Community-based hearing services for children in early childhood development centers using mobile technologies

by

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

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Unidentified hearing loss has a negative impact on a child’s speech, language and communication abilities. This in turn creates a barrier to social development and educational achievement placing a child at a risk for failure and drop out from school. Within low- and middle-income countries (LMICs) like South Africa, children have limited access to early identification services due to several challenges, including a shortage of human resources for ear and hearing care, a lack of appropriate equipment as well as other health care priorities. This study identified early childhood developmental centers (ECD) as a potential platform for the identification of children affected by hearing loss prior to school entry. It aimed to provide research-based recommendations for delivering hearing screening within ECD centers using a low-cost smartphone-based hearing screening application operated by community members with no formal training on hearing care. It also investigated the current knowledge and attitudes of ECD practitioners to ensure the acceptance and success of such programs. Lastly, this study aimed to determine the nature and profile of hearing loss in a community representative of typical LMICs.

A total of 6424 children (3446 females, 2978 males) between the ages of three to six years were recruited from 250 ECD centers to determine the efficacy and feasibility of a smartphone hearing screening application, hearScreen™. A referral rate of 24.9% was obtained with females 1.26 times
more likely to fail compared to males. An increase in age was associated with a decreased likelihood of test failure, with overall referral rates varying from 19.6 to 45.8% for children six and three years of age, respectively. The quality index reflecting test operator test quality increased to 99-100% during the first few months of testing, thus indicating reliable testing by non-specialist personnel with support in early roll-out phases. Mean test duration, including both initial and rescreen test times for both ears, was 68 seconds (SD 2.8) for participants that passed and 258.5 seconds (SD 251.2) for those who failed.

Only 39.4% of children who failed ECD screenings attended their follow-up appointment at their local primary health care (PHC) facility, of which 40.5% referred on their second screening. A total of 725 children received a diagnostic assessment. Diagnostic testing revealed that 9.3% of children presented with impacted cerumen and 18.7% presented with a hearing loss (56.5% bilateral). Conductive hearing loss (65.2%) was the most common type of hearing loss found in these children. No gender or age effects were found (p>0.01). The majority of preschool children who failed hearing screenings and received a diagnostic assessment were in need of intervention services for conductive hearing losses, followed by sensorineural and mixed losses.

A questionnaire was administered amongst 82 ECD practitioners to determine their current knowledge and attitudes towards hearing health in poor communities. More than 80% of ECD practitioners correctly identified genetics and ear infections as etiological factors of hearing loss. Gaps in knowledge regarding identification techniques for children three to six years of age and the impact of hearing loss in the classroom were evident. ECD practitioner’s duration of experience had a significant effect on overall knowledge and attitude. ECD practitioners displayed a positive attitude towards children receiving a hearing test (88.3%) and almost all participants indicated the need for more information regarding hearing loss (93.5%).

Findings from this study provide baseline data for future research, planning and implementation of ECD-based hearing health services within LMIC
contexts such as South Africa. Implementation of smartphone-based hearing screening programs within ECD centers is a feasible solution to improve access to ear and hearing care services to children in LMICs. Whist ECD practitioners demonstrated a general readiness for the implementation of ECD hearing screening programs, additional information and guidelines are needed to improve practitioner knowledge and attitudes. Using mobile health technologies offers a number of advantages that can support community-based hearing services and overcome some of the traditional challenges faced when screening within an informal educational setting.
KEYWORDS

Hearing screening
Preschool children
Early childhood development
Smartphone
Low- and middle-income countries
Community-based
Mobile health
Knowledge
Attitudes
Questionnaire
Practitioner
Mobile technologies
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<tr>
<td>dB</td>
<td>Decibel</td>
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<tr>
<td>kHz</td>
<td>kilohertz</td>
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<td>ECD</td>
<td>Early childhood development</td>
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<td>CHWs</td>
<td>Community healthcare workers</td>
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<td>LMICs</td>
<td>Low- and middle-income countries</td>
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<td>SLM</td>
<td>Sound level meter</td>
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<td>MPANLs</td>
<td>Maximum permissible ambient noise levels</td>
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<td>HL</td>
<td>Hearing loss</td>
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<td>NHS</td>
<td>Newborn hearing screening</td>
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<td>EHDI</td>
<td>Early hearing detection and intervention</td>
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<td>OAE</td>
<td>Otoacoustic Emission</td>
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<td>IHSP</td>
<td>Integrated School Health Policy</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>JCIH</td>
<td>Joint Committee of Infant</td>
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<td>HPCSA</td>
<td>Health Professions Council of South Africa</td>
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<td>ASHA</td>
<td>American Speech-Language-Hearing Association</td>
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<td>AAA</td>
<td>American Academy of Audiology</td>
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<td>NPO</td>
<td>Non-profit Organization</td>
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Hearing loss is one of the most common developmental disorders identifiable at birth, with its prevalence increasing throughout school years due to late identified, progressive or acquired hearing losses (American Academy of Audiology [AAA], 2011). According to the World Health Organization (WHO, 2018), 466 million people globally are affected by disabling hearing loss (>40 dB HL), with 34 million of these being children. Unidentified hearing loss negatively affects a child’s speech and language development, communication ability, educational achievement and social-emotional development resulting in social isolation and stigmatization (Joint Committee on Infant Hearing [JCIH], 2007; Mathers, Smith, & Concha, 2000; WHO, 2018). Furthermore, these negative effects of a hearing loss increase risk for failure and drop-out from school, thus placing a child at an economic disadvantage (Mathers et al., 2000; WHO, 2018). Even a unilateral hearing loss in children poses significant risk factors such as increased rates of grade failure, need for additional educational assistance and perceived behavioral issues in the classroom (Cho Lieu, 2004).

The first step to minimizing the negative consequences of a hearing loss is early identification of a new or developing hearing loss in one or both ears, followed by appropriate referral for diagnosis and treatment (AAA, 2011). Although the majority of hearing losses are preventable or treatable, there are limited prospects of identifying a hearing loss in children, particularly within low- and middle- income countries (LMICs) (Fagan & Jacobs, 2009; Goulios & Patuzzi, 2008; WHO, 2018). The JCIH (2007) released principles and guidelines to endorse the early detection and intervention for infants with hearing loss. Although the Health Professions Council of South Africa (HPCSA, 2007, 2018) accepts the JCIH position statement, early hearing detection and identification programs are still not mandated by hospitals in LMICs countries such as South Africa, where majority of children affected are
born and environmental risks are greater (Olusanya & Newton, 2007; Swanepoel, Störbeck, & Friedland, 2009). The result is that a large number of children are still unidentified at the time of school entry (Bamford et al. 2007; Khoza-Shangase & Kassner, 2013). The Integrated School Health Policy (ISHP, 2012a) of South Africa stipulates that hearing screenings should be conducted within schools, particularly within the foundational phase, however there is little indication of the need for hearing screening programs prior to school entry.

The main reasons reported for a lack of screening and follow-up programs within LMIC regions such as sub-Saharan Africa is a shortage of human resources for ear and hearing care, a lack of appropriate equipment as well as other health care priorities (Theunissen & Swanepoel, 2008; WHO, 2013). A greater concentration of human resources for ear and hearing health care is found in high- and upper-middle-income countries, while low- and middle-income countries account for more than 80% of individuals affected by hearing loss globally (Fagan & Jacobs, 2009; WHO, 2013). Studies conducted by the WHO (1998) have indicated between one audiologist per 0.5 million people to one per 6.25 million people, indicating a density ratio of one audiologist in developing countries as opposed to 300 audiologists in developed countries (Goulios & Patuzzi, 2008). Furthermore, the availability of audiologists was reported to be lowest in the African region, with an average estimate of one audiologist for every million people in sub-Saharan Africa (Fagan & Jacobs, 2009; WHO, 2013).

Within the public healthcare system of South Africa, hearing health care services are mostly provided at tertiary level, and occasionally at secondary healthcare facilities, such as provincial and regional hospitals, whilst primary health care has typically omitted hearing health services (Swanepoel, 2006). Additionally, audiologists are unequally distributed between the private and public health care sector, with majority entering the private health care sector (Swanepoel, 2006; Swanepoel et al., 2009). This increases the demand placed on individuals serving the public health sector that serves approximately 85% of the population (Swanepoel, 2006; Swanepoel et al.,
Additionally, high costs associated with screening and diagnostic equipment as well as the need for equipment to be operated by trained personnel places further strain on LMICs to successfully implement early hearing detection and intervention programs (Clark & Swanepoel, 2014). As such, the health systems of developing countries are unable to manage the added burden of non-fatal disabling disorders without external technical and financial support (Olusanya & Newton, 2007).

A proposed method to overcome the barriers to service delivery in underserved populations, is by capitalizing on connectivity and technology through the use of automation and mobile technology (Clark & Swanepoel, 2014). Automated audiometry is useful for screening programs and involves the use of computer-based algorithms to replicate standard protocols used by audiologists for performing behavioral air conduction and bone conduction hearing testing (Foulad, Bui, & Djalilian, 2013). This is ideal as a sequence of steps needs to be followed in order to obtain air and bone conduction pure-tone thresholds which can be implemented using a software-based testing system (Margolis & Morgan, 2008). This means that automated audiometry could be facilitated by non-specialist personnel. As automated audiometry becomes more standardized, test results will continue to become more accurate (Foulad et al., 2013). The use of automated audiometry could also reduce test time, therefore increasing the number of individuals assessed and ultimately reduce the costs of testing (Margolis & Morgan, 2008).

Mobile health or mHealth is the use of mobile technology, such as smartphones, tablet PCs, smartbooks and personal digital assistants (PDAs) to overcome health challenges (Friederici, Hullin, & Yamamichi, 2012). It has demonstrated promise to improve access to services, particularly within developing LMICs (Friederici et al., 2012). Smartphones provide an ideal platform for automated audiometry as they support headsets and the development of custom software applications (Foulad et al., 2013). Furthermore, with the widespread penetration of 1.08 billion smartphones of 5
billion mobile phones worldwide, a number of smartphone applications have already been developed to provide a range of audiological services (Clark & Swanepoel, 2014; Martínez-Pérez, de la Torre-Diez, Candelas-Plasencia, & López-Coronado, 2013).

An example of such an application is the UHear™ (Unitron) application, a downloadable screening audiometer on an iPod Touch or iPhone for self-assessment of air conduction thresholds. A study by Khoza-Shangase and Kassner (2013) aimed to investigate whether or not the UHear™ application was accurate to test hearing thresholds in school-aged children. However, results of this study revealed inaccurate elevated hearing thresholds when compared with the golden standard of conventional audiometry. Furthermore a subsequent study revealed that low frequency thresholds were less accurately measured in comparison to mid- to high frequency thresholds (Peer & Fagan, 2014). The EarTrumpet is another example of such an application which showed promise to successfully conduct automated hearing evaluations, however validation studies revealed that it does not allow for calibration according to prescribed standards (Foulad et al., 2013). Furthermore, these devices are operated on costly iOS devices which restrict accessibility in developing countries.

An android-based smartphone hearing screening application, hearScreen™, utilizing calibrated headphones with pre-specified screening protocols to assess hearing using automated test sequences has also been proposed. The hearScreen™ is a low cost alternative to conventional screening audiometry to identify hearing loss, operated on an entry-level smartphone running Android™ OS software and off-the-shelf circumaural headphones (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, & Hall, 2016a; Swanepoel, Myburgh, Howe, Mahomed & Eikelboom, 2014). hearScreen™ can be accurately calibrated according to current standards (ANSI/ASA S3.6-2010; ISO389-1, 1998), and shows clinical screening outcomes comparable to conventional screening with improved efficiency and quality control (Mahomed-Asmail et al., 2016a; Swanepoel et al., 2014). Since automated best protocols are employed with immediate automated interpretations of
results, non-specialist personnel can be trained to successfully operate the device. Yousuf Hussein et al. (2014) demonstrated that generalist healthcare workers could successfully screen for hearing loss using the hearScreen™ application during home-based visits, thereby lessening the burden on already limited ear and hearing care professionals.

hearScreen™ also employs noise monitoring algorithms which provides operators with real-time feedback on ambient noise levels and automatically retests frequencies where maximum noise levels were exceeded (Mahomed-Asmail et al., 2016a; Swanepoel et al., 2014). These advantages allow for remote hearing screenings to be conducted after which patient specific data and results collected on the smartphone application can be uploaded to a centralized cloud-based server through cellular networks for data management. Furthermore, hearScreen™ employs a geotag feature, which allows patients to be linked to the closest hearing health providers with text message notifications.

The hearScreen™ application has been validated to identify hearing health concerns in school-aged children (grade 1-3) (Mahomed-Asmail et al., 2016a). However, no systematic clinical validation has been conducted on younger preschool children that are typically more difficult to test. Performing hearing screenings in the preschool aged population is important to identify those children who did not have access to newborn hearing screening opportunities, earlier screening failures that were lost due to a lack of follow-up, as well as to identify late onset hearing loss that may interfere with language development and future school success (AAA, 2011). Furthermore, ensuring timely referrals and follow-up testing, as well as providing education toward the prevention of hearing loss are important steps that need to follow hearing screenings to overcome the negative consequences of a hearing loss (AAA, 2011).

Within South Africa, emphasis has been placed on the early identification of children with disabilities through the legislative requirement of promoting early childhood development (ECD) (Department of Social Development, 2009).
ECD centres are aimed at providing emotional, cognitive and physical development of children from birth to school going age (Department of Social Development, 2009). These ECD centers have the potential to serve as the first point of access to preventative hearing health care services to children from underserved populations. Research has demonstrated that by implementing ECD programs, developmental delays can be successfully prevented, as assessed by reductions in grade retention and the need for placement in special education (Anderson, et al., 2003). Furthermore, a study conducted in the US demonstrated that implementing hearing screenings in early childhood programs can help to identify a wide range of hearing health conditions that can potentially disrupt language acquisition, literacy, socialization and overall school readiness (Eiserman, Shisler, Foust, Buhrmann, Winston, & White, 2007). However, these programs made use of costly otoacoustic emissions (OAE) technology, which may not be feasible in LMICs. Thus, the aim of this study was to develop an effective, affordable and sustainable smartphone hearing screening program to support and promote hearing health care, in conjunction with ECD centers in an underserved community. Furthermore, this study aimed to facilitate an effective strategy to ensure timely referral and follow up of children who failed hearing screening.

Additionally, to ensure the acceptance of such a program, it is also important to determine the perception and knowledge of ECD practitioners, including teachers and principals regarding the importance of healthy hearing, the causes and impact of a hearing loss, identification and intervention for hearing loss as well ECD practitioner attitudes towards children affected. It is the responsibility of ECD practitioners to provide children with the skills and knowledge needed to allow them to learn and use every day functions as well as to advocate for these children by participating in community-based efforts to promote their wellbeing (Fourie, 2013). Thus, this study included the aim of determining the current knowledge and attitude of preschool principals and teachers towards hearing loss thereby providing a guide on how to empower them to support healthy hearing within an ECD context, as well as to promote healthy hearing with parents and caregivers.
2.1. Research objectives and design
The main aim of this project was to evaluate the clinical efficacy of a program supporting hearing health care in preschool children using a smartphone-based hearing screening, referral and follow-up platform in community-based early childhood development (ECD) centers.

In order to achieve the main aim, this project was divided into three research objectives, each constituting a research study that was submitted as an article to ISI accredited peer reviewed journals upon completion. These three studies are summarized below according to titles and objectives.

2.1.1. STUDY I: Community-based hearing screening for young children using an mHealth service-delivery model.

Objectives
To describe the efficacy of smartphone hearing screening in preschool children in terms of:

- Reliability of hearing screenings conducted
- Quality index of test operators
- Referral rate of the hearing screening program
- Follow-up return rate
- Compliance of the test environment
- Time proficiency of the smartphone hearing screening application

Research Design
This study employed an exploratory, descriptive cross-sectional research design (Leedy & Ormrod, 2010; Maxwell & Satake, 2006) yielding quantitative data. Exploratory research is used when research is in a preliminary stage and definitive conclusions arising from it are rare (Maxwell & Satake, 2006). This research design is exploratory and descriptive in nature, as it aimed to
investigate and describe a novel community-based approach to hearing health care for young preschool children within an ECD setting using an innovative mHealth application.

