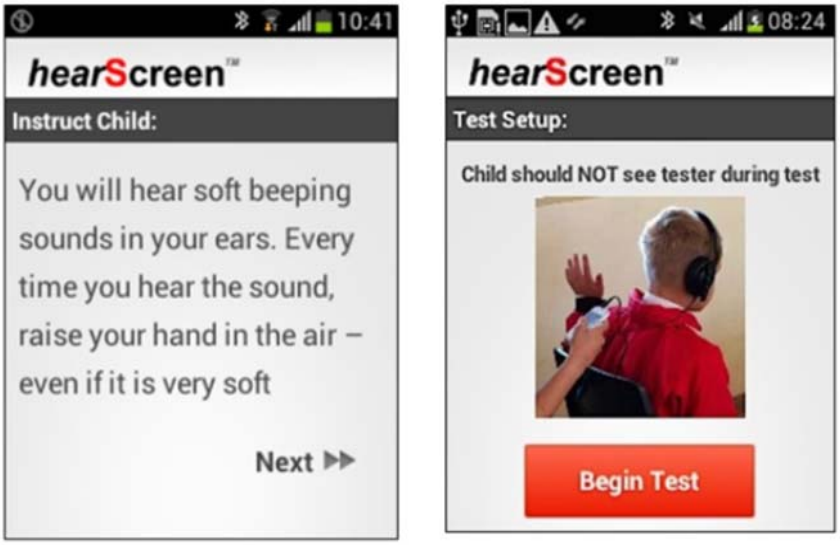

Figure 4.1. Onscreen hearScreen™ instructions provided to tester

Due to the automated test sequences of hearScreen™ being based upon the forced-choice response by testers, training was significantly less than for conventional

screening audiometry which requires prior knowledge and skill in adjusting frequencies and intensities on the audiometer in accordance with the screening protocol.

To ensure consistency for both screening methods left ears were tested first with an initial conditioning presentation at 1 kHz at an intensity level of 35 dB HL. This was followed by presentations of 25 dB HL at 1, 2, and 4 kHz. Stimulus presentation was repeated once if a child did not respond at a specific frequency level. Once data was collected for the left ear the same procedure was repeated in the right ear. No response at 25 dB HL at any frequency in an ear constituted an initial fail. Immediately following a fail result, the child was rescreened using the same screening audiometer. hearScreen™ provided the tester with onscreen guidelines on when to conduct a rescreen and when a child referred (Figure 4.2).

Average test time for both methods were recorded, excluding instructions and preparation time. For conventional screening the tester used a stop watch to record the time, whereas with hearScreen™ the test time was automatically recorded by the screening application. Furthermore, Maximum Permissible Ambient Noise Levels (MPANL) were recorded during testing with the smartphone screening application. The MPANL's per octave band for screening at 25 dB was 49, 57, and 61 dB SPL for 1, 2, and 4 kHz respectively (Swanepoel, Myburgh et al., 2014). The ambient noise level measurements were measured with a sound level meter (RION, NA-24) to ensure that test environment for diagnostic testing was in accordance to those indicated in the validation study (Swanepoel, Maclennan-Smith & Hall, 2013).

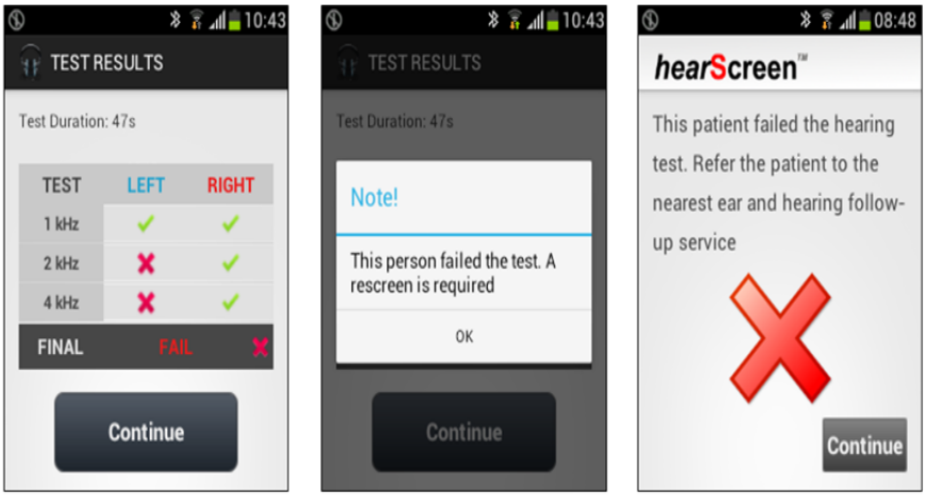

Figure 4.2. Rescreen and referral instructions provided by hearScreen™

Sensitivity and specificity usually requires diagnostic assessment of the entire sample. Sensitivity for the current study was determined conventionally by diagnostically testing each child who referred based on immediate rescreen on either screening technique (conventional and hearScreen™). Since the current study compared screening techniques of each child with diagnostic evaluations for referrals on both or either screening technique, the false negatives for each screening technique could be determined. To further investigate the possible occurrence of false negatives in children who passed both screenings a stratified sampling strategy was employed whereby every 15th child who passed both screens was tested diagnostically. In this way specificity could be determined by taking into consideration the true and false negatives for each technique. For diagnostic audiometry insert earphones were placed deeply within the external ear canal with circumaural headphones placed over the ears and the bone-conductor placed on the forehead. Children were instructed to press the response button every time they heard the tone, the KUDUwave recorded false positive results as a control. Behavioural air conduction thresholds and behavioural bone conduction thresholds were obtained at 0.5, 1, 2 and 4 kHz.

The school principal received hearing screening reports for all children tested. Based on the screening and diagnostic findings parents were provided with hearing screening reports and in the case of a referral, recommendations regarding follow-up assessments and interventions were made.

4.3.5. Data analysis

To evaluate the accuracy of the smartphone hearing screening, overall referral rates with the smartphone and conventional screening were compared using cross-tabulations of test outcomes for each child. Overall referral rates were obtained based on overall results following an immediate rescreen (two consecutive fail results) for each child. A Chi-square test was used to assess differences across testing with a level of $p<0.05$ set as significant. Sensitivity and specificity were calculated separately for each screening technique with reference to conventional diagnostic test results for each child. Sensitivity and specificity results obtained for hearScreen™ were compared to those obtained for conventional screening. Diagnostic test results revealed a hearing loss when an AC threshold greater than 25 dB at either 0.5, 1, 2 or 4 kHz was obtained. Noise level measurements recorded with hearScreen™ were averaged and compared to maximum permissible ambient noise levels (MPANL's) for the specified headphones (Swanepoel, Myburgh et al., 2014) at the screening level of 25 dB HL. Average test time between methods, excluding instructions and preparation time, was also determined with the paired sample t-test. Statistical analysis was conducted using SPSS (v22. Chicago, Illinois).

4.4. Results

Overall referral rates were 3.2% for smartphone hearing screening and 4.6% for conventional screening (Table 4.1). There was no significant difference ($p>0.05$; Chi-square test) between screening techniques for overall referral rate, across age categories or between initial and rescreen results (Table 4.1). Significantly more females referred ($p<0.05$; Chi-square test) for conventional screening compared to males (Table 4.1). Across frequencies the highest referral rates were noted at 1 kHz for both screening techniques with no statistical difference ($p<0.05$; Chi-square test). Average time for conducting an initial screen was significantly less ($p<0.001$; Paired sample t-test) with the smartphone hearing screening device (mean 54.5 seconds; SD 28.3) being 12.3% faster than conventional hearing screening (mean 62.2 seconds; SD 38.1).

Immediately following a fail result from either screening method, a rescreen was conducted using the same screening audiometer. A total of 99 children were rescreened with conventional screening and 79 children with the smartphone screening application.

Table 4.1. Referral rates for conventional and hearScreen™ screening

Referral rate	Participants (n)	Conventional screening	hearScreen™
Overall			
Initial screen	1070	9.3%	7.4%
*Rescreen**	1070	4.6%	3.2%
Gender			
Male	528	2.8%	3.0%
Female **	542	6.3%	3.3%
Age categories			
6 to < 8 years	221	4.1%	3.6%
8 to < 9 years	313	4.2%	2.9%
≥ 9 years	536	5.0%	3.2%
Ears			
Left	1070	3.2%	2.4%
Right	1070	3.4%	2.3%
Frequencies			
1 kHz left	1070	2.5%	1.7%
2 kHz left	1070	1.8%	1.4%
4 kHz left	1070	1.8%	1.3%
1 kHz right	1070	2.5%	1.6%
2 kHz right	1070	1.6%	1.6%
4 kHz right	1070	1.7%	1.2%

Distribution of referral rate across variables are based on final referral rate.

** Rescreen was done immediately after an initial refer result and reflects overall referral rate.*

** Statistical difference obtained between females and males ($p<0.05$; Chi-square test) for conventional screening

125 children underwent diagnostic audiometry. 31.2% (39/125) referred on either conventional or hearScreen™ screening, and 17.6% (22/125) referred on both screening techniques, while the remaining 51.2% (64/125) passed on both screening techniques. Only one child who referred on hearScreen™ and conventional screening could not be conditioned for diagnostic audiometry. Due to inconsistent responses, the child was excluded from data analysis. Of the remaining 124 children, 2.2% (12 male, 12 female) presented with a confirmed hearing loss (an AC threshold greater than 25 dB at either 0.5, 1, 2 or 4 kHz) when tested diagnostically. Sensitivity of the two techniques was similar with no statistically significant difference in performance (Table 4.2). Using a stratified sampling strategy to diagnostically test every 15th child who passed both screening techniques revealed no false negatives in either screening

technique. Six false negative cases were however identified for conventional and smartphone screening in cases where children passed on one screening technique and referred on the other. Conventional screening missed three unilateral mild-to-moderate conductive hearing losses, two bilateral mild-to-moderate conductive hearing losses and one moderate-to-severe mixed hearing loss. Whereas, the smartphone screening application missed three unilateral mild conductive hearing losses, two bilateral mild conductive hearing losses and one mild-to-moderate sensorineural hearing loss.

Table 4.2. Performance of conventional compared to hearScreen™ school-based screening (n=1070)

	Conventional screening	hearScreen™
Sensitivity	75.0%	75.0%
Specificity	97.0%	98.5%
Positive predictive value	36.7 %	52.9%
Negative predictive value	99.4%	99.4%
Positive likelihood value	25.3%	49.0%
Negative likelihood value	0.5%	0.3%

Sound in the test environment measured with a sound level meter (RION, NA-24) prior to data collection and twice during data collection revealed average noise levels ranging from 42.5 to 79.6 dBA (mean 65.1 SD 9.9).

Smartphone recorded noise levels exceeded MPANL's mostly at 1 kHz (Table 4.3). During the initial screen noise levels exceeded MPANL's at 1 kHz in the left ear a total of 84 times (7.9%) but the screen had a fail result in only two of these instances. A similar phenomenon was noted at 1 kHz in the right ear, with only three of 78 children failing despite noise exceeding MPANL's. Only three left ears and two right ears

referred on the rescreen at 1 kHz despite the present ambient noise levels. Among the referred ears, diagnostic assessment confirmed a hearing loss for two left ears and one right.

