

MHEALTH-SUPPORTED HEARING AND VISION SERVICES FOR PRESCHOOL CHILDREN IN LOW- INCOME COMMUNITIES

by

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**A thesis submitted in partial fulfilment
of the requirements for the degree**

PhD (Audiology)

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“In Him was life, and the life was the light of men. The light shines in the darkness, and the darkness has not overcome it.” ~John 1:4-5~

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.

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**UNIVERSITY OF PRETORIA
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PLAGIARISM DECLARATION

Full name: Susan Eksteen

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Title of thesis:

MHEALTH-SUPPORTED HEARING AND VISION SERVICES FOR PRESCHOOL CHILDREN IN LOW-INCOME COMMUNITIES

I declare that this thesis is my own original work. Where secondary material is used, it has been carefully acknowledged and referenced in accordance with university requirements.

I understand what plagiarism is and am aware of university policy and implications in this regard.



Signature

11 January 2020

Date

ETHICS STATEMENT

The author, whose name appears on the title page of this thesis, has obtained, for the research described in this work, the applicable research ethics approval.

The author declares that she has observed the ethical standards required in terms of the University of Pretoria's Code of Ethics for Research and the Policy and Procedures for Responsible Research.

PUBLICATIONS AND RESEARCH OUTPUTS

The thesis is based on the following original articles:

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Eksteen, S., De Kock, T., Swanepoel, D.S. (29–30 October 2018) Improving preschool hearing-screening outcomes: mHealth-enabled community-based first-line follow-up services. Presented at the *Coalition of Global Hearing Health*.

ABSTRACT

Title: mHealth-supported hearing and vision services for preschool children in low-income communities

Name: Susan Eksteen

Supervisor: Prof. De Wet Swanepoel

Co-supervisor: Prof. Robert H. Eikelboom

Department: Speech-language Pathology and Audiology

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Sensory inputs of hearing and vision during early childhood development support the achievement of language, speech and educational milestones. The early detection of sensory impairment is essential for facilitating early childhood development, socio-emotional well-being and academic success, in addition to obtaining sustainable educational development goals. The majority of children with sensory impairment live in low- and middle-income countries where services are often unavailable or inaccessible, because of the absence of systematic screening programmes for children, prohibitive equipment cost, a shortage of trained personnel and centralised service-delivery models. Therefore, research is needed to investigate whether a community-based mobile health (mHealth) supported service-delivery model for hearing and vision screening can increase access to hearing and vision services for children in resource-constrained settings.

This study aimed to describe an implemented hearing and vision screening programme and evaluate its success in terms of acceptability (consent return numbers), coverage (number of eligible children screened), referral rates and quality indicators (duration of tests and number of hearing tests conducted under conditions of excessive noise levels). The study also explored the challenges faced during a community-based screening programme and the strategies developed to address these. Four non-professionals were appointed and trained as community health workers (CHWs) to conduct combined sensory screening using mHealth technology (hearScreen application, hearXGroup, South Africa and Peek Acuity application, Peek

Vision, United Kingdom) on smartphones at preschools in low-income communities in Cape Town, South Africa. The consent form return rate was 82.0%, and the coverage rate was 94.4%. An average of 501 children were screened each month, at a cost of US\$5.63 per child. The number of children who failed hearing and vision screening was 435 (5.4%) and 170 (2.1%), respectively. Failing of hearing tests was associated with longer test times (odds ratio [OR]: 1.022; 95% confidence interval [CI]: 1.021–1.024) and excessive background noise levels at 1 kHz (e.g. OR for left ear: 1.688; 95% CI: 1.198–2.377). Failing of visual screening tests was associated with longer test duration (OR: 1.003; 95% CI: 1.002–1.005) and younger age (OR: 0.629; 95% CI: 0.520–0.761).

The study also aimed to describe and compare the performance of two screening protocols that were used in this preschool hearing screening programme to determine optimal referral criteria that is responsive to available resources. Secondary data analysis was done to compare a protocol using a single-frequency fail criterion (which 2,147 children were screened with between 1 October 2017 and 25 February 2018) with a screening protocol using a two-frequency fail criterion (which 5,782 children were screened with between 26 February 2018 and 30 November 2018). For both protocols, screening was done at a 25 dB hearing level (HL) at 1000, 2000 and 4000 Hz. Both protocols included an immediate rescreen at the frequencies that were failed. The referral rate was 8.7% ($n = 186$) for the one-frequency fail protocol and 4.3% ($n = 250$) for the two-frequency fail protocol. Compared to the one-frequency fail protocol, children screened with the two-frequency fail protocol were 52.9% less likely to fail (OR: 0.471; 95% CI: 0.385–0.575). Gender (OR: 0.807; 95% CI: 0.531–1.225) and age (OR: 0.996; 95% CI: 0.708–1.402) had no significant effect on screening outcomes. Maximum permissible ambient noise levels (MPANLs) were exceeded in 44.7% of cases in at least one ear at 1000 Hz across both protocols. There was no significant difference between the protocols for both true positive cases and false positive cases. Protocol (OR: 1.338; 95% CI: 0.854–2.098), gender (OR: 0.807; 95% CI: 0.531–1.225) and age (OR: 0.996; 95% CI: 0.708–1.402) demonstrated no significant effect on the odds of producing true positive results. Average time for conducting the screening was 72.8 s (78.66 SD) for the one-frequency fail protocol and 64.9 s (55.78 SD) for the two-frequency fail protocol.

Estimating the prevalence and describing the characteristics of sensory loss in a preschool population in low-income communities are important steps to ensure adequate planning and successful implementation of community-based hearing and vision care in this context. The study therefore also investigated the prevalence and characteristics of hearing and vision loss among preschool children (4 to 7 years) in an underserved South African community after implementing mHealth-supported community-based hearing and vision services. Children who failed hearing and vision screening were seen for follow-up assessments at their preschools. Follow-up assessments were also performed with smartphones and hearing and vision testing applications (hearTest application, hearX Group, South Africa and PeekAcuity app, Peek Vision, United Kingdom). A total of 10,390 children were screened at 298 preschools over 22 months. Of the children screened, 5.6% and 4.4% of children failed hearing and vision screening, respectively. Community-based follow-up hearing tests were done at the preschools on 88.5% (514) of the children, of whom 240 children (54.2% female) presented with hearing loss. A preschool-based follow-up vision test was conducted on 400 children (88.1%). A total of 232 children (46.1% female) had a vision impairment, and a further 32 children passed the test but had obvious signs of ocular morbidity. Logistic regression analysis found that age was a significant predictor of vision loss ($p < 0.001$): with every 1-year increase in age, participants were 51.4% less likely to have vision loss (OR: 0.49, 95% CI: 0.39–0.60). Age was not a significant predictor for hearing loss (OR: 0.821; 95% CI: 0.667–1.011). Gender was not a significant predictor of hearing loss (OR: 0.850; 95% CI: 0.658–1.099) or vision loss (OR: 1.185; 95% CI: 0.912–1.540). The prevalence of hearing loss at a pure tone average (PTA) of 25 dB HL ranged between 2.3% (240 out of 10,390; assuming none of the non-attenders and children who were unable to be tested had hearing loss) and 3.1% (321 out of 10,390; assuming all the non-attenders and children who were unable to be tested presented with hearing loss). The prevalence of vision loss ranged between 2.2% (232 out of 10,390; assuming none of the non-attenders had vision loss) and 2.8% (286 out of 10,390; assuming all the non-attenders presented with vision loss).

Findings of this research project indicate that mHealth-supported CHW-delivered hearing and vision screening in preschools provide a low-cost, efficient and accessible service that can improve the provision of affordable hearing and vision care. This

service-delivery model is affordable and scalable, because the same staff, needing minimal training, and the same equipment are used to screen for both vision and hearing. Timely identification of sensory losses is essential to ensure optimal outcomes and can be facilitated through community-based hearing and vision services by trained CHWs using mHealth technology. Future studies should aim to report on outcomes and the uptake and impact of interventions on the children diagnosed with sensory impairments following identification through a decentralised screening programme.

KEYWORDS

Community-based
Community-delivered
Community health workers (CHWs)
Decentralised healthcare
Early Childhood Development Centre (ECD centre)
Hearing loss
Hearing screening
Lay health workers (LHWs)
Low-income communities
Low- and middle-income countries (LMICs)
Mobile health technology (mHealth)
Protocols
Preschools
Preschool children
Referral criteria
Resource-constrained settings
Sensory loss
Sensory screening
Service-delivery model
Task sharing
Vision loss
Vision screening

ABBREVIATIONS

| | |
|----------------|---|
| App | Smartphone application |
| CHWs | Community health workers |
| CI | Confidence interval |
| dB | Decibel |
| dB HL | Decibel Hearing Level |
| ECD | Early childhood development |
| Hz | Hertz |
| kHz | kilohertz |
| LHWs | Lay health workers |
| LMICs | Low- and middle-income countries |
| mHealth | Mobile health technology |
| MPANL | Maximum permissible ambient noise level |
| NA | Not applicable |
| OR | Odds ratio |
| PCEHL | Permanent congenital early-onset hearing loss |
| PTA | Pure tone average |
| SD | Standard deviation |
| SDGs | Sustainable development goals |
| SMS | Short message service |
| SSA | Sub-Saharan Africa |
| US\$ | United States dollars |
| WHO | World Health Organization |

1 INTRODUCTION

1.1 BACKGROUND

Childhood hearing and vision loss are significant contributors to the global burden of disease (Global Burden of Disease study [GBD], 2021; Global Research on Developmental Disabilities Collaborators [GRDDC, 2018]; Olusanya et al., 2020), affecting 38.7 and 32.5 million children under the age of 10 years, respectively (Olusanya et al., 2020). Unidentified sensory loss negatively affects a child's speech and language development, communication ability, educational achievement and socio-emotional development, resulting in social isolation and stigmatisation (AAPOS, 2016; GBD, 2021; Mathers et al., 2001; Muse et al., 2013) . According to the World Health Organization (WHO), 60% of childhood hearing loss and 80% of vision loss can be treated or prevented if identified early (World Health Organization [WHO], 2017a, 2017b; WHO, 2021). Therefore, periodic hearing and vision screening are considered integral strategies for preventative paediatric healthcare (AAA, 2011; Emmett et al., 2019; GBD, 2021; Rahi et al., 2003; Stenfeldt, 2018; WHO, 2021).

Early detection of sensory impairments is essential for facilitating early childhood development, socio-emotional well-being and academic success, (Gilbert & Foster, 2001; Graydon et al., 2019; GRDDC, 2018; Stevens et al., 2011; Wilson et al., 2017) in addition to obtaining the sustainable development goals (SDGs) related to education (GRDDC, 2018; Olusanya et al., 2020; Sustainable development goals report [SDG], 2018). Screening at early childhood development centres (ECD centres) or preschools can identify children with congenital sensory losses or late-onset, progressive or fluctuating hearing and vision loss, and consequently allows facilitating intervention prior to school entry (Gilbert & Foster, 2001; GRDDC, 2018; Keffe, 2004; Rahi et al., 2003; Rono et al., 2018; WHO, 2021). The WHO recently released the "World Report on Hearing" that outlines the framework of a global public health response that is focused on integrated, people-centred ear and hearing care (WHO, 2021). The report

describes hearing screening programmes for preschool children as a cost-effective strategy to prevent and identify hearing loss. The report states that through the use of innovative technological solutions with evidence-based public health approaches to prevent and identify hearing loss, the projected increase in the prevalence of the condition can be curtailed, and the adverse effects of hearing loss can be mitigated (GBD, 2021; WHO, 2021).

The majority of children (80–90%) with sensory impairments live in low- and middle-income countries (LMICs), (GBD, 2021; Gilbert & Foster, 2001; Kamenov et al., 2021; Olusanya et al., 2020; Stevens et al., 2011; WHO, 2017b, 2021) where services are often unavailable or inaccessible, because of an absence of systematic screening programmes for children, prohibitive costs associated with equipment and facilities, severe shortage of trained personnel and centralised service-delivery models (Harris & Dodson, 2017; Kamenov et al., 2021; Swanepoel, 2020; WHO, 2021; Wilson et al., 2017).

In order to overcome the barriers to service delivery in underserved populations, alternative service-delivery models have been investigated (GBD, 2021; Swanepoel, 2017, 2020; WHO, 2021). A growing body of knowledge provides evidence for incorporating non-professionals using mobile health (mHealth) technology in community-based programmes (Dawood et al., 2020; Emmett et al., 2019; Jayawardena et al., 2018; Jayawardena et al., 2020; Louw et al., 2016; Manus et al., 2021; Swanepoel, 2020; Swanepoel et al., 2014; Van Wyk et al., 2019; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018) by capitalising on connectivity and automation (Clark & Swanepoel, 2014; Swanepoel et al., 2010; Swanepoel, 2020). mHealth technology allows task sharing, because trained community health workers (CHWs) can provide hearing and vision services with point-of-care devices at reduced cost with remote surveillance and the support of professionals, making services more accessible (Jayawardena et al., 2018; Kamenov et al., 2021; Shinn et al., 2019; WHO, 2021).

1.1.1 mHealth point-of-care technology for screening

Pure tone audiometry is an accurate tool for hearing screening in preschool children older than 3 years of age (AAA, 2011). Hearing screening can be performed either through conventional screening audiometry or through innovative mobile technology, developed to allow lay health workers to provide screening in communities (Jayawardena et al., 2018; WHO, 2021). Conventional screening methods require expensive and bulky equipment and intensive training of screeners in audiometric principles. It also has other limitations such as over-referral, lack of environmental noise monitoring and poor data capturing and management (Bamford et al., 2007; Fagan, 2012; Prieve et al., 2015; Stenfeldt, 2018). Recent technological advancements have made audiometric testing equipment more accessible, portable and easier to use in LMICs (Jayawardena et al., 2018, 2020; Rourke et al., 2016; Swanepoel, 2020). Increased global access to the Internet (Internet World Stats, 2021) is advancing healthcare delivery in LMICs through using Internet-supported technology (Obasola et al., 2015; Zhenwei Qiang et al., 2011). Smartphones have improved markedly in terms of processing power and penetration rates, and mobile networks cover 99% of the global population (World Bank, 2016). This resulted in an emerging body of evidence demonstrating how the use of mobile phones in health, or mHealth, can improve and reduce the cost of patient monitoring, medication adherence and communication with healthcare workers, especially in rural areas (Zakus et al., 2019; Zhenwei Qiang et al., 2011). Smartphone technology also provides tools for point-of-care health services and surveillance (Swanepoel, 2020).

The range of technology-based options that have recently emerged in the field of audiology include mobile-based software apps, automated hearing screening, boothless audiometry and telemedicine options (WHO, 2021). Boothless audiometry enables testing without the need for a sound booth, for example through the use of noise-cancellation headphones (Sandström et al., 2016; Visagie et al., 2015; WHO, 2021). Telemedicine is the delivery of health-related services and information via telecommunication technology (Biagio et al., 2014; Mars, 2013; WHO, 2021). In tele-audiology, audiological services can be provided remotely by transmitting findings and otoscopic images to an expert from the point of contact with a patient, and, conversely, transmitting the diagnosis back (Biagio et al., 2014; Skarzyński et al., 2016; Visagie et al., 2015).

The development of mobile software apps (Rourke et al., 2016; Sandström et al., 2016; Swanepoel et al., 2014) provides tools that are cost-effective and easy to use, and facilitates screening in school settings with limited training and resources (WHO, 2021). The transformational effect of tablets and smartphones in mobile audiometry is particularly evident in low-resource settings (Jayawardena et al., 2018; Rourke et al., 2016; Swanepoel, 2020). For example, automated hearing testing, enabled by technology that is programmed to provide the signal and analyse the individual's response, reduces the need for training of screening personnel (Govender & Mars, 2018; Margolis & Morgan, 2008; Van Tonder et al., 2017). An example of a free smartphone application that is based on speech recognition in noise to check for hearing loss, is the hearWHO app (WHO, 2021). This hearing screening method is based on a validated South African digits-in-noise test (hearZA) and can be accessed online, through mobile apps, and in community settings (De Sousa et al., 2018; Potgieter et al., 2016; WHO, 2021). A study by Jayawardena et al. (2018) compared different mHealth devices available for hearing screening. One of these mHealth apps is hearScreen, a smartphone hearing screening app with calibrated headphones that utilises pre-specified screening protocols to assess hearing using automated sequences (Jayawardena et al., 2018; Swanepoel et al., 2014). The hearScreen app is a low-cost device operable on an entry-level smartphone running Android OS software with off-the-shelf circumaural headphones (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). The app employs noise-monitoring algorithms, which provide operators with real-time feedback on ambient noise levels and automatically retests frequencies where maximum noise levels were exceeded (Madsen & Margolis, 2014; Mahomed-Asmail, et al., 2016; Swanepoel, 2020; Swanepoel et al., 2014).

Vision screening has also seen an increasing number of mobile apps to provide such services (Bastawrous et al., 2015; Donahue et al., 2013; Gounder et al., 2014; Nik-Azis et al., 2019; Zhang et al., 2013). Optotype visual acuity testing is the preferred method for vision screening in cooperative children 4 years and older (Donahue et al., 2013; Solebo et al., 2015). Several studies have researched the reliability of visual acuity measurements using tablets and smartphones (Bastawrous et al., 2015; Gounder et al., 2014; Nik-Azis et al., 2019; Zhang et al., 2013). A smartphone-based application (Peek Acuity app; peekVision, United Kingdom) that was designed and

validated to test visual acuity proved capable of accurate and repeatable acuity measurements, consistent with published data on the test–retest variability of acuity measured using traditional 5-letter-per-line retro-illuminated logMAR charts (Bastawrous et al., 2015). The Peek Acuity application is not dependent on familiarity with symbols or letters commonly used in the English language and uses a tumbling E method to test visual acuity (Bastawrous et al., 2015). The peekVision app can be used on the same entry-level smartphone as the hearScreen app, enabling both hearing and vision screening with the same hardware.

Since automated protocols with immediate, automated interpretations of results are used for both the hearScreen and Peek Acuity apps, non-specialist personnel can be trained to successfully operate the device (Bastawrous et al., 2015; Jayawardena et al., 2020; Manus et al., 2020; Yousuf Hussein et al., 2015). The mobility and affordability of mHealth technology used by trained non-professionals have been reported to be powerful enablers for the decentralisation of service delivery (Jayawardena et al., 2018; Suen et al., 2019; Swanepoel, 2020; WHO, 2021).

1.1.2 Screening facilitated by trained non-professionals

The use of lay health workers is increasingly being recommended to make hearing and vision screening more accessible in LMICs (Bhutta, 2019; Bright et al., 2019; Kamenov et al., 2021; Nik-Azis et al., 2019; WHO, 2021). By using the WHO workload indicators of staffing need calculations, a study by Kamenov et al. (2021) revealed a shortage of ear and hearing healthcare workers. The study demonstrated that in the African region, for example, 78% of the countries had less than one audiologist per million people (Kamenov et al., 2021). To overcome the skills shortage for ear and hearing care in many LMICs, task sharing is recommended by the WHO (Bhutta, 2019; Kamenov et al., 2021; Wilson et al., 2017; WHO, 2021). Task sharing involves the redistribution of clinical tasks, or their key components, among different cadres of healthcare teams (WHO, 2021). The appropriate reallocation of tasks, from highly qualified health workers to less qualified non-specialists, such as CHWs, allows more efficient use of available human resources (Kamenov et al., 2021; WHO, 2021). This could mean allocating tasks traditionally performed by audiologists or optometrists, for example hearing or vision screening, to non-specialists, such as CHWs, nurses or

technicians with additional relevant training (Bhutta, 2019; Bright et al., 2019; Kamenov et al., 2021).

Task shifting (where tasks are taken from one cadre and given to another) is a common strategy in public health programmes to increase access to services (Olaniran et al., 2017; Suen et al., 2019; WHO, 2021). LMICs are increasingly strengthening their CHW programmes, viewing this as an affordable and critical intervention in attaining universal health coverage (Thomas et al., 2021; Tulenko et al., 2013). CHWs should be recruited from the local community and have a general understanding of the language and culture of their community. They can, therefore, provide culturally appropriate health services to the community, and they also require shorter training than health professionals (Olaniran et al., 2017). A study by Thomas et al. (2021) supports evidence that CHW programmes can improve access to care in vulnerable communities through CHWs' own efforts and through referrals to clinics. The important role of CHWs in South Africa was further highlighted during the 2020 Covid-19 pandemic, with over 1 million Covid-19 screening activities that were conducted by CHWs in the Ekurhuleni district over a 9-month period (Thomas et al., 2021). Kamenov et al. (2021) named several issues that need to be considered when adopting task sharing in countries. Firstly, task sharing should be implemented alongside other strategies that are designed to increase the total of trained professionals. Secondly, a situation analysis should be done before allocating tasks to non-specialists. Thirdly, assigned tasks should be performed in accordance with the quality standards of the health regulations of the country. Fourthly, when roles and responsibilities are shifted from skilled to non-skilled cadres, supervision and support from specialists must be made available. Finally, automated devices or telemedicine strategies can be used as tools in facilitating the successful delivery of interventions in task sharing (Kamenov et al., 2021; WHO 2021).

Community-delivered hearing and vision care offers new approaches to task sharing through minimally trained non-professionals, e.g. lay health workers (LHWs) or CHWs (Bastawrous et al., 2015; Dawood et al., 2020; Donovan et al., 2019; Jayawardena et al., 2020; Shinn et al., 2019; Suen et al., 2019; Yousuf Hussein et al., 2015; WHO, 2021). Validated smartphone screening apps incorporating automated testing and measures of quality control (Arinze et al., 2015; Jayawardena et al., 2018; Levy et al.,

2018; Rourke et al., 2016; Swanepoel, 2020) allow minimally trained CHWs to decentralise hearing and vision screening and to identify cases for referral (Bastawrous et al., 2015; Mahomed-Asmail et al., 2016; Rono et al., 2018; Shinn et al., 2019; Swanepoel et al., 2014; Van Wyk et al., 2019; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein et al., 2015). Cloud-based data management systems allow surveillance of quality control metrics, such as the feasibility of test environments and the test reliability of operators, by an overseeing professional (Louw et al., 2016; Van Tonder et al., 2017; Van Wyk et al., 2019; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018).

Recent studies demonstrated that minimally trained non-specialist health workers (e.g. CHWs) are able to conduct hearing screening services equivalent to that of professional healthcare workers, when equipped with mHealth technology (Bright et al., 2019; Dawood et al., 2020; Shinn et al., 2019). CHWs have reported such apps as user-friendly and efficient (Bastawrous et al., 2015; UNESCO, 2017; Van Wyk et al., 2019; Yousuf Hussein, Swanepoel, Biagio de Jager, et al., 2018). Shinn et al. (2019) reported that, in addition to being able to screen with similar accuracy to otolaryngologists, CHWs exhibited independent critical thinking and, given their cultural and language background, were able to navigate situations in which children were difficult to test (Shinn et al., 2019). Task sharing and the utilisation of trained non-professionals expand the reach of service delivery in LMICs and allow for the scalability of community-based programmes (Jayawardena et al., 2020; Kamenov, 2021; Shinn et al., 2019; WHO, 2021).

1.1.3 Preschools as a platform for screening

The mobility of mHealth technology together with the utilisation of CHWs for screening are powerful enablers of decentralised community-based programmes (Bastawrous et al., 2015; Bright et al., 2019; WHO, 2021). Another important consideration in planning an effective community-based screening programme is identifying the optimal context for screening (WHO, 2021).

Sensory loss increases the risk for failure and drop-out from school, placing a child with sensory impairment at an economic disadvantage (Mathers et al., 2001). To

combat the ramifications associated with hearing and vision loss, early identification and timely intervention are essential (AAPOS, 2016; JCIH, 2007; WHO, 2021). An effective school health programme has been described as one of the most cost-effective investments a nation can make (WHO, 2021).

Detection of hearing and vision problems before school entry is important for identifying children who were not screened as newborns, children who suffered minimal sensory loss at birth and children who were referred for screening but were lost to follow-up, and for identifying late-onset hearing or vision loss that may interfere with language development and future school success (Mahomed-Asmail et al., 2016; WHO, 2021). Despite the widely documented benefits of newborn hearing screening, it is not mandatory in most countries (WHO, 2021), especially in LMICs such as South Africa (Khoza-shangase & Harbinson, 2015; Meyer & Swanepoel, 2011). In addition to neonatal sensory loss, acquired sensory loss in children should also be considered, especially in LMICs where environmental risks are greater and the prevalence of infections, such as otitis media and meningitis, causing sensory impairment is high (Biagio et al., 2014; Emmett et al., 2019; Graydon et al., 2019; Keeffe, 2004; Stevens et al., 2011; WHO, 2021).