2.1.2. STUDY II: Knowledge and attitudes of early childhood development practitioners towards hearing health in poor communities.

**Objectives:**

- To describe the current knowledge of ECD practitioners towards hearing health in order provide a guide for the future support and empowerment of ECD practitioners in underserved areas.
- To describe the current attitudes of ECD practitioners towards hearing health.

**Research Design**

A cross-sectional quantitative survey was used to determine the current knowledge and attitudes of ECD practitioners towards hearing health. This survey was quantitative in nature since data gathered to answer questions about the measured/dependent variables were of a numerical and categorical nature (Leedy & Ormrod, 2005).

2.1.3. STUDY III: Hearing loss in preschool children from a low income South African community.

**Objectives:**

To describe the prevalence and nature of hearing loss in a group of preschool aged children.

- To determine the incidence of hearing loss in a sample of preschool aged children using smartphone-based hearing screening followed by diagnostic audiometry.
- To describe the profile and nature of hearing loss in a sample of preschool aged children using diagnostic audiometry.
Research Design

An exploratory, cross-sectional research design using quantitative data was used for Study III (Kaplan, 1987; Maxwell & Satake, 2006). This study was exploratory in nature as it aimed to investigate the nature and profile of hearing loss in preschool children within a low- and middle-income South African context for which there is a dearth of information.

2.2. Research context

The community of Mamelodi is situated approximately 20km east of the City of Tshwane. This township was established in 1953 and started with a mere 16 houses built for Black people that were removed from other areas according to the Group Areas Act. The unofficial population of Mamelodi is currently close to one million (Stats SA, 2011). In order to achieve the objectives of Study I and II, all ECD centers located within the area of Mamelodi East and Mamelodi West were mapped and provided with the option of participating in this study. ECD centers (crèches) included both public and private facilities that provide learning and support to children between the ages of three to six years of age. Data was also collected from the clinics serving the community of Mamelodi East and Mamelodi West to achieve the objectives of Studies I and III.

2.3. Research participants

Random sampling was used to identify 250 ECD centers within the Mamelodi West and Mamelodi East areas. All preschool children attending these ECD centers (three to six years of age) were included in the study, if informed consent was provided by their parent/guardian. It was estimated that there are 10 000 preschool children within this community. If necessary, children tested at the ECD centers were referred to their closest referral clinic where follow-up data was collected. Practitioners employed by these ECD centers were also requested to participate in this study. Table 2.1 provides a detailed summary of the participant selection criteria, participant sampling method and sample size.
Table 2.1. Participant selection criteria, sampling method and sample size.

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| Participant Selection Criteria | - Participants only included preschool children aged three to six years.  
- Informed consent was initially obtained from the ECD principal to conduct screenings.  
- Both male and female participants were included.  
- Informed consent was obtained from participants’ caregiver/parent.  
- Assent was also obtained from the participant tested.  
- Participants had to be enrolled at the ECD center where testing was done. | All practitioners, including principals and teachers, at the ECD centers where hearing screenings were conducted were included using random sampling (Leedy & Ormrod, 2005) | All participants referred for diagnostic assessment following hearing screenings. |
| Participant Sampling | Non-probability purposive sampling (Leedy & Ormrod, 2001) | | |
| Sample Size | 6424 preschool children | 82 ECD practitioners | 725 preschool children |

2.4. Materials and apparatus for data collection

The following equipment was used during the proposed studies.

2.4.1. Hearing screening

Hearing screenings were conducted using the hearScreen™ smartphone application. The hearScreen™ smartphone application was initially operated on Samsung Trend Plus (S5301) smartphones (Android OS, 4.0) connected to supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany). In July 2016, the Samsung Trend plus smartphones were replaced with Samsung J2 Galaxy smartphones (Android OS, 5.1), which operated an upgraded version of the hearScreen™ software. The hearScreen™ calibration function was used to calibrate the headphones according to prescribed
standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Swanepoel et al., 2014). Calibration was performed using an IEC 60318-1 G.R.A.S. ear stimulator connected to a Type 1 sound level meter (SLM) (Rion NL-52). The hearScreen™ solution has been validated to monitor noise accurately within 1 and 1.5dB HL depending on the test frequency (Swanepoel et al., 2014). Data collected by the smartphone was uploaded to a secure cloud-based server at the end of each test day and was stored electronically.

2.4.2. Otoscopy
Otoscopy was conducted on all children who were seen for a follow-up diagnostic assessment. The external ear canal and tympanic membrane were examined using a handheld Welch Allyn (Welch Allyn, South Africa (Pty)(Ltd.) or Heine mini 3000 (Heine, Germany) otoscope.

2.4.3. Tympanometry
Tympanometry was conducted on all children seen for a diagnostic assessment. The GSI Auto Tymp (Grayson Stadler, Eden Prairie, USA) or an Interacoustics Impedance Audiometer AT 235 (William Demant, Smørum, Denmark) was used to determine middle ear functioning in terms of middle ear pressure, volume and compliance.

2.4.4. Diagnostic audiometry
The KUDUwave audiometer (GeoAxon, South Africa) was used to obtain hearing thresholds in children seen for follow-up testing at clinics. The KUDUwave audiometer is a computer-based device. Circumaural ear cups are placed over insert earphones for additional attenuation. This allowed for hearing assessments to be conducted outside a soundproof booth. A microphone on the outside of the circumaural ear cups provides monitoring of background noise. The audiometer hardware is contained within the circumaural ear cups that plugs into a Dell laptop via a USB cable. Additionally, an electronic patient response button is connected to the headset software interface that controls the KUDUwave audiometer.
In July 2016, the hearTest™ smartphone application was loaded onto the smartphones used for hearing screenings as an additional tool at clinics to obtain hearing thresholds. The hearTest™ smartphone application is also operated on Samsung J2 Galaxy smartphones (Android OS, 5.1) connected to supra-aural Sennheiser HD202 II headphones (Sennheiser, Wedemark, Germany) and can be calibrated according to prescribed standards. Noise levels were monitored by the hearTest™ application throughout the test procedure in order to ensure for reliable testing. Data collected by the smartphone was uploaded to a secure cloud-based server at the end of each test day and was stored electronically.

2.4.5. Questionnaire

The questionnaire used to determine maternal views on hearing loss by Swanepoel, Nizha and Almec (2008) was adapted for use with ECD practitioners within the South African context (Appendix A). The adapted questionnaire consisted of five items that were added to obtain ECD practitioner demographic information with an additional 23 items. The 23 items consisted of four items to determine the general knowledge of ECD practitioners towards healthy hearing and hearing loss; five items regarding the causes and risk factors of a hearing loss; 10 items regarding the identification and intervention for hearing loss; and four items to determine the attitudes of ECD practitioners towards children with a hearing loss. A choice of three responses were provided: ‘yes’, ‘unsure’ or ‘no’.

2.5. Data collection procedures

In order to realize the aims of this study, a team was formed that included a project manager, five trained testers in collaboration with community members and ECD centers as well as two members from the NEA Foundation. The NEA foundation is a community-based non-profit organization (NPO) involved in communities, aimed at creating opportunities for development and education for children (NEA Foundation, 2014). Additionally, the project was funded by Innovation Edge. Duties of the team included the following:
- Partnering with local NPO's and community members to locate potential ECD centers in the Mamelodi East and Mamelodi West area;
- Establishing an agreement with each ECD center to ensure mutual commitment and ownership;
- Raising awareness at ECD centers about healthy hearing through information sharing;
- Collaboration with local clinics regarding feedback of referrals and follow up visits.

The proposed research project was divided into three different studies. Data collection for the research project was completed over three phases.

2.5.1. Phase I: Community Mapping
During this phase, ECD centers within the Mamelodi East and Mamelodi West area were identified and mapped by community members drafted by the NEA Foundation over a period of three months, during which a profile was created for each. The aim was to establish a relationship and agreement with each ECD center to ensure mutual commitment and ownership. An information leaflet and informed consent letter (Appendix B) was provided to the principal of each ECD center to obtain permission to offer hearing screening service to the children enrolled at the ECD center. Information and posters regarding the importance of healthy hearing were also provided to each ECD center. Once consent was obtained, the ECD was requested to provide participant information leaflets and informed consent letters to all parents/caregivers (Appendix C), requesting permission for their child’s hearing to be screened. Assent was also obtained from children prior to testing (Appendix D).

2.5.2. Phase II: Pilot Implementation Phase
A pilot study aids in ensuring that accurate data is obtained and also increases the precision of the research method (De Vos, Strydom, Fouchè, & Delport, 2005). Five community members, who completed the mapping of the ECD centers, were trained by the researcher to conduct hearing screenings using the hearScreen™ smartphone-based screening application prior to the commencement of Phase II. These community members had no formal
training in ear and hearing health care. During the training session these community members were provided with adequate information regarding the importance of healthy hearing. They also received training and sufficient hands-on practice to manage the hearing screening application during this session, with specific emphasis on techniques to successfully screen younger children.

During the pilot phase, the first 1000 preschool children identified during phase one of the data collection period, received smartphone-based hearing screenings conducted by a trained tester. Additionally, each principal and teacher of the ECD centers visited during the pilot phase, were requested to complete the developed questionnaire (Appendix A). An estimated time frame of two months was set for the pilot study.

The procedure for data collection using the smartphone-based hearing screening application comprised of the following:

- Hearing screenings were only conducted on children between the ages of three to six years.
- Hearing screenings were only conducted if permission had been granted by the ECD center (Appendix B) and if the participant information leaflet and informed consent letter (Appendix C) was returned and completed by the parent/caregiver. Additionally, assent was obtained from all children prior to testing (Appendix D).
- Hearing screenings were conducted in a quiet room within the ECD center.
- Each child was provided with a simple explanation and demonstration of what the test entails and what was expected of him/her in his/her home language. The child was required to raise his/her hand each time that they heard the tone/beep presented.
- The tester entered the child’s name, surname, date of birth, gender, parent’s/caregiver’s contact details and the name of the ECD facility attended on the smartphone application.
- The tester then placed the headphones on the child's ears and sat behind the child before beginning the test.
A conditioning tone was initially presented in order to ensure that the child understood the instructions. If a child could not be conditioned reliably, the tester was required to note this on the hearScreen™ application and to refer the child to his/her closest referral clinic for a follow-screen by a qualified audiologist.

The hearing screening application employs automated test protocols. A sweep was performed at the test frequencies of 1, 2 and 4 kHz bilaterally at an intensity of 25 dB HL. The stimulus was repeated once if the child did not respond at any frequency.

The smartphone microphone measures noise levels in the environment prior to the commencement of the test. A warning was provided to the tester if the environmental noise was too high. The tester would then attempt to reduce background noise as much as possible or alternatively move to a quieter room before continuing the test.

Additionally, the hearScreen™ employs a smart noise-monitoring algorithm that only initiates a rescreen if noise levels exceed maximum permissible ambient noise levels (MPANLs) when there was no response from a patient. A warning is provided to the tester who was then required to reduce background noise or move to a quieter room. Testing was completed on the second trial even if noise levels could not be reduced sufficiently. Noise levels were automatically recorded by the smartphone application.

The child needed to respond by raising his/her hand to each tone presented to ‘pass’ the hearing screening. Failure to hear a tone at any frequency in either ear constituted an overall ‘refer’ result. A rescreen was initiated immediately and followed the same procedure (AAA, 2011). If a child referred on the immediate rescreen, he/she was referred to his/her closest referral clinic for a diagnostic hearing assessment (i.e. Mamelodi West or Stanza I clinic).

Results were communicated directly to parents/caregivers via text message. The SMS also provided a follow-up date and time at the closest referral clinic for a diagnostic hearing assessment. A referral letter was also provided to each parent/caregiver (Appendix E).

A summary of results was communicated to ECD facilities for
educational interventions (Appendix F).

- Test results collected by the smartphone application were immediately uploaded to a secure cloud-based server via a mobile network for data management.

Diagnostic testing was conducted by the researcher or qualified audiologist based at Mamelodi West Clinic or at Stanza I Clinic. The procedure for data collection on those participants who referred for diagnostic testing comprised the following:

- The researcher or qualified audiologist, using the hearScreen™ smartphone application, would first rescreen all children referred to the clinic. This enabled one to confirm the need for a diagnostic assessment, as well as to track attendance of follow up appointments.
- If necessary the researcher or audiologist carried out a diagnostic test battery. This consisted of otoscopy, tympanometry and automated audiometry. The audiologist provided a short explanation of what each test entailed and what was expected from the child to the parents/caregivers. Instructions were also provided to the child.
- An otoscopic examination was conducted to determine the condition of the external ear and tympanic membrane to identify any pathology such as excessive wax, discharge or perforation of the tympanic membrane.
- Acoustic immittance testing was conducted by placing a probe into the child’s ear to measure middle ear pressure, volume and compliance. This was done to determine the presence of any middle ear pathologies that may cause a temporary or fluctuating conductive hearing loss.
- Automated audiometry was conducted consisting of air conduction audiometry at 0.25 – 8 kHz using the KUDUwave audiometer or the hearTest™ smartphone application. Bone conduction audiometry was only conducted using the KUDUwave audiometer if air conduction thresholds exceed the normal range (>20 dB HL). Masking was automatically applied where needed. The child was instructed to raise his/her hand each time that he/she heard the tone/beep presented.
These results, in conjunction with otoscopy and tympanometry were used to identify the presence of a hearing loss in terms of type and degree.

- Once the testing was completed, results were explained to the parents/caregivers by the audiologist. Recommendations and/or referrals for intervention were made accordingly.

Procedure for data collection using the questionnaire comprised of the following:

- Each ECD principal and teacher was provided with a participant information leaflet attached to the developed questionnaire (Appendix A).
- This was provided on the test day at their ECD center prior to the commencement of the hearing screenings.
- If the principal/teacher agreed to participate in the study, he/she was requested to complete the attached questionnaire. The participant information leaflet clearly stated that if the questionnaire was completed, it implies that informed consent was given.
- The questionnaire was completed anonymously.
- Participants were required to answer five demographic questions and to provide an answer indicating 'yes', 'unsure' or 'no' for a further 23 items.
- The questionnaire took approximately 10 minutes to complete and was collected at the end of the test day.

2.5.3. Phase III: Implementation Phase

Data collected during Phase II of the study was analyzed and the adaptations mentioned below were made before the remaining preschool children received screening and follow-up services. It was found that children younger than four years of age were often difficult to condition to respond reliably to the instructions provided during smartphone hearing screenings. Thus, only children between the ages of four to six years were included in this phase of the study. Testers were retrained to conduct hearing screenings using the smartphone application to ensure more reliable testing. Automated text
message results to parents were changed to both English and Sepedi in order to improve follow-up rates. Additionally, upgrades to the hearScreen™ software and hardware were made. No adaptations were made to the developed questionnaire. Ongoing monitoring and evaluations were conducted throughout this phase. A time frame of 10 months was allocated to this phase of the study.

2.6. Procedure for data processing and analysis
The proposed research project was divided into three different studies, therefore the data processing and analysis procedures used for each were different. Data processing involves the integration of the data collected from diverse sources and the presentation of the data in a logical manner (Babbie & Mouton, 2001). Data preparation requires the researcher to code the data, enter the data and clean the data set (Terre Blanche, Durrheim, & Painter, 2006).

2.6.1. Study I: Community-based hearing screening for young children using an mhealth service-delivery model.
Data was extracted from the hearScreen cloud-based server to an MS Excel (2011) sheet and analyzed using SPSS v24 (Chicago, Illinois). Descriptive statistical measures were employed to describe and synthesize the quantitative data collected (Irwin, Pannbacker & Lass, 2008), including the referral rate of the smartphone hearing screening program, the follow-up rate based on patients who refer and attend follow-up diagnostic appointments, quality indices of test operators, the compliance of the test environment and the time efficiency of smartphone hearing screenings in preschool aged children. Binomial logistic regression analysis was used to determine the effects of age, gender and exceeded MPANLs on referral rates in children, with p<0.05 used to indicate a significant effect.