Table 4.3. Instances where noise level's during smartphone screening was above MPANL's

	1 kHz left	1 kHz right	2 kHz left	2 kHz right	4 kHz left	4 kHz right
Initial screen (n =1070)	7.9%	7.3%	0.2%	0%	0.1%	0.1%
Rescreen (n=79)	7.6%	6.3%	0%	0%	0%	0%

4.5. Discussion

The validity of a screening protocol is determined by the degree to which results are consistent with the actual presence or absence of the disorder (AAA, 2011). Sensitivity and specificity values support the validity of a screening technique. Sensitivity is indicative of the accuracy of the screening tool to correctly identify individuals with the target condition whilst specificity refers to the accuracy of the screening tool to correctly identify individuals without the target condition (Kam et al., 2014; Margolis, Frisina, & Walton, 2011; Wu et al., 2014). In order for the smartphone hearing screening (hearScreen^{TM}) to be a valid method for detecting children with hearing loss its performance must be comparable to that of conventional screening conducted manually with pure tone audiometers. Our study indicated no significant difference in sensitivity or specificity rates for smartphone compared to conventional hearing screening. Sensitivity was equivalent (75.0%) and for specificity the smartphone hearing screening was slightly higher (98.5%) than conventional screening audiometry (97.0%). This resulted in a lower referral (3.2% vs 4.6%) for the smartphone hearing

screening (Table 4.1). Furthermore, the smartphone screening yielded a false-positive rate (1.5%) lower than conventional screening (2.9%) (Table 4.2) suggesting slightly improved accuracy for correctly identifying children without a hearing loss. Reduced false-positives reduces unnecessary referrals that may improve cost-effectiveness and feasibility of a screening programme.

School hearing screening specificity reported in this study by both screening techniques are comparable to those previously reported. A possible reason for the reduced sensitivity rate obtained in this study could be due to the screening level of 25 dB HL that was utilized. This slightly raised screen level was selected due to noise levels in test environment and to ensure that within the resource-limited context of developing countries like South Africa the referral rate would not create an excessive burden on the health care system. Dodd-Murphy, Murphy, & Bess (2003) reported similar specificities to this study for educationally significant hearing loss, but high sensitivity (97.5%) was reported for a screening level of 25 dB HL when applied to known thresholds of children in three, six and nine. Sensitivity for both screening devices in our study was higher than those recently reported by Dodd-Murphy, Murphy & Bess (2014) for a 25 dB HL intensity level. The authors reported a sensitivity of 50% for children from grade one, two, three, five and seven who were screened on site, with the referral criteria set at 25 dB HL to determine minimal sensorineural hearing loss. The reason for the lower sensitivity reported by Dodd-Murphy, Murphy & Bess (2014) could be due to the fact that diagnostic evaluation was done months after the screenings. Furthermore, their study obtained a 38% sensitivity at 25 dB HL based on a retrospective analysis of known thresholds for children in grades 3, 6, 9, & 11.

We found gender effects in our hearing screening outcome with conventional screening having a referral rate for males (2.8%) significantly lower than females (6.3%). One possible contribution for this difference could be due to headphone placement affected by hair length or styles in girls that could have resulted in more low frequency leakage or standing waves. However, in contrast, previous study findings indicate that hearing loss is more common in boys due to the higher incidence of severe otitis media, noise induced hearing loss as well as genetic predisposition (Axelsson, Aniansson, & Costa, 1987; Barr, Anderson, & Wedenberg, 1973). There was no gender difference in hearing screening outcome for the smartphone hearing screening device (males 3.0%, females 3.3%). Limited findings have been reported on gender effects in school screening outcomes. Future investigations should report gender specific results to investigate this further.

There were no observable age effect in terms of referral rates. However, slightly higher referral rates were observed for the oldest age group (>9 years) utilizing conventional screening. The reason for the increase in referral rate as the age of the children increased is uncertain. In contrast the highest referral rate (3.6%) using smartphone hearing screening was evident for the youngest age group (6 < 8 years). Previous studies have reported similar findings with a decrease in referral rate as the age of children increase (Sideris & Glattke 2006; Dodd-Murphy, Murphy & Bess 2014). Younger populations typically have a higher incidence of middle ear disorders which typically lead to a higher referral rate (Swanepoel, Eikelboom, & Margolis, 2014).

There was a significant difference in test time for the two hearing screening techniques. This could be as a result of hearScreen™ automatically changing to the

next intensity and frequency based on the screening protocol, whereas, conventional screening required a manual change to frequency and intensity. On average, screening (excluding time taken for instructions and capturing demographic data) with the smartphone application was completed in less than a minute (mean 54.5s ± 28.3 SD) whereas with conventional screening, screening took just over a minute (mean 62.2s ± 38.1 SD). Smartphone screening was 12.3% faster compared to conventional screening. Time-efficiency with the smartphone hearing screening application may ensure screening larger numbers of children in a typical school day.

Environmental noise level is one of the most common concerns in hearing screening programs (AAA, 2011; ASHA, 1997; Bamford et al., 2007; FitzZaland & Zink, 1984; Lo & McPherson 2013). Consistent with professional recommendations (AAA, 2011; ASHA, 1997) and to ensure test environment for diagnostic testing was in accordance to those indicated in the validation study (Swanepoel, Maclennan-Smith & Hall, 2013), we used a sound level meter (RION, NA-24) to measure ambient noise levels in the test environment prior to screening. We subsequently conducted sound level measurements two more times, while data collection was being conducted on the same day. Noise levels ranged between 42.5 and 79.6 dBA (mean 65.1 SD 9.9). The ambient noise levels for this study were comparable to the ambient noise levels obtained (65.6 dBA, maximum 78.5 dBA) in the KUDUwave validation study (Swanepoel, Maclennan-Smith & Hall, 2013), thus results obtained from diagnostic audiometry on-site in this study serve as a valid reference standard.

Significant variability in noise levels throughout the day is common due to children or testers leaving the room, instructions been given, the ringing of the school bell or

groups of children walking pass the testing venue. The smartphone hearing screening application utilizes integrated noise monitoring referenced to MPANLs during testing. Thus hearScreen™ provides screening operators with real-time feedback on ambient noise levels to ensure compliance with standards (Swanepoel, Myburgh et al., 2014). We found that the recorded noise levels exceeded MPANL's mostly at 1 kHz, which may in part explain the higher referral rate at this frequency. Another factor to consider is remote frequency masking, Leibold and Neff (2011) reported that children younger than seven are at risk for remote frequency noise masking at 1kHz. The noise level monitoring function did not correct for remote frequency masking. As a result we recommend that the noise level monitoring function of hearScreen™ be programmed in remote bands at the same time as test bands. In the case of ambient noise levels being too high a warning signal appeared on the screen, the screener was then able wait for environmental noise to subside and then conduct a rescreen. Furthermore, noise levels were recorded and uploaded with test results. Referrals could also be cross-checked with noise levels to determine if the noise may have influenced the child's response. In this study five children referred on the rescreen when noise levels were too high. Three of these children presented with a hearing loss.

The data storage feature of hearScreen™ application utilising the connectivity available on the phone allowed data to be securely uploaded to a cloud-based server for remote monitoring and management. The data was uploaded by connecting phones to a WiFi hotspot at the school. Data transmission and the cloud server is encrypted and password protected ensuring. This feature streamlined and simplified data management.

In developing areas of the world, where more than 80% of persons with hearing loss reside, there are limited prospects of early detection for hearing loss (Skarżyński & Piotrowska, 2012; WHO, 2013b) due to barriers such as high cost of screening audiometers, operator training required to conduct conventional manual audiometric screening, over referrals due to lack of environmental noise monitoring, and poor data capturing and management (Swanepoel, Myburgh et al., 2014). Findings from this study indicate that a smartphone hearing screening solution like hearScreen™ may address many of these barriers. Smartphone hearing screening can provide a valid and effective screening tool incorporating quality control features for noise monitoring, pre-programmed screening protocols allowing less training of the tester and data capturing for remote monitoring and management.

4.6. Conclusion

Smartphone hearing screening offers an inexpensive alternative to conventional screening audiometry with specific application to school-based screening. The application utilizes inexpensive, widely available, smartphone and headphone technology for hearing screening. Sensitivity was similar and specificity slightly better for the smartphone hearing screening device compared to conventional screening audiometry. There was no significant difference for referrals with the two screening techniques although smartphone screening had a slightly lower referral rate. The noise monitoring function along with other strategies to control ambient noise may ensure effective screening with minimal influence from noise sources. Smartphone hearing screening was slightly more time-efficient than conventional screening. The limited training required to operate the hearScreen™ software and the automated test sequences mean that it can be used by lay-persons opening up new possibilities in

terms of service-delivery models. This smartphone hearing screening application therefore provides a low-cost, accurate and efficient screening solution for school-based screening that could be facilitated by non-health personnel with limited training.

CHAPTER 5

DIAGNOSTIC HEARING ASSESSMENT IN SCHOOLS: VALIDITY AND TIME-EFFICIENCY OF AUTOMATED AUDIOMETRY

Authors: Mahomed-Asmail, F.; Swanepoel, D.W. & Eikelboom, R. H.

Journal: Journal of American Academy of Audiology

Accepted: 25/08/2015

Proof of acceptance: Appendix J

Publication: 2016, Vol 27, pp. 42-48

5.1. Abstract

Background

Poor follow-up compliance from school-based hearing screening typically undermines the efficacy of school-based hearing screening programs. Onsite diagnostic audiometry with automation may reduce false-positives and ensure directed referrals.

Objective

To investigate the validity and time-efficiency of automated diagnostic air- and bone-conduction audiometry for children in a natural school environment following hearing screening.

Research design

A within-subject repeated measures design was employed to compare air- and bone-conduction pure-tone thresholds (0.5 to 4 kHz), measured by manual and automated pure tone audiometry.

Study sample

Sixty-two children, 25 males and 37 females with an average age of 8 years (SD 0.92; range 6 to 10 years) were recruited for this study. The participants included 30 children who failed on a hearing screening and 32 children who passed a hearing screening.

Data Analysis

Threshold comparisons were made for air- and bone- conduction thresholds across ears tested with manual and automated audiometry. To avoid a floor effect thresholds of 15 dB HL were excluded in analyses. The Wilcoxon signed ranked test was used to compare threshold correspondence for manual and automated thresholds and the paired samples t-test was used to compare test time. Statistical significance was set as $p \leq 0.05$.

Results

85.7% of air-conduction thresholds and 44.6% of bone-conduction thresholds corresponded within the normal range (15 dB HL) for manual and automated audiometry. Both manual and automated audiometry air- and bone-conduction thresholds exceeded 15 dB HL in 9.9% and 34.0% of thresholds respectively. For these thresholds average absolute differences for air- and bone-conduction thresholds were 6.3 dB (8.3 SD) and 2.2 dB (3.6 SD) and they corresponded within 10 dB across

frequencies in 87.7% and 100.0%, respectively. There was no significant difference between manual and automated air- and bone-conduction across frequencies for these thresholds.

Conclusion

Utilizing onsite automated diagnostic audiometry for children who fail hearing screening may improve the efficacy of school-based screening programs by reducing false-positives and ensuring directed referrals for audiological and/or medical intervention.

5.2. Introduction

Audition within normal ranges facilitates development and utilization of spoken communication (Ramkalawan & Davis, 1992). Damage to the auditory system or congenital dysfunction, may severely restrict or prevent development of spoken communication with associated effects on reading comprehension, cognitive development, socio-emotional functioning and ultimately academic achievement (Olusanya, Luxon, & Wirz, 2004; Olusanya & Newton, 2007; Ramkalawan & Davis, 1992; Yoshinaga-Itano, Sedey, Coulter, & Mehl, 1998). Currently, more than 32 million children globally present with a permanent hearing disability that threatens these developmental domains (WHO, 2013a).