Screening at schools represents a unique opportunity to conduct universal hearing and vision screening (WHO, 2021). Preschools have the potential to serve as the first point of access to preventative hearing and vision healthcare services to children from underserved populations. This platform provides an opportunity for the identification of hearing and vision problems that will constitute a barrier to future learning (Cedars et al., 2018; Kam et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). By early identification and initiation of intervention, the effect of unaddressed sensory loss can be mitigated (WHO, 2021). It is, therefore, also essential to ensure that a referral system is in place for children identified through screening, to allow access to further investigations and management (WHO, 2021).

1.2 RATIONALE

Employing innovative mobile technology used by trained non-professionals to provide screening in community contexts like preschools provides an opportunity to decentralise services.

Annually, about 1 million grade one pupils enter the schooling system in South Africa (Statistics South Africa, 2017). The Integrated School Health Policy (2012) describes services to screen children's hearing and vision in the foundation phase (grade one). In South Africa, schooling is not compulsory for children under the age of 6 years old, and most children in underserved communities attend ECD centres or preschools in the community before starting with grade one (foundation phase) in a public school (Statistics South Africa, 2017). There are currently no systematic screening programmes to detect childhood hearing loss and visual impairment in preschool children. Detecting hearing and vision problems before school entry facilitates a child's speech and language development, communication ability, educational achievement and socio-emotional development (Mathers et al., 2001; Muse et al., 2013; Wilson et al., 2017). Screening is the first step towards detection and identification of hearing loss and vision impairment; however, ensuring sustainable follow-up and timely referrals, in addition to providing education about the prevention of sensory loss and raising awareness about hearing and vision health in the community, is essential (WHO, 2021).

Despite expanding literature on community-based mHealth-supported screening programmes in preschool and school-going children in underserved communities (Emmett et al., 2019; Jayawardena et al., 2020; Mahomed-Asmail et al., 2016; Manus et al., 2020; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018), there is still a paucity of evidence in certain areas. Research is still needed to develop and evaluate mHealth-supported community-based screening programmes to guide best practice and scalable, sustainable service-delivery models (Suen et al., 2019; Swanepoel, 2020). Based on the findings from studies on screening programmes in Gauteng, South Africa (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018), an mHealth-supported screening programme was implemented in underserved communities in Cape Town, South Africa, in June 2017. During this programme, four non-professionals (CHWs) were appointed and trained to screen the hearing and vision of preschool children at ECD centres or preschools in the community, using mHealth technology.

Decentralised screening in communities, facilitated by non-professionals from the community using mHealth technology, to mitigate hearing and vision difficulties in preschool children require further investigation. Research that describes and evaluates an implemented mHealth-supported community-based service-delivery model that provides combined sensory screening to preschool children in an underserved area is necessary.

Therefore, this study aimed to describe and evaluate a community-based service-delivery model for hearing and vision screening for preschool children in low-income communities using mHealth technology. The study implications are intended to provide guidelines for scaled future implementation for hearing and vision impairment in this population in underserved communities. The efficacy of this service-delivery model was described in terms of quality indicators, coverage, referral rates, follow-up return rates and incidence of sensory losses.

The following research questions were the focus of this project:

- 1) Can an mHealth-supported community-based service-delivery model increase affordable access to hearing and vision services for children in low-income settings?*
- 2) Can referrals be optimised for a low-resource setting using a protocol with a two-frequency fail criteria versus a protocol with a one-frequency fail criterion for screening in a resource-constrained setting?*
- 3) What is the prevalence and characteristics of hearing and vision loss among preschool children (4 to 7 years) in an underserved South African community after the implementation of mHealth-supported community-based hearing and vision services?*

2 METHOD

2.1 RESEARCH OBJECTIVES AND STUDY DESIGN

The main aim of this project was to describe and evaluate an implemented community-based service-delivery model for hearing and vision screening (combined sensory screening) for preschool children by trained CHWs using mHealth technology. To achieve this aim, the research project was divided into three research objectives, each constituting a research study that was submitted as an article to an accredited, peer-reviewed journal upon completion. These three studies are summarised below according to titles, objectives and research design.

2.1.1 STUDY I: Hearing and vision screening for preschool children using mobile technology, South Africa.

Research objectives

To describe a community-based service-delivery model and evaluate its implementation success in terms of acceptability (consent return numbers), coverage (number of eligible children screened), quality indicators (duration of tests and number of hearing tests conducted under conditions of excessive noise levels), community-based second-screening attendances, diagnostic centre referral attendances and challenges and mitigation strategies.

Study design

A cross-sectional design for descriptive research using quantitative data was applied to describe acceptability, coverage, quality indicators and attendance rates of a screening programme.

2.1.2 STUDY II: Referral criteria for preschool hearing screening in resource-constrained settings: a retrospective comparison of protocols

Research objectives

To describe and compare two screening protocols utilised for mHealth-supported community-based preschool hearing screening in terms of referral rate, true positive rate and duration.

Study design

This study followed retrospective descriptive and comparative research designs using quantitative data to compare the field performance of a screening protocol with a two-frequency fail referral criterion to the performance of a screening protocol with a one-frequency fail referral criterion.

2.1.3 STUDY III: Community-based identification of hearing and vision loss in preschool children from low-income South African communities.

Research objectives

To describe the prevalence and characteristics of hearing and vision loss among preschool children (4 to 7 years) in an underserved South African community following the implementation of mHealth-supported community-based hearing and vision services.

Study design

This study followed a retrospective descriptive cross-sectional design using quantitative data to describe hearing and vision loss among preschool children.

2.2 ETHICAL CONSIDERATIONS

Ethical considerations were addressed to protect the rights and welfare of the participants involved in the study (Leedy & Ormrod, 2014). Prospective ethical clearance was obtained from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria, on 4 April 2017 by Prof. De Wet Swanepoel for the overarching screening project (Appendix A). In July 2019, the screening project was extended, and an addendum was submitted and approved by the Ethics Committee to continue until June 2021 (Appendix B). The researcher obtained ethical clearance from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria, on 31 October 2019 to retrospectively review a subset of the data that were

collected from July 2017 until September 2019, as part of the screening project (Appendix C).

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, 2014). For all three studies, each participant that underwent screening and follow-up diagnostic assessment was provided with a coded number to ensure that the participants were de-identified.

Protection from harm

There were no medical risks or discomforts associated with this study.

Permission

An ECD agreement, stipulating the services that will be provided and requesting permission for hearing and vision screening to be conducted on children attending the preschool, was provided to the principal of each preschool (Appendix D).

Informed consent

Informed consent is an important ethical consideration and was obtained from all participants prior to hearing and vision screening (Appendices E and F). To request permission for participation, an informed consent letter with a simplified explanation of the process of screening and the research component was provided to the parents or caregivers of the children who met the criteria of the screening project (Appendices E and F). Seeing that the informed consent letter was simplified (Appendix E), parents or caregivers requiring more information had the option to send a free text message to the CHW, who would then phone the parent or caregiver and read them a detailed script of informed consent (Appendix F). Before being screened, assent was obtained from the children by introducing the tester and explaining the procedure in age-appropriate language. The script for assent (Appendix G) was translated into English, Xhosa and Afrikaans.

Screening and 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 were able to withdraw from the study at any time.

Release of findings

Results are made available in the format of a doctoral thesis, a feedback report to the funder of the project (Hear the World Foundation) and scientific articles submitted to accredited, peer-reviewed journals. The study was conducted to provide guidelines for future scaled implementation, and results were and will be presented at conferences.

Storage of data

Data will be stored electronically for a minimum of 15 years at the University of Pretoria. De-identified data for each study have been deposited into a data repository and are publicly available (Appendix H).

2.3 RESEARCH CONTEXT

A combined sensory screening programme at ECD centres and preschools (henceforth referred to as “preschools”) in the townships of Khayelitsha and Mitchells Plain in the Western Cape province, South Africa, has been implemented since July 2017. ECD centres comprise mostly informal day care centres for preschool children in low-income communities in South Africa (Statistics South Africa, 2017). The joint population of Khayelitsha and Mitchells Plain was estimated as 702,234 in 2011, including 61,094 children aged 5 to 9 years (Statistics South Africa, 2011). The vast majority are not native English speakers (Statistics South Africa, 2011). Ninety-seven per cent (181,145 from 186,803) of households within the study area are classified as low- and middle-income, with 15.7% (294,08 from 186,803) having no income (Statistics South Africa, 2011).

2.4 RESEARCH PARTICIPANTS

All preschools in the areas of Khayelitsha and Mitchells Plain in the Western Cape, South Africa, were located and provided with the option of participating in the

screening project and research. At the preschools that agreed to participate, all children aged 4 to 7 years were given parental consent forms to be signed in order for them to be screened and included in the research. The children who returned signed parental consent forms were screened.

Purposive sampling was used for all three studies, and the sample sizes of the subsets of data that were analysed per study were as follows:

Study I: Sample size

Between 1 September 2017 and 31 December 2018, 8,023 preschool children (4 to 7 years of age) were screened.

Study II: Sample size

The sample in study II comprised 7,929 preschool children (4 to 7 years of age). Of these, 2,147 were screened between 1 October 2017 and 25 February 2018, using a protocol with a single-frequency fail criterion, and 5,782 children were screened between 26 February and 30 November 2018, using a protocol with a two- or more frequency fail criteria.

Study III: Sample size

Between 1 September 2017 and 30 June 2019, 10,390 preschool children (4 to 7 years of age) were screened.

2.5 RESEARCH MATERIAL AND APPARATUS

The following equipment was used during the screening project:

Data management software

mHealth Studio (hearX Group, South Africa) is an electronic health record synchronised between cloud and mobile versions that host point-of-care hearing and vision screening apps and associated data. The facility-mapping feature of the mobile platform was used to locate and map preschools (facility name, geolocation and

contact person). Data collected by the smartphone were uploaded through cellular networks at the end of each test (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014). mHealth app and server security were ensured through the use of local data encryption at rest using AES-256bit. Authentication with the server was secured via token authentication and use of SSL connections.

Smartphone hearing screening application

The hearScreen™ application (hearX Group, South Africa) was operated on a Samsung A3 smartphone (Android OS, v8.0) connected to supra-aural Sennheiser HD280 headphones (Sennheiser, Wedemark, Germany), calibrated according to prescribed standards adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-1. Calibration was performed using an IEC 60318-1&2 G.R.A.S. ear stimulator connected to a Type 1 SLM (Rion NL-52). This app utilises automated test sequences with pre-specified screening protocols for interpretation of results (subsection 2.6). The app has been validated to monitor environmental noise with the smartphone microphone (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018) and provides real-time feedback for CHWs on compliance to maximum permissible ambient noise levels (MPANLs), and allows remote asynchronous interpretation of test reliability by professionals. As part of a screener quality control feature, the screening mode included a randomised non-presentation instance, which meant that at one of the presentations no sound is generated. If the CHW indicated that there was a response present, it was logged against their profile, providing a quality index score for every CHW (Yousuf Hussein, Swanepoel, Biagio de Jager, et al., 2018). Data collected by the app were automatically uploaded through cellular networks at the end of each test to the cloud-based data management system (mHealth Studio, hearX Group, South Africa). Findings from a previous study that investigated community-based hearing screening for young children indicated increased reliability for children of 4 years and older using the testing method supported by the equipment (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018).

Smartphone visual acuity screening application

The Peek Acuity application (Peek Vision, UK) was used to screen visual acuity on the same Samsung A3 smartphone (Android OS, v8.0). This test follows the standard Early Treatment Diabetic Retinopathy Study (ETDRS) chart design, using a Tumbling E optotype, and is capable of acuity measurements consistent with test–retest variability of acuities measured using 5-letters-per-line retro-illuminated LogMAR (logarithm of minimum angle of resolution) charts (Bastawrous et al., 2015). After each test, data collected by the app were automatically uploaded to the cloud-based data management system (mHealth Studio, hearX Group, South Africa) through cellular networks.

Smartphone hearing test application

Air conduction threshold-searching audiometry was conducted using the validated hearTest app (Van Tonder et al., 2017) and the same Samsung A3 smartphone (Android OS, v8.0), connected to supra-aural Sennheiser HD280 headphones (Sennheiser, Wedemark, Germany). The equipment has been calibrated according to prescribed standards (ISO 389–1). The app is calibrated to monitor environmental noise with the smartphone microphone (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). A warning was given when environmental noise exceeded MPANLs, and the test could then be paused until the noise levels were within an acceptable range. Automated audiometry with pre-specified protocols consisted of air conduction testing at 0.5–8.0 kHz (subsection 2.6). The threshold determination sequence follows the threshold ascending method as specified in ISO 82531:1.5. Data collected by the app were automatically uploaded to the cloud-based data management system (mHealth Studio, hearX Group, South Africa) through cellular networks at the end of each test.

Otoscope

An otoscope (Heine Mini) with reusable specula was used to determine the condition of the external ear canal and tympanic membrane during the first-line follow-up. Otoscopic findings were recorded as notes on the hearTest app and automatically uploaded to mHealth Studio through cellular networks.

2.6 DATA COLLECTION PROCEDURES

An mHealth-supported screening programme was implemented in underserved communities in Cape Town, South Africa, from July 2017 until June 2019. Four non-professionals (CHWs) were appointed for this programme and trained to screen the hearing and vision of preschool children at their preschools in the community, using mHealth technology (subsection 2.5). Data collected during the screening programme were processed and analysed to achieve the stated study aims (subsections 2.7 and 2.8). The CHWs and the project manager were employed by the Carel du Toit Centre through funding from the Hear the World Foundation. The Carel du Toit Centre is situated in Parow, Cape Town, and offers an early intervention programme in addition to a pre-primary and foundation phase listening and spoken language environment for children with hearing impairment. The centre has a long-standing history of community-based screening and hearing healthcare initiatives that facilitated receptiveness in the community regarding diagnostic services and the credibility of the institution providing the services (De Kock et al., 2016; Friderichs et al., 2012). Hear the World Foundation is a corporate non-profit organisation founded by Sonova that works towards equal opportunities and better quality of life for people with hearing loss (www.hear-the-world.com).

The combined sensory screening project operated in two phases, namely the preparation and pilot phase (July and August 2017) and the implementation phase (September 2017 until June 2019). The service-delivery model for this combined sensory screening programme will be described in this section.

2.6.1 Personnel

Four non-professionals from the community were recruited, appointed and trained as CHWs to conduct the combined sensory screening. Advertisements were placed on noticeboards in the community, and interviews were conducted with candidates. The four CHWs (one project administrator and three screeners) were appointed on contract basis for the duration of the programme and were paid a monthly salary. The CHW who was appointed as both project administrator and screener had added responsibilities in her job description (including liaising with preschool principals and

referral hospitals and clinics; administrative tasks such as report compilation and record keeping/statistics; reminding parents of children who were referred to diagnostic services of appointments and management of the three screeners in the field). Based on the job description of the project administrator/screener, the CHW fulfilling that position was appointed on a higher salary scale. The CHWs were categorised as level one CHWs, based on their education and pre-service training, which consisted of some form of secondary education and subsequent informal training (Olaniran et al., 2017). The CHWs were from the community and had a deep understanding of the cultural beliefs and biases regarding health services and sensory impairments. None of them had previous formal training on hearing or vision healthcare.

The initial training of the CHWs was carried out over five days. Training included theoretical education about hearing and vision and the screening process, observation of screening in the field and practical training on using the equipment and assessing a child's responses. CHWs then performed screening under supervision. Weekly meetings were held where the CHWs met with an audiologist who acted as the project manager. This allowed for need-based training by providing an opportunity to address questions from the CHWs and for the audiologist to make observations when receiving feedback on the activities of that week.

2.6.2 Preparation and pilot phase

During this phase, a situational analysis of the potential pathways for referral of candidates requiring eye and hearing care was conducted, and follow-up pathways were established. The programme and outcomes of a pilot project in Gauteng were assessed to inform the combined hearing and vision service-delivery model (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). Protocols, referral pathways and a simplified consent form were pilot tested and finalised. Partnerships were formed with local non-profit organisations (NPOs) supporting ECD centres and preschools in the community. The preschool principals' forums were used as a platform to introduce the screening programme. Information leaflets about the services provided were issued to the principals and preschool staff. CHWs were recruited, interviewed, appointed and

trained. Prospective ethical clearance was obtained from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria, on 4 April 2017 by Prof. De Wet Swanepoel for the scope of the combined sensory screening project (Appendix A).

2.6.3 Screening procedure

During the implementation phase, preschools were located and a signed agreement was established with each principal. CHWs also distributed posters and shared information with preschool staff about hearing and vision health, the importance of hearing and vision for learning, risk factors and signs of sensory loss and what to do if sensory loss is suspected. Consent forms were distributed to all children of 4 to 7 years of age. Hearing and vision screening of all children who returned their consent forms were done by the CHWs at the preschool using mHealth technology (Fig. 2.1 and Fig. 2.2). The CHWs instructed the group of participants, in their native language, to raise their hands when they heard a sound. The action of raising their hands when a sound was heard was practised in the group. For the vision screening, children were instructed to indicate the direction in which the horizontal lines of the Tumbling Es pointed. This instruction was explained by showing a large poster of the Tumbling E and demonstrating the required action. This was also practised in the group. Afterwards the CHW would screen each child individually. The CHWs selected the facility on the mHealth application and entered the details of the participant. Hearing screening was done first and vision screening thereafter (Fig 2.1 and Fig 2.2).

For hearing screening, the predetermined protocol was selected on the hearScreen application. Screening was conducted in the quietest area possible at the preschool. The CHW, sitting behind the participant, played a conditioning tone at 40 dB hearing level (HL) at 1000 Hz in the left ear, which was the automated first step of the screening process. The conditioning feature of the application allowed the CHW to increase the intensity and to switch at which ear the tone would be heard. Once the CHW felt confident that the participant understood the instructions, the screening test was initiated (Fig 2.1). Ambient noise was monitored continuously throughout testing at each frequency. MPANLs specify the maximum ambient noise level allowed in a testing room to ensure that thresholds obtained are not elevated. If the ambient noise

exceeded MPANLs at any frequency, a warning was displayed on the app, and the CHW could then move to a quieter space or reduce background noise before continuing the test. Noise levels were automatically recorded, and testing was completed even if noise levels could not be reduced adequately (Van Wyk et al., 2019). A sweep test was performed at the intensity level of 25 dB HL at 1, 2 and 4 kHz, in that order. Left ears were tested first. The CHW could indicate on the smartphone screen whether a sound was heard or not. In case a sound was not heard, the automated protocol presented the sound again to confirm a no-response. If the child heard the sound, the automated protocol would confirm the response. If a screening test was failed, an immediate rescreen was done for the frequencies that were failed (Fig 2.1). Once the test was complete, the app immediately calculated and displayed both the overall pass or fail result and the results for each frequency. The protocol used from September 2017 until February 2018 specified that children who failed to respond correctly to a single frequency across both ears at 25 dB HL at 1, 2 and 4 kHz failed the screening. From February 2018 onwards, a new protocol specified that children who failed to respond correctly to two frequencies across both ears failed the screening. The final screening result was automatically uploaded to a cloud-based server via a mobile network for data management. Results were communicated directly via text messages to the parents or caregivers of participants. In cases where no contact numbers were available, the parents had access to the project administrator's number and could send a free "Please Call Me" text to be telephonically contacted with the results.

Immediately after the hearing screening, the CHW conducted a visual acuity screening using the peekAcuity app on the same child (Fig 2.2). For the vision screening, the CHWs had to stand a measured 2 m in front of the child with the screen of the smartphone facing the child. The child was reinstructed to show in what direction the Tumbling E pointed. Blind to what the correct response was, the CHW would swipe the screen in the direction as indicated by the child. The automated protocol, as determined by the peekAcuity app, would increase or decrease the size of the Tumbling E based on the response of the child. At the end of the test, the phone would vibrate to indicate that the test was completed. Once the test was completed, the app immediately calculated and displayed the results for each eye. An immediate rescreening was done if a child failed the first screening test (Fig. 2.2). Children with

a visual acuity of less than 0.3 LogMAR in both eyes or less than 0.4 LogMAR in one eye, regardless of acuity in the other eye, failed the visual acuity screening. Both the initial screening result and the rescreen result were automatically uploaded to a cloud-based server via a mobile network for data management. Results were communicated via text messages to the parents or caregivers of participants. Children who still failed the vision screening after the rescreen were placed on a list for diagnostic optometric evaluation appointments at primary healthcare facilities (Fig. 2.2). Parents were informed about the appointment with a letter and reminded by a phone call before the day of the diagnostic evaluation.

If the overall hearing screening was failed, the participant was seen by an audiologist for a first-line follow-up at the child's preschool a week or two weeks later, depending on the availability of the audiologist (Fig 2.1). Follow-up testing included otoscopy and automated air conduction threshold pure tone audiometry at 0.5–8.0 kHz, starting at an intensity level of 40 dB HL up to a minimum response level, using the hearTest application to determine the degree and configuration of hearing loss. A threshold was determined by the minimum intensity at which the participant reliably responded twice. The results of the air conduction audiometry, in conjunction with otoscopy, were used to identify cases for referral to a public healthcare facility for diagnostic testing and intervention (Fig 2.1). Criteria constituting hearing loss was a pure tone average (500–4000 Hz) of 25 dB HL or more in the better ear. Parents were informed about the referral and appointment at the public healthcare clinic with a letter and reminded by a phone call before the day of the diagnostic evaluation. Children who were difficult to condition, and therefore not tested successfully at first-line follow-up, were also referred to a public health audiology clinic for further testing.

If sensory loss was identified during the diagnostic evaluation, the child was absorbed into the healthcare system and further follow-up services and intervention were provided by public health services, for example hearing aid fittings, issuing of spectacles or medical intervention (Fig. 2.1 and Fig. 2.2). Feedback was provided to the project manager, who recorded results and tracked outcomes on a diagnostic audiological evaluation data sheet and a vision evaluation data sheet (Fig 2.1 and Fig 2.2).

Weekly meetings were held by the project manager (an audiologist) with all the CHWs. During these meetings, feedback from the field was given, challenges encountered were discussed and mitigation strategies were developed, and planning and preparation for the next week were done. Minutes were taken of these meetings and an inventory was kept of all the costs and challenges encountered.