2.6.2. Study II: Knowledge and attitudes of early childhood development practitioners towards hearing health in poor communities.
Responses from the questionnaires were coded into quantitative data in MS Excel (2011) that could also be analyzed using descriptive statistical
measures (Irwin, Pannbacker & Lass, 2008). Responses were assigned the following scores: yes=1; unsure=2; no=3. All responses were analyzed descriptively by making use of frequency distributions, averages and standard deviations. Fisher’s exact test was used to determine if gender and formal ECD training had an effect on individual survey items. Additionally, results of each question were totaled to get a score of participants’ knowledge (i.e. the lower the score, the better a participants knowledge). Linear regression analysis was conducted to determine the effect of age, gender, formal ECD training, and length of experience on participants’ overall knowledge.

2.6.3. Study III: Hearing loss in preschool children from a low income South African community.

Data extracted from the cloud-based server on an MS Excel (2011) sheet was used for statistical analysis. Additionally, data collected from the follow-up diagnostic assessments were coded into quantitative data in MS Excel (2011) that could also be analyzed using descriptive statistical measures (Irwin, Pannbacker & Lass, 2008). Data were analyzed using SPSS v25 (Chicago, Illinois). Descriptive statistical measures were used to analyze screening results, tympanometry findings, diagnostic results and otological status. Binomial logistic regression analysis was performed to determine the effects of age and gender on the prevalence of hearing loss, with p<0.05 used to indicate a significant effect.

2.7. Ethical considerations

Ethical considerations were addressed in order to protect the rights and welfare of the participants involved in the study (Leedy & Ormrod, 2010).

2.7.1. Confidentiality and Anonymity

A researcher must respect the privacy of the participants by keeping the nature and quality of the participants’ performance strictly confidential (Leedy & Ormrod, 2010). For Studies I and III, each participant that underwent screening and follow-up diagnostic assessment were provided with a coded number thus ensuring anonymity. Data entered onto the smartphone application and uploaded to the cloud-based server was only accessible to the
researcher. For Study II, participants were requested to complete the questionnaire anonymously, and no identifying information was documented.

2.7.2. Protection from harm
According to Leedy and Omrod (2010), the risk involved in participating in a study should not be greater than the normal risks of day to day living. There were no medical risks or discomforts associated with this study. This was clearly explained in the participant information leaflet and informed consent letters provided. Participants were also provided with a clear explanation of what was expected of him/her.

2.7.3. Permission
The proposed study was part of a larger project registered under Prof. De Wet Swanepoel, for which ethical clearance had been granted by the Research Ethics Committee of the Faculty of Humanities (Appendix G). The researcher also obtained ethical clearance from the Research Ethics Committee of the Faculty of Humanities prior to any data collection (Appendix H). Additionally, for the follow-up of participants at the clinic, this study was linked to a larger study led by Prof. Johannes Hugo titled “Researching the development, application and implementation of Community Oriented Primary Care (COPC). A study in Gauteng (Tshwane) and Mpumalanga Province.” An amendment to this study was proposed to include the current study, and ethical clearance was obtained from the Faculty of Health Science Research Ethics Committee on the 04/12/2015 (Appendix I). Furthermore, permission was requested from each ECD center prior to the collection of data (Appendix B).

2.7.4. Informed consent
Informed consent is an important ethical consideration that must be obtained from all participants prior to data collection. Participants should be informed of nature of the study as well as their level of involvement in the study (Leedy & Omrod, 2010). A participant information leaflet and informed consent letter was provided to the principal of each ECD center in order to request permission for hearing screening to be conducted on children enrolled within
the respective ECD center (Appendix B). Since the children tested were between the ages of three to six years, a participant information leaflet and informed consent letter was provided to their parents/caregiver requesting permission for their child to participate in the study (Appendix C). Additionally, child assent was obtained from each child prior to data collection (Appendix D). A participant information leaflet and informed consent letter was also provided to all ECD practitioners before administering the questionnaire (Appendix A).

Data collection only took place once informed consent was obtained from the respective participants. All participants were made aware that participation is voluntary and that they may withdraw from the study at any time.

2.8. Feasibility

The NEA Foundation is a non-profit organization aimed at creating opportunities for young children. Funding to support this project had been motivated for and received by the NEA Foundation from Innovation Edge. As a doctoral student and researcher from the University of Pretoria, we partnered with hearScreen™ and the NEA Foundation to support and ensure the effective facilitation of the project in Mamelodi East and Mamelodi West.

Strict time frames mentioned in the methodology section above were set in order to ensure that the data collection period of this project was completed within less than two years. Risk factors and solutions were also anticipated in order to ensure effective facilitation of this project. These are listed below:

2.8.1. ECD’s openness and willingness to partner with this initiative

Effective relationship building with ECD practitioners and creating awareness about the effects of hearing problems on a child’s social and educational development.

2.8.2. Consent from parents/caregivers for screening

Participant information leaflets and informed consent letters (Appendix C) were sent with homework books to the parents/caregivers. Additionally, the
ECD practitioners informed parents/caregivers of the proposed initiative and the importance thereof.

2.8.3. Absence of learners for screening on specific dates
Pre-arranged dates were communicated to ECD facilities and parents/caregivers.

2.8.4. Language barrier
Volunteers from the NEA Foundation were from the community of Mamelodi. They are fluent in English and African languages used within the community.

2.8.5. Non-attendance of follow-up appointments
Parents/caregivers received an SMS notification as well as a referral letter indicating the need for their child to attend a follow-up diagnostic appointment. Dates and times were provided to encourage attendance. Additionally, ECD practitioners were also provided with a summary of the children who failed the hearing screenings, to encourage and ensure that these children attend follow-up appointments.
3.1. Abstract

Background
Hearing loss is one of the most common developmental disorders identifiable at birth with its prevalence increasing throughout school years. However, early detection programs are mostly unavailable in low- and middle-income countries (LMICs) where more than 80% of children with hearing loss reside.

Objective
This study investigated the feasibility of a smartphone-based hearing screening program for preschool children operated by community healthcare workers (CHWs) in community-based early childhood development (ECD) centers.

Method
Five CHWs were trained to map ECD centers and conduct smartphone-based hearing screenings within a poor community in South Africa over a 12-month
period. The hearScreen™ smartphone application employed automated test protocols operating on low cost smartphones. A cloud-based data management and referral function allowed for remote monitoring for surveillance and follow up.

**Results**
6424 children (three to six years) were screened for hearing loss with an overall referral rate of 24.9%. Only 39.4% of these children attended their follow-up appointment at a local clinic, of which 40.5% referred on their second screening. Logistic regression analysis indicated that age, gender and environmental noise levels (1 kHz) had a significant effect on referral rates (p<0.05). The quality index reflecting test operator test quality increased during the first few months of testing.

**Conclusion**
Smartphone-based hearing screening can be used by CHWs to detect unidentified children affected by hearing loss within ECD centers. Active noise monitoring, quality indices of test operators and cloud-based data management and referral features of the hearScreen™ application allows for the asynchronous management of hearing screenings and follow-ups.

**3.2. Background**
Hearing loss is one of the most common developmental disorders identifiable at birth which, if left undetected, has a negative impact on a child’s speech, language, cognitive, educational and socio-emotional development (AAA, 2011; JCIH, 2007). Approximately 0.5 to 5 in every 1000 neonates and infants have congenital, early childhood onset sensorineural or severe-to-profound hearing loss (WHO, 2010). Hearing loss may lead to developmental delay and difficulty progressing in school if timely and optimal interventions are not provided (WHO, 2010). These children are therefore at a greater risk for failure and drop-out from school thus placing a child at an economic disadvantage (Mathers et al., 2000; WHO, 2018). Even a unilateral hearing loss in children poses significant risk factors such as increased rates of grade failure, the need for additional educational assistance, and perceived
behavioral issues in the classroom (Bess, Dodd-Murphy, & Parker, 1998; Cho Lieu, 2004; WHO, 2018).

Unfortunately, there are limited prospects of identifying hearing loss in children, particularly within developing regions such as sub-Saharan Africa where an estimated 6.8 million children suffer from permanent disabling hearing loss (Fagan & Jacobs, 2009; Goulios & Patuzzi, 2008; WHO, 2018). This may be attributed to the absence of early hearing detection and identification (EHDI) programs due to reasons including limited human resources for ear and hearing care, a lack of appropriate equipment, costs and other health care priorities (Theunissen & Swanepoel, 2008; WHO, 2013). The WHO estimates that there is only one audiologist per 0.5 million to 6.25 million people in the developing world, with countries in sub-Saharan Africa presenting with a ratio of one audiologist per 0.8 million people (Mulwafu, Ensink, Kuper, & Fagan, 2017; WHO, 2013).

Community-based hearing programs have been proposed as a way to improve access to ear and hearing care (Wilson, Tucci, Merson, & Donoghue, 2017). WHO primary ear and hearing care training manuals recommend that primary health care workers and community healthcare workers (CHWs) in LMICs are trained to stimulate and encourage greater prioritization of prevention, identification and treatment of hearing loss (WHO, 2006). Prevention or early identification can reduce the negative consequences of a hearing loss, is usually less expensive and can often be implemented at a community level (Wilson et al., 2017; WHO, 2012a). Costs may also be reduced by using innovative technologies using mobile health or mHealth applications (Clark & Swanepoel, 2014; Wilson et al., 2017).

With the widespread penetration of 4.92 billion mobile phones worldwide, of which more than 3.74 billion are smartphones, mHealth hearing applications are demonstrating promise to improve access to hearing services in LMICs (Clark & Swanepoel, 2014; Friederici et al., 2012; Kemp, 2017; Martinez-Pérez et al., 2013; Swanepoel & Clark, 2017). One such mHealth solution, validated in various contexts, is the hearScreen™ solution that allows a low
cost alternative to conventional hearing screening equipment whilst adhering to required acoustic calibration standards (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, & Hall, 2016a; Swanepoel et al., 2014).

The hearScreen™ mHealth solution allows for pre-specified screening protocols with automated sequences to be employed by non-specialist personnel (Swanepoel et al., 2014; Yousuf Hussein et al., 2016). This means generalist healthcare workers or school teachers can be trained to operate the device, after which patient specific data and results collected on the smartphone application can be uploaded to a centralized cloud-based server through cellular networks. This allows for asynchronous point-of-care diagnostics in difficult to reach populations, with cloud-based data management, surveillance and referrals that in turn may reduce the demand placed on already limited professional ear and hearing health human resources in developing countries.

A smartphone-based application may also offer other benefits essential when testing in informal settings, including environmental noise monitoring, quality control indices of test operators and data management (Mahomed-Asmail et al., 2016a; Swanepoel, et al., 2014). The hearScreen™ software employs noise monitoring algorithms which provides operators with real-time feedback on ambient noise levels, thereby providing a guide to minimize the effect of noise levels when testing in varying noise conditions (Mahomed-Asmail et al., 2016a; Swanepoel, et al., 2014). The hearScreen™ automatically retests frequencies where maximum noise levels were exceeded (Mahomed-Asmail et al., 2016a; Swanepoel, et al., 2014). Furthermore, smartphone applications can employ a geotag feature to immediately link patients to their closest hearing health providers or primary health care facility with text message notifications.

Pure tone audiometry screening in schools using the hearScreen™ application has demonstrated a low cost, accurate and efficient asynchronous screening solution that could be facilitated by non-specialist personnel with limited training (Mahomed-Asmail et al., 2016a). However, no systematic
clinical validation has been conducted for using this solution to identify younger, more difficult to test preschool children. Early childhood development (ECD) centres are aimed at providing emotional, cognitive and physical development of children from birth to school going age in addition to a focus on a child’s nutrition, health, psychological and other needs (Department of Social Development, 2009). With the integration of asynchronous, low-cost mHealth technologies, ECD centers in LMICs could therefore have the potential to serve as the first point of access to preventative hearing health care services for children from underserved populations prior to school entry. Therefore this study set out to determine the feasibility of a low cost, ECD hearing screening program for preschool children operated by CHWs using an mHealth point-of-care diagnostic and cloud-based data management, surveillance and referral system.

3.3. Method
3.3.1. Context
The study was conducted in the community of Mamelodi, City of Tshwane, Gauteng, South Africa. Mamelodi is situated approximately 20km east of the city. The unofficial population of Mamelodi is currently close to one million. Census indicates 110 703 households within the community of which only 61% are formal dwellings (Stats SA, 2011).

3.3.2. Participants
Non-probability purposive sampling was used to select participants. Initially, three CHWs were trained to map ECD centers and conduct hearing screenings. An additional two CHWs joined the project during the last three months to assist with the workload. CHWs were first trained to map ECD centers using the facility-mapping feature of the hearScreen™ application. This feature allowed CHWs to record the name of the ECD facility, geolocation, contact person and number of children enrolled. CHWs were thereafter trained to conduct hearing screenings using the hearScreen™ application. These participants had no formal training on hearing health care. Prior to implementation of the project, CHWs received a training session during which they were provided with information regarding ear and hearing
health care, and its importance, as well as training and hands-on practice with the hearing screening smartphone application.

Two hundred and fifty ECD centers were mapped in the community of Mamelodi East and West. ECD centers (Crèches) included both public and private facilities that provided learning and support to children between the ages of three to six years. These ECD centers were often informal in nature and based in the homes of local community members. Once consent was obtained from the principal of the ECD centers to conduct hearing screenings, consent letters were sent to the parents/caregivers. Data was collected over a 12-month period with the exception of three vacation periods.

3.3.3. Equipment
The hearScreen™ smartphone application was initially operated on Samsung Trend Plus (S5301) smartphones (Android OS, 4.0). In July 2016, the Samsung Trend plus smartphones were replaced with Samsung J2 Galaxy smartphones (Android OS, 5.1), which operated an upgraded version of the hearScreen™ software. Smartphones were connected to supra-aural Sennheiser HD280 Pro headphones (Sennheiser, Wedemark, Germany). The hearScreen™ calibration function was used to calibrate the headphones according to prescribed standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone (Madsen & Margolis, 2014).

The hearScreen™ application records a quality index of test operators, which gives an objective measure of their screen performance. During each test, a randomized false presentation of a sound is presented. The purpose of this presentation is to determine if the screener correctly records the response by the person tested as “no response”. The hearScreen™ then calculates a quality index on the tests completed by each screener to provide an indication of the reliability of the tests conducted by the test operator. This quality index was monitored throughout the project in order to guide and retrain testers when needed.
Noise levels are also recorded by the smartphone hearing screening application for each child during testing. In order to minimize false-positive results caused by exceeded noise levels, testing was not conducted at 0.5kHz. The hearScreen™ solution has been validated to monitor noise accurately (Swanepoel et al., 2014). Data collected by the smartphone was automatically uploaded to a secure cloud-based server through a 3G cellular network.

3.3.4. Procedures

Once mapping was completed, hearing screenings were only conducted on a set test date if consent was granted by both the ECD center and the parent/caregiver. ECD center staff allocated a room with the least noise possible for testing. Children were provided with a simple explanation and demonstration of what was required of him/her. The hearing screening application employed automated test protocols. In order to ensure that the child understood what was expected, testing began in the left ear with an initial conditioning tone at 1 kHz at an intensity level of 35 dB HL. Thereafter, a sweep was performed at the test frequencies of 1, 2 and 4 kHz bilaterally at a screening intensity of 25 dB HL (Swanepoel et al., 2014). The smartphone microphone measured noise levels in the environment and employed a smart noise-monitoring algorithm that only initiated a rescreen if noise levels exceeded maximum permissible ambient noise levels (MPANLs) when there was no response from a patient. The stimulus was repeated once if the child did not respond at any frequency. Once data was collected for the left ear, the same procedure was repeated in the right ear.