Most children with congenital hearing loss are potentially identifiable by newborn and infant hearing screening (Cunningham & Cox, 2003). However, around 20% of permanent mild, moderate or greater bilateral and unilateral impairments remain to be identified around the time of school entry (Bamford et al., 2007a). School-based hearing screening has been recommended by international societies (AAA, 2011; ASHA, 1997; Skarżyński & Piotrowska, 2012) for permanent, longstanding sensorineural hearing losses and frequently recurring conductive hearing losses. The recommended approach for school-based screening is a pure tone screen (AAA, 2011; ASHA, 1997; Bamford et al., 2007a) with an immediate rescreen administered after a fail result has been obtained (AAA, 2011). If a child fails on the rescreen diagnostic pure tone audiometry is recommended within 1 month and no later than 3 months after the initial screen (AAA, 2011; ASHA, 1997). Current evidence, however, indicates that poor follow-up compliance from school-based hearing screening (AAA, 2011) typically undermines the efficacy of school-based hearing screening programs.

In a large-scale metropolitan pre-school hearing screening program follow-up after referral was < 20% (Flanary et al., 1999).

Conducting diagnostic pure tone audiometry immediately after a fail result could reduce the characteristically poor follow-up rates (Swanepoel et al., 2013) by eliminating false positive screen results and identifying those who require audiological and/or medical intervention. However, the lack of compliant, sound-treated environments in typical school settings has traditionally precluded the administration of diagnostic air- and bone-conduction audiometry in a school setting (Swanepoel et al., 2013). Recent studies validated a mobile audiometer (KUDUwave, eMoyoDotNet, Pretoria, South Africa) to conduct manual diagnostic air- and bone-conduction audiometry outside a booth environment (Maclennan-Smith et al., 2013; Storey et al., 2014; Swanepoel et al., 2013). Testing in a school environment without a sound booth demonstrated that valid diagnostic pure-tone audiometry could be performed for children by an audiologist (Swanepoel et al., 2013).

Although this may be a possible solution, the shortage of available human resources does not make it practical to employ audiologists for diagnostic testing in schools. Globally there is an increasing gap in demand and capacity of audiologic services (Goulios & Patuzzi, 2008; WHO, 2013b), with availability of audiologists associated with income level (WHO, 2013b). Upper-middle and high-income countries typically report one audiologist per 110 000 people whereas low income regions such as Africa and Asia have reported between 0.5 and 3.4 million people per ENT surgeon with access to even smaller numbers of audiologists, and several (including Bangladesh, Indonesia, and Laos) reported having no audiologists and minimal provision of hearing

health care (Goulios & Patuzzi, 2008). This is however not only a developing world problem, with Windmill and Freeman (2013) reporting that the supply of audiologists in the U.S over the next 30 years will not meet the anticipated demand.

Automated audiometry, that can integrate with an asynchronous telehealth service model, may assist in making audiological services available by allowing procedures to be conducted without a hearing healthcare professional present onsite (Swanepoel, Clark et al., 2010). Generally automated audiometry involves automation of the test sequences required for hearing assessment (Margolis & Morgan, 2008). It is ideally suited for pure-tone testing as a sequence of steps can be implemented using a software-based testing system to obtain a threshold (Margolis & Morgan, 2008).

A recent literature review and meta-analysis on automated audiometry (Mahomed et al., 2013) revealed similar test–retest reliability for automated and manual threshold audiometry. Typically automated audiometry thresholds were within typical test–retest and inter-tester variability of manual thresholds in adults (Eikelboom et al., 2013; Ho, Hildreth, Lindsey, 2009; Margolis, Frisina, & Walton, 2011a; Margolis & Moore, 2011; Swanepoel, Mngemane et al., 2010). This review found only five validation studies on automated audiometry in children, of which thresholds obtained with automated audiometry were comparable to those obtained with manual audiometry (Almqvist & Aursnes, 1978; Hartly & Siengenthalar, 1964; Margolis et al., 2011; Picard et al., 1993; Wood et al., 1973). Only two of these studies included bone conduction (Wood et al., 1973; Pichard et al., 1993). Of these air- and bone- conduction studies only one included testing in a more natural environment without a sound-treated room. The

literature review recommended further investigation for automated audiometry in children.

Automated diagnostic air- and bone- conduction testing in a school environment may improve the efficacy of school-based screening programs by reducing the false-positives and ensuring timely and direct referrals for audiological and/or medical intervention. This study therefore aimed to investigate the validity and time-efficiency of automated diagnostic air- and bone- conduction audiometry for children in a natural school environment as part of a school hearing screening program.

5.3. Methods

Ethical clearance for this study was obtained from the Ethics Committee, University of Pretoria, South Africa and the Gauteng Department of Education, South Africa. Children were recruited from five public government schools in underserved regions of the Gauteng Province, South Africa. In all cases children provided informed assent and parents provided informed consent prior to participation.

5.3.1. Subjects

Hearing screening was conducted twice on all children with two different screening audiometers (conventional and smartphone-based) (Mahomed-Asmail, Swanepoel, Eikelboom, MyBurgh, & Hall, 2016). 30 children who failed a hearing screening (11 failed on conventional screening, 6 failed smartphone-based screening, 13 failed on both screens) were evaluated diagnostically with automated and manual audiometry. A further 32 children who passed on both manual and smartphone-based screening were tested diagnostically with both automated and manual audiometry. A total

sample of 62 children (6 to 10 years old) was recruited for diagnostic pure-tone audiometry evaluations.

5.3.2. Equipment

The conventional screening audiometers were a GSI Auto Tymp (Grason Stadler, Eden Prairie, USA) or an Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark), both using TDH 39P headphones (Telephonics, Huntington, N.Y). Both audiometers were calibrated according to ISO 389-1 (1998) prior to test commencement. The two smartphone screening audiometers used were Samsung Galaxy Pocket Plus S5301 phones running the hearScreen™ Android OS application with supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany)(see Swanepoel et al., 2014 for detailed description).

Diagnostic audiometry was performed with the KUDUwave (eMoyoDotNet, Pretoria, South Africa). This audiometer has been validated in a school-setting and previously described by Swanepoel, Maclennan-Smith, Hall (2013). The KUDUwave is a Type 2 Clinical Audiometer (IEC 60645-1/2) controlled by software on a computer (Acer Travelmate 2492). The audiometer hardware is encased in circumaural earcups and powered by a USB cable plugged into the notebook. The transducers include embedded, custom insert earphones, which were covered by the circumaural cups after insertion. A response button was connected to the KUDUwave device to record patient responses to stimuli. The insert earphones were calibrated in accordance with ISO 389-2 and the B-71 (Radioear, New Eagle, PA) bone oscillator according to ISO 389-3.

5.3.3. Procedures

Screening was conducted by audiology students from the University of Pretoria who were trained in the use of both screening audiometers. Testing was conducted under direct supervision of the Faheema Mahomed-Asmail who also conducted the manual diagnostic audiometry. As part of a validation study (Mahomed-Asmail et al., 2016), each participant underwent two screens, one smartphone-based and one conventional screen. Screening audiometry was conducted, according to recommended guidelines (ASHA, 1997; AAA, 2011) using a screening level of 25 dB HL.

Diagnostic audiometry was conducted in a counterbalanced sequence, alternating between manual and automated audiometry. Testing was only conducted down to 15 dB HL as hearing of children is considered normal if all thresholds are at or below 15 dB HL (Clark, 1981; Smith et al., 2005). Air- and bone-conduction was determined across 0.5, 1, 2, 4 kHz for manual and automated diagnostic audiometry. Both manual and automated testing was conducted with air- conduction pure tones delivered via deeply inserted foam tips covered by circumaural earcups. Forehead placement bone-conduction audiometry was conducted with both ears occluded by the deep insertion of the earphones. Testing was conducted in a natural environment provided by the school, which constituted either a classroom, administrative or media room. Five stations were set up in the venue provided, two for conventional screening, two for smartphone hearing screening and one for diagnostic audiometry. Sound in the test environment measured with a sound level meter (RION, NA-24, Japan, Tokyo) prior to data collection and twice during data collection revealed average noise levels ranging from 42.5 to 79.6 dBA (mean 65.1 SD 9.9).

For both manual and automated threshold testing, air-conduction thresholds were recorded using the routine modified 10 dB descending and 5 dB ascending method (modified Hughson-Westlake method) commencing at 1 kHz at 40 dB HL in the left ear and proceeding to the lower frequencies before recording thresholds at high frequencies, and then testing the right ear. In the absence of a response at 40 dB HL, the intensity was increased in steps of 10 dB until a response was noted from where the bracketing method recommenced. Bone-conduction threshold testing was administered using the modified Hughson-Westlake method after abnormal air-conduction thresholds were obtained, in the same frequency order followed by air-conduction testing. A continuous contralateral effective masking level of 20 dB HL above the air-conduction threshold of the non-test ear was used for the forehead bone-conduction audiometry (ASHA, 2005).

The KUDUwave had two microphones on the circumaural earcup that monitored the environmental noise in octave bands during testing to determine the maximum ambient noise level (MPANL) allowed for establishing a threshold, this was visually represented in real-time within the software. The MPANLs for the KUDUwave as reported in a recent paper (Swanepoel, Myburgh et al., 2014) indicate that the combined transducer attenuation levels are similar to those for a mini 5-cm panel booth (Franks, 2001) and exceed those of typical transportable sound-treated booths (Frank, 2001). During manual testing, whenever the noise exceeded the MPANL allowed for establishing a threshold as indicated by the effective attenuation level in the KUDUwave software, the audiologist waited for the transient noise to abate and then continued the testing. During automated testing, the software automatically paused testing until the ambient noise was within permissible limits.

5.3.4. Analysis

Threshold comparisons were made for air- and bone- conduction thresholds across 124 ears (62 participants). To evaluate results without the possible influence of a floor-effect (testing was only conducted down to 15 dB HL), a comparative analysis between thresholds (manual vs automated audiometry) was done where thresholds of 15 dB HL in either manual or automated test conditions were excluded. Threshold data for air- and bone- conduction manual and automated audiometry (>15 dB HL) were analyzed descriptively, with average differences, average absolute differences and respective distributions. We determined corresponding thresholds between manual and automated audiometry, expressed as a percentage of cases within 5 dB, within 10 dB and differing by 15 dB or more. Due to the nonparametric nature of the threshold data the Wilcoxon signed ranked test was used to compare hearing thresholds between manual and automated test modes. The paired samples t-test was used to compare test time, excluding instructions and preparation time, the statistical significance was set as $p \leq 0.05$.

The AMCLASS® classification criteria was used to classify audiograms (Margolis & Saly, 2007). A hearing loss was classified as conductive when a 10 dB air-bone gap at three or more frequencies, or a 15 dB air-bone gap at any one frequency was present, whereas a sensorineural hearing loss was noted when the configuration was not ‘normal’ and there was no significant air-bone gap (Margolis & Saly, 2007). An asymmetrical hearing loss was present when there is three or more interaural differences of 10 dB or more, two interaural differences of 15 dB or more, or one interaural difference of 20 dB or more. Degree and type of hearing loss were reported

for each participant to determine if there was a difference in diagnosis between the two test procedures.