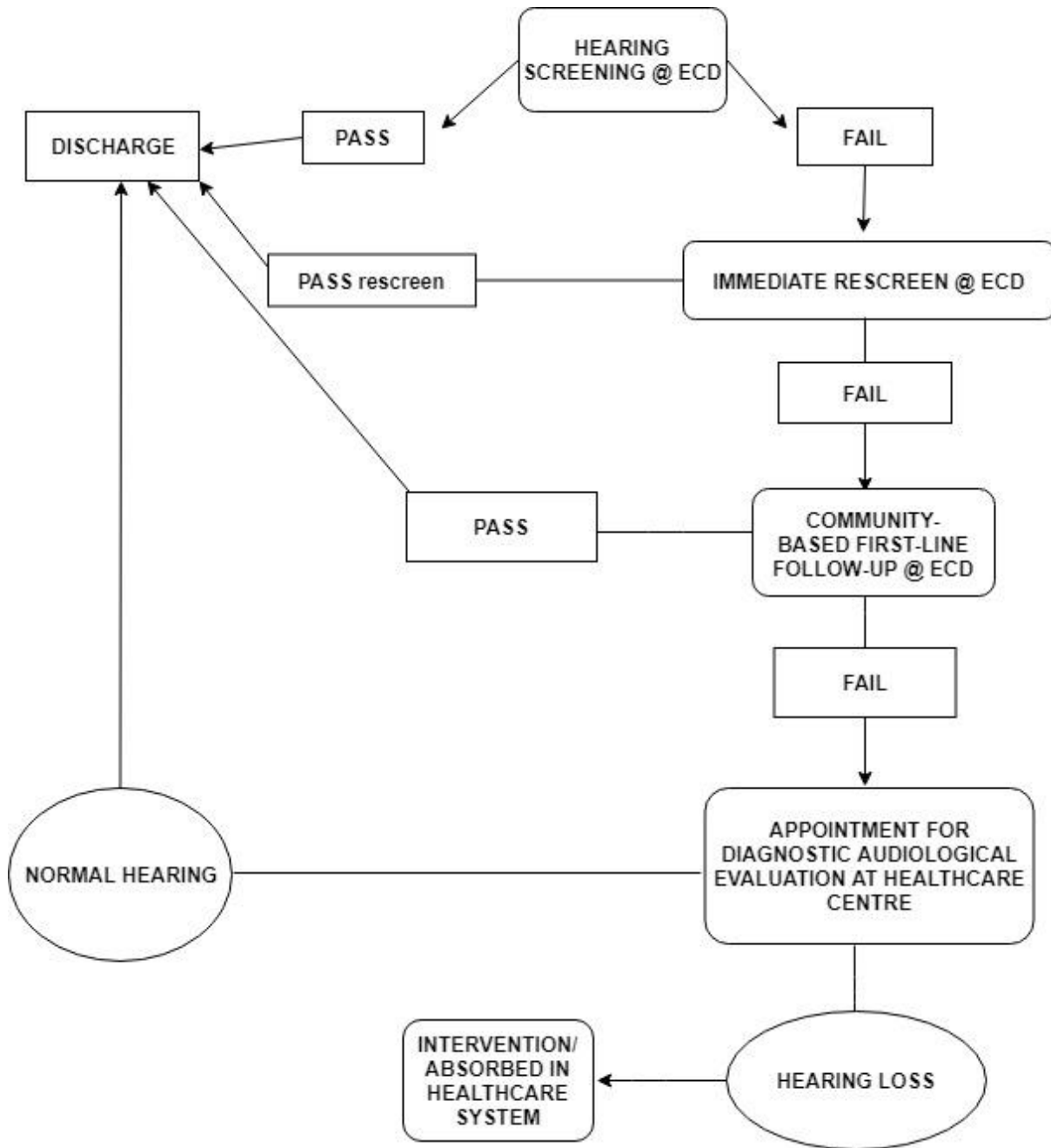


Figure 2.1 Community-based hearing screening service-delivery model

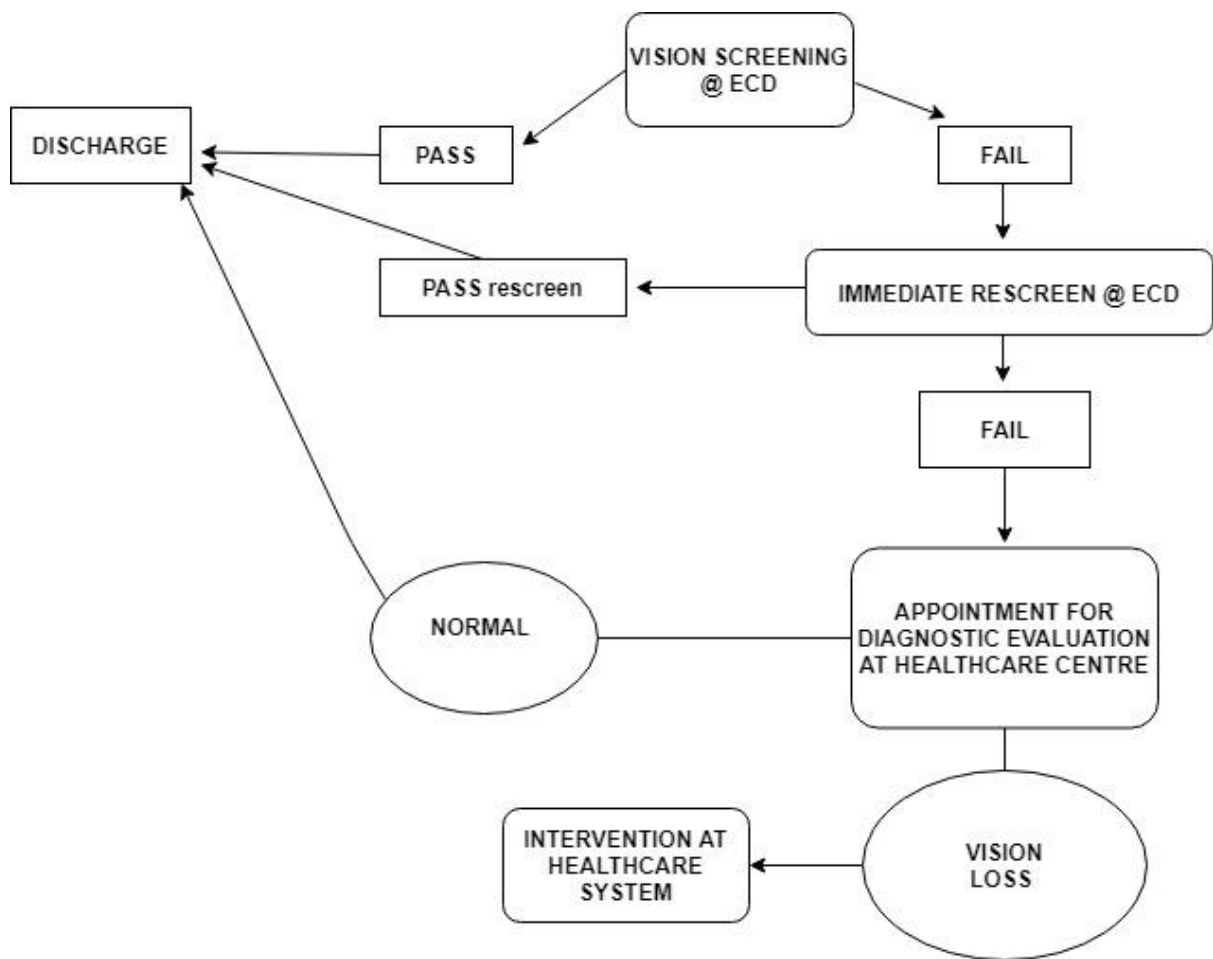


Figure 2.2 Community-based vision screening service-delivery model

2.7 DATA PROCESSING

Subsets of the data collected during the screening programme (as described in subsection 2.5 and 2.6) were reviewed to investigate Studies I–III.

Exported mHealth Studio data on MS Excel sheet

Data were extracted from the secure cloud-based server (mHealth Studio) to a Microsoft (MS) Excel (2011) sheet by the implementation partner. Data were de-identified and a data sheet with the following information was compiled: gender, age, facility where screening occurred, duration of screening tests, screening test results and noise measurements. It also contained first-line follow-up test results, thresholds, noise measurements and otoscopic findings. Data were processed, categorised and coded (e.g. otoscopic findings were classified and coded as either “no signs of external or middle ear abnormalities” or “obvious signs of external or middle ear abnormalities”) to allow data analysis.

Field notes from the implementation partner

De-identified field notes recorded by screeners, audiologists and the project manager, containing information about weekly meetings, financial reports, referrals made, feedback from referral pathways and outcomes, were reviewed retrospectively. This included a diagnostic audiometry data sheet recorded on MS Excel, containing data about attendance, otoscopic and tympanometric findings and behavioural pure tone audiometry results. The attendance of and results of diagnostic optometry appointments were recorded on a vision evaluation data sheet.

2.8 DATA ANALYSIS

A subset of the data that were collected for the scope of the combined sensory screening programme was processed and analysed to achieve objectives for Studies I–III.

Extracted data, in addition to data obtained through field notes, were placed on a MS Excel (2011) sheet for statistical analysis using Statistical Package for Social Sciences (SPSS version 26). To answer the three proposed research objectives, descriptive and inferential statistical measures were employed to describe and synthesise the quantitative data collected. All analysed data were clearly presented in the form of tables or figures.

The procedures for data analysis, as per each of the three studies, are described below:

Study I data analysis

Descriptive statistics were employed to describe the coverage rate (how many eligible participants were screened), noise levels, test times, fail rates, second-screen rates and follow-up return rates after referral to diagnostic centres. Two regression models were constructed to investigate the influence of categorical and continuous predictors on screening outcome. The dependent variable, which is dichotomous, was hearing screening outcome (model 1) and vision screening outcome (model 2). The continuous independent variables were age and test duration (and for model 1, noise levels at each frequency that exceeded permissible levels) and the categorical independent variable was gender. A p -value cut-off was set at 0.05 and indicated the level of significance throughout this study.

Study II data analysis

Descriptive statistics were used to describe the two protocols in terms of sample gender and age, screening duration, referral rate and true positive rate. Descriptive statistics were used to determine the incidence of exceeded MPANLs during screening. The Shapiro-Wilk test was used to test for normality (Field, 2018). Not all variables were normally distributed, and, therefore, nonparametric tests were used. A p -value cut-off was set at 0.05 and indicated the level of significance throughout this study. The two-proportions z -test was used to compare referral rate, true positive rate and false positive rate between the two protocols. Two multivariate logistic models were built. The dependent variable, which is dichotomous, was screen result (model 1) and final result (after a follow-up hearing test; model 2). The covariate (continuous

independent variable) was age and the factors (categorical independent variables) were gender (females benchmarked against males) and protocol (adapted protocol benchmarked against the conventional protocol). A multiple linear regression model was used to estimate the association between test duration and protocol, age and gender.

Study III data analysis

Descriptive statistics were utilised to define prevalence of and characteristics of hearing loss and vision loss in the study population. Two logistic regression models were built to estimate the association between the presence of sensory loss and gender and age. The dependent variable, which is dichotomous, was hearing loss (model 1) and vision loss (model 2). The continuous independent variable was age and the categorical independent variable was gender. A p -value cut-off was set at 0.05 and indicated the level of significance throughout this study.

3 HEARING AND VISION SCREENING FOR PRESCHOOL CHILDREN USING MOBILE TECHNOLOGY, SOUTH AFRICA

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3.1 ABSTRACT

Objective: To implement and evaluate a community-based hearing and vision screening programme for preschool children in the Western Cape, South Africa, supported by mobile health technology (mHealth) and delivered by community health workers (CHWs).

Methods: We trained four CHWs to provide dual sensory screening in preschool centres of Khayelitsha and Mitchells Plain during September 2017–December 2018. CHWs screened children aged 4–7 years using mHealth software applications on smartphones. We used logistic regression analysis to evaluate the association between screening results and age, sex and test duration, and, for hearing, excessive background noise levels.

Results: CHWs screened 94.4% (8023/10 362) of eligible children at 271 centres at a cost of 5.63 United States dollars per child. The number of children who failed an initial hearing and visual test was 435 (5.4%) and 170 (2.1%), respectively. Hearing test failure was associated with longer test times (odds ratio, OR: 1.022; 95% confidence interval, CI: 1.021–1.024) and excessive background noise levels at 1 kilohertz (kHz) (e.g. OR for left ear: 1.688; 95% CI: 1.198–2.377). Visual screening failure was associated with longer test duration (OR: 1.003; 95% CI: 1.002–1.005) and younger age (OR: 0.629; 95% CI: 0.520–0.761). Of the total screened, 111 (1.4%) children were diagnosed with a hearing and/or visual impairment.

Conclusion: mHealth-supported CHW-delivered hearing and vision screening in preschool centres provided a low-cost, acceptable and accessible service, contributing to lower referral numbers to resource-constrained public health institutions.

3.2 INTRODUCTION

Sensory inputs of hearing and vision during early childhood development support the achievement of optimal language, speech and educational outcomes (Stewart-Brown & Haslum, 1988; Wilson et al., 2017). Early detection of sensory impairments is essential for facilitating early childhood development, socioemotional well-being and academic success, (Mathers et al., 2001; Muse et al., 2013; Stewart-Brown & Haslum, 1988; Wilson et al., 2017) as well as the sustainable development goals related to education (Sustainable development goals report, 2018).

Hearing and vision impairments are the most common global developmental disabilities in children younger than 5 years, affecting 15.5 and 25.2 million, respectively, 95% of whom live in low- and middle-income countries (Bastawrous et al., 2015; GRDDC, 2018; Stevens et al., 2011b). Services are usually unavailable or inaccessible in these countries because of an absence of systematic screening programmes for children, prohibitive equipment cost and a shortage of trained personnel (Harris & Dodson, 2017; Mulwafu et al., 2017; Wilson et al., 2017; WHO, 2012). An awareness and knowledge of sensory impairments, their potential impact on a child's development and potential rehabilitative solutions are also poor among

early childhood practitioners in underprivileged communities (Yousuf Hussein, Swanepoel, Biagio de Jager, et al., 2018).

The evidence base on the value of community-based programmes incorporating mobile health technology (mHealth) for hearing and vision loss is growing (Rono et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein et al., 2015). Community health workers (CHWs) (Olaniran et al., 2017) play an important role in improving access to hearing services, including in screening and raising community awareness (O'Donovan et al., 2019; Yousuf Hussein et al., 2015). mHealth has been recognized as increasingly important in supporting the achievement of the sustainable development goals (Novillo-Ortiz et al., 2018) and addressing access and affordability in underserved populations (Bastawrous et al., 2015; Swanepoel, 2017); it also has the potential to improve health system efficiency, quality of preventative care and health outcomes (Agarwal et al., 2016; Zhenwei Qiang et al., 2011). Validated smartphone applications (apps), including automated tests for hearing and vision screening, pre-specified screening protocols for result interpretation, cloud-based data management for surveillance of programme performance and geolocation-based referral, allow CHWs to undertake decentralized screening and identify cases for referral (Bastawrous et al., 2015; Mahomed-Asmail et al., 2016; Rono et al., 2018; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein et al., 2015). CHWs have reported such apps as user-friendly and efficient (Bastawrous et al., 2015; Yousuf Hussein, Swanepoel, Biagio de Jager, et al., 2018; UNESCO, 2017).

The feasibility of community-based services facilitated by CHWs and supported by mHealth for hearing screening in homes and in early childhood development centres (informal day care centres for preschool children) in Gauteng, South Africa, has already been assessed (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein et al., 2015). A model based on preschool centres is particularly relevant for low- and middle-income countries, where systematic newborn hearing screening is unavailable (Olusanya et al., 2004) and school-entry screening is potentially the first point of access to services.

Continuing from these feasibility studies, we implemented an mHealth-supported screening programme in which children's hearing and vision services were provided by CHWs in preschool centres. We describe this community-based service-delivery model and evaluate its success in terms of acceptability (consent return numbers), coverage (number of eligible children screened), quality indicators (duration of tests and number of hearing tests conducted under conditions of excessive noise levels), community-based second screening attendances and diagnostic centre referral attendances. We also discuss the challenges met during this implementation and the strategies developed to overcome these.

3.3 METHODS

3.3.1 Study setting and preparation

We implemented our screening programme within the preschool centres of the partially informal townships of Khayelitsha and Mitchells Plain of the Western Cape province, South Africa, during September 2017 to December 2018 (Statistics South Africa, 2017). The joint population of Khayelitsha and Mitchells Plain was estimated as 702 234 in 2011, including 61 094 children aged 5–9 years (Statistics South Africa, 2011). Most are not native English speakers (Statistics South Africa, 2011). The majority (97.0%; 181145/186803) of households within the study area are classified as low- and middle-income, with 15.7% (29408/186803) having no income (Statistics South Africa, 2011).

Before implementation, we conducted a situational analysis of the potential referral routes to hearing and vision services and established follow-up pathways. We tested and finalized a simplified one-page consent form and screening protocols. We formed partnerships with local non-profit organizations supporting the preschool centres in the community and introduced the screening programme via the quarterly symposiums of preschool centre principals.

3.3.2 Appointment of CHWs

We appointed four CHWs to conduct the combined sensory screening across all preschool centres within the study area. We placed an advertisement on notice boards within the community and conducted interviews with candidates. The four CHWs (one project administrator/screener and three screeners) were appointed on a contract basis for the duration of the programme and were paid a monthly salary. Members of the community themselves, these CHWs had a deep understanding of relevant cultural beliefs and biases regarding health services and sensory impairments. None of the CHWs had received any formal training on hearing or vision health care previously.

The audiologist managing the project delivered a 5-day training course to the CHWs on hearing and vision theory, the screening process, observation of screening in the field, practical training on using the equipment and assessment of a child's responses. The course was held at the Carel du Toit Centre, Cape Town, South Africa, the site of the project implementation partner and employer of the audiologist. The course delivery costs were included in the project management fee. CHWs performed initial screening under supervision. The project manager chaired weekly meetings at the Carel du Toit Centre with the CHWs, allowing for further training based on any queries.

3.3.3 Implementation

We mapped all preschool centres (facility name, geolocation and contact person) within the study area using the facility-mapping feature of the mobile platform and invited principals to sign a participation agreement. Within the participating centres, the parents of attending children (4–7 years) indicated their agreement to be included in the study by returning a signed consent form. To increase accessibility, we provided the parent or caregiver with the option to complete the form either in English or in their native language. CHWs distributed posters and leaflets within the preschool centres, emphasized the importance of hearing for learning to centre staff and shared information on the risk factors and signs of hearing loss.

Using mHealth, CHWs performed hearing and vision screening of all children who returned signed consent forms at their respective preschool centres during the 265 screening days held over the 16-month period. The amount of time spent on screening at a particular preschool centre depended upon its size. At any one centre, screening

was usually available for some portion of a single day up to a maximum of 2 days at a date agreed in advance with the preschool principal. CHWs performed an immediate rescreen if a child failed the first screening test. Screening results were automatically sent to the child's parent or caregiver via text message through the mHealth cloud platform. In the case of no available contact number, parents had access to the project administrator's number and could send a free text to the project administrator, requesting a telephone call with the results.

Children who failed the initial hearing screening (at 25 decibel [dB] hearing level at 1, 2 and 4 kilohertz [kHz]) and rescreening (at 25 dB hearing level at the frequencies at which the child failed the initial test) received a community-based second screening (at 0.5–8 kHz) 1 week later at their preschool, including otoscopy. The project audiologist conducted this second screening, enabling the CHWs to continue with their schedule of initial screenings. Children who failed this second screening were referred to public health diagnostic audiology services. Children who failed the initial vision screening and rescreening (a visual acuity of less than 0.3 LogMAR (logarithm of minimum angle of resolution) in both eyes, or less than 0.4 LogMAR in one eye regardless of acuity in the other eye) were referred to primary health care facilities for a diagnostic optometric evaluation.

Parents were informed about their child's referral by letter and reminded by telephone the day before the diagnostic evaluation. All follow-up services and interventions were provided by public health services, for example, hearing aids, spectacles or other medical intervention. CHWs kept a record of all costs incurred and challenges encountered and provided feedback to the project manager who tracked results and outcomes.

3.3.4 Technology

The mHealth technology platform (hearX Group, Pretoria, South Africa) synchronizes patient results between the cloud and the smartphone software. The smartphones host point-of-care hearing and vision screening apps. We used the mHealth evidence reporting and assessment checklist to review and report on our mHealth-supported programme (Agarwal et al., 2016).

CHWs used the hearScreen app (hearX Group) on a Samsung A3 smartphone with the operating system Android version 8.0 (Google, Mountain View, United States of America), connected to supra-aural Sennheiser HD280 headphones (Sennheiser, Wedemark, Germany) that had been calibrated according to prescribed standards (International Organization for Standardization, ISO 389–1). We calibrated the app to monitor environmental noise with the smartphone microphone (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). Children who failed the initial screen and immediate rescreen were referred to a second screening, at which children were tested via the validated hearTest app (van Tonder et al., 2017) for threshold testing on the same device across a wider range of frequencies (0.5–8 kHz).

The publicly available Peek Acuity application (Peek Vision, London, United Kingdom) was used to screen visual acuity on the same smartphone. This test follows the standard Early Treatment Diabetic Retinopathy Study chart design, using a Tumbling E optotype, and is capable of acuity measurements consistent with test–retest variability of acuities measured using 5-letters-perline retro-illuminated LogMAR charts (Bastawrous et al., 2015).

Data collected by the smartphone were uploaded to the cloud storage through mobile telephone networks at the end of each test (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014). We ensured the security of the mHealth app and server through use of local data encryption at rest using Advanced Encryption Standard 256 bit. We secured authentication with the server via the use of Secure Sockets Layer connections. We ensured that access to smartphone and cloud-based data were protected by user password.

3.3.5 Data collection and analysis

We extracted data from the secure cloud-based server to an Excel (Microsoft, Redmond, USA) spreadsheet for statistical analysis using Statistical Package for the Social Sciences software (IBM, Armonk, USA). Using Excel, we recorded and quantified test outcomes (pass or fail), test durations and the numbers being referred

to and attending second screenings and diagnostic centres. We used logistic regression analysis to evaluate the association between screening outcome and age, sex and test duration for both vision and hearing screening; for hearing, we also evaluated the association between test outcome and excessive noise levels at each frequency. Significance was set at $P < 0.05$.

3.3.6 Ethical considerations

Ethical clearance was obtained from the Research Ethics Committee of the Faculty of Humanities of the University of Pretoria on 4 October 2017 (GW20170922HS).

3.4 RESULTS

The 271 preschool centres participating in our study included a total of 10 362 children. Signed consent forms were returned for 8497 (82.0%) of these children and 8023 (94.4%) of eligible participants were in attendance on screening days to undergo hearing and visual screening (Table 3.1; Fig. 3.1 and Fig. 3.2). One in three (32.3%) parents completed the consent form in their mother tongue as opposed to English. An average of 500 children were screened each month, at a cost of 5.63 United States dollars per child (Table 3.2).

Table 3.1 Children screened for hearing and visual impairment via mHealth-supported community-based programme, South Africa, September 2017–December 2018

| Outcome | Children screened <i>n</i> = 8023 | | |
|--|-----------------------------------|-------------------------|------------------------------------|
| | Hearing impairment | Visual impairment | Both hearing and visual impairment |
| No. (%) who failed initial screening | 2313 (28.8) | 266 (3.3) | 58 (0.7) |
| No. (%) who failed immediate rescreen | 435 (5.4) | 170 (2.1) ^a | 19 (0.2) |
| Of 3972 boys | 205 (5.2) | 84 (2.1) | 10 (0.3) |
| Of 4051 girls | 230 (5.7) | 86 (2.1) | 9 (0.2) |
| Of 1066 children aged 4 years | 55 (5.2) | 40 (3.8) | 4 (0.4) |
| Of 3671 children aged 5 years | 213 (5.8) | 84 (2.3) | 12 (0.3) |
| Of 3286 children aged 6–7 years | 167 (5.1) | 46 (1.4) | 3 (0.1) |
| Mean test duration (SD), sec^b | 66.8 (62.3) | 91.8 (51.9) | 158.6 (85.9) |
| Of those who passed | 59.2 (44.2) | 91.2 (50.2) | 149.3 (69.4) |
| Of those who failed | 200.2 (136.9) | 109.0 (86.6) | 323.9 (172.1) |
| No. (%) of those who failed immediate rescreen and attended community-based second screen | 389 (89.4) | NA | NA |
| No. (%) of those who failed community-based second screen | 124 (31.9) | NA | NA |
| No. (%) of total who received diagnostic referral | 124 (1.5) | 170 (2.1) ^a | 19 (0.2) |
| No. (%) who attended referral | 94 (75.8) | 109 (64.1) ^c | 9 (47.4) |
| No. (%) of total with confirmed diagnosis | 54 (0.7) ^d | 55 (0.7) ^e | 2 (0.02) ^f |

NA: not applicable; SD: standard deviation.

^a This number includes 123 children who failed the immediate rescreen plus 47 children who were erroneously not rescreened.