Failure to respond at 25 dB HL at any frequency in any ear constituted an initial fail. In such cases, children were reconditioned and an immediate rescreen was initiated which followed the same procedure (AAA, 2011). If a child referred the immediate rescreen at the ECD center, he/she was referred to their local clinic for a second hearing screening. The second hearing screening followed the same procedure used at the ECD centers i.e. a screening followed by an automated immediate rescreening if a child failed to respond to any frequency an any ear. Thereafter a diagnostic hearing
assessment was conducted if necessary. This was done by automatically sending a text message notification to parents via the cloud-based server. Additionally, results and test quality were remotely monitored from the cloud-based data management portal. ECD facilities were provided with a summary of results for educational interventions.

3.3.5. Data analysis
Data were extracted from the cloud-based server to an MS Excel (2011) sheet and analyzed using SPSS v24 (Chicago, Illinois). Referral rates, test times, noise levels and quality indices of testers were analyzed using descriptive statistical measures. Binomial logistic regression analysis was used to determine the effects of age, gender and exceeded MPANLs on referral rates in children, with p<0.05 used to indicate a significant effect. Frequency distributions were also used to analyze the quality indices of tester.

3.4. Results
A total of 6424 children (3446 females, 2978 males) between the ages of three to six years were screened at ECD facilities. Initial screen referral rates were 34.8% (Table 3.1.), with no significant difference between left and right ears (p>0.05, chi-square).

| Table 3.1. Referral rate for smartphone hearing screenings in ECD centers |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
|                             | Screening at ECD centers    | Second screening at clinics  |
|                             | Participants (n)            | Referral Rate (%)           | Participants (n)            | Referral Rate (%) |
| Initial screen              | 6424                        | 34.8                        | 617                         | 50.2             |
| Left overall                | 6424                        | 25.2                        | 617                         | 36               |
| Left 1kHz                   | 6424                        | 18.5                        | 617                         | 27.9             |
| Left 2kHz                   | 6424                        | 14.1                        | 617                         | 19.6             |
| Left 4kHz                   | 6424                        | 9.8                         | 617                         | 18.3             |
| Right overall               | 6424                        | 26.4                        | 617                         | 39.9             |
| Right 1kHz                  | 6424                        | 21                          | 617                         | 30.6             |
| Right 2kHz                  | 6424                        | 13.7                        | 617                         | 22.2             |
A total of 2227 children were rescreened automatically after the initial failed screen resulting in an overall referral rate of 24.9% varying from 19.6 to 45.8% for children six and three years of age, respectively (Table 3.2.). A rescreen was not completed for nine participants due to a tester inadvertently selecting to skip the procedure. Mean test duration, including both initial and rescreen test times for both ears, was 68 seconds (SD 2.8) for participants that passed and 258.5 seconds (SD 251.2) for those who failed.

Table 3.2. Referral rate in children according to gender and age groups

<table>
<thead>
<tr>
<th>Gender</th>
<th>Screening at ECD centers</th>
<th>Rescreening at clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participants (n)</td>
<td>Referral Rate (%)</td>
</tr>
<tr>
<td>Female</td>
<td>3446</td>
<td>26.9</td>
</tr>
<tr>
<td>Male</td>
<td>2978</td>
<td>22.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age groups</th>
<th>Screening at ECD centers</th>
<th>Rescreening at clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participants (n)</td>
<td>Referral Rate (%)</td>
</tr>
<tr>
<td>3 years</td>
<td>504</td>
<td>45.8</td>
</tr>
<tr>
<td>4 years</td>
<td>1519</td>
<td>30</td>
</tr>
<tr>
<td>5 years</td>
<td>2259</td>
<td>22</td>
</tr>
</tbody>
</table>
Average noise levels recorded during the initial screen at ECD centers were 44, 41 and 40 dB for 1, 2 and 4 kHz respectively. MPANLs were exceeded occasionally during the initial and immediate rescreens conducted at 1, 2 and 4 kHz at both ECD centers and clinics (Table 3.3.).

Table 3.3. Instances where noise levels exceeded MPANLs during smartphone screening

<table>
<thead>
<tr>
<th>Frequencies</th>
<th>1kHz</th>
<th>2kHz</th>
<th>4kHz</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>Initial</td>
<td>8.3%</td>
<td>7.2%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Screen (n=6424)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate rescreen</td>
<td>6%</td>
<td>5.7%</td>
<td>0.3%</td>
</tr>
<tr>
<td>(n=2227)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>6.2%</td>
<td>6.5%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Screen (n=650)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate rescreen</td>
<td>5.5%</td>
<td>7.1%</td>
<td>1.0%</td>
</tr>
<tr>
<td>(n=309)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A binomial logistic regression was performed to ascertain the effect of gender, noise levels at each frequency as well as age on overall results obtained at the ECD centers. The logistic regression model was statistically significant ($\chi^2(8)=185.412$, p<0.001) and correctly classified 75.1% of the cases. Referral rates were significantly affected by age (p<0.01; B: -0.004; 95% CI lower: 0.996, 95% CI upper: 0.997), gender (p<0.01; B: 0.231; 95% CI lower: 1.122, 95% CI upper: 1.415), and noise levels at 1 kHz in the left ear (p<0.01; B: 0.356; 95% CI lower: 1.103, 95% CI upper: 1.847). Females were 1.26 times more likely to fail compared to males, and increasing age was associated with a decreased likelihood of failure.
Failures were monitored and referred to their local clinic for a follow up via the cloud-based data management system. The follow-up constituted a rescreen and diagnostic test if indicated. A total of 617 children attended their follow-up appointments (Table 3.1), indicating a follow-up return rate of 39.4%. The overall follow-up screen referral rate was 40.5%. The mean test duration recorded was 170.7 seconds (SD 199.3) and 141.5 seconds (SD 188.2) for pass and failure rates respectively.

Quality indices of test operators were monitored throughout the test period. Table 3.4 displays the increase in quality indices of the first three test operators over a five-month period.

<table>
<thead>
<tr>
<th>Table 3.4. Quality index of test operators</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Tester 1 No. of children screened</td>
</tr>
<tr>
<td>Quality index (%)</td>
</tr>
<tr>
<td>Tester 2 No. of children screened</td>
</tr>
<tr>
<td>Quality index (%)</td>
</tr>
<tr>
<td>Tester 3 No. of children screened</td>
</tr>
<tr>
<td>Quality index (%)</td>
</tr>
</tbody>
</table>

3.5. Discussion
Performing hearing screenings within preschool aged populations is important to identify hearing health concerns that may interfere with language development and future school success (AAA, 2011). Within LMICs, ECD centers have the potential to serve as the first point of access to identify these children. This study provides a baseline for the implementation of a low cost, ECD hearing screening program operated by CHWs using an mHealth point-of-care diagnostic and cloud-based data management and referral system.

The referral rate in the preschool aged population (three to six years) using the hearScreen™ application was 24.9%. Studies using conventional pure tone audiometry reported similar referral rates of 21.5% (two to six years) and
21.3% (three and a half to six years) (Adebola, Ayodele, Oyelakin, Babarinde, & Adebola, 2013; Sideris & Glattke, 2006). In contrast, a recent study conducted using the hearScreen™ smartphone application indicated a significantly lower referral rate of 4.3% for older children aged five to seven (Swanepoel et al., 2014). Higher referral rates in the current study are likely due to the fact that testing was conducted in a poor community where risk factors such as otitis media are higher, and due to the inclusion of younger children aged three and four years who presented with high referral rates. Results indicated a lower risk of failure in older compared to younger children. A previous study reported similar findings with a decrease in referral rate as the age of children increase (Dodd-Murphy, Murphy, & Bess, 2014).

Referral rates of the current study were greatest in children aged three years (45.8%) as opposed to older children, which prompted the researchers to discontinue testing this age group. A study by Sideris and Glattke (2006) found that children younger than four years were often unable to perform pure tone screening, suggesting that pure tone audiometry requires a higher level of cognitive maturity. Additionally, the incidence of acute otitis media and otitis media with effusion is high in LMICs with a higher incidence in children between the ages of two to five years thus adding to a higher referral rate (Biagio, Swanepoel, Laurent, & Lundberg, 2014; Monasta et al., 2012; Swanepoel, Eikelboom, & Margolis, 2014).

Environmental noise can also have an effect on referral rates, particularly when testing within an ECD setting where noise levels often fluctuate due to the absence of a sound treated room, children leaving or entering the test environment, testers providing instructions or groups of children walking past the test room (AAA, 2011; Dodd-Murphy et al., 2014; Swanepoel et al., 2014). A smartphone-based mHealth solution like hearScreen™ utilizes integrated noise monitoring, providing operators with real-time feedback on noise levels to allow testers to minimize noise levels before continuing with tests. Results and corresponding noise levels analyzed on the centralized cloud-based server indicated that only noise levels at 1 kHz had a significant effect on referral rates obtained in comparison to 2 and 4 kHz test frequencies.
Previous studies using the hearScreen™ application also reported similar effects when testing at the lower frequency of 1 kHz (Mahomed-Asmail et al., 2016a; Swanepoel et al., 2014; Yousuf Hussein et al., 2016).

Increasing screening intensities to 30 dB HL at 1 kHz to compensate for high noise levels in future community-based studies could reduce the incidence of exceeded MPANLs and false-positive results, but may decrease the validity of the screening process as mild losses may be missed (Dodd-Murphy et al., 2014; Yousuf Hussein et al., 2016). The European Consensus Statement on Hearing, Vision, and Speech Screening in Pre-School and School-age Children indicated that although hearing screenings will produce over-referrals, false positives are preferred over false negatives (Skarżyński & Piotrowska, 2012).

Gender effects were evident in smartphone hearing screening outcomes with females more likely to refer than males. Mahomed-Asmail et al. (2016a) also reported a significantly higher referral rate in school-aged females using conventional screening, however these gender effects were not evident when using smartphone hearing screening. One possible reason was attributed to hair length or styles in girls that could have affected headphone placement. Further investigations on gender-specific results are needed.

During follow-up appointments at clinics, ECD screening results were initially pulled from the cloud-based data system and analyzed. Thereafter, children received a second rescreen at the clinic. This was done in order to avoid unnecessary diagnostic assessments and to reduce the workload on already strained audiologists. Less than half (40.5%) of the children who failed their ECD screening, failed the second screen at the clinic. The referral rate dropped by a further 5% (35.7%) when excluding more difficult to test children aged three to four years. Some influences which may have contributed to the difference in referral rates, include ambient noise levels, headphone placement, visual distractions, and examiner instructions and expertise (Dodd-Murphy et al., 2014).
Mean test durations, including the initial and immediate rescreen of both ears, were 177.8 and 174.3 seconds when testing at ECD centers and clinics respectively. Wu et al. (2014), reported a slightly shorter test duration of 149.4 seconds when using a smartphone hearing screening application. Higher test times at ECD centers could be attributed to the longer test times recorded with failure rates (258.5 seconds) in comparison to pass rates (68 seconds) due to the additional time required to recondition the child being rescreened. Furthermore, mean screen times were significantly higher for three year olds when testing at ECD centers (193.4 seconds) and clinics (239.8 seconds). Only initiating a rescreen for failed frequencies during rescreens, instead of repeating the entire screen sequence, may reduce test times.

Although parents were notified of their child’s result via an SMS sent automatically from the cloud-based system, a low follow-up return rate of 39.4% was found. We suspect that this rate was affected by a long waiting period before follow-up appointments, parents changing their mobile phone number and not notifying the ECD center and difficulties with taking leave from work, which may result in loss of income for informal workers. Other reasons that may account for non-attendance includes lack of transportation, fear and uncertainty about the referral clinic, lack of education regarding hearing loss and a lack of visibility of services (Bright, Malwafu, Thindwa, Zuurmond, & Polack, 2017). More precise reasons for non-attendance should be investigated in future studies. Incorporating a system to send a second text message reminder three days prior to a child’s appointment may assist in improving follow-up rates (Leong et al., 2006; Stein, Lewin, & Fairall, 2007). Alternatively, immediate onsite hearing assessments could be incorporated into the screening program.

Immediate onsite automated audiometry could motivate parents to attend follow-up appointments by providing an immediate indication of the severity of a hearing problem and thereby also reduce the number of appointments that parents need to attend at clinics (Swanepoel, Maclellan-Smith, & Hall, 2013). Using onsite automated diagnostic audiometry, facilitated by the same smartphone, could ensure direct referrals for audiological or medical
intervention, and may also reduce false positive results (Mahomed-Asmail, Swanepoel, & Eikelboom, 2016b; Sandström, Swanepoel, Myburgh, & Laurent, 2016; van Tonder, Swanepoel, Mahomed-Asmail, Myburgh, & Eikelboom, 2017). In turn this will improve the cost–effectiveness, feasibility and credibility of the screening program with parents and physicians (Dodd-Murphy et al., 2014).

Asynchronous cloud-based monitoring and surveillance allowed for quality indices of test operators to be monitored throughout the test period to ensure quality control (Table 4). This guided project managers to provide feedback, additional information and more training to CHWs to ensure reliable test results. High quality indices of test operators shows that CHWs can successfully screen for hearing loss in children. The integrated cloud-based data management system also allowed for advanced features like location-based referrals via text message, reporting and determining follow-up return rates at clinics.

3.6. Conclusion
ECD hearing screening programs using an mHealth point-of-care diagnostics and cloud-based data management and referral systems can be successfully implemented by CHWs within LMICs to identify children prior to school entry. This mHealth model provides a means to improve the cost-effectiveness, quality, efficiency and access to hearing health services in poorer communities particularly where hearing health care providers are unavailable. Quality control features including integrated noise monitoring, quality control indices of test operators and data management allows for asynchronous remote management to ensure reliable testing and to intervene when necessary. Age contributed significantly to high referral rates, suggesting an optimal screening age of five to six years of age. Environmental noise also posed a challenge when testing at the frequency of 1 kHz. Methods to improve the parental follow-up rate should be explored in future studies.
4.1. Abstract

Objective

Within the educational sector of low- and middle- income countries (LMICs), formal and informal early childhood development (ECD) centers are often the first point of contact for majority of children. Since early hearing detection services are mostly absent in LMICs, these ECD centers may serve as the first point of access to screenings for these children. ECD practitioner awareness regarding hearing and hearing loss is essential for the successful implementation of hearing screening programs. This study thus investigated the current knowledge and attitudes of ECD practitioners towards childhood hearing loss in a community representative of typical LMIC contexts.

Method

Purposive sampling was used to identify ECD centers and participants across a community. Thereafter, a cross-sectional quantitative survey (82 items) was
administered amongst 82 ECD practitioners.

Results
More than 80% of ECD practitioners correctly identified genetics and ear infections as etiological factors of hearing loss. Gaps in knowledge regarding identification techniques for children three to six years of age and the impact of hearing loss in the classroom were evident. ECD practitioner’s duration of experience had a significant effect on overall knowledge and attitude (p<0.05; F(1,53)=8.68). ECD practitioner displayed a positive attitude towards children receiving a hearing test (88.3%) and almost all participants indicated the need for more information regarding hearing loss (93.5%).

Conclusions
This study demonstrated a general readiness amongst ECD practitioners for the implementation of ECD hearing screening programs in LMICs, however additional information and guidelines are needed to improve practitioner knowledge and attitudes.

4.2. Introduction
Hearing loss is one of the most common developmental disorders identifiable at birth which, if left undetected, has consequences on a child’s language development, communication ability, educational attainment, vocational achievement and social-emotional development (AAA, 2011; JCIH, 2007; Mathers et al., 2000). The most effective way to avoid these negative consequences is through the establishment of early hearing detection and intervention (EHDI) programs such as newborn hearing screening (NHS) programs (Swanepoel & Almec, 2008). However, such programs are often unavailable to babies born within low- and middle-income countries (LMICs). In LMICs like South Africa, EHDI programs are limited due to socio-economic and health care barriers, limited contextual research evidence, and a lack of financial and human resources (Olusanya & Newton, 2007; Swanepoel et al., 2009; WHO, 2010). The result is that a large proportion of children are still unidentified at the time of school entry, thus increasing a child’s risk for failure and drop-out from school (Bamford et al., 2007; Mathers et al., 2000; WHO,
Within LMICs such as South Africa, emphasis has been placed on the early identification of children with disabilities through the legislative requirement of promoting early childhood development (ECD) (Department of Social Development, 2009). ECD centres are aimed at providing emotional, cognitive and physical development of children from birth to school going age (Department of Social Development, 2009). These ECD centers have the potential to serve as the first point of access to preventative hearing health care to children who were not screened at birth, or who acquired a childhood hearing loss hereafter. A study by Eiserman et al. (2007) conducted in the US demonstrated that implementing hearing screenings in early childhood programs can help to identify a wide range of hearing health conditions that can potentially disrupt language acquisition, literacy, socialization and overall school readiness. However, these programs made use of costly otoacoustic emissions (OAE) technology, which may not be feasible in LMICs.