5.4. Results

Sixty-two children, 25 males and 37 females with an average age of 8 years (SD 0.92; range 6 to 10 years) were included in this study. A total of 496 air-conduction and 47 bone-conduction thresholds were obtained across the frequency spectrum for comparison.

Distribution of hearing thresholds across different categories of manual and automated audiometry are shown in Table 5.1. 85.7% of air-conduction thresholds corresponded within the normal range (≤15 dB HL) for manual and automated audiometry. In 3.8% of cases where manual air-conduction thresholds were 15 dB HL automated thresholds were more than 15 dB HL of which 73.7% were at 20 dB HL. 44.6% of automated and manual bone-conduction thresholds corresponded within the normal range (≤15 dB HL). 8.5% of manual bone-conduction thresholds were higher than 15 dB HL, where automated bone-conduction thresholds were obtained at 15 dB HL. When manual bone-conduction thresholds were obtained at 15 dB HL, 12.8% of automated bone-conduction thresholds were >15 dB HL (Table 5.1).

Table 5.1. Distribution (n) of AC and BC thresholds for Manual (M) and Automated (A) Audiometry

Thresholds	0.5 kHz	1 kHz	2 kHz	4 kHz	Total
AC					
≤ 15 dB HL for M and A	102	105	108	110	425
> 15 dB HL for M, ≤ 15 dB for A	0	2	0	1	3
> 15 dB HL for A, ≤ 15 dB for M	6	6	3	4	19
> 15 dB HL for M and A	16	11	13	9	49
BC					
≤ 15 dB HL for M and A	8	4	5	4	21
> 15 dB HL for M, ≤ 15 dB for A	0	2	1	1	4
> 15 dB HL for A, ≤ 15 dB for M	2	1	2	1	6
> 15 dB HL for M and A	6	4	4	2	16

Of 496 air-conduction thresholds, 447 (90.1%) were excluded when comparing air-conduction thresholds without the influence of any possible floor effect (Table 5.2). The remaining 49 air-conduction thresholds presented with average thresholds of 42.0 dB (22.9 SD) for manual and 41.8 dB (23.9 SD) for automated audiometry. Correspondence between 0 and 10 dB for manual and automated air-conduction thresholds was 87.7 % across frequencies. 65.9% (31/47) of bone-conduction threshold were excluded due to the floor effect. The remaining thresholds averaged to 23.8 dB (5.9 SD) for manual audiometry and 23.4 dB (4.4 SD) for automated audiometry. Both automated and manual thresholds ranged between 20 dB HL and 40 dB HL (Table 5.2). No statistically significant ($p>0.05$, Wilcoxon signed ranked test) difference was found between manual and automated air- and bone-conduction thresholds across the frequencies when comparisons for thresholds of 15 dB HL in both manual and automated conditions were excluded.

Table 5.2. Average Differences* and Average Absolute Differences* in dB between Manual and Automated Air- and Bone-conduction Thresholds and Threshold Correspondence in Cases where Thresholds were >15 dB HL in Both Conditions

	AC	BC
Av. Diff		
N	49	16
Mean	0.2	0.3
SD	10.5	4.3
Abs Av. Diff		
Mean	6.3	2.2
SD	8.3	3.6
Corresponding thresholds (%)		
Within 5 dB	69.4	87.6
Within 10 dB	18.3	12.5
Within ≥15 dB	12.2	-

*Thresholds recorded with automated diagnostic testing subtracted from thresholds recorded with manual diagnostic testing

Eight participants (age range: 7 to 9.1 years) presented with a hearing loss. In seven of these cases, the classifications of severity and degree of hearing loss for the manual and automated audiometry were in agreement. These included two asymmetrical severe conductive hearing losses, two asymmetrical mild sensorineural hearing loss, one asymmetrical severe mixed hearing loss, one moderate mixed hearing loss and one bilateral moderate mixed hearing loss. In the single case where the classification of manual and automated audiograms did not correspond, the manual audiogram indicated a mild conductive hearing loss, while the automated audiogram revealed a mild mixed hearing loss due to a 40 dB HL drop in BC at 0.5 kHz.

On average manual audiometry (144.8 seconds, 95.8 SD) was 11.9 seconds faster than automated audiometry (156.7 seconds, 96.9 SD) across all participants. Test time for the eight participants with hearing loss indicated that manual audiometry (218.1 seconds, 130.3 SD) was 15 seconds faster than automated audiometry (233.8

seconds, 130.7 SD). There was no significant differences between test time for manual and automated audiometry however in both instances ($p>0.05$; $t=-1.8$).

5.5. Discussion

The validity refers to the ability of a new method to measure what it is supposed to measure (Dobie, 1983). For pure-tone threshold determination, any system or technique to be validated has to be compared with conventional manual pure-tone audiometry as the gold standard (Burns & Hinchcliffe, 1957; Mahomed et al., 2013). Results of the current study confirmed equivalent hearing thresholds for children tested with automated pure tone audiometry compared to manual testing.

Average threshold differences between manual and automated audiometry in this study, when the floor effect was excluded, were comparable to those reported in a meta-analysis (Mahomed et al., 2013). Threshold differences for automated and manual audiometry reported in the meta-analysis ranged between −5.0 dB (5.3 SD) and 2.1 dB (8.7 SD) across the frequency spectrum (Mahomed et al., 2013). The overall air-conduction average absolute difference (6.3 dB ± 8.3 SD) obtained without the influence of the floor effect are in line with those previously reported for adults and children (Margolis et al., 2010; Sparks, 1972; Swanepoel, Mngemane et al., 2010, Margolis & Moore, 2011).

Bone-conduction threshold differences between manual and automated audiometry were within typical test-retest variability (10 dB) for bone conduction thresholds obtained (Roeser & Clark, 2007). Average absolute differences obtained for bone conduction (2.2 dB, ±3.6 SD), without the influence of the floor effect, were lower than

those obtained for air-conduction in this study. Furthermore, the average absolute differences reported in this study are lower than those previously reported (Margolis et al., 2010). A possible reason for this could be the fact that insert earphones were not always deeply inserted and that could have led to an occlusion effect in lower frequencies.

Automated audiometry correctly identified and classified 87.5% (7/8 participants) of hearing losses identified by manual audiometry. The single audiogram classified differently according to AMCLASS® classification presented with a 25 dB bone conduction difference at 0.5 kHz. Although thresholds obtained resulted in a different classification, automated audiometry was able to determine that the participant had a hearing loss and thus a referral could be made.

No significant differences were obtained between test time for manual and automated audiometry. Automated audiometry took 15 seconds longer when participants with a hearing loss test time was determined and 11.9 seconds longer across all participants. Automated audiometry takes longer to determine thresholds than manual audiometry in 'difficult to test' participants such as young children (Picard et al., 1993). Picard et al. (1993) indicated that the reason for shorter manual test time in some cases, is as a result of examiners taking shortcuts to obtain results with ‘difficult to test’ participants, while automated audiometry maintains rigid adherence to a predetermined procedure resulting in extended test time.

Findings from the current study provide evidence that valid diagnostic air- and bone-conduction pure-tone hearing thresholds can be recorded using automated

audiometry in school environments. Mobile automated diagnostic audiometry for children immediately after they fail a school-based hearing screening is possible. This could address the high occurrence of follow-up failures in school screening by providing immediate diagnostic testing on all children who refer. This will reduce unnecessary referrals due to false-positive screen results and will allow directed referrals to audiological and/or medical intervention based on diagnostic audiometry.

In countries where a limited number of trained audiologists and resources are available, the ability to conduct automated diagnostic assessments onsite could be very beneficial to school-based hearing screening programs (Goulios & Patuzzi, 2008; Windmill & Freeman, 2013; WHO, 2013c). It would also allow the audiologist more time to carry out additional tasks such as direct patient contact, counselling and aural rehabilitation (Swanepoel et al., 2013; Wood et al , 1973).

A limitation of the study included the 15 dB HL lower limit which resulted in the floor effect. Future research in the field of automated audiometry in a school-setting is required in order to determine if a full audiogram across 0.125 to 8 kHz can be determined by testing down to 0 dB HL. Furthermore, an additional limitation include the lack of control for the possibility of an occlusion effect on BC thresholds in lower frequencies. Investigations are also required to determine if follow-up rates actually do improve due to the reduction in false-positive rates. In addition automated diagnostic testing in adverse acoustic test environments should be investigated.

5.6. Conclusion

Employing automated diagnostic audiometry, for children who fail a hearing screening, at the completion of a school-based program, may improve the efficacy of a school-based screening program by reducing false-positives. This study demonstrates accurate air- and bone-conduction threshold determination using an automated audiometer in a natural environment. The immediate availability of diagnostic pure-tone audiometry following a school screening referral could improve timely and direct referrals for audiological or medical intervention or both.

CHAPTER 6

HEARING LOSS IN URBAN SOUTH AFRICAN SCHOOL CHILDREN (GRADE 1 TO 3)

Authors: Mahomed-Asmail, F.; Swanepoel, D.W. & Eikelboom, R. H.

Journal: International Journal of Paediatric Otorhinolaryngology

Accepted: 18/02/2016

Proof of acceptance: Appendix J

Publication: 2016, Vol 84, pp. 27-31.

6.1. Abstract

Objective

This study aimed to describe the prevalence and characteristics of hearing loss in school-aged children in an urban South African population.

Method

Children from grade one to three from five schools in the Gauteng Province of South Africa formed a representative urban South African sample for this study. All children underwent otoscopic examinations, tympanometry and pure tone screening (25 dB HL at 1, 2 and 4 kHz). Children who failed the screening test and 5% of those who passed the screening test underwent diagnostic audiometry.

Results

A total of 1070 children were screened. Otoscopic examinations revealed that a total of 6.6% ears had cerumen and 7.5% of ears presented with a type-B tympanogram. 24 children (12 male, 12 female) were diagnosed with hearing loss. The overall prevalence of hearing loss was 2.2% with Caucasian children being 2.9 times more (95% confidence interval, 1.2 - 6.9) likely to have a hearing loss than African children.

Conclusion

Hearing loss prevalence in urban South African school-aged children suggest that many children (2.2%) are in need of some form of follow-up services, most for medical intervention (1.2%) with a smaller population requiring audiological intervention (0.4%).

6.2. Introduction

The World Health Organization estimates that hearing loss is the most prevalent disabling condition globally (WHO, 2013a). In 2013 the global prevalence of disabling (>40 dB HL) hearing loss was estimated at 360 million, with 32 million of these being children (<15 years) (WHO, 2013a). Permanent bilateral hearing loss in infants (>40 dB HL) was estimated to affect approximately 798 000 newborns annually with more than 90% of these residing in developing countries (Olusanya, Emokpae, Renner, & Wirz, 2009; Olusanya & Newton, 2007), and close to 20% of them being identified only around the time of school entry (Bamford et al., 2007).

Numerous studies from developing areas of the world report varying hearing loss prevalence rates among school children. These figures range from 1.4% in China (Lü et al., 2011) and 1.75% in Saudi Arabia (Al-Rowaily et al., 2012), to as high as 11.9% in India (Rao, Subramanyam, Nair, & Rajashekhar, 2002). The varying ranges in prevalence is also seen in sub-Saharan Africa with prevalence ranging between 56% to 13.9% across studies in rural areas of Kenya (Hatcher et al., 1995) and Nigeria (Olusanya, Okolo, & Ijaduola, 2000) respectively.