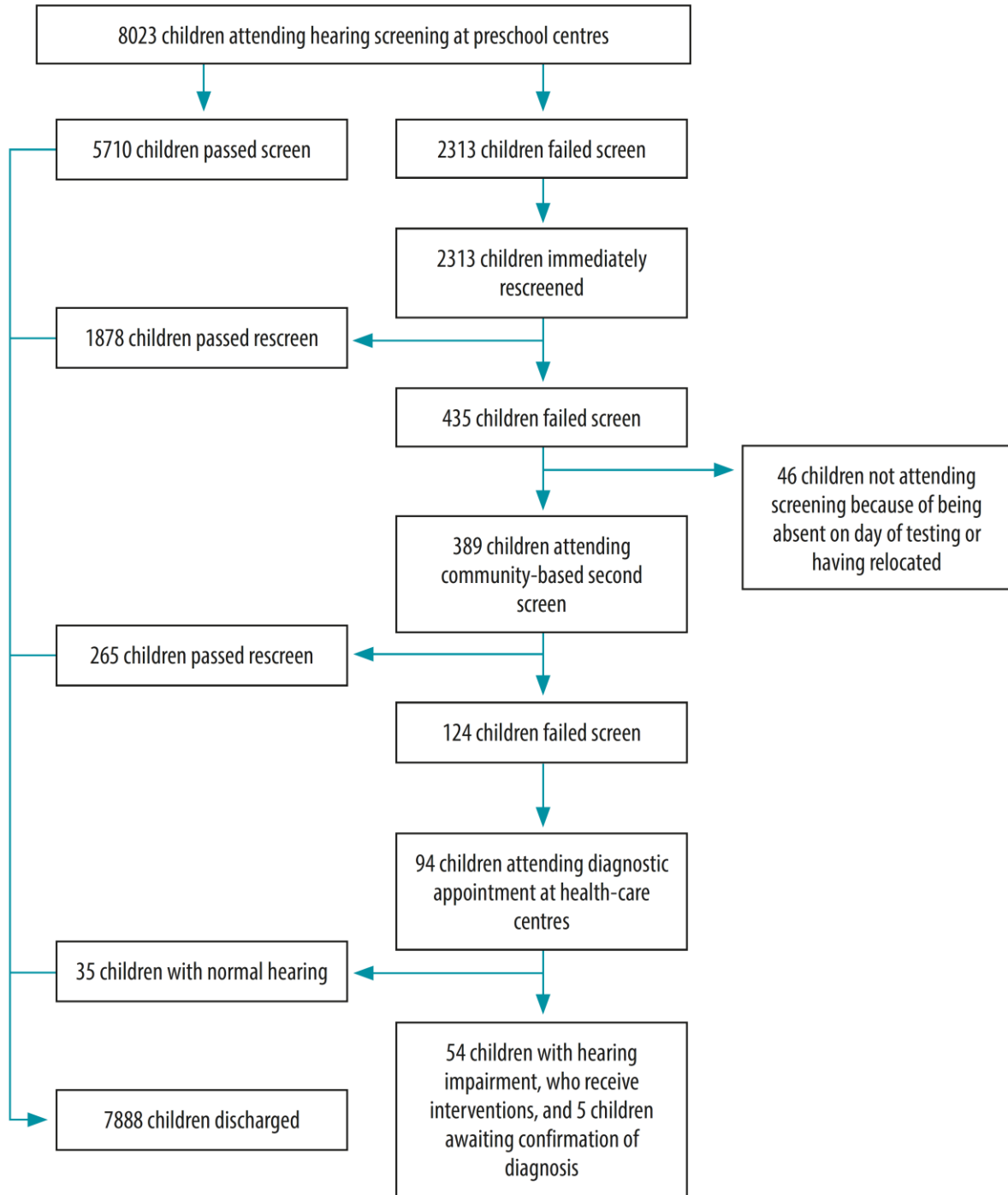
^b Initial screen duration for vision; combined initial and immediate rescreen for hearing.

^c 21 awaiting appointment.

^d 5 awaiting confirmation.

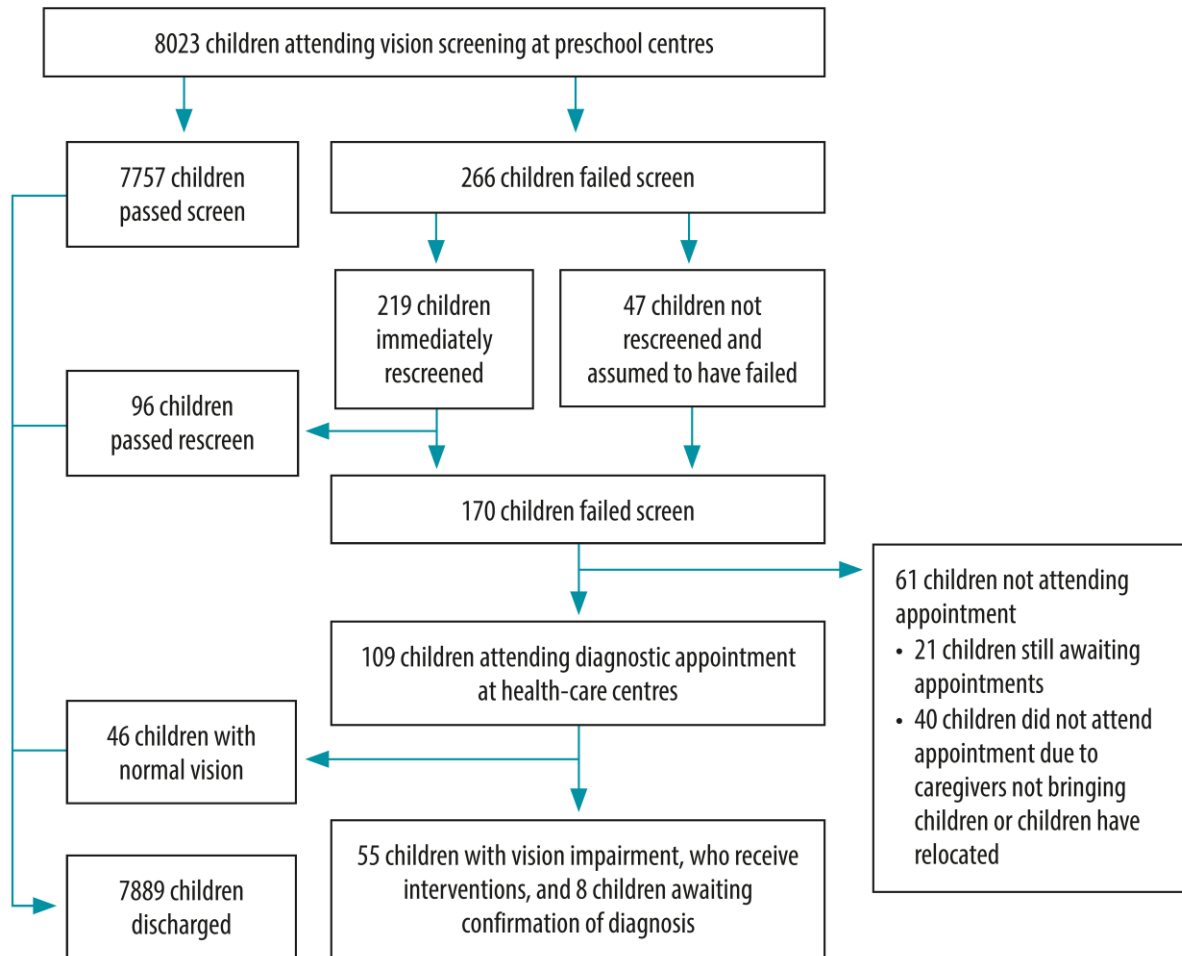
^e 8 awaiting confirmation.

^f 11 awaiting confirmation



mHealth: mobile health technology

Figure 3.1 mHealth-supported community-based screening for hearing impairment, South Africa, September 2017–December 2018



mHealth: mobile health technology

Figure 3.2 mHealth-supported community-based screening for visual impairment, South Africa, September 2017–December 2018

Table 3.2 Cost of screening for hearing and visual impairment via mHealth-supported community-based programme, South Africa, September 2017–December 2018

| Service or goods | US\$ | | |
|--|---------------------------------------|----------------|-----------------------------|
| | Total cost for programme ^a | Cost per month | Cost per child ^b |
| Mobile testing devices (four hardware sets) | 4 163.78 | 260.24 | 0.52 |
| Software (hearScreen, Peek Acuity) | 4 404.80 | 275.30 | 0.55 |
| Device calibration | 499.69 | 31.23 | 0.06 |
| Telecommunication | 1 432.00 | 89.50 | 0.18 |
| Salaries of CHWs (three screeners) | 14 604.16 | 912.76 | 1.82 |
| Salaries of CHW (both project administrator and screener) | 9 759.04 | 609.94 | 1.22 |
| Project management (including delivery of training course to CHWs) | 3 560.32 | 222.52 | 0.44 |
| Travelling (2.77 Rand per km) ^c | 4 243.84 | 265.24 | 0.53 |
| Administration | 1 545.60 | 96.60 | 0.19 |
| Programme resources (stationery, power banks, posters) | 968.80 | 60.55 | 0.12 |
| Total | 45 182.03 | 2823.88 | 5.63 |

CHW: community health worker; US\$: United States dollars.

^a Programme was running over 16 months.

^b Total number of children was 8023.

^c In April 2019, 1 South Africa Rand is equivalent to US\$ 0.069

The number of children who failed the initial screen and rescreen was 435 (5.4%) and 170 (2.1%) for hearing and vision, respectively (Table 3.1). Hearing test failure was associated with longer test duration (odds ratio, OR: 1.022; 95% confidence interval, CI: 1.021–1.024) and noise levels exceeding maximum permissible ambient noise levels at the 1 kHz test frequency (e.g. for left ear, OR: 1.688; 95% CI: 1.198–2.377; Table 3.3), but not with sex (OR: 0.891; 95% CI: 0.702–1.131). CHWs failed to perform an immediate vision rescreen for 47 children and these children were assumed to have failed. Vision test failure was associated with a younger age (OR: 0.629; 95% CI: 0.520–0.761) and longer test duration (OR: 1.003; 95% CI: 1.002–1.005), but not with sex (OR: 0.928; 95% CI: 0.726–1.186). Mean initial test duration for children who passed the screening was 59.2 and 91.2 seconds for hearing and vision, respectively (Table 3.1).

Table 3.3 Maximum permissible ambient noise levels being exceeded at different test frequencies during hearing screening, South Africa, September 2017-December 2018

| Ear | MPANL's exceeded during screening <i>n</i> = 8023 | | | | | |
|-------|---|-------------------------|-----------|-------------------------|----------|---------------------------|
| | 1 kHz | | 2 kHz | | 4 kHz | |
| | No. (%) | OR (95% CI) | No. (%) | OR (95% CI) | No. (%) | OR (95% CI) |
| Left | 2816 (35.1) | 1.688 (1.198– 2.377) | 144 (1.8) | 1.772 (0.510– 6.162) | 80 (1.0) | 0.534 (0.156 – 1.821) |
| Right | 2808 (35.0) | 2.770 (1.931– 3.974) | 128 (1.6) | 1.835 (0.482– 6.988) | 88 (1.1) | 1.790 (0.307 – 10.427) |

CI: confidence interval; kHz: kilohertz; OR: odds ratio; MPANL: maximum permissible ambient noise level.

Of the 389 children who attended a second hearing screening, 124 (31.9%) failed the hearing test again and were referred for a diagnostic evaluation (Table 3.1). Of the 265 children who passed the second hearing screening, the audiologist referred 66 (24.9%) for wax removal at their local clinic. Of the 94 children who attended a diagnostic referral appointment, 54 (43.5%) were diagnosed with a hearing impairment and nine (7.3%) were discharged from audiology, but referred for other developmental interventions; another five children have follow-up appointments to confirm hearing status (Table 3.1).

A total of 55 children were diagnosed with a visual impairment; however, 21 children were still awaiting diagnostic optometry appointments at the time of reporting (Table 3.1). Of the 8023 children screened, 111 (1.4%) were confirmed with either a hearing or visual impairment, or both.

3.5 DISCUSSION

Our mHealth-supported community-based hearing and visual screening programme was successful in several ways. The programme had a low cost of screening per child, high participation numbers, high attendance of those who failed initial screening and immediate rescreening at the community-based second screening and overall low proportion of children receiving a diagnostic referral to a public health institution. The programme encountered several challenges, such as CHW safety, logistics and technology, for which we developed mitigation strategies (Box 3.1).

Box 3.1 Challenges and mitigating strategies of mHealth-supported community-based programme, South Africa, September 2017–December 2018

Safety in community: link to CHW WhatsApp group, with warnings about protests or high-risk areas to avoid on certain days; considering the cultural hierarchy, one CHW was a male.

Safety of equipment: arrangements were made at the local clinic to safely lock away equipment overnight.

Charging equipment: CHWs charged power banks at home, and then used to charge devices overnight.

Noise levels in preschool centres: (i) mHealth monitored noise for quality control; (ii) tests were conducted in neighbours' homes if the centre was too noisy, involving the community further; and (iii) future protocol for high-noise settings will involve screening at 30 dB (instead of 25 dB) hearing level at 1 kHz.

Absenteeism: (i) project administrator telephoned the preschool centre principal in advance to inform parents that children should attend on that day; (ii) staff fetched children from home or telephoned parents to bring children; and (iii) school and cultural holidays were avoided for screening, but used for CHW training and administration.

Travelling in community: the implementation partner (Carel du Toit Centre) provided a car allocated to community outreach for CHWs to use.

Language diversity: we appointed a diverse team of CHWs from the communities who could speak local languages.

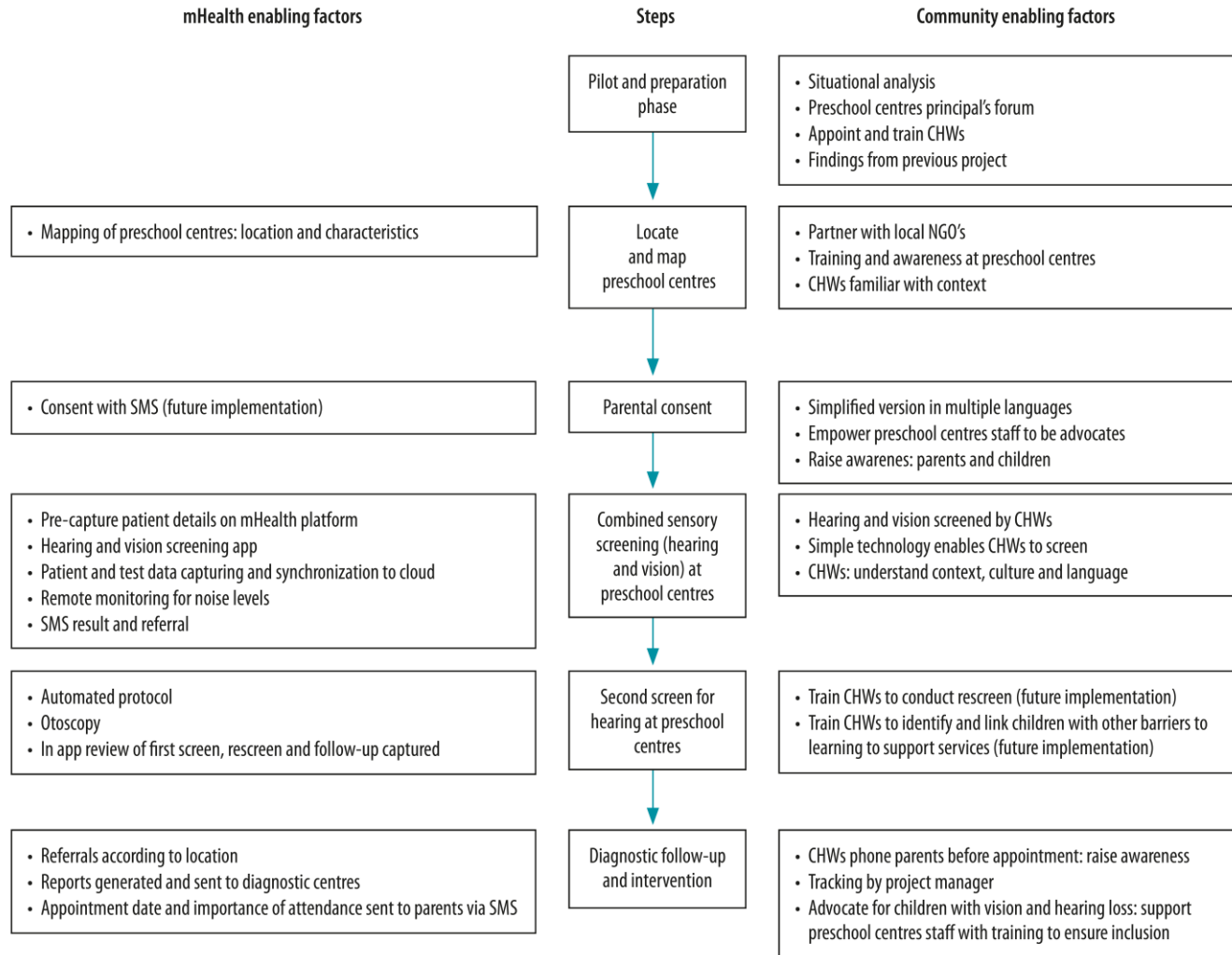
Informed consent: we provided a simplified single-page consent form in multiple languages, as well as the option for parents to send a free text requesting a call from the project administrator.

Diagnostic follow-up attendance: parents were reminded of diagnostic appointments by telephone the week before the appointment, with the CHW emphasizing the importance of attendance, in the parents' native language.

Technology: (i) CHWs informed the project manager of problems; (ii) we held retraining and problem solving during weekly meetings; and (iii) we reported challenges and suggestions to hearX Group for developers to consider.

CHW: community health worker.

Use of the same equipment and minimally trained staff to screen both hearing and vision contributed to the affordability and scalability of the service-delivery model (Fig. 3.3) (Mahomed-Asmail et al., 2016; Rono et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). The low cost per child for dual screening reported in this study (Table 3.2) could be reduced further as CHWs continue to gain experience and efficiencies are increased.



App: smartphone application; CHW: community health worker; mHealth: mobile health technology; NGOs: nongovernmental organizations; SMS: short message service.

Figure 3.3 Enabling factors of service-delivery model for hearing and vision care for preschool children, South Africa

Employing CHWs from the community was invaluable for raising awareness with preschool centre staff and parents (Bright et al., 2017; UNESCO, 2017; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). Selecting communities where an existing public health pathway to intervention was already in place was another important factor contributing to the success of the model (de Kock et al., 2016; Friderichs et al., 2012). A high informed consent return was supported by strong community involvement and the provision of simplified forms in local languages. The consent return could be further improved through a free text messaging service (Fig. 3.3).

Locating the second screening for hearing impairment at the respective preschool centre yielded a high proportion of attendance compared with an earlier project in which rescreening took place at public health care institutions (89.4% versus 39.4%) (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). Although an improved hearing test failure rate was achieved from initial screening and rescreen by CHWs (435/8023, 5.4%) to second screening by audiologist (124/8023, 1.5%), with further training, this second screening could also be conducted by CHWs to reduce the costs further. By achieving a final overall proportion of 1.5% for hearing impairment referral, our programme reduced the number of referrals to resource constrained public health institutions (Mahomed-Asmail et al., 2016; Sandström et al., 2016; van Tonder et al., 2017; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). We hypothesize that the high proportion of diagnostic appointment attendance (75.8%) was attributable to the early confirmation of initial screening results, reducing the amount of follow-up appointments (Swanepoel et al., 2013; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018), and the use of reminders sent to parents (Chi et al., 2006).

We identified background noise levels as a significant influence of screening outcome. Most of the failed hearing tests at which background noise levels were excessive (5624/6064, 92.8%) were recorded at the lowest pure tone test frequency (1 kHz); this issue could be addressed by increasing the hearing level (from 25 to 30 dB) to minimize noise interference at this test frequency (Dodd-Murphy et al., 2014; Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein et al., 2015).

Mean test duration for hearing screening (combined initial and immediate rescreen time) was shorter than for a previous study (66.8 versus 177.8 sec) (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018), because hearing level was only rescreened at frequencies failed in the initial screening. Longer test durations were associated with failed screening outcomes for both hearing and vision; this is because more test trials were required for true positives. Longer test durations associated with false positives were because of poor comprehension of instructions and delayed or incorrect responses (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018).

The importance of an automatically initiated rescreen (included for hearing but not visual screening) was highlighted by the fact that 47 children were not immediately rescreened for vision due to tester error (Dodd-Murphy et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). Age did not affect results for hearing screening, but vision failure rates were twice as high in children aged 4 years compared with children aged 6–7 years, possibly because of a lack of comprehension or attention (Metsing et al., 2018).

Our observed prevalence of hearing (0.7%) and visual (0.7%) impairments was lower than the previously published estimates for young children of 2.4% and 3.9%, respectively (GRDDC, 2018; Rono et al., 2018; Stevens et al., 2011). This might be because children with impairments are potentially less likely to attend a preschool centre, are still awaiting confirmation of status or, in the case of more severe impairments, have already been identified and are attending impairment-specific programmes. We could not find other published results with which to compare our observed prevalence of dual sensory problems. Although small, this prevalence highlights the importance of screening for both hearing and visual impairment; identifying an impairment in one modality does not predispose or preclude an impairment in the other.

Our study had limitations. No ophthalmic supervision was provided to CHWs and no measure of the quality of CHWs was available. A control group would have been valuable. The resource constraints in low- and middle-income countries were

highlighted by the number of children still awaiting appointments at the end of the study period (Harris & Dodson, 2017; Mulwafu et al., 2017; WHO, 2012).

Children with disabilities in LMICs are often unsupported without timely detection (WHO, 2012). In accordance with the leave no one behind movement that supports the sustainable development goals (Sustainable development goal report, 2018; Leave No One Behind Report, 2016), we have shown that a decentralized mHealth-supported service-delivery system can provide increased access to hearing and vision services for preschool children in poor communities. Efficient design of such a system requires a holistic approach, including the use of digital technology, the training and monitoring of CHWs, the support of community partners and effective referral systems.

Future research should focus on evaluating the cost-effectiveness and impact of detection and intervention on educational and psychosocial outcomes; the perceived acceptability of such screening programmes to parents and caregivers; and the potential integration of other mHealth services, for example, developmental delay screening (van der Merwe et al., 2019), towards a more comprehensive community-based service.

3.6 ACKNOWLEDGEMENTS

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4 REFERRAL CRITERIA FOR PRESCHOOL HEARING SCREENING IN RESOURCE-CONSTRAINED SETTINGS: A COMPARISON OF PROTOCOLS.

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4.1 ABSTRACT

Purpose

This study aimed to describe and compare the performance of two screening protocols used for preschool hearing screening in resource-constrained settings.

Methods

Secondary data analysis was done to determine the performance of two protocols implemented during a preschool hearing screening program using mobile health technology in South Africa. Pure-tone audiometry screening at 25 dB HL for 1000, 2000, and 4000 Hz in each ear was used by both protocols. The fail criterion for the first protocol (2,147 children screened) constituted a no-response on one or more

frequencies in either ear. The second protocol required two or more no-responses (5,782 children). Multivariate logistic regression models were used to investigate associations between outcomes and protocol, age, gender, and duration.

Results

Fail rates for the one-frequency fail protocol was 8.7% ($n = 186$) and 4.3% ($n = 250$) for the two-frequency fail protocol. Children screened with the two-frequency fail protocol were 52.9% less likely to fail ($p < .001$; OR = 0.471; 95% confidence interval [0.385, 0.575]). Gender ($p = .251$) and age ($p = .570$) had no significant effect on screening outcome. A percentage of cases screened (44.7%) exceeded permissible noise levels in at least one ear at 1000 Hz across both protocols. True- and false-positive cases did not differ significantly between protocols. Protocol type ($p = .204$), gender ($p = .314$), and age ($p = .982$) did not affect the odds of being a true-positive result. Average screening time was 72.8 s (78.66 SD) and 64.9 s (55.78 SD) for the one-frequency and two-frequency fail protocols, respectively.

Conclusion

A two-frequency fail criterion and immediate rescreen of failed frequencies significantly reduced referral rate for follow-up services that are often overburdened in resourced-constrained settings. Future protocol adaptations can also consider increasing the screening levels at 1000 Hz to minimize the influence of environmental noise.

4.2 INTRODUCTION

Hearing loss is a significant health problem and, if undetected, can have a detrimental impact on the speech and language development, educational attainment, and social-emotional development of children (Joint Committee on Infant Hearing of the American Academy of Pediatrics et al., 2013; Wilson et al., 2017). A systematic analysis for the Global Burden of Disease Study in 2016 indicated that 15.5 million children under the age of 5 years had hearing loss (Global Research on Developmental Disabilities Collaborators, 2018). The prevalence of childhood hearing loss is substantially higher in low- and middle-income countries (LMICs) than in high-income regions due to

increased environmental risk factors such as infectious diseases (Emmett, Robler, Wang, et al., 2019; Wilson et al., 2017).