A recent study demonstrated that smartphone-based hearing screening may provide a low-cost, accurate and efficient screening solution with specific application to school-based screening (Mahomed-Asmail et al., 2016a). Furthermore, with limited training, non-health personnel such as community health workers or ECD practitioners can successfully conduct such screenings, thereby reducing the demand on already limited ear and hearing health professionals (Mahomed-Asmail et al., 2016a; Yousuf Hussein et al., 2016).

In order to successfully implement ECD hearing screening programs, it is important to first determine the perception and knowledge of ECD practitioners regarding the importance of healthy hearing, the causes and effects of a hearing loss, identification and intervention for hearing loss as well ECD practitioner attitudes towards children affected. This will assist to identify practical steps required to facilitate its acceptance. A study conducted in Singapore revealed educational deficits amongst ECD practitioners in normal development and across a range of developmental and behavioral disorders.
(Lian et al., 2008). This was true despite a positive attitude among ECD practitioners towards receipt of additional information and support to better prepare them to recognize and manage children with disabilities (Lian et al., 2008). The presence of a childhood hearing loss may easily be overlooked due to the fact that it is an invisible epidemic, which cannot be detected by a clinical examination. Additionally, childhood hearing loss often goes unnoticed due to factors including the misconception that a child is still too young, poor practitioner training and awareness, lack of resources, and cultural values and religious beliefs around inclusion of children with disabilities (Ebrahim, Seleti, & Dawes, 2013).

Establishing baseline information on the current knowledge and perceptions of ECD practitioners on hearing and hearing loss is an essential first step towards the success of ECD hearing screening programs. Subsequently appropriate and sufficient information on ear and hearing health care can ensure that ECD practitioners are better equipped to identify children affected by hearing loss, and to guide the access of services (WHO, 2012a). Unfortunately, limited knowledge currently exists on the views and knowledge of ECD practitioners on childhood hearing loss in LMICs. A recent study was conducted by Ehlert (2017) in South Africa to determine the perceptions of primary school teachers regarding hearing loss. However this study focused on noise-induced hearing loss, revealing a need for hearing conservation programs in schools as well as training of teachers in order to be successful. The current study was therefore conducted to investigate the knowledge and attitude of ECD practitioners towards childhood hearing loss in a community representative of typical LMIC contexts.

4.3. Method
4.3.1. Context
The study was conducted in the community of Mamelodi, City of Tshwane, Gauteng, South Africa. Mamelodi is situated approximately 20 km east of the city. This township was established in 1951 and started with a mere 16 houses built for Black people that were removed from other areas according to the Group Areas Act. The unofficial population of Mamelodi is currently
close to one million. Census indicates 110 703 households within the community of which only 61% are formal dwellings (Stats SA, 2011).

4.3.2. Subjects
Purposive sampling was used to identify ECD centers and participants within the Mamelodi East and Mamelodi West communities. All practitioners employed by these ECD centers, including principals and teachers, were invited to participate in this study. This created a sample that was representative of teachers from an informal urban developing South African community.

Each consenting participant was given adequate time to complete the questionnaire. A total of 82 participants completed the questionnaire.

4.3.3. Questionnaire
The questionnaire used to determine maternal views on hearing loss developed by Swanepoel and Almec (2008) was adapted for use with ECD teachers within the South African context. The adapted questionnaire consists of five added items to determine ECD practitioner’s demographic information, with an additional 23 closed items requiring a choice of three responses: ‘yes’; ‘unsure’; or ‘no’.

The existing questionnaire was adapted by adding four items to determine the general knowledge of ECD teachers towards healthy hearing and hearing loss. The items regarding the causes and risk factors of a hearing loss were simplified and adapted into five items for use with ECD practitioners. The four items regarding the identification and intervention for hearing loss were also adapted for use with ECD practitioners with an additional five items added to determine ECD practitioners’ knowledge of the impact of hearing loss in the classroom. The items regarding superstitious cultural beliefs were omitted. Two items regarding attitudes towards hearing loss were adapted and one item was omitted. Additionally, two items were added to determine ECD practitioner’s attitude towards inclusion.
Table 4.1. Distribution of ECD practitioner responses (%) on childhood hearing loss

<table>
<thead>
<tr>
<th>Questions</th>
<th>Responses (%)</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>Unsure</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Worked with a child with hearing loss</td>
<td>35.4</td>
<td>20.7</td>
</tr>
<tr>
<td>2. Child with hearing loss in current ECD center</td>
<td>29.3</td>
<td>32.9</td>
</tr>
<tr>
<td>3. Hearing loss is an important problem</td>
<td>86.4</td>
<td>12.3</td>
</tr>
<tr>
<td>4. Healthy hearing is important</td>
<td>90.1</td>
<td>9.9</td>
</tr>
<tr>
<td><strong>Knowledge: Causes/Risk Factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Children can be born with a hearing loss</td>
<td>84.1</td>
<td>15.9</td>
</tr>
<tr>
<td>6. Certain illnesses can cause a hearing loss</td>
<td>69.5</td>
<td>23.2</td>
</tr>
<tr>
<td>7. Ear infection can cause a hearing loss</td>
<td>80.2</td>
<td>16.0</td>
</tr>
<tr>
<td>8. Hearing loss can affect some children more than others</td>
<td>61.3</td>
<td>26.3</td>
</tr>
<tr>
<td>9. Hearing loss is common in young children</td>
<td>51.3</td>
<td>45.0</td>
</tr>
<tr>
<td><strong>Knowledge: Identification &amp; Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Hearing loss can be identified at any age</td>
<td>69.5</td>
<td>26.8</td>
</tr>
<tr>
<td>11. Children (3-6 years of age) can be accurately diagnosed with a hearing loss</td>
<td>37.0</td>
<td>28.4</td>
</tr>
<tr>
<td>12. Hearing loss can be treated</td>
<td>69.5</td>
<td>30.5</td>
</tr>
<tr>
<td>13. Children with hearing loss can attend school</td>
<td>81.5</td>
<td>14.8</td>
</tr>
<tr>
<td>14. Children with hearing loss can have the same educational opportunities as normal hearing children</td>
<td>64.6</td>
<td>20.7</td>
</tr>
<tr>
<td>15. Hearing loss impacts listening in the classroom</td>
<td>67.5</td>
<td>23.8</td>
</tr>
<tr>
<td>16. Hearing loss impacts speech and language</td>
<td>58.8</td>
<td>32.5</td>
</tr>
<tr>
<td>17. Hearing loss impacts reading</td>
<td>54.5</td>
<td>26.0</td>
</tr>
<tr>
<td>18. Hearing loss impacts behavior</td>
<td>63.6</td>
<td>22.1</td>
</tr>
<tr>
<td>19. Hearing loss impacts interaction with peers</td>
<td>73.7</td>
<td>15.8</td>
</tr>
<tr>
<td><strong>Attitudes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Would like children to have a hearing test</td>
<td>88.3</td>
<td>11.7</td>
</tr>
<tr>
<td>21. Would include children with hearing loss in the classroom/ECD</td>
<td>61.0</td>
<td>31.2</td>
</tr>
<tr>
<td>22. Children with hearing loss should be referred to special schools</td>
<td>67.5</td>
<td>22.1</td>
</tr>
<tr>
<td>23. Would like more information on hearing loss</td>
<td>93.5</td>
<td>6.5</td>
</tr>
</tbody>
</table>
4.3.4. Procedure and analysis

All ECD centers within the target area were mapped. ECD principals and practitioners were thereafter approached at each ECD center and asked to participate in the study after which a date was set for data collection. On the test date, ECD practitioner at their respective center were provided with an information leaflet attached to the developed questionnaire. Questionnaires were administered by a team member of a non-profit organization working in the community ECD’s. The administrator was fluent in English and the African languages used by the community to ensure that the participants understood all the information and what was required of him/her. Participants were given the opportunity to ask for clarification. All questionnaires were completed anonymously and took approximately 10 minutes to complete.

The data collected was coded into quantitative data in MS Excel (2011). Responses were assigned the following scores: yes=1; unsure=2; no=3. All responses were analyzed descriptively by making use of frequency distributions, averages and standard deviations. Fisher’s exact test was used to determine if gender and formal ECD training had an effect on individual survey items. Additionally, results of each question were totaled to get a score of participants’ knowledge (i.e. the lower the score, the better a participants knowledge). Linear regression analysis was conducted to determine the effect of age, gender, formal ECD training, and length of experience on participants’ overall knowledge.

4.4. Results

From the 82 questionnaires administered, one participant did not provide any of the demographic information requested. Of the remaining 81 respondents, 93% were female and 7% were male. Participants’ ages ranged from 19 years to 61 years (mean=36.9; range=42). Participants’ home languages covered all 11 official languages of South Africa, however the majority spoke Zulu (25%), Sotho (21.3%), Northern Sotho (20%) and Ndebele (7.5%).

Five participants did not report a qualification (i.e. did not respond to this question). Of the remaining 76 participants, 47.4% (n=36) reported having a
high school certificate, 34.2% (n=26) received a higher certificate or diploma and 1.3% (n=1) received a degree in education. Length of experience ranged from one to 25 years (mean 7.6; SD 5.424; range=24).

Results indicated that 35.4% (n=29) of respondents had previously worked with children with a hearing loss and 29.3% (n=24) are currently working with a child with a hearing loss (Table 4.1). The majority indicated that hearing loss (86.4%) and healthy hearing (90.1%) are important.

ECD practitioner’s knowledge regarding causes and risk factors for hearing loss was highest for congenital hearing loss (84.1%) and ear infection (80.2%). Additionally, a substantial number of ECD practitioner (69.5%) recognized that illnesses could cause a hearing loss.

The majority (69.5%) of respondents indicated that hearing loss could be identified at any age, however, only 29.3% of these respondents indicated that children three to six years of age could be accurately diagnosed with a hearing loss. Respondents’ knowledge of the impact of hearing loss in the classroom is illustrated in Figure 4.1.

![Figure 4.1. Distribution of responses regarding impact of hearing loss in the classroom](image-url)
The majority of ECD practitioner (61%) were positive towards the inclusion of children with hearing loss in the classroom (Table 4.1), however a higher number (67.5%) indicated that these children should be referred to special schools. The attitude of ECD practitioner towards hearing tests was very positive (88.3%) and almost all participants indicated that they wanted more information regarding childhood hearing loss (93.5%).

Formal ECD training had a significant effect on knowledge as participants demonstrated the correct knowledge regarding illnesses that could cause a hearing loss, identification of hearing loss at any age and hearing loss impacting listening in the classroom (p<0.05; Fishers exact). Linear regression analysis indicated that gender, age and formal ECD training had no significant effect on participants overall knowledge and attitudes regarding childhood hearing loss (p>0.05). Only ECD practitioner’s duration of experience had a positive, significant effect on overall knowledge and attitudes towards childhood hearing loss (p<0.05; F (1,53)=8.68).

4.5. Discussion

Contextual evidence on knowledge and perceptions around childhood hearing loss by ECD practitioners is essential to ensure acceptance and support of hearing screening programs in these facilities. This study is the first to provide a baseline of current ECD practitioner knowledge and attitudes towards hearing health within a poor LMIC community setting. Responses regarding ECD practitioner’s overall knowledge and attitudes towards hearing health were generally positive. Most ECD practitioners recognized that hearing health in children is important and displayed a positive attitude towards hearing screenings. This may be indicative of ECD practitioner readiness for the introduction and implementation of ECD hearing screening programs within LMICs (Swanepoel & Almec, 2008).

Knowledge of ECD practitioners regarding etiological factors for hearing loss was generally favorable. The majority of ECD practitioners correctly identified genetics (84.1%) and ear infections (80.2%) as etiological factors of hearing loss. These ECD practitioners may have previously worked with children with
ear infections as the incidence of acute otitis media and otitis media with effusion is high in LMICs (Biagio et al., 2014; Monasta et al., 2012; WHO, 2010). Additionally, more than 60% recognized that certain illnesses could cause a hearing loss and that the effects of hearing loss could vary.

ECD practitioner knowledge scores regarding the identification of hearing loss demonstrated some uncertainty with 69.5% indicating that hearing loss could be identified at any age, whilst only a third (29.3%) of these respondents thought children 3-6 years of age can be accurately diagnosed. Knowledge around screening and diagnostic audiological procedures was limited considering available methods to detect hearing loss in children of any age (AAA, 2011; Cunnigham & Cox, 2009). Various reasons could be attributed to this gap in knowledge including the fact that LMICs have a lack of EHDI programs, no systematic ECD screening programs, limited school screening programs, and hearing services are mostly unavailable in public health care systems which majority of the population rely on (Swanepoel et al., 2009; WHO, 2013, 2018).

The majority of participants (81.5%) were knowledgeable regarding the attendance of schools by children with a hearing loss, however a greater number of ECD practitioners felt that these children should be referred to special schools rather than be included in a mainstream classroom. According to a review conducted by Avramidis and Norwich (2002), ECD practitioners may be positive towards the general philosophy of inclusion, however they hold differing attitudes towards school placements depending on the nature of the child’s disability. ECD practitioners may be more willing to include students with mild sensory impairments than students with more complex needs (Avramidis & Norwich, 2002). Furthermore, almost all ECD practitioners indicated the need for more information on hearing loss, which, if provided, may improve willingness to include children with a hearing loss in a mainstream setting.

Although most ECD practitioners were knowledgeable about the impact of hearing loss in the classroom, a significant amount of ECD practitioners
(37.2%) were unsure or responded incorrectly. These responses highlight a need for increased emphasis regarding the educational impact of hearing loss on learners in teacher education programs. Resources like the WHO primary ear and hearing care training manuals have been recommended for training community health workers in LMICs to educate teachers about hearing loss, its impact and management, as well as to encourage them to include this in their teaching programs (WHO, 2012a).

Other influences reported to have an effect on practitioner knowledge and attitudes includes teacher-related variables such as gender, age, length of teaching experience, experience of contact, beliefs, socio-political views, as well as educational environmental-related variables, such as the support from specialists (Avramidis & Norwich, 2002). The current study found this to be true for length of teaching experience, with significantly higher scores in both knowledge and attitude by respondents who reported more years of experience. Formal ECD training was also found to have a significantly positive effect on knowledge scores however, this was limited to illnesses as a cause of hearing loss, the ability to identify hearing loss at any age, and the impact of hearing loss on listening in the classroom.

4.6. Conclusion
Within LMICs, ECD practitioner’s knowledge and attitudes around hearing and hearing loss are important for the successful implementation of screening programs, particularly within these poorer settings where ECD centers may serve as the first point of access for screening. The current study found gaps in knowledge regarding methods for the identification of hearing loss as well as the impact of hearing loss in the classroom. Attitudes towards inclusion of children with a hearing loss may be improved by providing information and guidelines to ECD practitioners on how to identify and support a child with a hearing loss in the classroom. Length of experience was found to have a significant influence on knowledge and attitude scores of ECD practitioners. Overall, ECD practitioner’s knowledge and attitudes from this LMIC context was favourable, demonstrating a general readiness for implementation of hearing screening programs within ECD facilities.
Abstract

Objective

This study aimed to determine and describe hearing loss among preschool children in a South African community representative of typical low- and middle income countries (LMIC).

Method

Children between the ages of 3-6 years received a hearing screening at their early childhood development (ECD) center. If a child failed the hearing screening, he/she was seen for a follow-up rescreen and diagnostic assessment if necessary at their ECD center or closest referral clinic. Diagnostic testing consisted of otoscopy, tympanometry and pure-tone diagnostic audiometry.