A number of studies have been conducted across South Africa to investigate the prevalence of middle ear pathology and sensorineural hearing loss (SNHL) in Caucasian and African children. Early studies indicated that the prevalence of middle ear pathology among young children varied between 13.4% and 29.4% (Celliers, Rossouw, Meyer, & Hurter, 1988; Meyer, Hurter, & Van Rensburg, 1987; Meyer & Van den Berg, 1985). In a study conducted on 2036 elementary school children (5-10 years of age), reported 5% of ears with indications of otitis media with effusion (Van Rooy et

al., 1995). Similar findings were reported in a study of 2457 grade 1 children (Swart, 1996), with a prevalence of 6.5% of possible middle ear pathologies.

The prevalence of sensorineural hearing loss (SNHL) was reported to be 1.8% for children between the ages of 1 and 12 years (Meyer, Hurter, & Van Rensburg, 1987), and 2% and 2.1% in two other communities (Swart, 1996; van Rooy et al., 1995). Higher prevalence rates were reported in KwaZulu-Natal with 13% of black children and 14.3% for Indian children presenting with a sensorineural hearing loss (Bhoola & Hugo, 1995). The most recent study conducted in the Western Cape indicated a referral rate of 7.9% (North-Matthiassen & Singh, 2007).

Although prevalence data have been previously reported (Celliers, Rossouw, Meyer, Hurter,1988; Meyer & Van den Berg, 1985; Meyer, Hurter, Van Rensburg,1987; van Rooy et al., 1996; Bhoola & Hugo, 1995), the method of determining a hearing loss varied across the studies, with some basing it on a screening results only (Meyer, Hurter, Van Rensburg,1987; Van Rooy et al.,1995; Bhoola & Hugo, 1995). Furthermore, these studies utilized a wide-range of screening levels and pass/refer criteria. For example, Van Rooy (1995) used a pass/refer criteria of 25 dB HL or 30 dB HL, depending on the level of the background noise in the test environment. In addition, these studies were conducted primarily on children from rural areas whose ages varied between preschool to school-going age.

The prevalence of hearing loss in children in developed countries is typically lower than in developing countries; 1.49% has been reported for the UK (Fortnum, Summerfield, & Marshall, 2001) 2% for Sweden (Darin, Hanner, & Thiringer, 1997),

2.5% for Finland (Marttila, 1986) and 3.6% for Denmark (Parving, 1999). Fortnum et al. (2001) suggested that the reasons for differences in prevalence between developed and developing countries include the absence of regular hearing-screening programs, the impact of poverty and malnutrition, ignorance of hearing loss and paucity of accessible health care in developing countries.

School-based hearing screening in South Africa is required as part of the 2012 Integrated School Health Policy (ISHP, 2012a) . Unfortunately it is still far from common practice and screening is only available for a small minority of South African children (Shung-King, 2013). In order to ensure availability of referral services careful evaluation and planning of school-based screening needs to be conducted (Shung-King, 2013). Determining the prevalence of hearing loss in this population allows for adequate planning to ensure hearing health services are made available. Therefore, this study describes the prevalence and nature of hearing loss among school-aged children from grade one to three in a representative urban South African population.

6.3. Materials and methods

The investigation was conducted following approval from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria and Gauteng Department of Education, South Africa.

6.3.1. Study populations

The primary sampling unit was in five public government schools in underserved urban regions of Tshwane, Gauteng Province, South Africa. All students in grade one to three within the school, who had signed consent from their parent/caregiver and who

provided assent, were screened. A consecutive sample of 1070 school-aged children were screened which included Caucasian and African (Black, Coloured and Indian) individuals.

6.3.2. Data collection

6.3.2.1. Screening Phase

Screening was conducted by audiology students (40) from the University of Pretoria. As part of their practical training, under the direct supervision of the first author who conducted the validation checks throughout, they were required to complete fice days of screening. Testing was conducted in a quiet room provided by the school. Sound in the test environment was measured with a sound level meter (RION, NA-24, Japan, Tokyo) prior to data collection and twice during the data collection session. Noise levels ranged between 42.5 and 79.6 dBA (mean 65.1 SD 9.9).

Ears were examined using a handheld Welch Allyn (Welch Allyn, South Africa (Pty) Ltd.) or Heine mini 3000 (Heine, Germany) otoscope. Any abnormalities of the external ear canal and tympanic membrane were noted. Tympanometry was conducted to obtain information regarding the participant's middle ear status using one of two screening tympanometers: GSI Auto Tymp (Grayson Stadler, Eden Prairie, USA) or an Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark). Results were recorded in terms of middle ear pressure, static compliance and ear canal volume and classified based on the modified Jerger classification (Zielhuis, Rach, van den Broek, 1989).

Each child was screened twice as part of a validation study (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, Hall III, 2016), once with a conventional screening audiometer and once with a smartphone-based audiometer. For conventional screening the same screeners used for tympanometry were coupled with TDH 39P headphones (Telephonics, Huntington, N.Y.) to conduct the hearing screening. For smartphone screening, two sets of Samsung Galaxy Pocket Plus S5301 phones running the hearScreen™ Android OS application with supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany) were used. Screening audiometry was conducted, according to recommended guidelines (AAA, 2011; ASHA, 1997) using a screening level of 25 dB HL (Mahomed-Asmail et al., in press). Immediately following a fail result, the child was rescreened using the same screening audiometer. All screeners were calibrated according to ISO 389-1 (1998) standards prior to data collection.

6.3.2.2. Diagnostic Phase

Diagnostic audiometry was conducted on every child who failed one or both screenings (conventional and smartphone-based screen) and on 5% of the children who passed on both screenings (Mahomed-Asmail et al., 2016), to determine the prevalence and nature of hearing loss. Diagnostic audiometry was performed with a KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2). Testing was only conducted down to 15 dB HL as hearing of children is considered normal if all thresholds are at or below 15 dB HL (Clark, 1981; Smith et al., 2005). Diagnostic air- and bone-conduction was determined across 0.5, 1, 2, 4 kHz. Air-conduction pure tones were delivered via deeply inserted insert foam tips covered by circumaural earcups with forehead placement bone-conduction

audiometry conducted with both ears occluded by the deep insertion of the insert earphones. Testing was conducted in a natural environment provided by the school, which constituted either a classroom, administrative or media room. Thresholds were recorded using the routine 10 dB descending and 5 dB ascending method (modified Hughson-Westlake method) commencing at 1000 Hz at 40 dB HL in the left ear. A continuous contralateral effective masking level of 20 dB HL above the air-conduction threshold of the non-test ear was used for the forehead bone-conduction audiometry (ASHA, 1997).

The KUDUwave software actively monitored ambient noise levels across octave bands throughout both test procedures. Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold, the audiologist waited for the transient noise to subside.

6.3.3. Data analysis

Diagnostic audiometry results confirming a hearing loss provided the prevalence rate for this sample population. A hearing loss was defined as having at least one threshold more than 15 dB HL at 0.5, 1, 2 and 4 kHz in either ear (Clark, 1981; Smith et al., 2005). The AMCLASS® classification criteria was used to classify audiograms (Margolis & Saly, Le & Laurence, 2007). A hearing loss was classified as conductive when a 10 dB air-bone gap at three or more frequencies, or a 15 dB air-bone gap at any one frequency was present, whereas a sensorineural hearing loss was noted when the configuration was not normal (≤ 15 dB HL) and there was no significant air-bone gap. A unilateral hearing loss was obtained when one ear had normal hearing and the other had a hearing loss, with a bilateral hearing loss indicative of a hearing

loss was present in both ears. The participants were allocated into age groups: <7 years of age, from 7 to <9 years of age, and 9 years of age and greater.

Data analysis was done using SPSS v22 (Chicago, Illinois). Demographic data, otological status, tympanometric findings and screening results were analysed and presented using descriptive statistics. A binary logistic regression was performed to evaluate the effect of age, gender and race on the presence of a hearing loss in the sample, with the significant level at $p<0.01$.

6.4. Results

A total of 1070 consecutively screened children were included in the study with a mean age of 8 years (±1.1 SD; Range 6 to 12 years). Demographic distribution (Table 6.1) was 50.7% female and 83.5% African (16.5% Caucasian). The mean age of the African group (7.9 years, 1.0 SD) was significantly lower (t-test, $p<0.01$) than the Caucasian group (8.3 years, 1.1 SD). The most commonly spoken languages were Sotho (39.7%), Afrikaans (16.3%), English (15.9%), Zulu (8.8%) with 19.3% speaking one of the other official languages of South Africa.

Table 6.1. Demographic findings across study population and across children with hearing loss (HL)

Characteristics	% of total (n)	% Children with HL (n)
Gender		
Male	49.3% (528)	2.3% (12)
Female	50.7% (542)	2.2% (12)
Race		
African	83.5% (893)	1.7% (15)
Caucasian	16.5% (177)	5.1% (9)
Age		
< 7 years	16.3% (175)	6.2% (11)
7 to < 9 years	33.8% (362)	1.7% (6)
≥ 9 years	49.8% (533)	1.3% (7)

Only one child who referred both screens was excluded from the data analysis as the child could not be conditioned for diagnostic audiometry. A total of 125 children (61 failed on one or both screens, 64 passed on both screens) were tested diagnostically with 24 children diagnosed with a hearing loss indicating a hearing loss prevalence of 2.2% (12 male, 12 female). The youngest age group had a higher prevalence of hearing loss when compared to the older groups (6.2% versus 1.7% and 1.3% respectively) (Table 6.1). However, binary logistic regression revealed no significant age and gender effect. Race had a significant effect ($p>0.01$) indicating caucasian children to be 2.9 times (95% Confidence interval (CI), 1.2 - 6.9) more likely to have a hearing loss than African children.

Table 6.2. Nature of hearing loss present across subjects (n= 24)

Types	% (n)
Bilateral conductive	25.0% (6)
Bilateral sensorineural	8.3% (2)
Bilateral mixed	8.3% (2)
Unilateral conductive	29.2% (7)
Unilateral sensorineural	12.5%(3)
Unilateral mixed	16.7% (4)

Conductive hearing loss (57.1%) was the most common type of hearing loss that presented both unilaterally (29.2%) and bilaterally (25.0%) (Table 6.2).Of the 20 ears that presented with a conductive hearing loss, 13 had normal middle ear functioning, five ears presented with type B tympanograms, one ear presented with a type C2 tympanogram and only one with a perforated eardrum (Table 6.3). Furthermore, five children presented with a pure sensorineural hearing loss of varying degrees (1 mild, 2 mild-to-moderate, 2 severe to profound) (Table 6.4).

Table 6.3. Modified Jerger (1989) classification of middle ear (ME) findings (n=1070)

	Male		Female		All	
	Right ear	Left ear	Right ear	Left ear	Right ear	Left ear
Normal ME						
Type A and C1	88.5%	88.5%	92.8%	90.2%	90.7%	89.3%
Abnormal ME						
Type B	3.9%	4.7%	2.4%	3.9%	3.2%	4.3%
Type C2	7.6%	6.4%	4.6%	5.7%	6.1%	6.1%
Could not be obtained	0%	0.4%	0.2%	0.2%	0.1%	0.3%

Type A- admittance ≥ 0.2ml & ME pressure between -99 to +200 daPa; Type C1- admittance ≥ 0.2ml & ME pressure between -199 to -100 daPa; Type B- admittance ≤ 0.2ml or ME pressure ≤ -400, Type C2- admittance ≤0.2ml & ME pressure ≤-400 daPa

The most common otoscopic examination finding across the entire sample, excluding a normal ear canal and tympanic membrane (92.1%), was the presence of >75% cerumen in the ear canal (6.6%).