Newborn hearing screening services in LMICs are very scarce and potentially complex to initiate due to the requirement of specialized equipment and as many births occur outside of health facilities (Olusanya & Newton, 2007). Furthermore, even when newborn hearing screening is available, it does not identify late-onset, acquired, or many cases of progressive hearing loss (Bamford et al., 2007; Dodd-Murphy et al., 2014; Wilson et al., 2017). Approximately 60% of childhood hearing loss is due to preventable causes such as otitis media, noise exposure, ototoxicity, and vaccine-preventable infections such as measles, mumps, rubella, and bacterial meningitis (Emmett, Robler, Gallo, et al., 2019; Emmett, Robler, Wang, et al., 2019; Harlor et al., 2009; Wilson et al., 2017). Hearing screening in young children, for instance in preschool or school settings, can serve (McPherson et al., 2010; Skarzyński & Piotrowska, 2012) to identify the need for the further audiological assessment to detect and treat hearing loss (Bamford et al., 2007; Dodd-Murphy et al., 2014; Harlor et al., 2009; Talbot et al., 2012).

There are various challenges to the implementation of population-based hearing screening in the educational settings. These include variable protocols for testing and referral criteria, less than ideal test conditions, limited human and technology resources, competing national health priorities, and poorly integrated electronic data management systems (Bamford et al., 2007; Prieve et al., 2015; Stenfeldt, 2018). As a consequence, children in resource-constrained settings are rarely screened for hearing loss (Harris & Dodson, 2017; Levy et al., 2018; Mulwafu et al., 2016; Swanepoel & Clark, 2019; Wilson et al., 2017). Some of these challenges may be overcome by incorporating mobile health (mHealth) technologies and community-delivered hearing health care as these have the potential to decentralize and increase access to services in resource-constrained settings (Emmett, Robler, Wang, et al., 2019; Jayawardena et al., 2020; Manus et al., 2021; Suen et al., 2019; Swanepoel, 2020; van Wyk et al., 2019; World Health Organization [WHO], 2021; Yancey et al., 2019). mHealth technology, such as the validated hearScreen application (hearX Group), offers an inexpensive and mobile alternative to conventional evaluations by utilizing calibrated headphones on low-cost smartphones, employing a simple user

interface (Mahomed-Asmail et al., 2016; Sandström et al., 2016; Swanepoel, 2020; Swanepoel & Clark, 2019; van Tonder et al., 2017; Yousuf Hussein et al., 2016, 2018). Key enabling factors in these mHealth supported screening models are the utilization of community health workers (CHWs) and automated screening applications with pre-set protocols and advanced quality control measures that enable CHWs with minimal training to undertake screening (Dawood et al., 2020; Eksteen et al., 2019; Manus et al., 2021; O'Donovan et al., 2019; Swanepoel, 2020; van Wyk et al., 2019; WHO, 2021).

However, key questions still exist in planning hearing screening programs in resource-constrained settings such as the targeted hearing loss and protocol considerations (e.g., intensity levels and fail criteria) to minimize false positives and over referrals to resource-constrained health facilities. Paramount to the success of any hearing screening program is an established referral pathway that ensures follow-up services that enable identification of hearing loss and intervention (de Kock et al., 2016; WHO, 2021). Current protocols (American Academy of Audiology, 2011; American Speech-Language-Hearing Association, 1997) for screening programs of children 3 years of age or older typically recommend screening at 20 dB HL across 1000, 2000, and 4000 Hz in each ear and a fail result constituting a no-response at one or more frequencies. A typical variation includes a slightly higher screening level of 25 dB HL to minimize the influence of environmental noise on screening outcomes (Allen et al., 2004; Bamford et al., 2007; Meinke & Dice, 2007). A previous study investigating protocols used for school-based screening reported 25 dB HL to be most appropriate in resource-constrained settings (Mahomed-Asmail et al., 2016). However, no comparative studies have investigated the effect of adjusting a protocol with a single frequency fail criterion to a two or more frequencies fail criterion. Especially in resource-constrained settings, where referral rates and false-positive screening outcomes burden pressurized health facilities, the performance of a two-frequency fail protocol should be investigated and compared to the performance of a one-frequency fail protocol in the field. The aim of this study was to compare a screening protocol using a single-frequency fail criterion to a screening protocol using a two-frequency fail criterion for preschool screening in a resource-constrained setting facilitated by CHWs.

4.3 MATERIALS AND METHOD

A community-based hearing screening program for preschool children by CHWs was implemented using mHealth technologies in preschools in partially informal townships of the Western Cape, South Africa (Eksteen et al., 2019). During the course of the screening, two protocols (both screening at 25 dB HL for 1000, 2000, and 4000 Hz in each ear) that differed in fail criterion were used: (a) one-frequency fail protocol: No response at one or more frequency across both ears constituted a fail result; and (b) two-frequency fail protocol: No response at two or more frequencies across both ears constituted a fail result. The two different protocols were nonrandomized, and the first protocol was adapted and changed after referral rates were reported to burden the public health audiology clinics where children who failed the screening were referred to for diagnostic testing. A retrospective secondary data analysis was conducted using the data obtained through the implemented screening program. Institutional review board clearance for the study was obtained from the University of Pretoria (HUM020/1019).

4.3.1 Participants

All preschools located within the area of Khayelitsha and Mitchells Plain, Western Cape, South Africa, were contacted and were provided with the option of participating in this study. Preschool principals were contacted through quarterly preschools' forums organized by local non-governmental organizations in the community (Eksteen et al., 2019). Informed consent letters were given to the principals of preschools by CHWs to distribute to the children between the ages of 4 and 7 years attending these preschools (Eksteen et al., 2019). All children who returned a signed parental consent form were included in the study ($n = 7,929$). All preschool children screened from October 1, 2017, until February 25, 2018, were tested using the one-frequency fail protocol ($n = 2,147$), and children were tested with the two-frequency fail protocol from February 26, 2018, until November 30, 2018 ($n = 5,782$).

Four CHWs were appointed and trained to conduct the hearing screening of all children included in the study at their preschools. None of them had previous formal

training in hearing health care. The CHWs received practical training on using the equipment and assessing a child's responses over a period of 5 days (Eksteen et al., 2019). The training was conducted by a qualified audiologist, who also supervised screening in the field for 2 days. Weekly meetings were chaired by the audiologist during which retraining was done as needed. Emphasis was placed on techniques such as testing arhythmical, allowing some time without presenting a tone to ensure no false-positive responses and spending enough time to condition a child before starting the test.

4.3.2 Equipment/Apparatus

Screening audiometry was conducted with the hearScreen application and its cloud-based data management service mHealth Studio (hearX Group). This application utilizes automated test sequences with prespecified screening protocols for interpretation of results. The hearScreen application was operated on a Samsung A3 smartphone (Android OS, v8.0) connected to circumaural Sennheiser HD280 Pro headphones (Sennheiser), calibrated according to prescribed audiometry standards (ISO 389-1:2017; International Standardization Organization, 2017). Calibration was performed using a GRAS RA0039 artificial ear using an RION NL-52 sound-level meter, complying with ISO 60318-1:2009 (International Standardization Organization, 2009) and ISO 60318-2:2017 (International Standardization Organization, 2017). The application has been validated to record and monitor environmental noise using the smartphone microphone to monitor when maximum permissible ambient noise levels (MPANLs) during testing are exceeded (Swanepoel, Myburgh, et al., 2014). The MPANLs, at the screening level of 25 dB HL, were 56, 69, and 68 dB SPL for 1, 2, and 4 kHz, respectively (Madsen & Margolis, 2014).

Data collected by the smartphone were automatically uploaded through cellular networks at the end of each test to the cloud-based data management system (mHealth Studio, hearX Group). This electronic platform (mHealth studio) is synchronized between cloud and mobile versions that host the point of care hearing screening application and associated data. The mHealth application and server

security is ensured through use of local data encryption at rest using AES-256bit (Eksteen et al., 2019).

Audiological assessments at the first-line follow-up included threshold audiometry using the hearTest smartphone application (hearX group) and otoscopy (Welch Allyn otoscope). The hearTest application was operated on the same smartphone used for screening. The threshold determination sequence follows the Threshold Ascending method as specified in ISO 82531:1.5 (van Wyk et al., 2019). This application has been validated to record reliable air-conduction hearing thresholds (van Tonder et al., 2017).

4.3.3 Screening procedure

CHWs screened the hearing of children at preschools using the hearScreen application with calibrated circumaural headphones. The headphones were connected to the smartphone and calibrated before screening commenced. Only participants who returned signed parental consent forms, and gave assent, were screened. Participants were instructed by the CHWs in a group, in their native language, to raise their hands when they heard a sound. The action of raising their hand when a sound was heard was practiced in the group. Each child would then be called by the CHW to be screened individually. Screening was conducted in the quietest area of the preschool where space is allowed.

The predetermined protocol was selected on the mHealth hearing screening application, and the details of the participant were entered on the application. The selected criterion for the two different protocols are described in Table 4.1.

Table 4.1. Selected criterion for screening protocols

| Criterion | One-frequency fail protocol | Two-frequency fail protocol |
|--|---|---|
| Frequencies tested per ear (Hz) | 1000, 2000, 4000 Hz | 1000, 2000, 4000 Hz |
| Screening intensity (dB HL) | 25 | 25 |
| Fail criterion: no. of no-responses across both ears | 1 or more frequencies | 2 or more frequencies |
| Immediate rescreen | At frequencies failed during initial test | At frequencies failed during initial test |

The CHW, sitting behind the participant, played a conditioning tone at 40 dB HL at 1000 Hz in the left ear, which was the automated first step of the screening process. Within the conditioning feature of the application, the CHW had the option to increase intensity and switch ears where the tone would be heard. During the training and retraining of the CHWs, the goal of conditioning and the indications to increase the conditioning intensity level were discussed. Another feature of the application was that the test could be “paused” and the option of “talk forward” could be selected. This enabled the CHW to talk to the child through the smartphone’s microphone into the headphones to either re-instruct, praise, or motivate the child. Once the CHW felt confident that the participant understood the instructions, the screening test was initiated.

Ambient noise was monitored continuously throughout testing at each frequency. MPANLs specify the maximum ambient noise level allowed in a testing room to ensure that thresholds obtained are not elevated. If the ambient noise exceeded MPANLs at any frequency, this was displayed and therefore warned the CHW who could then move to a quieter space or reduce background noise before continuing the test. Noise levels were automatically recorded, and testing was completed even if noise levels could not be reduced adequately (van Wyk et al., 2019).

A sweep test was performed at the intensity level of 25 dB HL at 1000, 2000, and 4000 Hz, in that order. Left ears were tested first. The CHW presented the stimuli at random intervals and could indicate on the smartphone screen whether a sound was heard or not. In case a sound was not heard, the automated protocol presented the sound once again to confirm a no response. If the child heard the sound, the automated protocol would confirm the response. An immediate rescreen was done for the specific frequency/ frequencies that were failed following a fail result.

Once the test was complete, the application immediately calculated and displayed the results at each frequency and an overall “pass” or “fail” result. The final screening result was automatically uploaded to a cloud-based server via a mobile network for data management. The result of the immediate rescreen was considered to be the overall or final result and would be considered for referral to a first-line follow-up.

Results were communicated directly via text messages to parents/caregivers of participants.

If the overall screening result was a “fail”, the participant was seen by an audiologist for a first-line follow-up at the child’s preschool a week or 2 weeks later, depending on the availability of the audiologist. Follow-up testing included otoscopy and automated air-conduction threshold pure-tone audiometry at 0.5 to 8 kHz starting at an intensity level of 40 dB HL until a minimum response level, using the hearTest application to determine degree and configuration of hearing loss. A threshold was determined by the minimum intensity at which the participant reliably responded twice. The results of the air-conduction audiometry, in conjunction with otoscopy, were used to identify the presence of hearing loss and confirm the screening result. Criteria constituting hearing loss was a pure-tone average (500–4000 Hz) of 25 dB HL or greater in the better ear. If the child had a hearing loss as indicated by this first-line follow-up conducted by the audiologist at the child’s preschool, they were referred to a public health audiology clinic for further testing and intervention (Eksteen et al., 2019). Children who were difficult to condition, and therefore not tested successfully at the first-line follow-up, were also referred to a public health audiology clinic for further testing. These cases were excluded from the study analysis investigating true-positive rate.

4.3.4 Data analysis

Data were extracted from the secure cloud-based server to a Microsoft Excel 2016 sheet for statistical analysis using Statistical Package for Social Sciences SPSS (Version 26; IBM Corp., 2019). The overall referral rate was calculated as the number of children who failed an immediate rescreen after they presented with a “fail” at the initial screen. The truepositive rate was calculated as the number of children who failed the screening test and presented with a hearing loss confirmed at the first-line follow-up.

Descriptive statistics were used to compare the protocols in terms of sample gender and age, screening duration, referral rate, and true-positive rate. Descriptive statistics were used to determine the incidence of exceeded MPANLs during screening. The

Shapiro–Wilk test was used to test for normality (Field, 2018). Not all variables were normally distributed, and therefore, nonparametric tests were used, as nonparametric tests have been shown to be as powerful, or almost as powerful, as their normal theory counterparts (Gibbons & Chakraborti, 2010). A p-value cut-off was set at .05 and indicated the level of significance throughout this study. The two-proportion z test was used to compare referral rate, true-positive rate, and false-positive rate between the two protocols. Two multivariate logistic models were built. The dependent variable, which is dichotomous, was screen result (see Model 1) and final result (after a follow-up hearing test; see Model 2). The covariate (continuous independent variable) was age, and the factors (categorical independent variables) were gender (females benchmarked against males) and protocol (Protocol 2 benchmarked against Protocol 1). A multiple linear regression model was used to estimate the association between test duration and protocol, age, and gender.

4.4 RESULTS

A total of 7,929 preschool children received hearing screening over 16 months. Approximately half (50.4%) were female and mean age was 5.8 years (0.64 SD) ranging from 4.1 to 7.3 years of age. The number of children screened using the one-frequency fail protocol was 2,147; the two-frequency fail protocol was used on 5,782 children. Table 4.2 depicts the characteristics of the sample for the two protocols.

Table 4.2. Participant characteristics according to protocol

| Demographics | Number and percentage | One-frequency fail protocol | Two-frequency fail protocol |
|--------------------------|-----------------------|-----------------------------|-----------------------------|
| Children screened | N | 2147 | 5782 |
| Male | N | 1073 | 2857 |
| | % within protocol | 50.0% | 49.4% |
| Female | N | 1074 | 2925 |
| | % within protocol | 50.0% | 50.6% |
| Age in years | Mean (SD) | 5.6 (0.57) | 5.8 (0.65) |
| | Range (min – max) | 4.1 – 6.9 | 4.2 – 7.3 |

For the one-frequency fail protocol, the overall referral rate (i.e., after immediate rescreen of the 23.0% [$n = 493$] of children who had failed the initial screen) was 8.7% ($n = 186$; see Table 4.3). For the two-frequency fail protocol, the overall referral rate (i.e., after immediate rescreen of the 13.6% [$n = 786$] of children who had failed the initial screen) was 4.3% ($n = 250$; see Table 4.3). The overall referral rate across the different protocols was significantly different between tests (two-proportions z test).

Table 4.3: Referral rates across screening protocols

| Screening referrals | Ears | Number and percentage | One-frequency fail protocol | Two-frequency fail protocol | z-test stat p-value |
|---------------------------------|-------|-----------------------|-----------------------------|-----------------------------|---------------------|
| Children screened | | N | 2147 | 5782 | |
| Overall screen referral rate | | N | 186 | 250 | 7.532 |
| | | % within protocol | 8.7% | 4.3% | < 0.001* |
| <i>Referral rate at 1000 Hz</i> | Left | N | 73 | 148 | 2.020 |
| | | % within protocol | 3.4% | 2.6% | 0.043* |
| | Right | N | 70 | 171 | 0.698 |
| | | % within protocol | 3.3% | 3.0% | 0.485 |
| <i>Referral rate at 2000 Hz</i> | Left | N | 46 | 119 | 0.234 |
| | | % within protocol | 2.1% | 2.1% | 0.815 |
| | Right | N | 59 | 131 | 1.248 |
| | | % within protocol | 2.7% | 2.3% | 0.212 |
| <i>Referral rate at 4000 Hz</i> | Left | N | 64 | 104 | 3.248 |
| | | % within protocol | 3.0% | 1.8% | 0.001* |
| | Right | N | 73 | 101 | 4.465 |
| | | % within protocol | 3.4% | 1.7% | < 0.001* |

* Statistically significant difference at a 5% level of significance

Multivariate logistic regression demonstrated no significant effect of gender ($p = .251$) and age ($p = .570$) on screening outcome but a highly significant effect of protocol used. Compared to children tested with the one-frequency fail protocol, those tested with the two-frequency fail protocol were 52.9% less likely to fail ($p < .001$; OR = 0.471; 95% confidence interval [0.385, 0.575]).

Environmental noise exceeded MPANLs at 1000 Hz mainly across both protocols. A certain percentage (44.7%) of cases screened had exceeded MPANLs in at least one ear at 1000 Hz across both protocols.

Seventy children (16.1% of the total number of children who failed screening) were not tested at the first-line follow-up (due to absence on the day of testing [$n = 60$] or being unable to test [$n = 10$]; see Table 4.4). Of the children who underwent a follow-up test at their preschool, 42.2% (155/367) had confirmed hearing loss and were therefore considered true-positive cases (see Table 4.4). There was no significant difference between screening protocol performance (true and false-positive cases) between the two protocols (see Table 4.4). Multivariate logistic regression analysis evaluating the

effect of protocol, age, and gender on the final outcome of the follow-up hearing assessment demonstrated no significant effect.

Table 4.4: Screening performance for children who attended follow-up hearing assessments

| Screening performance | Number and percentage | One-frequency fail protocol | Two-frequency fail protocol | z-test p-value |
|------------------------------------|-----------------------|-----------------------------|-----------------------------|----------------|
| | N | 186 | 251 | |
| True positive | N | 60 | 95 | 1.208 |
| | % within protocol | 32.3% | 37.9% | 0.227 |
| False positive | N | 97 | 115 | 1.310 |
| | % within protocol | 52.2% | 45.8% | 0.190 |
| Unable to be tested | N | 6 | 4 | 1.128 |
| | % within protocol | 3.2% | 1.6% | 0.259 |
| Not tested at first-line follow-up | N | 23 | 37 | 0.713 |
| | % within protocol | 12.4% | 14.7% | 0.476 |

Average time to conduct the screening test was 72.8 s (78.66 SD) for the one-frequency fail protocol and 64.9 s (55.78 SD) for the two-frequency fail protocol, including the immediate rescreen if this was conducted. A multiple linear regression model for test duration, $F(716.667)$, $p < .001$, explained 26.6% of the variation (adjusted $R^2 = .266$), with only screening outcome significantly affecting test duration. Overall, test duration was 141.75 s longer for those who failed compared to those who passed ($p < .001$; $B = 141.75$; 95% confidence interval [136.53, 146.98]). Gender ($p = .314$), age ($p = .052$), and protocol ($p = .329$) were not significant predictors.

4.5 DISCUSSION

The recommended criterion for referral of hearing screening should be evidence-based and consider specific contextual resources to ensure an ethically responsible approach to screening (Allen et al., 2004; Kam et al., 2014; Mahomed-Asmail et al., 2016). This study compared two screening protocols utilized in an mHealth-supported hearing screening program facilitated by CHWs. The protocol with a single frequency fail criteria screening at 25 dB HL across 1000, 2000, and 4000 Hz had a significantly higher referral rate compared to the two-frequency fail protocol. This protocol requiring two or more no-responses at any frequencies across both ears had a higher true-positive rate, lower false-positive rate, and shorter screening duration, but which were not statistically significant.

Referral rate influences the sustainability of a screening program and should not be excessively high; otherwise, health care systems might be overburdened (Allen et al., 2004; Bamford et al., 2007; Mahomed-Asmail et al., 2016; Olusanya, 2008), especially in an LMIC where resources are limited (Allen et al., 2004; Kam et al., 2014; Swanepoel & Clark, 2019; Wu et al., 2014). Previous studies reported referral rates of 6.7% (Mahomed-Asmail et al., 2016), 7.6% (Dodd-Murphy et al., 2014), and 9.3% (Wu et al., 2014). Employing a protocol with two or more frequency fail criteria to decrease referral rate was confirmed in this study to be useful in reducing false positives (Allen et al., 2004). The referral rate for the one-frequency fail protocol was significantly higher (8.7%) than the two-frequency fail protocol's referral rate (4.3%). An immediate rescreen reduced the number of referrals across both protocols, corresponding with the findings from a previous study (Mahomed-Asmail et al., 2016), and so confirms recommendations that an immediate rescreen should be employed routinely in screening programs (Allen et al., 2004; Kam et al., 2014; van Wyk et al., 2019).

Acute otitis media and otitis media with effusion are reported to account for the majority of hearing loss in preschool children with hearing impairment (Wu et al., 2014) and are known to be high in LMICs (WHO, 2021; Yousuf Hussein et al., 2018). Therefore, transient conductive hearing losses secondary to otitis media is likely to increase the referral rate. Based on the target disorder set out in this study (pure-tone average [500–4000 Hz] of 25 dB HL or greater in the better ear), abnormal middle ear function causing a child not to respond to pure tones at 25 dB HL warranted referral for a diagnostic audiological evaluation.

Based on findings from studies that indicated significantly higher referral rates in children younger than 4 years of age (Cedars et al., 2018; Kam et al., 2014; Wu et al., 2014; Yousuf Hussein et al., 2018), this study only included preschool children between the ages of 4 and 7 years. We did not find an impact of children's age on screening results, in contrast to other studies that included children younger than 4 years of age (Cedars et al., 2018; Kam et al., 2014; Sideris & Glatke, 2006; Wu et al., 2014; Yousuf Hussein et al., 2018). In a study by Manus et al. (2021), where children 4 years and older were screened, age also did not have an impact on screening outcome. In agreement with other studies, gender did not have an impact on screening results (Cedars et al., 2018; Kam et al., 2014; Wu et al., 2014).

Overreferrals contribute to the burden faced by follow-up services, as well as reducing credibility with parents and physicians (Dodd-Murphy et al., 2014; Mahomed-Asmail et al., 2016). Compared to a study by Wu et al. (2014), where 18.8% of children who had positive screen results were diagnosed with hearing loss, the percentage of true-positive cases in this study is high. This might be due to the referral criterion of the screening or the fact that children who failed the first-line follow-up still had to be seen for a comprehensive diagnostic audiological evaluation, including wax removal, tympanometry, and bone conduction audiometry. We did not find an impact of protocol or children's age or gender on the final outcome after a follow-up hearing assessment. Despite not being significantly different, the higher true-positive rate for the two-frequency fail protocol (37.9%) compared to that of the one-frequency fail protocol (32.3%) is a factor to consider for community-delivered screening in a resource-constrained setting.

Duration of screening per protocol was another factor evaluated as time efficiency facilitates screening of larger numbers of individuals over a shorter period of time, contributing to the cost effectiveness of the program and avoiding disturbances of the child (Śliwa et al., 2011). Longer test durations were associated with failed screening outcomes across both protocols, probably due to the immediate rescreen or re-instruction of children struggling with the task (Eksteen et al., 2019). The two-frequency fail protocol's mean duration of screening was 8 s shorter than the one-frequency fail protocol. The difference between the protocols was not proven to be significant.

Noise poses a challenge to reliable screening in uncontrolled environments, such as educational settings (Allen et al., 2004; Kam et al., 2014; Levy et al., 2018; McPherson et al., 2010; Sideris & Glatke, 2006). It is critical to be able to monitor noise levels throughout community-based hearing screening (van Wyk et al., 2019) and is an advantage of recent mHealth screening apps (Paglialonga et al., 2019). In this preschool study, real-time ambient noise measurements by the smartphone indicate that test performance is likely affected when testing at 25 dB HL, especially at 1000 Hz in support of previous reports (Al-Rowaily et al., 2012; Levy et al., 2018; Mahomed-Asmail et al., 2016; Swanepoel, Myburgh, et al., 2014; Yousuf Hussein et al., 2016). To address this potential influence, increasing the screening intensity at 1000 Hz from

25 to 30 dB HL should be considered in future studies. A lower rate of false positives due to noise, at the risk of missing milder losses likely due to transient middle-ear effusion, may be a trade-off to consider in resource-constrained contexts.