Results

A total of 6424 children were screened at ECD centers with a referral rate of 24.9%. Follow-up assessments were conducted on 45.3% (725) of these
children. Diagnostic testing revealed that 9.3% of children presented with impacted cerumen and 18.7% presented with a hearing loss (56.5% binaural). Binary logistic regression revealed no gender or age effects (p>0.05). Conductive hearing loss (65.2%) was the most common type of hearing loss found in children.

Conclusions
Most preschool children who failed the hearing screening and received a diagnostic assessment were in need of intervention services for conductive hearing losses, followed by sensorineural and mixed losses.

5.2. Introduction
Hearing loss is the most prevalent disabling condition globally (WHO, 2012b). According to the WHO (2018), 466 million people globally are affected by disabling hearing loss (>40 dB HL), with 34 million of these being children. Disabling hearing loss in children constitutes a barrier to their optimal development of speech, language and cognitive skills, resulting in poor literacy and difficulty progressing in school (Wilson et al., 2017; WHO, 2010). This in turn has detrimental socio-economic consequences, particularly in low-income and middle-income countries (LMICs) where more than 80% of people with hearing loss live (Wilson et al., 2017).

Newborn hearing screening programs have been recommended for the early identification of children affected by hearing loss. However, such programs are still not mandated by hospitals in LMICs, such as in sub-Saharan Africa, where national health systems are too weak to bear the added burden of non-fatal but disabling disorders (Olusanya & Newton, 2007; Swanepoel et al., 2009). Even if children were screened at birth, a large proportion of hearing loss presents as delayed-onset hearing loss (Lü et al., 2011). Additionally, approximately 35% of preschoolers will have repeated episodes of ear infection that almost always cause temporary hearing loss (ASHA, 2004). Therefore, regular hearing screenings throughout early childhood is necessary (AAA, 2011; Fortnum, Summerfield, Marshall, Davis, & Bamford, 2001; Skarżyński & Plotrowska, 2012).
Early childhood development (ECD) centres are aimed at providing emotional, cognitive and physical development of children from birth to school going age (Department of Social Development, 2009). These ECD centers have the potential to serve as the first point of access to preventative hearing health care to children who were not screened at birth, or who later acquired a childhood hearing loss, prior to school entry (Department of Social Development, 2009; Yousuf, Swanepoel, Biagio de Jager, & Mahomed-Asmail, 2018a). Determining the prevalence of hearing loss in this population is an important step to ensure adequate planning and successful implementation of hearing care in such ECD centers. A number of studies have already reported varying prevalence rates of hearing loss among school children within LMICs. These figures ranged from as low as 1.4% in China (Lü et al., 2011), 1.75% in Southwestern Saudi Arabia (Al-rowaily, Alfayez, Aljomiey, Albadr, & Abolfotouh, 2012) and 2.2% in South Africa (Mahomed-Asmail, Swanepoel, & Eikelboom, 2016c), to as high as 11.9% in India (Rao, Subramanyak, Nair, & Rajashekkhar, 2002) and 20.9% in Egypt (Taha et al., 2010).

Varying prevalence rates in preschool children were also reported in sub-Saharan Africa, within Zimbabwe (2.4%) (Westerberg, 2005) and Nigeria (21.3%) (Adebola et al., 2013). The main causes for the high rate reported by Adebola et al. (2013) was the presence of otitis media (13.9%) and impacted cerumen (21.8%). High incidence rates of otitis media during the first five years of life have been found to be greatest within sub-Saharan Africa and South-Asia (Monasta et al., 2012). Biagio et al. (2014) indicated a high prevalence of 16.5% for children attending South African primary healthcare clinics, with a higher prevalence in younger (31.4%) than in older children (16.7%).

Whilst a number of studies have reported on the prevalence of hearing loss, evidence on the characteristics and causes of hearing impairment across Africa is very limited (Mulwafu et al., 2016; Stevens et al., 2011; Wilson et al., 2017). Methods of determining hearing loss also vary across existing studies with some basing it on a screen result only, whilst others require diagnostic
confirmation. This makes it difficult to compare prevalence data across studies, limiting the utility for improving service delivery (Mulwafu et al., 2016). Furthermore, research conducted within the South African context often focuses on the school-aged population rather than more-difficult to test preschool-aged children. Determining the occurrence and profile of hearing loss in this population is an important step to ensure informed planning and implementation of early childhood screening programs to promote school-readiness. The present study aimed to determine and describe hearing loss among preschool children (three to six years) in a South African community representative of typical LMIC contexts.

5.3. Method
5.3.1. Context
This study was conducted in the community of Mamelodi, City of Tshwane, Gauteng, South Africa. Census indicates 110,703 households within the community of which only 61% are formal dwellings (Stats SA, 2011). The unofficial population of Mamelodi is currently estimated close to one million (Stats SA, 2011).

5.3.2. Study population
Hearing screenings were offered to two hundred and fifty ECD centers within the community of Mamelodi East and West. ECD centers (crèches) included both public and private facilities that provided learning and support to children between the ages of three to six years. This was the first screening opportunity for majority of these children due to a lack of NHS services available in the public health care system (Olusanya, 2007; Swanepoel et al., 2009). If consent was obtained, these children received a hearing screening after which they were referred to their nearest clinic for a diagnostic assessment if necessary. Diagnostic assessments were also conducted on children aged seven years because they were six years of age at the time of screening.

5.3.3. Data collection
Screening phase
Five community healthcare workers (CHWs) were trained to conduct hearing screenings within ECD centers. If consent was obtained from the ECD center and the child’s parent/guardian, hearing screening was conducted using the hearScreen™ smartphone application (hearX group, Pretoria, South Africa) operated on Samsung J2 Galaxy smartphones (Android OS, 5.1). Smartphones were connected to supra-aural Sennheiser HD280 Pro headphones (Sennheiser, Wedemark, Germany) and calibrated according to prescribed standards (ISO 389-1:1998). A sweep was performed at the test frequencies of 1, 2 and 4 kHz bilaterally at a screening intensity of 25 dB HL. Failure to respond at any frequency in any ear constituted an initial fail. In such cases, children were reconditioned and an immediate rescreen was initiated. If a child referred the immediate rescreen at the ECD center by the same criteria, he/she was referred to their local clinic for a follow-up diagnostic assessment. This was done by automatically sending a text message notification to parents via the mHealth Studio (hearX group, Pretoria, South Africa) cloud-based server.

**Diagnostic phase**

The first author or a qualified audiologist based at the local clinics initially rescreened children who attended their follow-up appointment using the hearScreen™ smartphone application. This was done to reduce false positive results and minimize the need for unnecessary diagnostic assessments at the clinics where resources and time are limited. A number of children were also seen for follow-up assessments at their ECD center, rather than at the clinic, in order to improve follow-up rates. These children also received a second screen before determining if diagnostic assessment was necessary.

Children who received a diagnostic assessment underwent the following assessments. The external ear canal and tympanic membrane were examined using a handheld Welch Allyn (Welch Allyn, South Africa (Pty)(Ltd.) or Heine mini 3000 (Heine, Germany) otoscope. Any abnormalities were noted. If equipment was available at the clinic, tympanometry was conducted to determine middle ear status using the 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, Heuvelmans-Heinen, Rach, & Van Den Broek, 1989). Diagnostic audiometry was performed using either a KUDUwave (eMoyo, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2) or the hearTest™ smartphone application (hearX group, Pretoria, South Africa) operated on Samsung J2 Galaxy smartphones (Andriod OS, 5.1). Recent studies validated the KUDUwave and hearTest™ smartphone application to conduct audiometry outside a booth environment (Maclennan-Smith, Swanepoel, & Hall III, 2013; Storey, Mu, Nelson, Larsen, & White, 2014; van Tonder et al., 2017). Diagnostic air- and bone-conduction audiometry was determined across 0.5, 1, 2 and 4 kHz. Testing began at 1000 Hz in the left ear at 40 dB HL. Thresholds were obtained using the routine 10 dB descending and 5 dB ascending method (Hughson-Westlake method) and was only conducted down to 15 dB HL. Testing below 15 dB HL was not attempted due to environmental noise, and since the hearing of children is considered normal if all thresholds are at/or below 15 dB HL (Clark, 1981; Smith & Bale, 2005). Both audiometers actively monitored noise levels throughout the test procedure thereby guiding the audiologist to minimize exceeded maximum permissible ambient noise levels.

5.3.4. Data analysis

Data were analyzed using SPSS v25 (Chicago, Illinois). Descriptive statistical measures were used to analyze screening results, tympanometric findings, diagnostic results and otological status. Binomial logistic regression analysis was performed to determine the effects of age and gender on the prevalence of hearing loss, with p<0.05 used to indicate a significant effect.

5.4. Results

A total of 6424 children between the ages of three to six years were screened at ECD centers over a period of 12 months, with an initial referral rate of 24.9% (1602 children). Follow-up assessments were conducted on 45.3% (725) of these children at their ECD center (330 children) or closest referral
clinic (395 children). During follow-up assessments these children received a second screening and immediate diagnostic assessment when necessary. A total of 270 children (66.7% female) were seen for a diagnostic hearing assessment, of which 143 and 127 children were tested at clinics and ECD centers respectively. Impacted and excessive cerumen were the most common otoscopic findings after normal ear canal and tympanic membrane findings (Table 5.1.). Of these children, 25 (9.3%) that presented with impacted cerumen (7 unilateral; 18 bilateral) were excluded from data analysis, as they could not be tested diagnostically due to limited resources and time constraints. These children were referred for management. Additionally, 16 children (5.9%) were excluded due to inconsistent responses or the presence of excessive noise.

Table 5.1. Outer and middle ear functioning of children followed-up at clinics/ECD centers (%)

<table>
<thead>
<tr>
<th>Otoscopy (n=270)</th>
<th>% Right (n)</th>
<th>% Left (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>82.6(223)</td>
<td>84.4(228)</td>
</tr>
<tr>
<td>Excessive Cerumen</td>
<td>4.1(11)</td>
<td>4.1(11)</td>
</tr>
<tr>
<td>Impacted Cerumen</td>
<td>8.5(23)</td>
<td>8.1(22)</td>
</tr>
<tr>
<td>Red Tympanic Membrane/Fluid</td>
<td>4.8(13)</td>
<td>3.3(9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tympanometry (n=224)</th>
<th>% Right (n)</th>
<th>% Left (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>83.9(188)</td>
<td>84.4(189)</td>
</tr>
<tr>
<td>Type B</td>
<td>14.3(32)</td>
<td>12.9(29)</td>
</tr>
<tr>
<td>Type C</td>
<td>1.8(4)</td>
<td>2.7(6)</td>
</tr>
</tbody>
</table>

Data analysis was consequently conducted on the diagnostic results of 245 children. Hearing loss was present in 18.7% (46/245) of children. Table 5.2 displays the distribution of hearing loss according to gender and age. Binary logistic regression revealed no gender or age effects (p>0.05).
Table 5.2. Distribution of participant group and those with hearing loss according to age and gender in children tested diagnostically (n=245)

<table>
<thead>
<tr>
<th>Gender</th>
<th>% Distribution of participants (n)</th>
<th>% Children with hearing loss (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>65.7 (161)</td>
<td>16.1 (26)</td>
</tr>
<tr>
<td>Male</td>
<td>34.3 (84)</td>
<td>23.8 (20)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age groups</th>
<th>% Distribution of participants (n)</th>
<th>% Children with hearing loss (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 years</td>
<td>4.1 (10)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>4 years</td>
<td>18.0 (44)</td>
<td>13.6 (6)</td>
</tr>
<tr>
<td>5 years</td>
<td>22.0 (54)</td>
<td>24.1 (13)</td>
</tr>
<tr>
<td>6 years</td>
<td>39.6 (97)</td>
<td>18.6 (18)</td>
</tr>
<tr>
<td>7 years</td>
<td>16.3 (40)</td>
<td>20.0 (8)</td>
</tr>
</tbody>
</table>

Bone conduction audiometry, and tympanometry when available, were conducted to distinguish between conductive, sensorineural and mixed hearing losses. An air-bone gap, of 10dB or more, had to be present at two frequencies or more to qualify as a conductive loss. Conductive hearing loss (65.2%) was the most common type of hearing loss found in children followed by sensorineural (28.2%) and mixed (6.5%) hearing loss (Table 5.3.). Tympanometry was not conducted on 46 participants (17.0%) due to a lack of equipment at the clinics. Of the children who presented with conductive hearing losses, 27 presented with a Type B tympanogram, 10 presented with a Type C tympanogram, and 11 ears presented with type A tympanograms (Table 5.1.).

Table 5.3. Characteristics of hearing loss across participants (n=46)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of HL</td>
<td></td>
</tr>
<tr>
<td>Bilateral conductive</td>
<td>32.6(15)</td>
</tr>
<tr>
<td>Unilateral conductive</td>
<td>32.6(15)</td>
</tr>
<tr>
<td>Bilateral sensorineural</td>
<td>24.0(11)</td>
</tr>
<tr>
<td>Unilateral sensorineural</td>
<td>4.3(2)</td>
</tr>
<tr>
<td>Unilateral mixed</td>
<td>6.5(3)</td>
</tr>
<tr>
<td>Degree of HL according to the worst ear</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Inconsistent/Not tested</td>
<td>8.7(4)</td>
</tr>
<tr>
<td>Mild</td>
<td>54.3(25)</td>
</tr>
<tr>
<td>Mild to moderate</td>
<td>10.9(5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>10.9(5)</td>
</tr>
<tr>
<td>Moderate to severe</td>
<td>8.7(4)</td>
</tr>
<tr>
<td>Severe</td>
<td>2.2(1)</td>
</tr>
<tr>
<td>Mild to severe</td>
<td>4.3(2)</td>
</tr>
</tbody>
</table>

5.5. Discussion

A hearing loss was identified in 18.7% of the 245 preschool children who were seen for a diagnostic assessment from the screening program. Unfortunately, this does not reflect a true prevalence rate amongst this population since less than half of the children (45.3%) who referred on their initial hearing screening were seen for follow-up testing. Another study conducted within the South African context also revealed a poor follow-up return rate of 33% (Govender, Latiff, Asmal, & Ramsaroop, 2015). Default on follow-up return rates were attributed to the long waiting period before follow-up appointments, parents changing their mobile phone number and not notifying the ECD center, a lack of transportation, and difficulties with taking leave from work, which may result in loss of income for informal workers (Yousuf Hussein, Swanepoel, Mahomed, & Biagio de Jager, 2018b).

The use of smartphone hearing screening within ECD centers provided solutions to challenges often faced when testing in LMICs, such as the costs of equipment, lack of trained personnel and ambient noise in the test environment (Yousuf Hussein et al., 2018b). However, a limitation of using this method of screening, as opposed to objective hearing screening measures such as otoacoustic emission (OAE) testing or auditory evoked potentials (AEPs), is that children younger than four years of age could often not be conditioned to respond reliably at ECD centers or at their follow-up clinic (ASHA, 2004; Yousuf Hussein et al., 2018b). These children were referred to other healthcare facilities for such objective tests.
Of the 270 children who were seen for a follow-up assessment, 9.3% had failed the hearing screening due to the presence of impacted cerumen. Unfortunately, due to limited resources and time constraints at local clinics, these children were unable to receive a pure tone threshold test and were referred for treatment. Previous studies conducted within other low income communities in sub-Saharan Africa also revealed high incidence rates of impacted cerumen ranging between 6.6% and 38% (Adebola et al., 2013; Govender et al., 2015; Mahomed-Asmail et al., 2016c).

High incidence rates of excessive and impacted cerumen indicate a need for appropriate services to ensure required intervention. Impacted cerumen can cause a mild hearing loss, which may interfere with a child’s academic performance and cause behavioral problems in the classroom (Daud, Noor, Abd Rahman, & Sidek, 2010). Furthermore, a study by Olusanya (2003) found that children with a history of impacted cerumen were more like to have otitis media with effusion or a hearing loss of a more permanent nature. Thus the prevention of childhood hearing loss caused by cerumen impaction should be a public health concern, especially where there is no routine and systematic screening for hearing disorders (Olusanya, 2003).