Table 6.4. Characteristics of hearing loss across ears (n = 35)

Characteristics	% (n)
Type of hearing loss	
Conductive	57.1% (20)
Sensorineural	20.0% (7)
Mixed	22.9% (8)
Laterality	
Unilateral	37.1% (13)
Bilateral	31.4% (11)
Degree of deafness	
Mild	48.6% (17)
Mild-to-moderate	17.1% (6)
Moderate-to-Severe	14.3% (5)
Severe-to-Profound	20.0% (7)

6.5. Discussion

This study revealed a hearing loss prevalence of 2.2%. This is similar to prevalence findings from longitudinal studies conducted in developed countries, such as the 1.8% in USA (Serpanos, 2007), 2% in Sweden (Darin, Hanner & Thiringer, 1997) and 2.5%

in Finland (Marttila, 1986). These studies were conducted to determine the prevalence of hearing loss in preschool children over 4 to 10 year period utilizing a pass criteria of 20 dB HL as opposed to 25 dB HL used in this study. A higher prevalence rate would therefore be expected in the current study sample compared to those from developed countries if the same intensity level of 20 dB HL was used. Furthermore, the prevalence obtained in this study is far less than the 7.9% (North-Matthiassen & Singh, 2007) and the 5.6% (Hatcher et al., 1995) reported among previous African studies. A possible reason for the higher rate reported in these studies may be due to the fact that prevalence reported in these studies were based on referral rates and not on audiological diagnostic test findings. Based purely on referral rates, the current study had a prevalence of 5.6% similar to those previously reported (Hatcher et al., 1995; Van Rooy et al., 1995; Swart, 1996; North-Matthiassen & Singh, 2007).

Middle ear effusion is more common in younger children (Al-Rowaily et al., 2012; Swanepoel, Eikelboom, & Margolis, 2014) and may explain the higher prevalence rate of hearing loss in the youngest population of this study (4.9%). One in three conductive hearing losses presented with type B tympanogram and minimal wax.

The prevalence of SNHL (including unilateral, bilateral and mixed losses) in this study was only 1.0% (11/1070). These results indicate the need for referral services to ensure that these children are provided with appropriate intervention. Furthermore, the second most common otoscopic finding was >75% cerumen in the ear canal (6.6%), however, only 0.7% (8/1070) of these participants failed the screening, when investigated further seven of the participants presented with normal hearing and only one had a mild conductive component at 1 kHz. Excessive or impacted ceruman has

been reported by other studies to be one of the most frequent and common ear disorders (Hatcher et al., 1995).

No gender effects were noted in this study (Table 6.1), in accordance to those previously reported (Hatcher et al., 1995; Jacob et al., 1997; North-Matthiassen & Singh, 2007). However, there was a significant effect ($p>0.01$) of race with Caucasian children 2.9 times more likely to have a hearing loss than African children. The higher prevalence of hearing loss for children in the Caucasian group (5.1%) is in agreement with earlier studies from South Africa (Van Rooy et al., 1995). The reason attributed to this phenomenon in an earlier study was due to a higher prevalence of otitis media with effusion and retracted tympanic membranes in the Caucasian group compared to the African group (Van Rooy et al., 1995). Furthermore, a recent study in adults (Helzner et al., 2005) indicated that Caucasians were also more likely to have hearing loss followed by non-Caucasian, black individuals.

Unilateral hearing losses (54.2%, 13/24) were more common than bilateral losses, in line with results reported by North-Matthiassen & Singh (2007). A bilateral hearing loss may affect many areas of a child's development such as their language, social, psychosocial and behavioural development (Swart et al., 1995). However, children who present with unilateral hearing losses also have an increased rate of grade failure, need additional educational assistance and have perceived behavioural issues, which could deteriorate their educational achievement and ultimately vocational outcomes (Swart, 1995). As a result hearing loss identification, whether unilateral or bilateral, requires effective management in school-aged children to minimize these adverse effects.

This study provides prevalence data of hearing loss in a representative urban South African sample which assists in effective resource planning for the provision of school-based hearing health care services. A follow-up study is recommended to determine the follow-up services and referral pathways available in resource-limited countries like South Africa.

6.6. Conclusion

Hearing loss prevalence in school-aged children suggest that many children (2.2%) are in need of some form of follow-up service, most for medical intervention and a smaller number for audiological intervention. These findings provide valuable baseline data for realistic planning and appropriate implementation of hearing health services to ensure hearing screening is employed sustainably across South Africa for all children in accordance with the Integrated School Health Policy.

CHAPTER 7

DISCUSSION, CLINICAL IMPLICATIONS AND CONCLUSION

A worldwide drop in mortality rates and rise in life expectancy has increased the society's attention on reducing disability and handicap which includes deafness and hearing loss (Goulios & Patuzzi, 2008). According to World Health Organisation (2013b) half of all cases of deafness and hearing loss are avoidable through prevention, early diagnosis and management. Most children with congenital hearing loss are potentially identifiable by newborn and infant hearing screening (Cunningham & Cox, 2003). However, around 20% of permanent mild, moderate or greater bilateral and unilateral impairments remain to be identified around the time of school entry (Bamford et al., 2007).

School-based hearing screening has been recommended by international societies (AAA, 2011; ASHA, 1997) and a local policy (ISHP, 2012) for permanent, longstanding sensorineural hearing losses and frequently recurring conductive hearing losses. However, current school-based screening in South Africa is not being provided due to several challenges. One of the major challenges is the shortage of available human resources (Goulios & Patuzzi, 2008; WHO, 2013c).

Utilising innovations in technology and the growth in connectivity offer new ways of services through technological models, such as automated procedures and mobile health technology (Swanepoel, Clark et al., 2010). This can assist in alleviating the

high demand placed on the limited number of audiologists available. This study therefore investigated the development and provision of audiological services in the school setting taking into consideration the unique local demands of the South African population and context, in a socially and economical manner. This study aimed to provide research-based recommendations for clinical practice of school-based screening using innovative approaches.

The aim of this chapter is to draw general conclusions, implications and to critically evaluate the research conducted to make specific recommendations in the format of a proposed service plan for school-based hearing screening and provide future research recommendations.

7.1. Summary of findings

The ISHP (2012a, b) was developed in order to strengthen the country's school health services by addressing not only barriers to learning, but also other conditions which contribute to morbidity and mortality amongst learners during both childhood and adulthood. The recommendation provided by the ISHP (2012a), namely to include hearing screening in the school context, was investigated in seven urban schools and investigated across four studies. Study I, a within-subject study was conducted in two phases. This study finding recommend the use of 25 dB HL as a screening intensity together with an immediate rescreen as it reduces the referral rate significantly and will limit the burden of the screening programme on health care resources. These findings were utilized as a protocol for testing in study II to IV.

Study II, found that the hearScreen™ application obtained accurate and time-efficient results when compared to conventional screening on children. hearScreen™ allows commercially available, off-the-shelf, hardware to be used which provides an inexpensive solution that laypersons with limited training can operate since tests and interpretations are automated. This study found that hearScreen™ obtains equivalent sensitivity (75.0%) and specificity (98.5%) to conventional screening audiometry. Furthermore, no statistical significance ($p<0.05$; Chi-Square test) was found between the referral rate (3.2% vs 4.6%). However, there was a significant difference ($p>0.001$; paired sample *t* test) in time taken as the smartphone screening application (hearScreen™) was 12.3% faster than conventional screening.

The lack of compliant, sound-treated environments in typical school settings has traditionally precluded the administration of diagnostic air- and bone-conduction audiometry in a school setting (Swanepoel, Maclennan-Smith, Hall, 2013). Study III found that conducting automated diagnostic audiometry using the KUDUwave, a Type 2 Clinical Audiometer controlled by computer software, for children who fail hearing screening can improve the efficacy of school-based screening programs by reducing false-positives and ensuring directed referrals for audiological and/or medical intervention (Swanepoel et al., 2013).

Study IV indicates that the overall prevalence rate of hearing loss in the representative urban sample was 2.2%, with hearing loss being more prevalent in the Caucasian group (5.1%). A binary logistic regression revealed a significant effect for race ($p>0.01$) indicating that caucasian children are 2.9 times more likely to have a hearing loss than African children. The hearing loss prevalence in school-aged children suggest that

many children (2.2%) are in need of some form of follow-up service, most for medical intervention and a smaller number for audiological intervention. By conducting regular hearing screening, preventative measures can be ensured which will improve a child's hearing potential and in turn improve their academic success. This study proves that urgent development of audiological services in schools is needed to ensure that sufficient provision of services for the school-aged population is available.

7.2. Clinical implications

In light of the high prevalence of hearing loss in children and the effect of hearing loss on a child's education, screening programs should be implemented and provided for all school-aged children as recommended by the ISHP (2012a). The empirical findings of this study can be used to inform the ISHP (2012a, b) in an evidence based manner.

The test protocol provided by the ISHP (2012b) states that a screening level of 20 dB HL should be used across 1, 2 and 4 kHz for children in grade one, four and eight. No indication of a rescreen and follow-up procedures are mentioned. Furthermore, according to the ISHP (2012b), hearing screening should be conducted by a school health nurse using a pure tone sweep on a calibrated audiometer, however, no indication of a specific audiometer is given. The smartphone-based application, hearScreen™, can be seen as a screening tool that meets this standard as it uses a pure tone sweep with preselected frequencies presented at predetermined levels. Furthermore, the supra-aural headphone utilized can be acoustically calibrated according to prescribed standards (ANSI/ASA S3.6-2010; ISO 389-1, 1998).

7.2.1. Service delivery model for school-based hearing screening

The conclusions drawn from studies I to IV were utilized to develop and propose a service delivery model for school-based hearing screening in school settings. The objective of this model is to serve as a working document to complement the ISHP (2012a, b) in the form of contextual, evidence-based recommendations and proposed infrastructures. Screening should be conducted annually on all children in grade one (ISHP, 2012a, b) and on all children at risk for academic failure or children whose parent/caregiver/teacher has concerns regarding their hearing, speech, language, or learning ability (AAA, 2011; ISHP, 2012a, b). Furthermore, all children with previous or ongoing ear disease should be screened. Figure 7.1 depicts the service delivery model proposed.