Employing validated mHealth technologies that support CHWs, government and community screening programs can improve capacity for effective large-scale hearing screening (Emmett, Robler, Wang, et al., 2019; Jayawardena et al., 2020; Shinn et al., 2019; Suen et al., 2019; Swanepoel, 2020). In order for CHWs to deliver such care with new technologies, it is important that screening protocols are selected appropriately to maximize true positives and minimize excessive referral rates tailored to contextual health care system capacity. This study demonstrated that a protocol that includes a two-frequency fail criteria had an acceptably low referral rate and a high true-positive rate. Limitations of the current study included that sensitivity and specificity for these protocols could not be determined, and the study design was not a randomized controlled trial, and so type of facility and time varied between the protocols and may have influenced the impacts thereof. For resource allocation in screening programs, however, the referral rate provides valuable metrics to plan services. Future studies comparing otoacoustic emission screening outcomes to pure-tone audiometry screening in these communities would be of interest as a potential tool to screen children younger than 3 years of age too.

4.6 CONCLUSION

A protocol employing a two-frequency fail criterion and immediate rescreen of failed frequencies significantly reduced referral rate for follow-up services that are often overburdened in resourced-constrained settings. Future protocol adaptations can also consider increasing the screening levels at 1000 Hz to minimize the influence of environmental noise. Using validated mHealth screening technologies operated by CHWs that employ optimized screening protocols can support scalable screening programs in resource-constrained settings.

4.7 ACKNOWLEDGEMENTS

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5 COMMUNITY-BASED IDENTIFICATION OF HEARING AND VISION LOSS IN PRESCHOOL CHILDREN FROM LOW-INCOME SOUTH AFRICAN COMMUNITIES.

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5.1 ABSTRACT

Background

The majority of children with sensory impairments live in low- and middle-income countries where services are usually unavailable or inaccessible, because of an absence of systematic screening programmes for children, prohibitive equipment cost and a shortage of trained personnel. This study aimed to describe hearing and vision loss among preschool children (4-7 years) in an underserved South African community following community-based mobile health (mHealth) supported hearing and vision services.

Methods

Hearing and vision screening were done by trained community health workers at preschools in the communities of Khayelitsha and Mitchell's Plain, Cape Town, from September 2017 until June 2019, using mHealth technology. Children who failed

hearing and vision screening were seen for follow-up assessments at their preschools. Follow-up assessments were conducted using smartphones that host point-of-care validated and calibrated hearing and vision testing applications (hearTest app, hearX Group, South Africa and PeekAcuity app, Peek Vision, United Kingdom). Descriptive statistical analysis and logistic regression analysis were conducted after extracting data from a secure cloud-based server (mHealth Studio, hearX Group) to Microsoft Excel (2016).

Results

A total of 10390 children were screened at 298 preschools over 22 months. Of the children screened, 5.6% and 4.4% of children failed hearing and vision screening respectively. Community-based follow-up hearing tests were done at the preschools on 88.5% (514) of children of whom 240 children (54.2% female) presented with hearing loss. A preschool-based follow-up vision test was done on 400 children (88.1%). A total of 232 children (46.1% female) had a vision impairment, and a further 32 children passed the test but had obvious signs of ocular morbidity. Logistic regression analysis found that age was a significant predictor of vision loss ($p < 0.05$), but not for hearing loss ($p = 0.06$). Gender was not a significant predictor of hearing ($p = 0.22$) or vision loss ($p = 0.20$).

Conclusions

Hearing loss is prevalent in at least 22 per 1000 and vision loss in at least 23 per 1000 preschool children in an underserved South African community. Timely identification of sensory losses can be facilitated through community-based hearing and vision services supported by mHealth technology.

5.2 INTRODUCTION

Childhood hearing and vision loss are significant contributors to the global burden of disease (GRDDC, 2018; Olusanya et al., 2020) affecting 38.7 and 32.5 million children under 10 years, respectively (Olusanya et al., 2020). According to the World Health Organization (WHO), the majority of childhood hearing loss (60%) and vision loss (80%) can be treated or prevented if identified early (WHO, 2017a, 2017b). Therefore,

periodic hearing and vision screening are considered integral strategies for preventative paediatric health care (American Academy of Pediatrics, 2003; Emmett et al., 2019; Rahi et al., 2003; Stenfeldt, 2018). Early detection of sensory impairments is essential for facilitating early childhood development, socioemotional well-being and academic success, (Gilbert & Foster, 2001; GRDC, 2018; Graydon et al., 2019; Stevens et al., 2011; Wilson et al., 2017) as well as the sustainable development goals (SDGs) related to education (GRDC, 2018; Olusanya et al., 2020; SDG, 2018). Early-childhood screening in preschools can identify children with congenital sensory losses, as well as those with late-onset, progressive, or fluctuating hearing and vision loss, thus facilitating intervention prior to school entry (GRDC, 2018; Gilbert & Foster, 2001; Keffe, 2004; Rahi et al., 2003; Rono et al., 2018).

Unfortunately, the majority of children (80 to 90%) with sensory impairments live in low- and middle-income countries (LMICs) (Gilbert & Foster, 2001; Olusanya et al., 2020; Stevens et al., 2011; WHO, 2017b) where services are usually unavailable or inaccessible, because of an absence of systematic screening programmes for children, prohibitive equipment cost and a shortage of trained personnel (Harris & Dodson, 2017; Olusanya et al., 2014; Wilson et al., 2017). The prevalence of hearing and vision loss for children aged between 5 and 9 years are estimated at 4.5% and 3.1% respectively in sub-Saharan Africa in contrast to 2.2% and 1.3% respectively in high-income North America, demonstrating the need for attention to sensory impairment in LMICs (Olusanya et al., 2020). Most cases of childhood hearing and vision loss have preventable causes that are common in low-to-middle-income countries (LMICs) and is often related either to infection or nutrition (Bush et al., 2015; Emmett et al., 2019; Graydon et al., 2019; Keffe, 2004; Stevens et al., 2011). Unfortunately, children with disabilities in LMICs have considerably limited access to non-emergency health resources (Bush et al., 2015; Wilson et al., 2017) and are therefore prone to be left behind under the SDGs era without timely and appropriate intervention from early childhood (Keffe, 2004; Olusanya et al., 2020; UNESCO, 2017).

Estimating the prevalence of sensory loss in this population is an important step to ensure adequate planning and successful implementation of community-based hearing and vision care in preschools in this context. There is a lack of contemporary

population-based information about childhood hearing loss and visual impairment, from which the scope and priorities for prevention and treatment can be identified (Gilbert & Foster, 2001; GRDC, 2018; Jayawardena et al., 2020; Kumar et al., 2019; Olusanya et al., 2020; Rahi et al., 2003; Stevens et al., 2011). Particularly in high-burden LMICs, where these disabling conditions are highly prevalent, more studies of hearing and vision impairment prevalence are needed, in order to generate more accurate estimates of trends in sensory impairments (GRDC, 2018; Olusanya et al., 2020; Stevens et al., 2011). Until recently, these surveys have been complex to undertake, relying on expensive equipment and trained staff, explaining the lack of data. The past few years have seen a rapid expansion of the evidence base on the value of community-based programmes incorporating solutions based on smartphone and internet technologies (mobile health (mHealth) technology) for hearing and vision services (Bastawrous et al., 2015; Jayawardena et al., 2020; Manus et al., 2021; Rono et al., 2018; Yousuf Hussein et al., 2018). A South African study recently reported the first smartphone-based hearing and vision screening for preschool children (Eksteen et al., 2019). In order to overcome loss to follow-up previously shown to affect the outcomes of screening programmes (Arinze et al., 2015; Emmett et al., 2019; Manus et al., 2021; Yousuf Hussein et al., 2018), a community-based first-line follow-up assessment for those who failed screening was also done by utilizing mHealth technology (Eksteen et al., 2019).

The aim of this study was to describe hearing and vision loss among preschool children (4-7 years) in an underserved South African community following mHealth supported community-based hearing and vision services.

5.3 METHODS

Institutional Review Board clearance for the study was obtained from the University of Pretoria (HUM020/1019).

5.3.1 Context and population

A community-based hearing and vision screening program for preschool children by community health workers (CHWs) was implemented using mHealth technologies (Eksteen et al., 2019, 2021). This program was undertaken in preschools of the partially informal townships of Khayelitsha and Mitchells Plain of the Western Cape province, South Africa, from September 2017 to June 2019. The joint population of Khayelitsha and Mitchells Plain was estimated as 702234 in 2011, including 61094 children aged 5–9 years (Statistics South Africa, 2011). The majority (97.1%; (181145/186803)) of households within the study area are classified as low- and middle-income (Statistics South Africa, 2011). All children between the ages of 4 and 7 years attending preschools in the targeted areas for whom consent was obtained, received hearing and vision screening tests. Children who failed either test had a follow-up assessment at their preschool. If indicated, children were referred to their nearest clinic for intervention. This study estimated the prevalence of hearing and vision loss, based upon the results of the follow-up assessment.

5.3.1.1 Initial screening for hearing and vision

Hearing and vision screening were done by trained CHWs at the preschools in the community using smartphones that host point-of-care validated hearing and vision screening applications (hearScreen app, hearX Group, South Africa and Peek Acuity app, Peek Vision, United Kingdom). A detailed description of the screening procedures and equipment were previously described (Eksteen et al., 2019, 2021). Thresholds for failing the hearing screening were set at 25 dB hearing level at 1, 2 and 4 kHz from September 2017 until December 2018, and 30 dB HL at 1kHz and 25 dB HL at 2 and 4 kHz from January to June 2019. Children were considered to have failed the initial vision screening if they had a visual acuity of less than 0.3 LogMAR in both eyes, or less than 0.4 LogMAR in one eye regardless of acuity in the other eye (WHO, 2017b).

5.3.1.2 Follow-up assessments

All children who failed the screening were scheduled to undergo a follow-up assessment at their preschool.

Children who failed the hearing test received a follow-up assessment by an Audiologist at their preschool a week or two later (depending on case load and capacity of the Audiologist). The follow-up hearing assessment included otoscopy (Welch Allyn otoscope) and air conduction threshold pure tone audiometry using the validated hearTest app (hearX Group, South Africa) (Sandström et al., 2016; van Tonder et al., 2017) on a Samsung A3 smartphone with the operating system Android version 8.0 (Google, United States of America), connected to supra-aural Sennheiser HD280 headphones (Sennheiser, Wedemark, Germany). Equipment had been calibrated according to prescribed standards (International Organization for Standardization, ISO 389–1). The app is calibrated to monitor environmental noise with the smartphone microphone (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). A warning was given when environmental noise exceeded minimal permissible ambient noise levels and the test could be paused until the noise levels were within an acceptable range. Automated audiometry consisted of air conduction testing at 0.5 to 8kHz starting at an intensity level of 40dB HL until a minimum response level of 10dB HL. The threshold determination sequence follows the Threshold Ascending method as specified in ISO 82531:1.5. As no tympanometry or bone conduction audiology was done at the follow-up assessment, cases were categorized into children with “no signs of external or middle ear abnormalities” or “obvious signs of external or middle ear abnormalities” based on the otoscopic evaluation conducted by the Audiologist. “Obvious signs of external or middle ear abnormalities” included observations of occluding wax, otorrhoea or abnormal tympanic membrane. Criteria constituting hearing loss was pure tone average (PTA) (0.5 – 4kHz) of 25 dB HL or greater in the worse ear (Emmett et al., 2019). Degree of hearing loss was largely based on the classification by the World Health Organization (26 – 40 dB HL being “mild”, 41 – 60 dB HL “moderate”, 61 – 80 dB HL “severe” and 81 dB HL or greater “profound”) (WHO, 2017a); 25 dB HL was included in the “mild” category.

Children who failed the initial vision screening were retested on the same day at their preschool by the CHWs, using the Peek Acuity application on the same smartphone (Peek Vision, London, United Kingdom). This test follows the standard Early Treatment Diabetic Retinopathy Study chart design, using a Tumbling E optotype, and is capable of acuity measurements consistent with test–retest variability of acuities

measured using 5-letters-perline retro-illuminated LogMAR (logarithm of minimum angle of resolution) charts (Bastawrous et al., 2015). Vision loss was indicated when the visual acuity was less than 0.3 LogMar in both eyes, or less than 0.4 LogMar in the better eye. Degree of vision loss was categorized as “Mild” (0.4 LogMar), “Moderate” (0.5 – 0.9 LogMar), “Severe” (1 – 4 LogMar) and “No Response” (5 LogMar) (American Academy of Pediatrics, 2003).

5.3.1.3 Referrals after follow-up assessments

Children presenting with hearing or vision loss at the follow-up assessment were referred to public health audiology or optometry clinics in their area for further assessments and intervention. Children whose hearing was unable to be tested due to inconsistent and unreliable responses, were recorded on the database as “unable to test” and referred for evaluation at the health care clinics. Children who presented with “Normal” results (-0.1 – 0.3 LogMar), but had obvious signs of ocular abnormality (such as strabismus or a teacher’s report of visual difficulty), were recorded on the database as “ocular morbidity” and referred for evaluation at the health care clinics. Parents of children who were referred were notified of the outcome via a letter and phone call. A future study will report on the outcome of the clinic visits.

5.3.2 Data storage and analysis

Data collected by the smartphone were uploaded to a cloud storage facility through mobile telephone networks at the end of each test (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014), using the mHealth Studio platform (hearX Group, South Africa). The security of the mHealth app and server are provided by local data encryption at rest using Advanced Encryption Standard 256 bit.

Data were extracted from the secure cloud-based server (mHealth Studio) to Microsoft Excel (2016) and coded according to test outcomes (sensory loss or not) and severity of loss for descriptive statistical analysis. Logistic regression was used to estimate the association between the presence of sensory loss and gender and age using IBM

SPSS Statistics for Windows (version 25.0 Armonk, NY). A p-value cut off was set at 0.05 and indicated the level of significance throughout this study.

5.4 RESULTS

A total of 10390 children (50.2% female) with a mean age of 5.7 years (SD 0.61) were screened at 298 preschools over 22 months.

The overall screening referral rate was 5.6% (581 children) resulting from hearing screening and 4.4% (453) resulting from vision screening. Seventy-two children (0.7%) failed both hearing and vision screening at the initial assessment.

5.4.1 Follow-up hearing test

Follow-up hearing tests at the preschools were done on 88.5% (514) of children of whom 240 children (54.2% female) presented with hearing loss (Table 5.1). Fourteen of the children who failed the hearing screening and who were seen for a follow-up assessment, were unable to be tested due to inconsistent responses. They were referred to the health care clinic for further tests, but they were not included as children with a hearing loss in this study. Half (260, 51%) of children presented with normal hearing at the follow-up hearing test and were discharged from the programme. Prevalence for hearing loss at a PTA of 25dB HL ranged between 2.3% (240/10390) (assuming none of the non-attenders and “unable to test” children had hearing loss) and 3.1% (321/10390) (assuming all the non-attenders and “unable to test” children presented with hearing loss). Of the 136 children with obvious signs of external and/or middle ear abnormalities, 95 (69.9%) had occluding wax and 41 (30.1%) had abnormal middle ear findings (Table 5.1). The laterality and degree of hearing loss is shown in Table 5.1.

Table 5.1. Characteristics of hearing loss across participants seen for follow-up by audiologist at preschools (n=240).

| <i>Characteristics</i> | <i>Bilateral % (n)</i> | <i>Unilateral % (n)</i> | <i>All losses % (n)</i> |
|--|----------------------------|-----------------------------|-----------------------------|
| Hearing Loss | | | |
| No signs of external or middle ear abnormality | 64.4% (67/104) | 35.6% (37/104) | 43.3% (104/240) |
| External or middle ear abnormality | 64.7% (88/136) | 35.3% (48/136) | 56.7% (136/240) |
| All hearing losses | 64.6% (155/240) | 35.4% (85/240) | 100% (240/240) |
| Degree of hearing loss according to the worst ear | | | |
| Mild (25 - 40 dB HL) | 63.6% (84/132) | 36.4% (48/132) | 55.0% (132/240) |
| Moderate (41 - 60 dB HL) | 66.3% (57/86) | 33.7% (29/86) | 35.8% (86/240) |
| Severe (61 - 80 dB HL) | 27.3% (3/11) | 72.7% (8/11) | 4.6% (11/240) |
| Profound (81 dB HL or greater) | 100% (11/11) | 0 | 4.6% (11/240) |

dB HL: decibels in hearing level

5.4.2 Follow-up vision test

A follow-up vision test was done on 400 children (88.1%) on the same day that they failed the initial screening at the preschool. A total of 232 children (46.1% female) had a vision impairment at the set criteria (Table 5.2), and a further 32 children passed the test but had obvious signs of ocular morbidity. Prevalence of vision loss ranged between 2.2% (232/10390) (assuming none of the non-attenders had vision loss) and 2.8% (286/10390) (assuming all the non-attenders presented with vision loss). The laterality and degree of vision loss is shown in Table 5.2.

Table 5.2. Characteristics of vision loss across participants seen for follow-up vision test at preschools (n=232).

| <i>Characteristic</i> | <i>Bilateral % (n)</i> | <i>Unilateral % (n)</i> | <i>All losses % (n)</i> |
|---|----------------------------|-----------------------------|-----------------------------|
| Vision Loss | | | |
| All vision losses | 59.1% (137/232) | 40.9% (95/232) | 100% (232/232) |
| Degree of vision loss according to the worst eye | | | |
| Mild (0.4 LogMar) | 100% (11/11) | 0 | 4.7% (11/232) |
| Moderate (0.5 – 0.9 LogMar) | 56.2% (50/89) | 43.8% (39/89) | 38.4% (89/232) |
| Severe (1 – 4 LogMar) | 66.7% (12/18) | 33.3% (6/18) | 7.8% (18/232) |
| No Response (5 LogMar) | 56.1% (64/114) | 43.9% (50/114) | 49.1% (114/232) |

LogMar: Logarithm of the Minimum Angle of Resolution

Table 5.3 displays the prevalence of hearing loss and vision loss in the population of children screened at their preschools.

Table 5.3. Prevalence of sensory losses in the population of children screened at preschools (n=10390).

| <i>Characteristics</i> | <i>All losses % (n)</i> | <i>Bilateral % (n)</i> | <i>Unilateral % (n)</i> |
|--|-------------------------|------------------------|-------------------------|
| Hearing Loss | | | |
| No signs of external or middle ear abnormality | 1.0% (104/10390) | 0.6% (67/10390) | 0.4% (37/10390) |
| External or middle ear abnormality | 1.3% (136/10390) | 0.8% (88/10390) | 0.5% (48/10390) |
| All hearing losses | 2.3% (240/10390) | 1.5% (155/10390) | 0.8% (85/10390) |
| Degree of hearing loss according to the worst ear | | | |
| Mild (25 - 40 dB HL) | 1.3% (132/10390) | 0.8% (84/10390) | 0.5% (48/10390) |
| Moderate (41 - 60 dB HL) | 0.8% (86/10390) | 0.5% (57/10390) | 0.3% (29/10390) |
| Severe (61 - 80 dB HL) | 0.1% (11/10390) | 0.02% (3/10390) | 0.08% (8/10390) |
| Profound (81 dB HL or greater) | 0.1% (11/10390) | 0.1% (11/10390) | 0 |
| Vision Loss | | | |
| All vision losses | 2.2% (232/10390) | 1.3% (137/10390) | 0.9% (95/10390) |
| Degree of vision loss according to the worst eye | | | |
| Mild (0.4 LogMar) | 0.1% (11/10390) | 0.1% (11/10390) | 0 |
| Moderate (0.5 – 0.9 LogMar) | 0.9% (89/10390) | 0.5% (50/10390) | 0.4% (39/10390) |
| Severe (1 – 4 LogMar) | 0.2% (18/10390) | 0.1% (12/10390) | 0.1% (6/10390) |
| No Response (5 LogMar) | 1.1% (114/10390) | 0.6% (64/10390) | 0.5% (50/10390) |

dB HL: decibels in hearing level; LogMar: Logarithm of the Minimum Angle of Resolution.

Table 5.4 displays the distribution of sensory losses according to age and gender in children tested at their preschool. Logistic regression analysis found that age was a significant predictor of vision loss ($p < 0.001$), with each year older a participant was 51.4% less likely of having vision loss (OR: 0.49, 95% CI:0.39 – 0.60). Age was not a significant predictor of hearing loss ($p > 0.05$). Gender was not a significant predictor of hearing ($p > 0.05$) or vision loss ($p > 0.05$).

Table 5.4. Prevalence of sensory impairment according to age and gender.

| | | Distribution of participants (n) | % of children with hearing loss (n) | % of children with vision loss (n) | % of children with combined sensory loss (n) |
|---------------|----------------------|---|--|---|---|
| Total | | 100% (10390) | 2.3% (240) | 2.2% (232) | 0.3% (27) |
| Gender | Female | 50.2% (5215) | 2.5% (130) | 2.1% (107) | 0.2% (12) |
| | Male | 49.8% (5175) | 2.1% (110) | 2.4% (125) | 0.3% (15) |
| Age | 4 – 5 years | 17.4% (1808) | 2.5% (45) | 3.7% (67) | 0.5% (9) |
| | 5.1 – 6 years | 55.0% (5715) | 2.4% (137) | 2.4% (136) | 0.3% (17) |
| | 6.1 – 7 years | 27.6% (2867) | 2.0% (58) | 1.0% (29) | 0.03% (1) |

5.5 DISCUSSION

This study aimed to estimate and describe hearing and vision loss among preschool children (4-7 years) in an underserved South African community. A critical issue in health services research related to infants and children is that of timely, necessary, and appropriate referrals for early childhood intervention services (GRDDC, 2018; Keffe, 2004; Olusanya et al., 2020). The development of mHealth has provided more opportunities for sensory screening at preschools in the community, to facilitate increased access to hearing and vision services. In this study, 5.6% and 4.4% of children failed the initial hearing and vision screen, respectively. These estimates compare well with previous studies reporting estimate referral rates of 5.6% for hearing (Mahomed-Asmail et al., 2016) and 3.6% for vision (Manus et al., 2021). Despite literature reporting that hearing and vision loss commonly co-occur (Bakhshae et al., 2009; Nikolopoulos et al., 2006), only 0.7% of children failed both hearing and vision screening, indicating the value of offering dual sensory screening at the same time, as identifying an impairment in one modality does not predispose or preclude an impairment in the other (Eksteen et al., 2019). This service-delivery model, where trained CHWs are utilized to screen both hearing and vision using the same

smartphone, has been shown to be efficient and low-cost (Eksteen et al., 2019; Manus et al., 2021).

A high proportion of the children who failed the screens completed the follow-up assessments (88.5% for hearing and 88.3% for vision). These figures are high compared to rates of 32.5% and 25.1% reported by Manus et al. (2021) and 45.3% reported by Hussein et al. (2018), when follow-up assessments were done at the health care facilities. Loss to follow-up after screening is widely reported as a barrier to healthcare (Arinze et al., 2015; Emmett et al., 2019; Manus et al., 2021; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). In previous studies, reasons for poor follow-up rates were attributed to transportation costs, leave of absence from work and long waiting periods at health care facilities (Bright et al., 2019; Keffe, 2004; Yousuf-Hussein, Swanepoel, Mahomed-Asmail., 2018). The high follow-up rates of this study demonstrate the value of decentralized follow-up assessments conducted at the preschools in the community (Eksteen et al., 2019; Zeng et al., 2020). In this study, the follow-up hearing tests were done by an audiologist. In low-resource settings, the availability and capacity of audiologists may pose a challenge to scaling up this model. For future implementation of such services, it is therefore proposed to enable CHWs to gather both threshold audiometric data and otoscopic images using a unified smartphone-based platform (Jayawardena et al., 2020). With smartphone-enabled otoscopes (smartphones coupled with specialized cameras allowing otoscopy to be utilized on the same platform), CHWs can easily capture images of the ear canal and tympanic membrane and save them to be shared and referenced in the future (Jayawardena et al., 2020; Moshtaghi et al., 2017). The utilization of trained CHWs can further contribute to the affordability and the efficiency of the applied service-delivery model (Eksteen et al., 2019; Jayawardena et al., 2020; Manus et al., 2021).