In comparison to previous studies, bilateral hearing loss (56.5%, 26/46) was found to be more common than unilateral hearing loss (Mahomed-Asmail et al., 2016c; Stevens et al., 2011). Appropriate management of both bilateral and unilateral hearing loss is important since even a unilateral hearing loss increases rates of grade failure, the need for additional educational assistance, and perceived behavioral issues in the classroom (Bess et al., 1998; Cho Lieu, 2004; WHO, 2018).

Gender and age did not have a significant effect on results, in accordance with those previously reported by Mahomed-Asmail et al. (2016c). Conductive hearing loss (12.2%, 30/245) was the most common type of loss followed by sensorineural (5.3%, 13/245) and mixed (1.2%, 3/245) losses (Table 5.3.). A study by Swart, Van Rooy, Ross and Bellinghan (1996) on 2457 first year entry school children in the South African industrial areas of Witbank and
KwaGuqa also found conductive hearing loss to be more common with bilateral sensorineural deafness present in 2.1 per 1000 and 6.5% of participants presenting with middle ear disease. Another more recent study conducted in Zimbabwe identified conductive and sensorineural hearing losses in 1.4% (79/135) and 1.0% (56/135) of preschool children tested respectively (Westerberg, 2005). High incidence rates in the current study indicates a need for referral services in South Africa in order to ensure for appropriate treatment and follow-up service. Otitis media may account for the high incidence rate of conductive hearing loss, with acute otitis media and otitis media with effusion reported to be the most common cause of hearing loss in children between the ages of two to five years, particularly within LMICs (Biagio et al., 2014; Monasta et al., 2012; Swanepoel, Eikelboom, & Margolis, 2014).

5.6. Conclusion

A hearing loss was identified in 18.7% of pre-school children who attended their follow-up diagnostic assessments, thus ensuring the continuation of medical or audiological services where needed. Results indicated that most preschool children who failed their hearing screening and received a diagnostic assessment needed intervention services for conductive hearing loss (65.2%), followed by sensorineural (28.2%) and mixed losses (6.5%). Cerumen impaction was also a common finding amongst preschool children. While these results may assist in the effective implementation of hearing screenings for pre-school children, true hearing loss prevalence data for young children in LMICs like South Africa still remains elusive with majority of research focused on the school aged population. This makes the planning and provision of hearing health services within the preschool aged population challenging (Mcpherson & Swart, 1997).
According to the WHO (2010), 50% of all cases of deafness and hearing impairment are avoidable through prevention, early diagnosis and management. 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).

Within LMICs such as South Africa, high rates of unidentified hearing loss in children are largely attributable to a lack of hearing screening programs (Olusanya & Newton, 2007; Swanepoel et al., 2009). This may be due to national health systems that are too weak to bear the added burden of non-fatal but disabling disorders (Olusanya & Newton, 2007; Swanepoel et al., 2009). Additionally, a large proportion of hearing loss present as delayed-onset hearing loss, with approximately of 35% of preschoolers presenting with repeated episodes of otitis media that almost always causes a temporary hearing loss (ASHA, 2004; Lu et al., 2011). Thus regular hearing screening throughout childhood is important.

With the integration of asynchronous, low-cost mHealth technologies, early childhood development (ECD) centers in low- and middle-income countries (LMICs) like South Africa can serve as the first point of access to preventative hearing health care services for children from underserved populations. Since mHealth applications can be automated with recommended screening protocols pre-programmed, means community members can be trained to conduct the screening in a decentralized community-based model of care. This provides an opportunity for children to be identified and provided with intervention prior to school entry, which in turn promotes school-readiness.

Screening and follow-up diagnostic assessments within this population is important to ensure informed planning and implementation of early childhood
screening programs. The aim of this chapter is to draw general conclusions, implications and to critically evaluate the research conducted within ECD and primary healthcare (PHC) facilities. Additionally, specific recommendations in the format of a proposed service plan for early childhood hearing screening are made along with future research recommendations.

6.1. Summary of Findings

ECD centers within the underserved communities of Mamelodi East and Mamelodi West were initially mapped to extend identification and intervention services. Smartphone hearing screenings were conducted on 6424 children attending these ECD centers. Study I demonstrated that smartphone-based hearing screening can be successfully operated by non-specialist personnel to detect children affected by hearing loss within ECD centers.

Advanced features of the hearScreen™ smartphone application allowed for asynchronous surveillance and management. Such features included active noise monitoring, quality control indices of test operators and cloud-based data management and referral systems. The hearScreen™ solution utilizes integrated noise monitoring, providing operators with real-time feedback on noise levels to allow testers to minimize noise levels before continuing with tests. The integrated cloud-based data management system allows for remote monitoring of testing thus allowing for an audiologist or program coordinator to intervene when necessary. Additionally, quality indices of test operators could be monitored on the cloud-based server throughout the test period thereby guiding project managers to provide feedback, additional information and more training to testers to ensure reliable test results. Integrated cloud-based data management system also allowed for advanced features such as location-based referrals via text message, reporting and determining follow-up return rates at clinics.

Results indicated that environmental noise had a significant effect on results when testing at the frequency of 1 kHz (p<0.01). Additionally, age contributed significantly to high referral rates (p<0.01), suggesting an optimal screening
age of five to six years of age, as opposed to children three to four years of age.

Establishing baseline information on the current knowledge and perceptions of ECD practitioners on hearing and hearing loss is an essential step towards the acceptance and success of ECD hearing screening programs. Study II found that ECD practitioners recognized that hearing health in children is important and displayed a positive attitude towards hearing screenings. This may be indicative of ECD practitioner readiness for the introduction and implementation of ECD hearing screening programs within LMICs (Swanepoel & Almec, 2008). ECD practitioner’s knowledge and attitudes from this LMIC context were also favourable regarding the etiological factors of hearing loss and the inclusion of children affected by hearing loss. However, gaps in knowledge regarding methods for the identification of hearing loss as well as the impact of hearing loss in the classroom were found. Additionally, attitudes towards the inclusion of children with a hearing loss may be improved by providing information and guidelines to ECD practitioners on how to identify and support a child with a hearing loss in the classroom.

Study III indicated the presence of a hearing loss in 18.7% of preschool children who attended their follow-up diagnostic assessment. Most of these children were in need of intervention services for conductive hearing losses, followed by sensorineural and mixed losses. Additionally, cerumen impaction (9.3%) was also a common finding amongst preschool children. The result of this study demonstrated that hearing health services in ECD centers are needed to ensure that the early detection and appropriate care is available for preschool children.

6.2. Clinical implications
The presence of a hearing loss can have a detrimental effect on a child’s speech, language and educational outcomes, thus increasing a child’s risk for failure and drop out from school (Mathers et al., 2000; WHO, 2018). In light of the high incidence of hearing loss found in preschool children (18.7%), screening programs should be further researched and implemented within
ECD centers. Considering the affordability of smartphone-based hearing screeners, community centers or local NPO’s could be motivated to train personnel and to offer such services. Additionally, smartphone-based vision screening can also be offered, thereby ensuring that both senses crucial to educational success are screened. This will provide an opportunity for children in underserved areas to reach services, which they would otherwise not have had access to.

The empirical findings of this study can be used to guide future research for the implementation of smartphone-based hearing screening programs within ECD centers. Findings suggest an optimal screening age of five to six years. Methods to reduce the effects of noise levels at 1 kHz should be investigated. Strategies to improve the follow-up compliance rate should also be investigated in future studies, such as a second text message reminder, immediate onsite diagnostic audiometry and parent/caregiver education. Additionally, parent education prior to hearing screenings may improve the return of consent letters as well as improve follow-up return rates for further testing.

This study also demonstrated many advantages of using the hearScreen™ smartphone application in ECD centers. One such advantage is that it utilizes automated test protocols that non-specialist personnel, such as community members or even ECD practitioner, can be trained to operate successfully. The hearScreen™ application can also monitor noise levels, which is usually important when testing at the lower frequency of 1 kHz in ECD centers. Additionally, results can be uploaded to a secure cloud-based server for remote surveillance by a qualified audiologist.

Whilst ECD practitioners demonstrated a general readiness for implementation of hearing screening programs, gaps in knowledge regarding the identification and impact of hearing loss as well as poor attitudes towards inclusion were found. These finding should be used to better educate ECD practitioners in future, thereby ensuring commitment and mutual ownership. Furthermore, ECD centers could also be used as a platform to educate
parents/caregivers regarding the importance of healthy hearing.

6.3. Service delivery model for ECD hearing screening program
The results of studies I-III were used to develop and propose a service delivery model for hearing screenings within ECD centers. Hearing screenings should be conducted annually on children between the ages of five to six years of age who are enrolled at ECD centers. Hearing screenings should also be conducted on children whose parents/caregivers or teachers are concerned regarding their hearing, speech, language or education ability, as well as on children with a history of middle ear infections. Figure 6.1 depicts the service delivery model proposed.
Figure 6.1. Flowchart of proposed early childhood development (ECD) hearing screening model

Audiologist/Program coordinator

- Identify and train screen personnel e.g. community workers/ECD practitioners
- Ongoing monitoring, support and assistance to screen personnel
- Identify ECD centers and establish a contact person
- Follow-up diagnostic testing, intervention and referrals

Obtain informed consent from ECD principal and parents

Smartphone-based hearing screening within schools

Screening of children (3-6 years)
Protocol: Sweep performed at 1kHz (25 dB HL), 2kHz (25 dB HL), 4kHz (25 dB HL)

Screening result: Pass
- Referral letter provided to the school
- Second screening conducted by Audiologist at local clinic
- Diagnostic testing, appropriate referrals or treatment conducted by Audiologist

Screening result: Refer
- Referral letter and sms notification sent to parents for follow-up screen and diagnostic test if needed
A multidisciplinary/transdisciplinary team approach may be used, with the key role players including an audiologist and/or team co-ordinator, screen personnel, ECD practitioners including principals and teachers as well as parents/caregivers. Screen personnel may consist of community workers or even ECD practitioners. The audiologist is responsible for training the screen personnel on how to conduct smartphone-based hearing screenings (Integrated School Health Policy [ISHP], 2012b). He/she should also be available to monitor and provide ongoing support and assistance to screen personnel. Additionally, the WHO primary ear and hearing care training manuals are useful resources, which can be adapted to educate personnel regarding ear and hearing care (WHO, 2006).

A team manager should ensure all equipment is calibrated prior to testing, establish contact with the ECD centers and implement and supervise the screening program (ASHA, 1997). Once contact has been made with the ECD center, an ECD practitioner should be nominated as the ‘contact person’ throughout the program. It will be the responsibility of this individual to ensure that information leaflets and informed consent letters are sent to and returned by parents/caregivers.

A smartphone screening technology like the hearScreen™ can be customized for screening conducted within the ECD context. Screening can only be conducted on children whose parents/caregivers have provided informed consent (AAA, 2011). A screening protocol of 25 dB HL as opposed to 20 dB HL as typically recommended for school age screening (AAA, 2011) at 1, 2 and 4 kHz could prevent excessive failures due to noise. If the child passes the pure tone screen no further investigation is needed. If a child fails at any frequency, an immediate rescreen should be initiated (AAA, 2011). If a child fails the immediate rescreen, he/she can be referred for a follow-up diagnostic assessment at their nearest primary healthcare (PHC) facility. It is recommended that the results of children be provided to their school body to ensure that those who referred are followed-up.

It is proposed that the audiologist, based at PHC facilities, initially conduct a
second screen prior to a diagnostic assessment. This will minimize the need for unnecessary diagnostic assessments at PHC facilities where there are often limited resources and time constraints. Automated diagnostic threshold audiometry results should be interpreted by the audiologist who will provide further recommendations for treatment or referrals.

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

6.4.1 Study strengths
Strengths of the current project include the following:

- While the Integrated School Health Policy (ISHP, 2012a) for South Africa recommends hearing screening in school-aged children, no mention is made of screening for hearing loss in children prior to school entry. This study demonstrates the potential for ECD centers to serve as the first platform to identify and provide children affected by hearing loss with intervention prior to school entry.
- This study was the first to investigate the efficacy of the hearScreen™ smartphone application on preschool children. It provided solutions to challenges often faced when screening in a school-based setting within the South African context such as the costs of equipment, lack of trained personnel and ambient noise in the test environment.
- The study demonstrated that non-specialized personnel could successfully conduct hearing screenings on preschool children aged five to six years.
- Hearing screenings were conducted on a large sample size that ensures more precise analysis.
- This study provided statistical information on the incidence and nature of hearing loss within the preschool aged population, which is limited in LMIC South African communities.
- Children who were identified during the hearing screening program were provided with a diagnostic assessment and thus a continuation of
services needed.

• Current information regarding the knowledge and attitudes of teachers toward hearing loss is often limited, particularly within developing countries. This study is the first to provide a baseline of current ECD practitioner knowledge and attitudes towards hearing health within a poor LMIC community setting. Additionally, the developed questionnaire can be adapted and used in future studies.

6.4.2. Study limitations
Limitations of the current project include the following:

• Consent forms were often not completed by parents/caregivers. This resulted in a smaller sample (6424 children) of the population being reached than envisioned (10 000 children).

• Due to poor follow-up compliance rates at clinics, true prevalence rates could not be determined in Study III. Additionally, these children were not tested diagnostically and could therefore not be provided with the appropriate intervention needed.

• Children between the ages of three to four years occasionally could not be conditioned during diagnostic assessments at the clinics. These children were referred for further testing to other healthcare facilities equipped to provide additional services that are usually not available at PHC facilities, due to a lack of equipment. These children were often lost to follow-up. Their results could therefore not be included in the data set in study III, resulting further in a small sample and affecting prevalence results.

• Due to a high number of participants and limited time, conventional screening could not be conducted alongside with smartphone hearing screenings at ECD centers. This means that true sensitivity and specificity could not determined in Study I.

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

- The use of smartphone technology to improve follow-up return rates amongst parents/caregivers after failed hearing screenings should be investigated to ensure the feasibility of ECD screening programs. This can be achieved by sending additional text message reminders along with links to information regarding the importance of hearing health.

- Future studies should also investigate the true prevalence of hearing loss in preschool children in within low- and middle- income areas of South Africa.

- The current knowledge and attitudes of parents/caregivers towards the importance of healthy hearing should be investigated. This will guide the education of communities regarding the importance and necessity of ear and hearing health. In turn, this may ensure that parents/caregivers are motivated to have their child’s hearing screened as well as attend follow-up appointments.

- The efficacy and feasibility of using immediate onsite smartphone-based automated diagnostic audiometry in preschool children within ECD centers should be investigated in future studies. This may lessen the number of appointments that parents need to attend at clinics and ensure that children receive a diagnostic assessment. Additionally, providing parents with more detailed results may motivate parents to seek intervention. The use of smartphone-based automated audiometry at ECD centers may also lessen the workload on already time-constrained audiologists based at local clinics.

- The sensitivity and specificity of smartphone-based hearing screening in young preschool children should be investigated. Additionally, the sensitivity and specificity at all intensity levels (20, 25 and 30 dB HL) should be investigated. Investigating a higher screening intensity, particularly at lower frequencies (1 kHz), may help to account for the effects of noise on results.

- Future validation studies should investigate the validity of the screening application, hearScreen™, when administered by ECD teachers.
6.6. Conclusion
Within LMICs like South Africa, access to early childhood hearing services is severely limited. Integrating smartphone-based hearing screening services within ECD centers is a novel approach, which was explored for the first time within a South African setting. Results demonstrated that the implementation of such a program is a feasible solution to improve access to ear and hearing care services. It provided an opportunity for children from underserved areas to access ear and hearing health care which they otherwise would not have had access to. This allowed for children affected by hearing loss to receive intervention prior to school entry, thus promoting school readiness. However, methods to improve follow-up return rates still needs to be explored in future studies. Whist ECD practitioners demonstrated a general readiness for the implementation of ECD hearing screening programs, additional information and guidelines are needed to improve practitioner knowledge and attitudes.