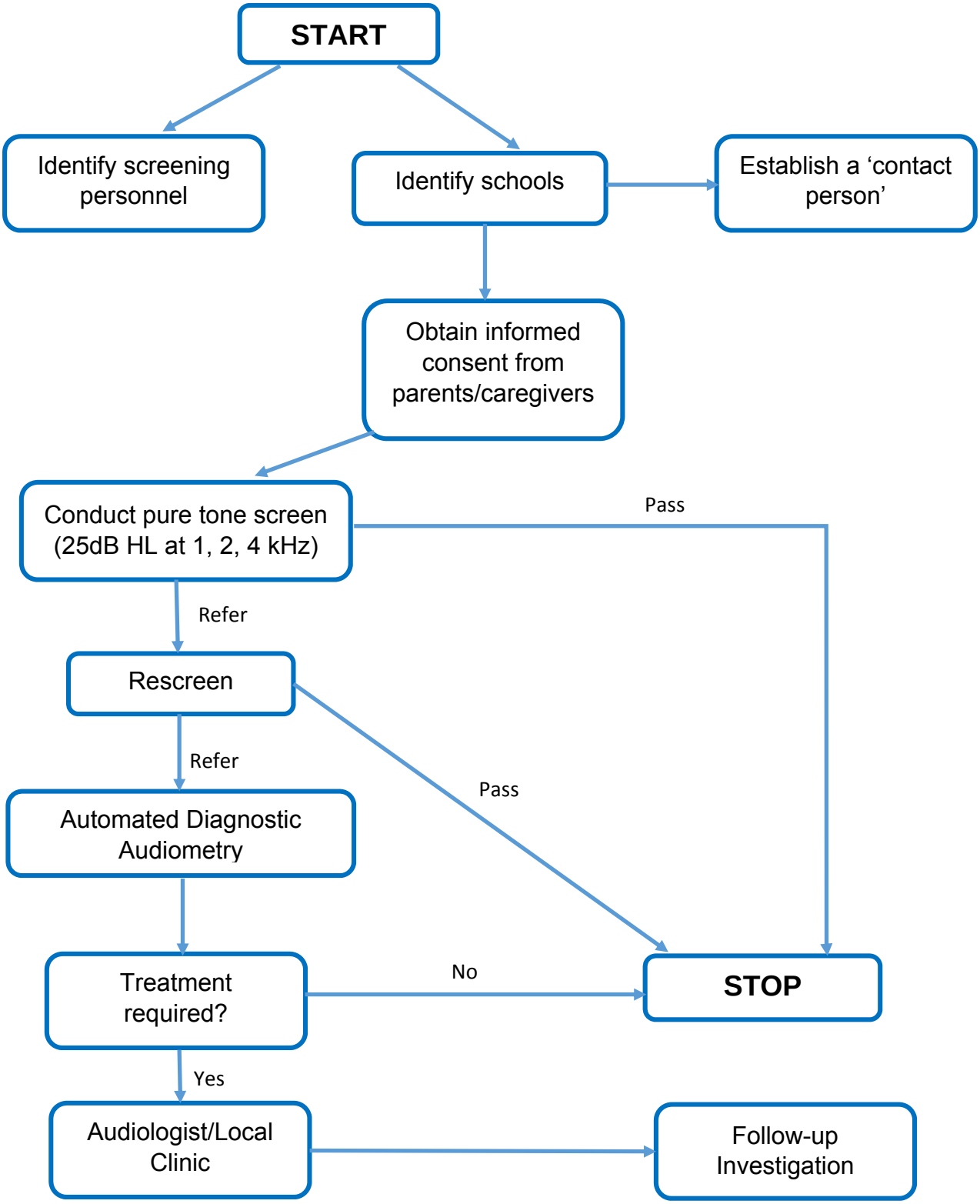

Figure 7.1. Flowchart of proposed school-based hearing screening model

The implementation of school-based hearing screening for early detection of hearing loss needs to include a transdisciplinary/multidisciplinary team approach. The primary role players include audiologists, screening personal (school health nurses), team manager, teachers and caregivers/parents.

It is the responsibility of the audiologist to train the school-health nurses (ISHP, 2012a, b). The school-health nurses should be trained on how to conduct the pure tone screening and facilitate the automated diagnostic audiometry. A team manager should ensure all equipment is calibrated prior to testing, establish contact with the school and implement and supervise the screening program (ASHA, 1997).

Once contact with the school/s has been established an individual from the school/s should be nominated who will assist in the screening at the school level and be the 'contact person' throughout the screening program at that school. It is the responsibility of the 'contact person' to assist in ensuring the informed consent letters have been signed by parents/caregivers of children that need to be screened. Once informed consent from parents/caregivers are provided (AAA, 2011; ASHA, 1997) screening can commence.

The school health nurse should conduct the pure tone screen at 25 dB HL across 1, 2 and 4 kHz, using a devise that is light, battery-operated and includes quality control and data management. If the child passes the pure tone screen no further investigation is needed. If a child refers at any frequency a rescreen should be conducted (AAA, 2011), if a refer is obtained on the rescreen, the child could receive automated

diagnostic audiometry. The automated diagnostic audiometry results should be interpreted by an audiologist who will provide further recommendations.

In the case of children presenting with a mixed or conductive hearing loss a referral to a local clinic for medical treatment should be made. Whereas, children presenting with a sensorienural loss will be referred to an audiologist for intervention. All referrals should be sent to parents/caregivers of the child through the establish 'contact person'. Furthermore, it is advisable that all referrals be documented and sent to the school body for their record and to ensure that each child who referred is followed-up. The audiologist should request information regarding the outcome of follow-up audiological evaluations or medical examinations. This will allow the audiologist to monitor, and may participate in, the management of the child.

All screening and automated diagnostic results should be stored on a server for reference purpose or comparison at follow-up assessments. This may further aid in effective management of the screening program.

7.3. Study strengths and limitations

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

7.3.1. Study strengths

Strengths of the current project include the following:

- The Integrated School Health Policy (ISHP, 2012a, b) for South Africa acknowledges the importance of hearing screening by including it as part of all

the health phases with priority on grades 1, 4 and 8. However, it is far from common practice in South Africa and is not reaching majority of the South African school population (Shung-King, 2013) due to a number of challenges. This project provides alternative solutions to potentially overcome some of the challenges faced which include the cost of equipment, the ambient noise in the test environment and poor follow-up of compliance which hinder the implementation of school-based screening.

- This project was the first to investigate the true validity of the smartphone screening application, hearScreen™. This project revealed that hearScreen™ can be used as an alternative to conventional screening audiometry.
- This project also investigated the use of automated diagnostic audiometry in a school setting which indicated that automated diagnostic audiometry can be used as an alternative to conventional diagnostic audiometry.

7.3.2. Study limitations

Limitations of the current project include the following:

- Only children in grades 1 to 3 who provided assent and whose parents/caregivers provided informed consent were included in this study. This resulted in a small urban sample of the large South African population being used which is not entirely representative of the South African population.
- A limitation of the current project included the omission of an immediate rescreen during the first phase of study I, to determine the reduction in referral rate at 20 and 30 dB HL. However, this would have extended test time opening up the possibility of fatigue and a possible order effect.

- An additional limitation of study I was that true sensitivity and specificity of results at the screening intensity levels (20 dB HL, 25 dB HL and 30 dB HL) was not determined.
- As school health nurses are responsible for screening they should have been used to conduct the screening instead of trained audiology students.
- The inclusion of diagnostic audiometry testing down to 0 dB HL in study III would have contributed valuable information and would have reduced the influence of the floor effect obtained in this study.
- An additional limitation of study III included the lack of control for the possibility of an occlusion effect on BC thresholds in lower frequencies.
- Furthermore, the lack of follow-up data across all four studies, could not ensure appropriate intervention was provided and the reduction in false-positive rates could not be investigated.

7.4. Recommendations for future research

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

- It is recommended that future research should be conducted on a randomized sample, including all children in grade 1 in rural and urban communities in South Africa.
- The sensitivity and specificity of each screening intensity level (20 dB HL, 25 dB HL and 30 dB HL) should be investigated to determine its validity in order to draw up an effective screening protocol for resource-limited contexts.

- An investigation should be conducted on the validity of the screening application, hearScreen™, when administered by teachers or school nurses. Their attitudes and perceptions regarding their involvement in screening should also be investigated.
- Future validation studies should investigate the validity and use of hearScreen™ on pre-school children.
- Large-scale longitudinal studies utilising the recommended service delivery model at different schools should be conducted to determine the effectiveness and efficiency of such a model.
- Future research in the field of automated audiometry in a school-setting is required in order to determine if a full audiogram across 0.125 to 8 kHz can be determined by testing down to 0 dB HL. The use of automated diagnostic testing in adverse acoustic test environments, in school settings, should also be investigated.
- Referral pathways available in resource-limited countries like South Africa should also be investigated to ensure the feasibility of school-based screening programs.

7.5. Conclusion

Utilizing mobile technology together with a screening protocol of 25 dB HL and a rescreen administered for every refer result in conjunction with automated diagnostic audiometry has been proposed as a feasible solution to overcome the numerous challenges faced by school-based hearing screening programs. Utilizing the proposed service delivery model may improve the efficacy of school-based screening programs

by reducing false-positives and ensuring directed referrals for audiological and/or medical intervention.

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APPENDICES

APPENDIX A

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

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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

10 April 2014

Dear Prof Vinck

Project:	**School-based hearing screening and diagnosis using automated and mobile health technologies**
Researcher:	**F Mahomed**
Supervisor:	**Prof D Swanepoel**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**27038158**

Thank you for your response to the Committee's correspondence of 7 April 2014.

I have pleasure in informing you that the Research Ethics Committee formally **approved** the above study at an *ad hoc* meeting held on 9 April 2014. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should 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: karemn.harris@up.ac.za

APPENDIX B

Approval letter Gauteng Department of Education

GAUTENG PROVINCE
Department: Education
REPUBLIC OF SOUTH AFRICA

For administrative use:
Reference no. D2015 / 012 A

GDE AMENDED RESEARCH APPROVAL LETTER

Date:	**8 April 2014**
Validity of Research Approval:	**8 April 2014 to 3 October 2014**
Previous GDE Research Approval letter reference number	**D2014/192 dated 5 August 2013**
Name of Researchers:	**Professor D. Swanepoel and Mahomed F.**
Address of Researcher:	**Pilgrims Place # 2**
	31 Tsetsebe Street
	Monument Park
	0181
Telephone Number:	**082 782 4009**
Email address:	**dewet.swanepoel@up.ac.za**
Research Topic:	**A comparative study of school entry hearing screening in public schools: conventional audiometry versus smartphone-based screening.**
Number and type of schools:	**Nine Primary Schools**
District/s/HO	**Tswane South,Tswane North and Tswane West**

Re: Approval in Respect of Request to Conduct Research

This letter serves to indicate that approval is hereby granted to the above-mentioned researcher to proceed with research in respect of the study indicated above. The onus rests with the researcher to negotiate appropriate and relevant time schedules with the school/s and/or offices involved to conduct the research. A separate copy of this letter must be presented to both the School (both Principal and SGB) and the District/Head Office Senior Manager confirming that permission has been granted for the research to be conducted.

Makhado
2014/04/08

1

Making education a societal priority

Office of the Director: Knowledge Management and Research
9th Floor, 111 Commissioner Street, Johannesburg, 2001
P.O. Box 7710, Johannesburg, 2000 Tel: (011) 355 0506
Email: David.Makhado@gauteng.gov.za
Website: www.education.gpg.gov.za

GAUTENG PROVINCE
Department: Education
REPUBLIC OF SOUTH AFRICA

For administrative use:
Reference no. D2014/192

GDE RESEARCH APPROVAL LETTER

Date:	**5 August 2013**
Validity of Research Approval:	**5 August 2013 to 20 September 2013**
Name of Researcher:	**Prof D Swanepoel and Mahomed F**
Address of Researcher:	**Pilgrims Place # 2**
	31 Tsessebe Street
	Monument Park
	0181
Telephone Number:	**082 782 4009**
Email address:	**dewet.swanepoel@up.ac.za**
Research Topic:	**A comparative study of school-entry hearing screening in public schools: conventional audiometry versus smartphone- based screening.**
Number and type of schools:	**NINE Primary Schools**
District/s/HO	**Tshwane South,Tswane North and Tshwane West**

Re: Approval in Respect of Request to Conduct Research

This letter serves to indicate that approval is hereby granted to the above-mentioned researcher to proceed with research in respect of the study indicated above. The onus rests with the researcher to negotiate appropriate and relevant time schedules with the school/s and/or offices involved to conduct the research. A separate copy of this letter must be presented to both the School (both Principal and SGB) and the District/Head Office Senior Manager confirming that permission has been granted for the research to be conducted.