Out of the children who failed hearing and vision screening, 41.3% presented with hearing loss and 51.2% presented with vision loss at the follow-up assessment and were referred for treatment in the health care system. The community-based follow-up assessments assure selective referrals, thereby reducing the burden upon the health care systems and scarce specialized healthcare professionals (Bush et al., 2015; Eksteen et al., 2019; Jayawardena et al., 2020).

Due to the risk of loss to follow-up at health care centres, it is more accurate to report the prevalence of sensory losses according to the follow-up assessments at the preschools at that point in time (Manus et al., 2021; Yousuf-Hussein, Swanepoel, Mahomed-Asmail, 2018). The prevalence for hearing loss in this study ranged between 2.3% and 3.1%, depending on the assumptions for the proportion of non-respondents who were cases. Different criteria and testing methods and age cut-offs are used to determine sensory losses across studies, making it difficult to compare these prevalence estimates with the existing literature (Mulwafu et al., 2016; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). The global prevalence of disabling hearing impairment (defined as PTA \geq 35 dB HL in the better ear) among children 5–14 years of age was reported as 1.4% and prevalence in sub-Saharan Africa was 1.9% (Stevens et al., 2011), whereas a study by Olusanya et al. (2020) reported global prevalence in 5-9 year olds for hearing loss as 3.8% and 4.5% for sub-Saharan Africa (criteria constituting hearing loss was PTA \geq 20 dB HL in the better ear). Prevalence estimates have also been reported in preschool children in sub-Saharan Africa, ranging from 2.4% in Zimbabwe (Westerberg et al., 2005) and to 21.3% in Nigeria (Adebola et al., 2013).

About half of the children with hearing loss (53.5%) had obvious signs of external and/or middle ear abnormalities. The prevalence of ear disease might have been even higher, as tympanometry was not conducted and therefore not all middle ear pathology was identified (Emmett et al., 2019; New Zealand Health Technology Assessment, 1998). The high prevalence of occluding wax and abnormal middle ear findings in the current study are in line with recent reports from the WHO, which postulates that the leading causes of childhood hearing loss in LMICs are conductive and treatable (WHO, 2018). Studies have found conductive hearing loss to be the most common type of hearing loss found in preschool children in South Africa (65% in both studies) (Kuschke et al., 2020; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). This indicates a need for referral services in sub-Saharan Africa in order to ensure for appropriate treatment and follow-up service and highlights ear disease as a public health concern (Kumar et al., 2019; Kuschke et al., 2020; Olusanya et al., 2004; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018).

The prevalence of bilateral hearing loss was found to be more common than that of unilateral hearing loss, in agreement with reports of others (Kuschke et al., 2020; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). Also in agreement with other studies, mild hearing loss was most prevalent, followed by moderate loss (Kuschke et al., 2020; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). This may be partially explained by impacted wax and otitis media and its sequelae (Kuschke et al., 2020; Olusanya et al., 2020; Stevens et al., 2011; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). Early identification and appropriate management of both bilateral and unilateral hearing loss, as well as milder degree of hearing impairment are important since even a unilateral or mild hearing losses negatively affect educational outcome (Dodd-Murphy et al., 2014; Kumar et al., 2019; Olusanya et al., 2020; WHO, 2018). Only 0.1% of children screened had a severe hearing loss and 0.1% of children had a profound hearing loss. In recent years, an increase of targeted hearing screening in Cape Town, South Africa, resulted in more children with permanent congenital or early-onset hearing loss (PCEHL) being identified and diagnosed at health care centres before the age of 4 years (de Kock et al., 2016; Kuschke et al., 2020). Therefore, children with sensory losses between 4 to 7 years might already be enrolled into intervention programmes and preschools specifically for children with disabilities, thus excluding them from the prevalence reported in this study.

Prevalence of vision loss in the current study ranged between 2.2% and 2.8%. The global prevalence, as well as the prevalence in Sub-Saharan Africa, for 5-9 year olds are estimated at 3.1% for vision loss (Olusanya et al., 2020). In comparison to previous studies, mild vision loss was least prevalent (Olusanya et al., 2020). The severity of vision loss was based on degree of loss in the worst eye, possible contributing to the high prevalence of results indicating “No response” in this study.

More than half (137) of children with vision loss had bilateral loss and 95 had unilateral loss. Thirty-two children passed the visual acuity assessment, but had obvious ocular abnormality. Nirmalan (2003) found that CHWs can be trained effectively to identify children with ocular abnormalities and they should not be limited to screening for vision impairment alone (Nirmalan et al., 2003). Therefore, training of the CHWs should include identification of obvious signs of visual impairment (such as strabismus), in order for children who passed screening but present with abnormalities to also be

referred for follow-up assessments and intervention. In LMICs, the majority of vision loss is either preventable or treatable (Gilbert & Foster, 2001; Keeffe, 2004). Therefore, early identification and intervention through vision screening is a priority within the WHO VISION 2020 (Right to Sight) programme (Gilbert & Foster, 2001).

It is reported that sensory impairments commonly co-occur, with an estimated 40 to 60% of children with hearing loss also having some degree of vision loss (Bakhshae et al., 2009; Nikolopoulos et al., 2016). In the population of children diagnosed with PCEHL at health care centres (Kuschke et al., 2020), there will most probably be a higher incidence of co-occurring sensory losses than the 0.3% of children found to have combined sensory losses in this study. Another consideration is that early childhood education is not compulsory in South Africa and it is possible that not all young children with sensory deficits attended preschool facilities targeted in this study (Eksteen et al., 2019; Yousuf-Hussein et al., 2018).

In agreement with previous studies, gender did not have a significant effect on sensory losses (Kumar et al., 2019; Mahomed-Asmail et al., 2016; Yousuf-Hussein, Swanepoel, Mahomed-Asmail, 2018). Age was a predicting factor of vision loss, however, the strength of the correlation was poor. The higher prevalence of vision loss in younger children might be ascribed to younger children not yet being enrolled in special schools or receiving treatment elsewhere. Other studies also showed no association between hearing impairment and age (Mahomed-Asmail et al., 2016; Yousuf-Hussein, Swanepoel, Mahomed-Asmail, 2018).

5.5.1 Strengths and limitations

Strengths of this study include a large study population, assessment of both hearing and vision, as well as the use of validated tools for community-based screening and assessments. The hearing assessment protocol did not include tympanometry or bone conduction audiometry and therefore, the nature (conductive versus sensory-neural versus mixed hearing loss) and cause of hearing loss could not be determined. The visual assessment protocol did not include a basic ocular examination using torchlight

and may have resulted in an underestimation of ocular morbidity. The cause of vision loss was also not determined.

5.6 CONCLUSION

According to this study, hearing loss is prevalent in at least 22 per 1000 and vision loss is prevalent in at least 23 per 1000 preschool children in an underserved South African community. Children who were identified with sensory losses were referred to health care clinics where they received interventions (e.g. medical management, hearing aids or spectacles). Future studies aim to report on causes of visual or hearing loss, as well as outcomes and the impact of interventions on the children diagnosed with sensory impairments. Timely identification of sensory losses is essential to ensure optimal outcomes and can be facilitated through community-based hearing and vision services supported by mHealth technology.

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6 GENERAL DISCUSSION, CLINICAL IMPLICATIONS AND CONCLUSIONS

Sensory inputs of hearing and vision during early childhood development support the achievement of optimal language, speech and educational outcomes. Early detection of sensory impairment is essential for facilitating early childhood development, socio-emotional well-being and academic success, in addition to obtaining the sustainable development goals related to education (Gilbert & Foster, 2001; Graydon et al., 2019; GRDDC, 2018; Stevens et al., 2011; Wilson et al., 2017).

The majority of children with sensory impairments live in LMICs where services are usually unavailable or inaccessible, because of an absence of systematic screening programmes for children, prohibitive equipment cost, a shortage of trained personnel and centralised service-delivery models (Harris & Dodson, 2017; Kamenov et al., 2021; Olusanya et al., 2020; Swanepoel, 2020; Wilson et al., 2017). Service-delivery models incorporating mHealth technology and community-delivered healthcare have the potential to decentralise and increase access to services in resource-constrained settings (Emmett et al., 2019; Jayawardena et al., 2020; Manus et al., 2021; Shinn et al., 2019; Suen et al., 2019; Swanepoel, 2020; Van Wyk et al., 2019; Yancey et al., 2019).

The main aim of this study was to describe and evaluate a service-delivery model for hearing and vision screening for preschool children in low-income communities. This research project first aimed to describe an implemented mHealth-supported community-based combined sensory screening service-delivery model and evaluate its success in terms of acceptability, coverage, referral rates and quality indicators. The study also described the challenges met during this implemented screening programme and the strategies developed to overcome these. To determine optimal referral criteria that is responsive to available resources in this context, the study subsequently aimed to describe and compare the performance of two screening

protocols that were used in the implemented screening programme. Finally, the prevalence and characteristics of hearing and vision loss among preschool children (4–7 years) in an underserved South African community following the implemented mHealth-supported community-based hearing and vision services were investigated and described.

6.1 Overview of research findings

Over a period of 22 months, a total of 10,390 children were screened at 298 preschools by four trained CHWs using mHealth technology. The 82% return rate for consent forms and the hearing and vision screening of 94.4% of eligible participants during Study I indicated good acceptability and a high coverage rate for the screening programme. CHWs distributed posters and leaflets within the preschools and emphasised the importance of hearing and vision for learning to preschool staff and shared information on the risk factors and signs of sensory loss. Use of the same equipment and minimally trained staff to screen both hearing and vision contributed to the affordability and scalability of the service-delivery model, with combined sensory screening done at a full-cost of US\$5.63 per child in Study I. Of the children screened, 5.6% and 4.4% of children failed hearing and vision screening, respectively. Hearing screening failure was associated with longer test duration (OR: 1.022; 95% CI: 1.021–1.024) and noise levels exceeding MPANLs at 1 kHz (e.g. for left ear, OR: 1.688; 95% CI: 1.198–2.377), but not with gender (OR: 0.891; 95% CI: 0.702–1.131). Vision screening failure was associated with a younger age (OR: 0.629; 95% CI: 0.520–0.761) and longer test duration (OR: 1.003; 95% CI: 1.002–1.005), but not with gender (OR: 0.928; 95% CI: 0.726–1.186). Mean initial test duration for children who passed the screening was 59.2 and 91.2 s for hearing and vision, respectively. Mitigation strategies for several challenges encountered during the screening programme, such as CHW safety, logistics and technology, were developed and described in Study I. The two main identified enabling factors of a service-delivery model for hearing and vision care for preschool children were mHealth technology and community-delivered care.

In Study II, two hearing screening protocols, only differing in referral criteria (referral after failing a single frequency versus referral after failing two frequencies), used in a

community-based service-delivery model were compared. The study focused on describing the referral rate, true positive and false positive rate and the duration of screening for both protocols. The referral rate was 8.7% for the one-frequency fail protocol and 4.3% for the two-frequency fail protocol. Compared with the one-frequency fail protocol, children screened with the two-frequency fail protocol were 52.9% less likely to fail ($p < 0.001$; OR: 0.471; 95% CI: 0.385–0.575). Therefore, Study II proved that by employing a protocol with a two-frequency or more fail criteria, referral rate is significantly decreased. Gender ($p = 0.251$; OR: 0.807; 95% CI: 0.531–1.225) and age ($p = 0.570$; OR: 0.996; 95% CI: 0.708–1.402) had no significant effect on the screening outcome. A total of 44.7% of cases screened had exceeded MPANLs in at least one ear at 1000 Hz across both protocols. The protocols did not differ significantly from each other for either true positive cases or false positive cases. Protocol ($p = 0.204$; OR: 1.338; 95% CI: 0.854–2.098), gender ($p = 0.314$; OR: 0.807; 95% CI: 0.531–1.225) and age ($p = 0.982$; OR: 0.996; 95% CI: 0.708–1.402) demonstrated no significant effect on the odds of delivering a true positive result. Average time to conduct the screening was 72.8 s (78.66 SD) for the one-frequency fail protocol and 64.9 s (55.78 SD) for the two-frequency fail protocol.

Study III found that a high proportion of the children who failed the screening completed the follow-up assessments at the preschools (88.5% for hearing and 88.3% for vision). These follow-up rates are high in comparison to other studies where the follow-up assessments were performed at healthcare facilities, and demonstrate the value of decentralised service-delivery. Logistic regression analysis found that age was a significant predictor of vision loss ($p < 0.001$); with every 1-year increase in age, participants were 51.4% less likely to have vision loss (OR: 0.49, 95% CI: 0.39–0.60). Age was not found to be a significant predictor of hearing loss ($p = 0.06$; OR: 0.821; 95% CI: 0.667–1.011). Gender was not a significant predictor of hearing loss ($p = 0.22$; OR: 0.850; 95% CI: 0.658–1.099) or vision loss ($p = 0.20$; OR: 1.185; 95% CI: 0.912–1.540). The prevalence for hearing loss at a PTA of 25 dB HL ranged between 2.3% (240 out of 10,390; assuming none of the non-attenders and children unable to be tested at the follow-up hearing test had hearing loss) and 3.1% (321 of 10,390; assuming all the non-attenders and children unable to be tested presented with hearing loss). The prevalence of vision loss (a visual acuity of less than 0.3 LogMar in both eyes or less than 0.4 LogMar in the better eye) in this study ranged between 2.2%

(232 out of 10,390) and 2.8% (286 out of 10,390), depending on assumptions for the proportion of non-respondents who had vision loss. Combined sensory losses were prevalent in 0.3% of the children in this study, indicating the value of simultaneous dual sensory screening, as identifying an impairment in one modality does not predispose or preclude an impairment in the other. About half of the children with hearing loss (53.5%) had obvious signs of external and/or middle ear abnormality, highlighting the need for referral services to ensure appropriate treatment and follow-up care.

6.2 Clinical implications

mHealth-supported hearing and vision screening performed by CHWs in preschools provided a low-cost, accessible service of an acceptable standard that improved access to hearing and vision care. This service-delivery model, in which non-professional members from the community were successfully trained and appointed as CHWs to screen for both hearing and vision using automated mHealth technology with preset protocols and quality control measures (Donovan et al., 2019; Jayawardena et al., 2020; Manus et al., 2021; Swanepoel, 2020; Van Wyk et al., 2019), contributes to the base of evidence of approaches that promote equitable and cost-effective healthcare (GBD, 2021; WHO, 2021). The successful utilisation of affordable and validated mobile technology together with task sharing to address the shortage of qualified professionals can enable early identification of sensory losses (WHO, 2021). This approach has profound implications for expanding access to healthcare in LMICs where screening is hampered by a shortage of healthcare providers (Bhutta, 2019; GBD, 2021; Kamenov et al., 2021;; Shinn et al., 2019; WHO, 2021).

Research demonstrated that CHWs with minimal training are able to conduct hearing screening services equivalent to that of trained professionals when using validated mHealth technology (Bright et al., 2019; Dawood et al., 2020; Shinn et al., 2019). This approach of task sharing expands the reach of service delivery in LMICs, supporting the use of scalable community-based programmes (Dawood et al., 2020; Jayawardena et al., 2020; Suen et al., 2019). Task sharing shifts the burden of screening away from already overwhelmed professional healthcare providers in

LMICs by using minimally trained CHWs who are readily available (Shinn et al., 2019). This, in turn, releases professional healthcare workers who could then provide services for children requiring further investigations and management after screening (WHO, 2021). Furthermore, CHWs, who are competent in the language and the culture of those they serve, are typically better able to explain the reasons for screening and referrals, thereby promoting high consent return rates and follow-up return rates, as seen in this study (Thomas et al, 2021).

Using the same equipment and trained CHWs to conduct the combined sensory screening contributed to the affordability and scalability of this service-delivery model (Rono et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018). While a previous study reported poor reliability of hearing screening for children younger than 4 years of age (Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018), age was not a predictor of hearing screening outcomes in the target population of this study (4–7 years of age). Consequently, the behavioural audiometry hearing screening method was confirmed to be appropriate for this age group. The average combined duration of hearing and vision screening, including an immediate rescreen, was less than 3 min. Therefore, the proposed screening method is time efficient and facilitates screening of larger numbers of individuals over a shorter period of time, contributing to the cost effectiveness of the program and minimising disruption of the child (Silwa et al., 2011). The yield of sensory losses (confirmed hearing or visual impairment or both) after the diagnostic appointments in Study I were 111 children. However, the reported yield only included confirmed cases, which did not include the following: children still awaiting appointments or confirmation of loss after a follow-up appointment (n=45); those not seen for follow-up appointments due to defaulting their appointments (n=86); children who had normal sensory functioning but were referred for other developmental interventions (n=9); or children who passed the first-line follow-up hearing test but had to be referred for wax removal at the clinic due to excessive wax (n=66). Therefore, community based screening facilitated identification of 317 children in need of comprehensive, diagnostic assessments and/or possible intervention.

The presence of CHWs at preschools to conduct screening also provided an opportunity to educate preschool staff and raise awareness in the community about

hearing and vision loss (UNESCO, 2017; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018). Figure 6.1 is an example of a poster that was developed and distributed in preschools to inform staff about risk factors for and signs of sensory loss and how to respond to flagged cases. Observations from the field and the development of mitigation strategies for challenges encountered during the implementation of the programme provided valuable insights and knowledge for future scaled projects (Box 3.1). To maximise the accessibility of a screening programme, the central issue of comprehensible informed consent had to be bridged (Jack et al., 2014; Worthington, 2002). Therefore, a simplified one-page consent form, available in English and Xhosa or Afrikaans (depending on the child's mother tongue), was sent to the parents or caregivers before screening. A third (32.3%) of the consent forms were completed in another language than English, illustrating the need for informed consent to be made more accessible by considering context and culture.

The described decentralised service-delivery model was enabled by the low cost and mobility of the mHealth technology used, in addition to task sharing that facilitated community-based care. Table 6.1 summarise the factors that contributed to the successful implementation of each stage of the screening programme. Employing validated mHealth technology, used by CHWs, can assist the government to effectively implement mass community-based hearing screening programmes (Emmett et al., 2019; Jayawardena et al., 2020; Shinn et al., 2019; Suen et al., 2019; Swanepoel, 2020). For CHWs to deliver such services with new technology, it is important that screening protocols are selected appropriately to maximise true positives and minimise excessive referral rates to avoid overload of the healthcare system (Allen et al., 2004; Kam et al., 2014; Mahomed-Asmail et al., 2016). Therefore, the recommended criterion for referral of hearing screening and the targeted hearing loss should be evidence-based and consider specific contextual resources to ensure an ethically responsible approach to screening (Allen et al., 2004; Kam et al., 2014; Mahomed-Asmail et al., 2016). Over-referrals contribute to the burden faced by follow-up services, as well as reducing credibility with parents and physicians, whereas false negatives result in children with minimal to mild hearing loss being missed. This trade-off between over-referral and sensitivity to minimal hearing loss is an ongoing debate (Stenfeld, 2018). Appraisal of the referral criteria of the screening protocols

implemented in the community-based service-delivery model in Study II demonstrated that screening performed at 25 dB HL at 1, 2 and 4 kHz with a two-frequency fail criteria significantly reduced referral rates. Reduced referrals positively impact resourced-constrained settings where follow-up services are often overburdened. An immediate rescreen reduced the number of referrals across both protocols, corresponding with the findings from a previous study (Mahomed-Asmail et al., 2016). This confirms recommendations that an immediate rescreen should be routinely employed in screening programmes (Allen et al., 2004; Kam et al., 2014; Van Wyk et al., 2019). Since milder losses may be attributed to transient conductive rather than permanent SNHL and considering the context of LMICs, true positive rate is an important indicator of program performance. Despite not being statistically significant, the higher true-positive rate for the two-frequency fail protocol (37.9%) compared to the one-frequency fail protocol (32.3%) is a factor to consider for community-delivered screening in a resource-constrained setting. Study I and II indicated that future protocol adaptations should also consider increasing the screening levels (e.g. from 25 dB HL to 30 dB HL) at 1000 Hz to minimise the influence of environmental noise at the lower frequencies (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel, Mahomed-Asmail, et al., 2018; Yousuf Hussein et al., 2015). A lower rate of false positives caused by noise, at the risk of missing milder hearing loss possibly caused by transient middle ear effusion, may be a trade-off to consider in resource-constrained contexts, where excessive referrals can undermine the success of a screening programme.

Preschool-based first-line assessments resulted in a high follow-up return rate in Study III. The high follow-up rates of Study III demonstrated the value of decentralising follow-up assessments (Zeng et al., 2020). This is an important consideration for service-delivery models (Figure 6.2), where practically possible, and can be facilitated by upskilling CHWs to perform this step, using mHealth diagnostic and triage technology (Bright et al., 2019; De Sousa et al., 2020; Shinn et al., 2019). For future implementation of such services, it is proposed that task sharing should be extended by enabling CHWs to gather both threshold audiometric data and otoscopic images with smartphone-enabled otoscopes, using a unified smartphone-based platform (Jayawardena et al., 2020; Moshtaghi et al., 2017). CHWs should also be trained to identify children with obvious ocular abnormalities (such as strabismus), and refer

them for diagnostic assessment and intervention (Nirmalan et al., 2003). After the preschool-based follow-up assessment, only 41.3% and 51.2% of children who failed the hearing and vision screening presented with hearing and vision loss and were referred to primary healthcare facilities for diagnostic assessment and treatment. Therefore, in addition to achieving a high follow-up return rate, the community-based follow-up assessments assured selective referrals, thereby reducing the burden on the healthcare systems and scarce, specialised healthcare professionals (Bush et al., 2015; Jayawardena et al., 2020).

Obtaining population-based information about childhood hearing loss and visual impairment enables adequate planning and successful implementation of community-based hearing and vision care, and is especially valuable for clinicians, project managers and policymakers. Children identified with sensory losses were referred to healthcare clinics where they would have received interventions (e.g. medical management, hearing aids or spectacles). It is essential to conduct a situational analysis of the potential referral routes for hearing and vision services and of established follow-up pathways before implementing a screening service (WHO, 2021; De Kock et al., 2017; Friderichs et al., 2012).



If you are concerned about a child's ears/hearing or eyes/vision - please refer them as soon as possible:

| | | |
|--------------------|--------------------|--------------|
| Audiology services | Optometry services | Local clinic |
| | | |



Figure 6.1. Example of poster distributed in preschools during community-based screening.