Utilizing innovative mHealth applications, like the hearScreen™ smartphone application, assisted in overcoming a number of barriers faced when testing within the educational setting, such as the costs of equipment, and ambient noise levels in the test environment. Additionally, this study demonstrated that non-specialist personnel could be successfully trained to screen for hearing loss in preschool children using the hearScreen™ application, thus lessening the burden placed on already limited ear and hearing professionals.
7. REFERENCES:


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Learning.


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8. APPENDIXES
Appendix A:

Participant Information Letter for Informed Consent and Questionnaire
Dear Principal/Teacher

**TITLE OF STUDY:** SUPPORTING HEARING HEALTH FOR PRESCHOOL CHILDREN IN COMMUNITY EARLY CHILDHOOD DEVELOPMENT CENTERS WITH MOBILE TECHNOLOGIES

I, Shouneez Yousuf Hussein, am a doctoral student at the Department of Speech Language Pathology and Audiology, University of Pretoria. You are invited to volunteer to participate in our research project on *Community-Based Hearing Services for Children in Early Childhood Development Centers using Mobile Technologies*.

This letter serves to provide information to help you decide if you want to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any other questions, do not hesitate to ask. You should not agree to take part unless you are comfortable with what is expected of you.

For the purpose of this study the University of Pretoria has partnered with a non-profit organization, NEA Foundation, to develop a program to support healthy hearing by providing hearing screenings in preschool children in Mamelodi. This will help to identify any problems that may affect a child’s development and school success due to hearing problems.

As an ECD principal/teacher we would like you to complete a questionnaire regarding hearing health. The results of the questionnaire will enable us to support and assist teachers in the future to promote healthy hearing. This will take no more than 10 minutes of your time. A member from the NEA team will collect the questionnaire from you before they leave the school. It will be kept in a safe place to ensure confidentiality. Please do not write your name
on the questionnaire. This will ensure confidentiality. We will be available to help you with the questionnaire should you require any assistance.

Your participation in this study is voluntary. You can refuse to participate or stop at any time without giving any reason. Once you have given the questionnaire back to us, you cannot recall your consent, as we will not be able to trace your information. The data collected will be stored for research and archiving purposes for a minimum of 15 years according to the University of Pretoria Regulations.

**Note:** The implication of completing the questionnaire is that informed consent has been obtained from you. Thus any information derived from your form (which will be anonymous) may be used for e.g. publication, by the researchers.

We sincerely appreciate your help.

Sincerely,

Prof. De Wet Swanepoel
Research supervisor

Shouneez Yousuf Hussein
Researcher: PHD student

Consent

Herewith I _______________________ (name) provide consent to participate in the above study and I acknowledge that the information will be used for research purposes as specified above.

Signature ______________________  Date________________________
Questionnaire: Current Knowledge and Attitudes of Teachers in Early Childhood Developmental Centers

1. Gender: __________________________
2. Age: __________________________
3. Home Language: __________________________
4. Highest level of qualification and date received: __________________________
5. Length of teaching experience: __________________________

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>Unsure</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1. Have you worked with a child with a hearing loss?</td>
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<tr>
<td>2. Do you currently have a child with a hearing loss in the ECD center?</td>
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<tr>
<td>3. Do you think hearing loss is an important problem?</td>
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<tr>
<td>4. Do you think healthy hearing is important?</td>
<td></td>
<td></td>
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<tr>
<td><strong>Knowledge: Causes/Risk factors</strong></td>
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<tr>
<td>5. Children can be born with a hearing loss</td>
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<tr>
<td>6. Certain illnesses can cause a hearing loss</td>
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<tr>
<td>7. Ear infection can cause a hearing loss</td>
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<tr>
<td>8. Hearing loss can affect some children more than others</td>
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<tr>
<td>9. Hearing loss is common in young children</td>
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<tr>
<td><strong>Knowledge: Identification and intervention</strong></td>
<td></td>
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<tr>
<td>10. Hearing loss can be identified at any age</td>
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<tr>
<td>11. Children (3-6 years of age) are too young to be accurately diagnosed with a hearing loss</td>
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<tr>
<td>12. A hearing loss can be treated</td>
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<tr>
<td>13. Children with hearing loss can attend school</td>
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<tr>
<td>14. Children with hearing loss can have the same</td>
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<tr>
<td>Educational Opportunities</td>
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<td>educational opportunities as normal hearing children</td>
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</tbody>
</table>

| 15. Hearing loss impacts listening in the classroom | |
| 16. Hearing loss impacts speech and language development | |
| 17. Hearing loss impacts reading | |
| 18. Hearing loss impacts behavior | |
| 19. Hearing loss impacts interaction with peers | |

<table>
<thead>
<tr>
<th>Attitudes</th>
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<tbody>
<tr>
<td>20. I would like children to have a hearing test</td>
<td></td>
</tr>
<tr>
<td>21. I would include children with hearing loss in the classroom/ECD</td>
<td></td>
</tr>
<tr>
<td>22. Children with hearing loss should be referred to special schools</td>
<td></td>
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<tr>
<td>23. I would like more information on hearing loss</td>
<td></td>
</tr>
</tbody>
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Appendix B:

Participant Information Leaflet and Informed Consent Letter for ECD Centers
Dear Principal

**TITLE OF STUDY:** COMMUNITY-BASED HEARING SERVICES FOR CHILDREN IN EARLY CHILDHOOD DEVELOPMENT CENTERS USING MOBILE TECHNOLOGIES.

For the purpose of this study the researchers from the University of Pretoria has partnered with a non-profit organization, NEA Foundation, to develop a program to support healthy hearing by providing hearing screenings for preschool children in Mamelodi. This will help to identify any problems that may affect a child’s development and school success due to hearing problems.

It usually takes between 10 and 15 minutes to complete 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.

Please note that the hearing screening information obtained will 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 wishes to withdraw from the research project they may do so without any negative consequences. The data collected will be stored for research and archiving purposes for a minimum of 15 years according to the University of Pretoria regulations.

If you agree for hearing screening services to be provided at your ECD center, kindly complete the form below.

Kind regards

Prof De Wet Swanepoel

Ms Shouneez Yousuf Hussein

Consent

Herewith I ________________________ (name) grant permission for hearing services to be provided at __________________________(ECD center) and I acknowledge that the information will be used for research purposes as specified above.

Signature ________________________
Date __________________________
Appendix C:

Participant Information Leaflet and Informed Consent Letter for Parents/Caregivers
Dear Parent

1) INTRODUCTION
   We would like to invite your child to participate in a research study. This information leaflet will help you to decide if you want your child to participate. Before you agree you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask.

2) THE NATURE AND PURPOSE OF THIS STUDY
   For the purpose of this study the researchers from the University of Pretoria has partnered with a non-profit organization, NEA Foundation, to develop a program to support healthy hearing by providing hearing screenings for preschool children between the ages of 3 – 6 years in Mamelodi. This will help to identify any problems that may affect a child’s development and school success due to hearing problems.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED
   Your child will receive a hearing screening at his/her school/ECD center by a volunteer from the NEA Foundation that will test how well he/she can hear. Headphones will be placed over your child’s ears and your child will be required to indicate whether he/she heard the sound that is presented by raising his/her hand. The hearing screening usually takes no more than 10 to 15 minutes to complete. If your child fails a screening test, you will receive an SMS notification as well as a referral letter from
the school for a diagnostic assessment at a local clinic (Mamelodi West clinic) that offers hearing services.

4) **RISK AND DISCOMFORT INVOLVED**
   There are no risks involved in participating in the study. The tests are pain free and should not cause any discomfort.

5) **POSSIBLE BENEFITS OF THIS STUDY**
   By participating in this study, your child will be given a free hearing service test at his/her school/ECD center. The results of this study will also help to improve hearing health in your community and other communities in the future.

6) **WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**
   Your child’s participation in this study is entirely voluntary. You can refuse for your child to participate or stop at any time during the study without giving any reason.

7) **INFORMATION AND CONTACT PERSON**
   The contact persons for the study are:
   NEA Foundation team (Charles): 062 318 6114
   Mrs Shouneez Yousuf Hussein: 072 634 9906 (PHD student)
   Alternatively you can contact my supervisor:
   Prof De Wet Swanepoel 012 420 4280

8) **CONFIDENTIALITY**
   All information that you give will be kept strictly confidential. Once we have analyzed the information no one will be able to identify you. Research reports and articles in scientific journals will not include any information that may identify your child or your child’s school. The data collected will be stored for research and archiving purposes for a minimum of 15 years according to the University of Pretoria Regulations.
9) **CONSENT TO PARTICIPATE IN THIS STUDY**

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

Herewith I __________________(parent/guardian) of

________________________ (child’s name)__________________________ (child’s surname) __________ (male/female) born on ___/___/___ (date of birth)

hereby give permission that he/she can be screened for their hearing at

_____________________________ (School/ECD Name) by the volunteers from NEA Foundation and the University of Pretoria.

The screening will take place at the school on

_____________________________2016

Signed at _________________ on __________ of ____________

Phone number of parent/guardian __________________________

Signature of parent/guardian ______________________________

**NB: Your child must be 3 years or older to undergo a hearing screening**
Appendix D:
Child Assent Form
ASSENT FORM

Child’s name and surname:________________________
ECD Center: __________________________

This person tests people’s hearing –
he/she wants to learn more about your hearing.

Earphones will be put on your ears so that you 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 cross the happy picture below.
Appendix E:

Referral Letter to Parents/Caregivers
HEARING ASSESSMENT

Dear Parent/Caregiver,

_________________________ (child’s name) ________________________ (child’s surname) was screened for hearing problems on the ___/___/___ (date) at ________________________(school/ECD).

Your child did not pass the hearing test and is referred for further testing to Mamelodi West clinic (Schabangu Street, Mamelodi West, 0122) on the ___/___/___ (date of appointment).

NB: This is important as a hearing problem can affect your child’s learning and school success.
Appendix F:

Summary of Referrals for ECD Centers
Date: _________________________

Dear Principal/Teacher/ECD practitioner

Thank you for providing consent so that hearing screenings could be provided to the children attending your ECD center on the __________________. The following children did not pass the hearing screening and were referred to Mamelodi West clinic for further testing:

1. _____________________________________________
2. _____________________________________________
3. _____________________________________________
4. _____________________________________________
5. _____________________________________________
6. _____________________________________________
7. _____________________________________________
8. _____________________________________________
9. _____________________________________________
10. _____________________________________________
11. _____________________________________________
12. _____________________________________________
13. _____________________________________________
14. _____________________________________________
15. _____________________________________________
16. _____________________________________________
Appendix G:

Ethical Clearance from the Faculty of Humanities (A)
5 April 2016

Dear Prof Swanepoel

Project: Health for pre-school children in community-based early childhood centres using mobile technologies
Researcher: Prof DCD Swanepoel
Department: Speech Language Pathology and Audiology
Reference: GW20160207HS (staff research)

Thank you for your response to the Committee’s correspondence of 8 March 2016.

I am pleased to inform you that the above application was approved by the Research Ethics Committee on 5 April 2016, conditional to written permission being granted by:

- The early childhood centres

Please note that data collection may not commence prior to these centres giving permission and subject to final approval by this committee. To facilitate the administrative process, please respond to Ms Tracey Andrew at tracey.andrew@up.ac.za or Room HB 7-27, at your earliest possible convenience.

Sincerely

[Signature]

Prof MME Schoeman
Deputy Dean: Postgraduate Studies and Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

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

Ethical Clearance from the Faculty of Humanities (B)
29 July 2016

Dear Prof Vinck

Project: Supporting hearing health for pre-school children in community early childhood development centers with mobile technologies
Researcher: S Yousuf Hussein
Supervisor: Prof DeWet Swanepoel
Department: Speech-Language Pathology and Audiology
Reference number: 28121262(GW20160706HS)

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

I am pleased to inform you that the above application was approved by the Research Ethics Committee on 28 July 2016. Data collection may therefore commence.

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

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

We wish you success with the project.

Sincerely

[Signature]

Prof Maxi Schoeman
Deputy Dean: Postgraduate Studies and Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

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

Research Ethics Committee Members: Prof MME Schoeman (Deputy Dean); Prof KL Harie; Dr L Blokland; Dr R Fassalt; Ms KT Govinder; Dr E Johnson; Dr C Pamblanco; Dr C Puttergill; Dr D Rayburn; Prof GM Spies; Prof E Taijard; Ms B Tsebo; Dr E van der Koosborst; Mr V Sibhole
Appendix I:

Ethical Clearance from the Faculty of Health Sciences
Approval Certificate

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

Ethics Reference No.: 102/2011

Title: Researching the development, application and implementation of Community Oriented Primary Care (COPC). A study in Gauteng (Tshwane) and Mpumalanga Province

Dear Johannes Hugo

The Amendment as described in your documents specified in your cover letter dated 3/12/2015 received on 3/12/2015 was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 4/12/2015.

Please note the following about your ethics amendment:

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

Ethics amendment is subject to the following:

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

We wish you the best with your research.

Yours sincerely

Dr R Soemers, MBChB, MMed (Int), MPharmMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

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

• FIFA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
• IRB 0000 2335 IDRG0001763 Approved dd 22/04/2014 and Expires 22/04/2017.
Appendix J:

Proof of Acceptance of Articles
Dear Mrs. Shouneez Yousuf Hussein,

I am pleased to tell you that your work has now been accepted for publication in International Journal of Pediatric Otorhinolaryngology. Your accepted manuscript will now be transferred to our production department and work will begin on creation of the proof. If we need any additional information to create the proof, we will let you know. If not, you will be contacted again in the next few days with a request to approve the proof and to complete a number of online forms that are required for publication.

When your paper is published on ScienceDirect, you want to make sure it gets the attention it deserves. To help you get your message across, Elsevier has developed a new, free service called AudioSlides: brief, webcast-style presentations that are shown (publicly available) next to your published article. This format gives you the opportunity to explain your research in your own words and attract interest. You will receive an invitation email to create an AudioSlides presentation shortly. For more information and examples, please visit http://www.elsevier.com/audioslides.

Interactive Case Insights: The journal encourages authors to complement their case reports and other articles of an educational nature with test questions that reinforce the key learning points. These author created questions are submitted along with the article (new or revised) and will then be made available in ScienceDirect alongside your paper. More information and examples are available (at http://www.elsevier.com/about/content-innovation/interactive-case-insights). Test questions are created online (at http://elsevier-apps.sciverse.com/GadgetICRWeb/verification). Create the test questions, save them as a file to your desktop, and submit them along with your (new or revised) manuscript through EES. That's it! For questions, please contact icihelp@elsevier.com

Thank you for submitting your work to this journal.
With kind regards,
Robert J. Ruben, MD
Editor-in-Chief
International Journal of Pediatric Otorhinolaryngology
Dear Shouneez Yousuf Hussein,

I am very pleased to inform you that your work has now been accepted for publication in Global Health Action. It was accepted on Apr 12, 2018. Congratulations.

The next steps are that you will hear from the production team when typeset proofs are ready to be checked.

Thank you for submitting your work to Global Health Action. We look forward to receiving your next contribution.

With kind regards,

Stig Wall, Professor
Senior and founding editor
Global Health Action
Dear Mrs. Shounee Yousuf Hussein,

I am pleased to tell you that your work has now been accepted for publication in International Journal of Pediatric Otorhinolaryngology.

Your accepted manuscript will now be transferred to our production department and work will begin on creation of the proof. If we need any additional information to create the proof, we will let you know. If not, you will be contacted again in the next few days with a request to approve the proof and to complete a number of online forms that are required for publication.

Interactive Case Insights: The journal encourages authors to complement their case reports and other articles of an educational nature with test questions that reinforce the key learning points. These author created questions are submitted along with the article (new or revised) and will then be made available in ScienceDirect alongside your paper. More information and examples are available (at http://www.elsevier.com/about/content-innovation/interactive-case-insights). Test questions are created online (at http://elsevier-apps.sciverse.com/GadgetICRWeb/verification). Create the test questions, save them as a file to your desktop, and submit them along with your (new or revised) manuscript through EES. That’s it! For questions, please contact icihelp@elsevier.com

Thank you for submitting your work to this journal.

With kind regards,

Robert J. Ruben, MD
Editor-in-Chief
International Journal of Pediatric Otorhinolaryngology