The following conditions apply to GDE research. The researcher may proceed with the above study subject to the conditions listed below being met. Approval may be withdrawn should any of the conditions listed below be flouted:

Approved
2013/08/08

Office of the Director: Knowledge Management and Research
9th Floor, 111 Commissioner Street, Johannesburg, 2001
P.O. Box 7710, Johannesburg, 2000 Tel: (011) 355 0506
Email: David.Makhado@gauteng.gov.za
Website: www.education.gpg.gov.za

APPENDIX C

Letter of informed consent to principal of the schools

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Principal,

TO: SCHOOL PRINCIPAL

RE: SCHOOL-AGED HEARING SCREENING BY AUDIOLOGY STUDENTS FROM THE UNIVERSITY OF PRETORIA

The Department of Speech-Language Pathology and Audiology at the University of Pretoria renders hearing screening services free of charge. Students under supervision of a qualified Speech-Language Therapist and Audiologist provide the services. It usually takes between 10 and 15 minutes to complete and if a child refers a screening test, diagnostic audiometry will be conducted and the school and parents will receive a referral letter. Parents will have to provide informed consent to have their children's hearing screened and for allowing their child's data to be used for research purposes (see attached informed consent letter to parents).

Please note that the hearing screening information obtained may be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If the parent or child wants to withdraw from the research project at any time they may do so without any negative consequences. Data will be stored at the Department of Speech-Language Pathology and Audiology, University of Pretoria for 15 years for research and archiving purposes.

We trust that you will find the above in order and look forward to hear from you regarding the provision of hearing screening services at your school.

Sincerely,

Ms. F. Mahomed-Asmail
Researcher

Prof. D.W. Swanepoel
Research Supervisor

APPENDIX D

Letter of informed consent to parents/caregiver

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear parent

The Department of Speech-Language Pathology and Audiology at the University of Pretoria renders hearing screening services free of charge. Students under supervision of a qualified Speech-Language Therapist and Audiologist provide the services. It usually takes between 10 and 15 minutes to complete and if your child refers a screening test, diagnostic audiometry will be conducted and the school and where necessary you will receive a referral letter. Please note that the hearing screening information obtained may be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If you or your child wants to withdraw from the research project at any time you may do so without any negative consequences to yourselves. Data will be stored at the Department of Speech-Language Pathology and Audiology, University of Pretoria for 15 years for research and archiving purposes.

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

Kind regards

Ms. F. Mahomed-Asmail
Researcher

Prof. D.W. Swanepoel
Research Supervisor

For office use:
Partcipant no.:_____

Consent:

Herewith I _____ (name) grant permission that hearing screening may be conducted on my child, _____(name) and I acknowledge that the information may be used for research purposes as specified above.

_____ _____

Signature of parent / guardian: **Date**

APPENDIX E

Participants informed assent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

ASSENT FORM

This person is an audiologist – someone who tests people's hearing – he/she wants to learn more about your hearing.

Earphones will be put on your ears so that I can hear very soft sounds [illustrate].

You will have to listen very carefully to hear them.

When you hear the sound you must tell the person doing the testing.

The tests will not hurt.

If I want to stop a test you can tell the person testing you. She will not be cross.

If you will help this person to test your hearing write your name below or draw a picture of yourself.

This is my name / this is a drawing of me:

APPENDIX F

Letter indicating participant has passed the screen

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Parent

Thank you for providing consent so that _____'s hearing could be screened on the _____20__. Results obtained indicate that currently there is no problem with your child's hearing and no further investigation is needed. It is recommended that your child have his/her hearing screened annually.

Kind regards,

Ms. F. Mahomed-Asmail
Researcher

Prof. D.W. Swanepoel
Research Supervisor

APPENDIX G

Referral letter

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Date: _____

Dear_____

A hearing screening procedure and diagnostic audiometry was conducted on the _____20__. During the evaluation it was noted that your child should be referred for further assessment. For this reason we would like to refer you to:

	Professional person:		**Reason:**
	Audiologist		Complete hearing evaluation recommended (referred screen)
	Ear-nose-and-throat specialist		Excessive wax in ear
			Negative pressure in the middle ear
			Other_____

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

_____
Ms. F. Mahomed-Asmail
Researcher

_____
Prof. D.W. Swanepoel
Research Supervisor

APPENDIX H

Participant worksheet 1

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Partic numb:_____

Participant worksheet

Background information:

Name of school:	**Grade:**
Name of student:	**DOB:**
Age: _____years_____months	**Gender:**
First language:	**Race:**

Otoscopic Examination:

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

Tympanograms:

	Type	**Volume**	**Pressure**	**Compliance**
Right ear				
Left ear				

MANUAL Pure tone screening: **conducted: 1st / 2nd**

	1000 Hz	**2000 Hz**	**4000 Hz**	**Overall result**
Right ear	pass / refer	pass / refer	pass / refer	pass / refer
Left ear	pass / refer	pass / refer	pass / refer	pass / refer

Time taken:_____

RETEST- MANUAL

	1000 Hz	**2000 Hz**	**4000 Hz**	**Overall result**
Right ear	pass / refer	pass / refer	pass / refer	pass / refer
Left ear	pass / refer	pass / refer	pass / refer	pass / refer

Time taken:_____

Smartphone Pure tone screening: **conducted: 1st / 2nd**

	1000 Hz	**2000 Hz**	**4000 Hz**	**Overall result**
Right ear	pass / refer	pass / refer	pass / refer	pass / refer
Left ear	pass / refer	pass / refer	pass / refer	pass / refer

Time taken:_____

RETEST- Smartphone Pure tone screening:

	1000 Hz	**2000 Hz**	**4000 Hz**	**Overall result**
Right ear	pass / refer	pass / refer	pass / refer	pass / refer
Left ear	pass / refer	pass / refer	pass / refer	pass / refer

Time taken:_____

Pass/Refer **Reason**:_____

Refer to: ENT/Audiologist/ Other:_____

APPENDIX I

Participant worksheet 2

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Participant worksheet 2

Diagnostic testing:

partic no._____

MANUAL Diagnostic testing:

AC	0.5 kHz	1 kHz	2 kHz	4 kHz
R ear				
L ear				

BC	0.5 kHz	1 kHz	2 kHz	4 kHz
R ear				
L ear				

Time Taken:____

AUTOMATED diagnostic testing:

AC	0.5 kHz	1 kHz	2 kHz	4 kHz
R ear				
L ear				

BC	0.5 kHz	1 kHz	2 kHz	4 kHz
R ear				
L ear				

Time taken:___

APPENDIX J

Proof of acceptance of articles

Health SA Gesondheid Decision

Ms. Ref. No.: HSAG-D-15-00001R1
Title: Referral criteria for school-based hearing screening in South Africa: considerations for resource-limited contexts
Health SA Gesondheid-Journal of Interdisciplinary Health Sciences

Dear Mrs. Mahomed-Asmail,

I am pleased to inform you that your paper "Referral criteria for school-based hearing screening in South Africa: considerations for resource-limited contexts" has been accepted for publication in Health SA Gesondheid-Journal of Interdisciplinary Health Sciences.

Below are comments from the editor and reviewers.
Kindly implement these comments when doing your final galley proofing

Thank you for submitting your work to Health SA Gesondheid-Journal of Interdisciplinary Health Sciences.

Yours sincerely,

Lizell Leonie Smit
Managing Editor
Health SA Gesondheid-Journal of Interdisciplinary Health Sciences

EANDH Decision

From:	"Ear and Hearing" <em@editorialmanager.com>
To:	"Faheema - Mahomed-Asmail" <faheema.mahomed@up.ac.za>
Date:	Wednesday - July 22, 2015 5:23 PM
Subject:	EANDH Decision
Attachments:	Mime.822

CC: sanfchri@isu.edu

RE: EANDH-D-15-00019R2, entitled "Clinical validity of hearScreen™ smartphone hearing screening for school children"

Dear Ms Mahomed-Asmail,

I am pleased to inform you that your work has now been accepted for publication in Ear and Hearing. All manuscript materials will be forwarded immediately to the production staff for placement in an upcoming issue.

Open access payments are securely processed through an LWW site that is separate from your Editorial Manager submission site. If you have not visited http://wolterskluwer.qconnect.com before, you will need to register a username and password as this site will not recognize your Editorial Manager information. Once you have registered, you can enter payment information and your open access processing charges are securely processed. Then your article will appear on the journal site as an open access article.

Thank you for submitting your interesting and important work to the journal.

http://eandh.edmgr.com/

With Kind Regards,
Brenda
Brenda Ryals, PhD
Editor-in-Chief
Ear and Hearing

Chris Sanford
Section Editor

Editorial Review Board Comments:
Section Editor's Comments:
The authors have done an excellent job responding to the reviewers' comments and suggestions. Based on a final review by myself, it is my recommendation that the manuscript be accepted for publication.
Thank you for submitting your work to the Journal, Ear and Hearing.
Chris Sanford, Section Editor**From:** gary.jacobson@vanderbilt.edu

JAAA Decision:

To: <faheema.mahomed@up.ac.za>, <mahomedfaheema@gmail.com>
CC: <jaaa@vanderbilt.edu>
Date: 2015/08/25 06:06 PM
Subject: Journal of the American Academy of Audiology - Decision on Manuscript ID 15-041.R3
25-Aug-2015

Dear Dr. Mahomed-Asmail:
It is a pleasure to accept your manuscript entitled "DIAGNOSTIC HEARING ASSESSMENT IN SCHOOLS: VALIDITY AND TIME-EFFICIENCY OF AUTOMATED AUDIOMETRY" in its current form for publication in the Journal of the American Academy of Audiology.

I would like to bring to your attention the fact that published articles are not only printed but are also posted on the JAAA Web site. Online you can include supplementary files that would otherwise be prohibitively expensive to print, such as figures in color, flowcharts that exceed the dimensions of a printed page, or lengthy appendixes of supporting data.

Audio and video files are also welcome in the online journal. Audio files might, for example, be used to clarify the nature of the auditory stimuli referred to in a study. Such files would include recordings of unusual stimuli (e.g., chirps, glides, and filtered noise bursts), unusual or synthesized speech stimuli, sentences containing key words, speech stimuli that have been degraded in various ways, speech stimuli before and after analog and digital signal processing, recordings of stimuli in virtual space, and recordings of stimuli from within real ear canals. Video files might picture a baby being screened for hearing loss, a client being tested with a new procedure, or a research participant responding to audio stimuli.
Keep in mind that audio and video files should be created using professional recording and editing software. Any MIME (multipurpose Internet mail extensions) file type may be used, and there is no limit to the number or size; however, it is important to remember that readers must have the necessary program(s) in order to view them.

I encourage you to take full advantage of these capabilities. They are certain to improve the readers' appreciation of your article.

Thank you for your fine contribution. On behalf of the Editors of the Journal of the American Academy of
Audiology, we look forward to your continued contributions to the Journal.

Sincerely,
Gary
Dr. Gary Jacobson
Editor-in-Chief, Journal of the American Academy of Audiology
gary.jacobson@vanderbilt.edu

IJPORL Decision

Ref. No.: IJPORL-D-16-00036R1

Title: Hearing loss in urban South African school children (grade 1 to 3)

International Journal of Pediatric Otorhinolaryngology

Dear Mrs. Faheema Mahomed-Asmail,

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Thank you for submitting your work to this journal.

With kind regards,

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