Table 6.1. Enabling factors of an mHealth-supported community-based programme for hearing and vision screening in preschool children

| | | Service-delivery model: Stages | | | | | | |
|-------------------------|---------------------------|--|--|--|--|---|---|--|
| | | Pilot & preparation phase | → Locate & map preschools | → Distribute & collect consent | → Hearing & vision screening (incl. immediate rescreen) | → Preschool-based follow-up | → Referrals and reporting | → PHC* diagnostic assessment, treatment and intervention |
| Enabling factors | mHealth technology | <ul style="list-style-type: none"> - Select affordable (e.g. off-the-shelf smartphones and calibrated headphones), automated, user-friendly and validated) technology with quality control metrics that advise on the feasibility of test environments and test operator. - Must have integrated cloud-based data management systems that allow remote support and surveillance of professionals. - E.g. hearScreen and peekAcuity apps on Samsung smartphones linking to mHealth studio. | <ul style="list-style-type: none"> - Plot the location of preschools by using a mapping feature app that connects & uploads locations and information about facilities to a cloud-based data management system. | <ul style="list-style-type: none"> - Pre-capture patient details from returned consent forms into the data management system that synchronises with an app (under facilities). - The app only allows testing if the tester indicates that informed consent was obtained. - Future implementation: e-Consent with SMS. | <ul style="list-style-type: none"> - Pre-captured patient details on mHealth platform. - Patient & test data capturing & synchronisation to cloud. - Same equipment (smartphone) that host validated apps for hearing (e.g. hearScreen) and vision (e.g. peekAcuity) screening. - Pre-specified and automated protocols & automated interpretation of results. - Simple, intuitive user interface - Off-the-shelf circumaural headphones calibrated to ISO standards. - Noise-monitoring algorithms ensuring on-site and remote monitoring for noise levels. - Quality index algorithms to monitor performance of CHWs. - Automated SMS results sent to parents. - Future implementation: flag learners with other barriers to learning in-app | <ul style="list-style-type: none"> - Screening results and patient data on app uploaded to cloud-based network (through cellular networks) for data management: referrals identified and follow-up arranged according geolocation. - In-app review of screen result. - Air conduction threshold pure tone audiometry validated app (e.g. hearTest) on the same hardware as screening. - Noise-monitoring and quality control algorithms. - Future implementation: smartphone-enabled otoscopes. - Future implementation: Include a “could not test” option for children not conditioned. - Future implementation: automated apps with preset protocols and quality control measures allow CHWs to conduct first-line follow-up.. | <ul style="list-style-type: none"> - Results sent to parents through automated SMS. - Summative report of results can be generated and sent to preschool principals. - Referrals according to geolocation. - Reports generated and sent to diagnostic centres. - Appointment and importance of attendance sent to parents via SMS. - Future implementation: link learners flagged for other developmental delays to services and support. | <ul style="list-style-type: none"> - Diagnostic services at PHC clinics, using the same platform: viewing of patient test results, tracking follow-up returns. - Feedback provided to CHWs to support the child, parent and preschool. |

| | | | | | | | |
|-----------------------------|--|--|---|--|--|--|--|
| | | | | and link to services & support. | | | |
| Community-based care | <ul style="list-style-type: none"> - Situation analysis of existing referral pathways. - Consider learning from previous projects. - Recruit, appoint and train CHWs from the community to enable task shifting. - Consider context and cultures of community. - Connect with local, community-based organisations supporting preschools in the community. - Attend preschool principle's forums: share information, introduce programme & establish partnerships. | <ul style="list-style-type: none"> - Partner with local organisations & forums. - CHWs familiar with context, culture and community. - Training and awareness drives at preschools (ensure buy-in). | <ul style="list-style-type: none"> - Consider context: simplified version in multiple languages (no more than 1 page). - Empowered preschool staff to be advocates. - Raise awareness under parents and children. - Buy-in and commitment from principals and parents (facilitated by relationship with CHW and knowledge about importance of screening). | <ul style="list-style-type: none"> - Inclusive technology allows CHWs to screen both hearing and vision (task shifting). - CHWs understand context, language & cultural beliefs. - CHWs have relationships, credibility & are advocates (point of access for services). - Trained to condition children age-appropriately and read responses. - Selected CHWs comfortable working with children from this age group. - Decentralised | <ul style="list-style-type: none"> - Decentralised (on-site at preschool). - Support teachers to facilitate inclusion of children with delays. - Future implementation: train CHWs to conduct follow-up. - Future implementation: Train CHW to identify and link children with other barriers to learning to support services. | <ul style="list-style-type: none"> - Situational analysis and meeting with role players to establish referral pathways. - Build on previous community projects: level of readiness in community. - CHW phone parents before appointment at PHC to remind & raise awareness. | <ul style="list-style-type: none"> - Surveillance by project manager (feedback & tracking). - Children identified absorbed into health care system. - Intervention provided by health care system (medical/assistive devices/rehabilitation/school placement) - Advocate for children with vision and hearing loss: support preschool staff with training to ensure inclusion. |

*PHC: primary healthcare

6.3 Study strengths and limitations

A critical evaluation of this research project was conducted to evaluate its strengths and limitations.

6.3.1 Study strengths

- Study I was the first study to report on an implemented combined sensory screening programme in preschools and contributed to a novel service-delivery model utilising minimally trained CHWs, employed from the community, and mHealth technology to deliver community-based care.
- Evaluation of a long-term service-delivery implementation with employed CHWs and dedicated programme managers ensured the identification of enabling factors at grassroots level.
- First-hand and practical experience of challenges encountered, strategies developed and adaptations made to streamline and optimise service-delivery was documented and could be used to describe the service-delivery model as implemented in the field.
- The documented information from the field about challenges encountered and mitigation strategies in Study I can inform realistic planning of future similar screening programmes.
- Study I retrospectively reviewed an implemented screening programme with a large study population, and findings can therefore be generalised to other resource-constrained settings or similar contexts.
- The use of validated mHealth technology with integrated cloud data management enabled accurate data capturing of a large-scale screening programme.
- Study II was the first to explore and compare a conventional, single-frequency fail protocol to an adapted protocol. Therefore, the findings from Study II provided novel evidence-based protocol recommendations to be employed in resource-constrained settings.

- Study III included a large study population, assessment of both hearing and vision and the use of validated tools for community-based screening and assessments.
- Study III reported on the prevalence and characteristics of hearing and vision loss according to follow-up assessments conducted at the preschools in the community at that point in time. Due to the risk of loss to follow-up at healthcare centres, it is more accurate to report the prevalence of sensory losses according to these assessments (Manus et al., 2021; Yousuf Hussein, Swanepoel, Mahomed-Asmail, 2018).

6.3.2 Study limitations

- The project manager was an audiologist, and no ophthalmic supervision was provided to CHWs during Study I and Study III. This was a limitation because no expert opinion or guidance regarding the vision aspect of the screening and service-delivery could be given during the programme. The obvious benefits of the programme manager being an audiologist included being able to adjust hearing screening protocols, provide audiology supervision and log mHealth snags; therefore, the lack of insight into the field of ophthalmology can be assumed to be a limitation.
- The app used for vision screening, Peek Acuity, has a function that requires the test operator to indicate whether the child that is tested wear spectacles or not before the test can commence. Unfortunately, this data was not included or considered in our data analysis. This is a limitation, as the data could have added valuable information on children fitted with corrective eyewear before the screening programme.
- Except for measures of environmental noise, no consistent measure of the quality of CHWs test reliability was available in Studies I, II and III. This was expected to be reported as mHealth snags and software updates. As remote surveillance of quality control measures is key when minimally trained non-professionals conduct screening (Swanepoel, 2020), this was a limitation.
- To determine the effect of the screening programme in Study I, a control group, receiving no hearing or vision screening, would have provided a valuable baseline to compare the group who participated in the programme with.

- The test duration times reported in Studies I, II and III did not record the time taken to condition a child. The hearScreen, hearTest and peekAcuity apps only started to record the duration of a test when the actual test was started. However, especially when testing young children, instruction on and conditioning of the desired behaviour is needed prior to commencement of the test. This is an important aspect of testing, as it increases reliability. This process can prolong the duration of the test and should be taken into consideration for a more accurate reflection of the screening time.
- For Study II, it would have been valuable to determine the sensitivity and specificity of the different protocols. Unfortunately, due to time constraints and limited human resource capacity, children who passed the screening could not be selected to undergo first-line follow-up to determine specificity and sensitivity.
- Study II used secondary data analysis and was not a randomised controlled trial; therefore, the type of facility and times of testing varied between the protocols and may have influenced some outcomes. During the screening programme, the two protocols were consecutively used. The second protocol was initiated after the project manager noticed high referral rates with the single-frequency fail protocol. Conducting a randomised controlled trial would have allowed the impact of the adapted protocol to be determined while reducing bias and variables.
- Studies II and III used data from the community-based first-line follow-up hearing assessment, where only otoscopy and pure tone audiometry was performed to determine a result. Children who failed this assessment still had to be seen for a more comprehensive diagnostic audiological evaluation, including wax removal, tympanometry and bone conduction audiometry. Data on the true positive rate of screening tests (Study II) and the prevalence of hearing loss (Study III) was, therefore, based on a preliminary audiology assessment and not a diagnostic assessment.
- The nature (conductive, sensory-neural or mixed hearing loss) and cause of the hearing loss could not be determined in Study III, because of the first-line follow-up protocol. The protocol included air audiometry and otoscopy, but not

tympanometry, acoustic reflexes and bone conduction audiometry due to equipment, time and human resource constraints.

- The visual assessment protocol in Study III did not include a basic ocular examination with a torchlight and may have resulted in an underestimation of ocular morbidity. This exceeded the scope of the screening programme but should be considered for future programmes.

6.4 Recommendations for future research

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

- Future research should focus on the perceived acceptability of such screening programmes for parents and caregivers, preschool principals, staff and CHWs.
- There is still a paucity of evidence about the costs and cost-effectiveness of decentralised community-based hearing care (Suen et al., 2019; WHO, 2021). For future implementation and government-level adoption of such services, cost-effectiveness studies are essential.
- The outcomes of the clinic visits regarding attendance rates, yield, predicting factors and the nature of hearing and vision loss after the initial diagnostic assessments should be investigated and reported.
- The uptake of referrals and interventions of children identified with sensory loss through the screening programme should be investigated. In cases where appointments were defaulted or interventions declined, the reasons should be investigated.
- Future studies should aim to report on educational and psychosocial outcomes and the impact of interventions on children diagnosed with sensory impairments following identification through a decentralised screening programme.
- Based on the findings from this study, it is recommended to adapt the two-frequency fail hearing screening protocol by increasing the screening intensity at 1000 Hz from 25 to 30 dB HL, to address the potential influence of

environmental noise. Randomised controlled trials for further evaluation of optimal protocols in resource-constrained settings are therefore needed.

- For future implementation of mHealth-supported community-based services, it is proposed to enable CHWs to gather both threshold audiometric data and otoscopic images using a unified smartphone-based platform (Jayawardena et al., 2020). A study by Bright et al. (2019) suggests that non-specialist health workers can be involved in surveys of the prevalence and causes of hearing loss. The utilisation of CHWs for a preschool-based first-line follow-up assessment should be piloted and investigated.
- Vision screening results were affected by age, with younger children being more likely to present with vision loss. Future studies should aim to determine the reliability of vision screening in this population of children of 4 to 7 years old. The possibility of older children being less likely to fail the screening due to already wearing spectacles at the time of screening, should be investigated in future studies.
- The mHealth technology for both hearing and vision screening have the capacity to determine the degree of sensory loss, with threshold determination following a screen fail. The potential of a severity screen in which the degree of loss is immediately determined after a screening test should be investigated.
- Future research, especially in LMICs, needs to investigate mHealth-supported hearing and vision care services from detection to intervention and ongoing support (Swanepoel, 2020).
- The potential integration of other mHealth services, for example developmental delay screening (Van der Merwe et al., 2019), towards a more comprehensive community-based service should be piloted and investigated.
- The impact of community awareness campaigns and information sharing sessions at preschool forums should be evaluated.

6.5 Conclusion

This study investigated mHealth-supported community-based preschool screening in low-income communities in the Western Cape, South Africa. The screening programme was unique in that non-professional community members were trained as

CHWs providing both hearing and vision screening at preschools using mHealth point-of-care apps with quality control features and automated test sequences, enabling task sharing from higher cadre health providers to CHWs.

The study found that a protocol with a two-frequency fail criterion and immediate rescreening of failed frequencies significantly reduced referral rates for follow-up services that are often overburdened in resourced-constrained settings. A protocol adaptation that should be considered is to increase the screening level at 1000 Hz to minimise the influence of environmental noise.

Findings of this research project indicate that mHealth-supported CHW-delivered hearing and vision screening in preschools provide a decentralised, low-cost, efficient and accessible service that can improve the provision of affordable hearing and vision care for preschool children in LMICs. Efficient design of such a system requires a holistic approach, including the use of digital technology, the training and monitoring of CHWs, the support of community partners and effective referral systems. This type of digital platform facilitated by CHWs can allow value-added integration of other mHealth services, for example developmental delay screening, towards a more comprehensive community-based service.

Timely identification of sensory losses is essential to ensure optimal outcomes and can be facilitated through community-based hearing and vision services provided by minimally trained CHWs, supported by mHealth technology. Future studies should aim to report on the outcomes and impact of interventions on children diagnosed with sensory impairments following identification through a decentralised screening programme.

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8 APPENDICES

APPENDIX A

Ethical approval letter
Research Ethics Committee
Faculty of Humanities
University of Pretoria



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

4 October 2017

Dear Prof Swanepoel

Project: Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model
Researcher: Prof DCDE Swanepoel
Department: Speech-Language Pathology and Audiology
Reference number: Staff research (GW20170922HS)

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** at an *ad hoc* meeting held on 4 October 2017. 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.

We wish you success with the project.

Sincerely

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

Research Ethics Committee Members: Prof MME Schoeman (Deputy Dean); Prof KL Harris; Dr L Blokland; Ms A dos Santos; Dr R Fasselt; Ms KT Govinder; Dr E Johnson; Dr C Panebianco; Dr C Puttergill; Dr D Reyburn; Dr M Taub; Prof GM Spies; Prof E Taljard; Ms B Tsebe; Dr E van der Klashorst; Dr G Wolmarans; Mr V Sithole

APPENDIX B

Ethical approval extension letter for amendment of protocol

Research Ethics Committee

Faculty of Humanities

University of Pretoria



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

HumanITIES 100.
— 1919 - 2019 —

12 June 2019

Dear Prof Swanepoel

Project: Hearing and vision screening for preschool children using mHealth technologies: A community-based service-delivery model
Researcher: Prof DCDE Swanepoel
Department: Speech-Language Pathology and Audiology
Reference number: GW20170922HS (Staff research) (Amendment to protocol)

Thank you for the application to amend the existing protocol that was approved by the Committee on 4 October 2017.

I have pleasure in informing you that the amendment was **approved** the Research Ethics Committee at an *ad hoc* meeting held on 12 June 2019. Further data collection may therefore continue until June 2021 and is extended to include the Mbekwini area.

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

We wish you success with the project.

Sincerely

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

APPENDIX C

Ethical approval letter
Postgraduate Research Ethics Committee
Faculty of Humanities
University of Pretoria



1 November 2019

Dear Mrs S Eksteen

Project Title: mHealth supported community-based hearing and vision services for preschool children in low-income communities.
Researcher: Mrs S Eksteen
Supervisor: Prof DCDW Swanepoel
Department: Speech Language Path and Aud
Reference number: 26014981 (HUM020/1019)
Degree: Doctoral

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

The Research Ethics Committee notes that this is a literature-based study and no human subjects are involved.

The application has been **approved** on 31 October 2019 with the assumption that the document(s) are in the public domain. Data collection may therefore commence, along these guidelines.

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. However, should the actual research depart significantly from the proposed research, a new research proposal and application for ethical clearance will have to be submitted for approval.

We wish you success with the project.

Sincerely

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

Fakulteit Geesteswetenskappe
Lefapha la Bomotheo

Research Ethics Committee Members: Prof MME Schoeman (Deputy Dean); Prof KL Harris; Mr A Bizos; Dr L Blokland; Dr K Booyens; Dr A-M de Beer; Ms A dos Santos; Dr R Fasselt; Ms KT Govinder; Andrew; Dr E Johnson; Dr W Kelleher; Mr A Mohamed; Dr C Puttergill; Dr D Reyburn; Dr M Soer; Prof E Taliard; Prof V Thebe; Ms B Tsebe; Ms D Mokala

APPENDIX D

Facility agreement form



EARS & EYES FOR EDUCATION

INFORMATION & INFORMED CONSENT DOCUMENT FOR ECD CENTERS

Dear Principal,

EARS AND EYES FOR EDUCATION (3E) PROJECT: FREE SENSORY SCREENING AT ECD'S

We are developing a program to support healthy learning by providing hearing and vision screenings for pre-school children between the ages of 5 – 6 years in Cape Town. This will help to identify any problems that may affect a child's development and school success due to hearing or vision problems. It usually takes between 10-15 minutes to complete and the school and parents will receive a referral letter if the child needs further testing. Parents will have to provide informed consent to have their children's hearing and vision screened and for allowing their child's data to be used for research purposes.

Please note that the hearing and vision screening information obtained may be used for research purposes. In this case, all identifying information will be kept confidential and data analysis will be conducted anonymously. If the parent or child 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. The title of the study is: *Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model.*

Your centre will be invited to attend free training regarding healthy hearing and information sessions on how to support learning for a child with a hearing impairment in your school. This will enhance services that your centre delivers.

If you agree for hearing and vision screening services to be provided at your ECD center, kindly complete the form below. Please phone 064 1322848 for more information.

Ms Susan Eksteen

Consent

Herewith I _____ (name) grant permission for hearing and vision screening to be provided at _____ (ECD centre) and I acknowledge that the information will be used for research purposes as specified above. My contact details are (email/telephone number) _____.
Address of ECD: _____.

Signature

Date



APPENDIX E

**(1) Informed consent form:
English and Xhosa**

**(2) Informed consent form:
English and Afrikaans**



EARS & EYES FOR EDUCATION

FREE EARS AND EYES TEST AT SCHOOL

Dear parent/caregiver,

Please read the letter, sign the letter and send it back to school tomorrow.

Hearing and seeing is very important for your child to be able to learn. There will be hearing and vision (seeing) tests at school for children 5 to 6 years old, free of charge. You must give permission for us to test your child's hearing and vision. The test won't hurt and will take about 15 minutes. If your child has normal hearing and vision, your child will "pass" the test. If your child needs to be tested again, we will tell you. The results will be sent to you via SMS.

We would like to use the results of the test for research. None of your child's personal details will be used in the research and will be kept confidential. You can say if you don't want your child to be part of the study* at any time.

If you want more information, please phone or send a 'please call me' to: 0641322848.

In order to give permission for your child to get a free hearing and vision test at school, you must complete the following table:

| | | |
|---|-------------------|-----------------------|
| Parent/Caregiver's name and surname: | | |
| Cellphone number(s): | | |
| Child's name and surname: | | |
| Child's date of birth: | ___ / ___ / _____ | (DATE / MONTH / YEAR) |
| Child's gender: | MALE | FEMALE |
| I give permission for my child to get a free hearing and vision screening at school: | YES | NO |
| I give permission for the test results to be used for research. (Your child's information will be kept confidential): | YES | NO |
| Signature of parent/caregiver: | | |

*The study that will be done with the information of the children who has been screened is called "Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model."





EARS & EYES FOR EDUCATION

UKUHLOLWA KWENDEBE NAMEHLO SIMAHLA ESIKOLWENI

Mzali obekekileyo

Sicela ufunde lembalelwano, utyikitye wandule uyibuyisele esikolweni ngomso. Ukubona nokuva kubalulekile emntwaneni ukuze akwazi ukufunda. Kuzakubakho uhlolo lwendlebe namehlo apha esikolweni somntwana simahla. Kubantwana abaneminyaka emihlanu ukuya kwemithandathu (5-6). Sicela imvume kuwe yokuhlola umntwana wakho ukuba uyeve kwaye uyabona kakuhle.

Oluvavanyo alubuhlungwanga kwaye luzakuthatha imizuzu elishumi elinesihlanu. Iziphumo zokuba umntwana wakho uyabona kwaye uyeve kakuhle zizakuthunyelwa ngomyalezo (SMS). Ukuba umntwana kufuneka enze olunye uvavanyo sizakwazisa.

Singathanda ukusebenzisa iziphumo zoluhlolo ekwenzeni uphando kodwa igama nefani yomntwana ziyakugcinwa ziyimfihlo.

Xa ufuna ingcazelo, sicela utsalelele lenombolo 0641322848. Okanye uthumele please call me.

Ukuze unike imvume yokuba umntwana wakho ahlolwe indlebe namehlo simahla. Gcwalisa inkcukacha zakho.

| | | |
|---|--|------------|
| Igama nefani yomzali | | |
| Umxeba wakho | | |
| Igama nefani yomntwana | | |
| Umhla nonyaka wokuzalwa komntwana | ___ / ___ / ___ (UMHLA / INYANGA / UNYAKA) | |
| Isini somntwana | YINTOMBI | YINKWENKWE |
| Ndinika imvume yokuba umntwana wam ahlolwe | EWE | HAYI |
| Ndinika imvume yokuba iziphumo zomntwana wam zisetyenziswe ekwenzeni uphando (Ulwazi malunga nomntwana liyakugcinwa liyimfihlo) | EWE | HAYI |
| Tyikitya (Umzali) | | |

Olulwazi luzakwenziwa kubobonke abantwana lubizwa ngokuba: "Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model."





EARS & EYES FOR EDUCATION

FREE EARS AND EYES TEST AT SCHOOL

Dear parent/caregiver,

Please read the letter, sign the letter and send it back to school tomorrow.

Hearing and seeing is very important for your child to be able to learn. There will be hearing and vision (seeing) tests at school for children 5 to 6 years old, free of charge. You must give permission for us to test your child's hearing and vision. The test won't hurt and will take about 15 minutes. If your child has normal hearing and vision, your child will "pass" the test. If your child needs to be tested again, we will tell you. The results will be sent to you via SMS.

We would like to use the results of the test for research. None of your child's personal details will be used in the research and will be kept confidential. You can say if you don't want your child to be part of the study* at any time.

If you want more information, please phone or send a 'please call me' to: 0641322848.

In order to give permission for your child to get a free hearing and vision test at school, you must complete the following table:

| | | |
|---|---|--------|
| Parent/Caregiver's name and surname: | | |
| Cellphone number(s): | | |
| Child's name and surname: | | |
| Child's date of birth: | ___ / ___ / _____ (DATE / MONTH / YEAR) | |
| Child's gender: | MALE | FEMALE |
| I give permission for my child to get a free hearing and vision screening at school: | YES | NO |
| I give permission for the test results to be used for research. (Your child's information will be kept confidential): | YES | NO |
| Signature of parent/caregiver: | | |

*The study that will be done with the information of the children who has been screened is called "Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model."





EARS & EYES FOR EDUCATION

GRATIS GEHOOR- EN OOGTOETSE BY DIE SKOOL

Geagte ouer/versorger,

Lees asseblief die brief, teken die brief en stuur dit môre terug skool toe.

Om te hoor en sien is baie belangrik vir jou kind om in staat te wees om te leer. Daar sal gratis gehoor- en oogtoetse by die skool gedoen word vir kinders tussen die ouderdom van 5 en 6 jaar oud. Jy moet toestemming gee vir ons om jou kind se ore en oë te toets. Die toets vat 15 minute en sal nie u kind seer maak of ongerief veroorsaak nie. Indien jou kind normale gehoor en visie het, sal jou kind die toets "slaag". As jou kind verder getoets moet word sal ons jou laat weet. Die resultate sal aan jou gestuur word via 'n SMS.

Ons wil graag die resultate gebruik vir navorsing. Geen van jou kind se persoonlike inligting sal in die navorsing gebruik word nie en dit sal vertroulik gehou word. Jy kan op enige oomblik sê as jy nie wil hê dat jou kind deel moet wees van die studie* nie.

As jy meer inligting wil hê, bel asseblief 0641322848, of stuur 'n 'please call me' na die nommer.

Om toestemming te gee vir jou kind om 'n gratis gehoor- en oogtoets te kry by die skool, moet jy die volgende tabel invul en die brief terug stuur skool toe.

| | | |
|---|---------------------------------------|---------|
| Ouer/Versorger se naam en van: | | |
| Selfoon nommer(s): | | |
| Kind se naam en van: | | |
| Kind se geboortedatum: | ___ / ___ / _____ (DAG/ MAAND / JAAR) | |
| Kind se geslag: | MANLIK | VROULIK |
| Ek gee toestemming vir my kind om 'n gratis gehoor- en oogtoets te kry by die skool: | JA | NEE |
| Ek gee toestemming vir die toetsresultate om in navorsing gebruik te word. (Jou kind se inligting sal vertroulik gehou word): | JA | NEE |
| Handtekening van ouer/versorger: | | |

*Die studie wat gedoen gaan word met die resultate van die siftingstoets is: "Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model."

APPENDIX F

Parent or guardian information sheet and informed consent document



EARS & EYES FOR EDUCATION

PARENT OR GUARDIAN INFORMATION & INFORMED CONSENT DOCUMENT

(FULL SCRIPT- participants will be given a number that they can phone or that they can send a *please call me* to if they require more information after they have received the informed consent document from school. This will be read to them in their mother tongue. The document will also be sent to the parent or the caregiver should they request it)

TITLE OF STUDY: Hearing and vision screening for preschool children using mHealth technologies: a community-based service-delivery model

Dear Parent/Caregiver

1) INTRODUCTION

We would like to invite your child to participate in a research study. This information 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, 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 the group hearX, as well as a non-profit organization, Carel du Toit Centre, to develop a program to support healthy learning by providing hearing and vision screenings for pre-school children between the ages of 4 to 6 years in Cape Town. This will help to identify any problems that may affect a child's development and school success due to hearing or vision problems.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

Your child will receive a hearing screening at his/her school/ECD centre by a screener who is appointed for the project. The screener 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 screener will also test how well he/she can see. A picture will be shown to your child and your child will be required to show the direction in which the legs are pointing. The hearing and vision screening usually takes no more than 15 minutes to complete. If your child fails a screening test, you will receive a SMS notification as well as a referral letter from the school for a diagnostic assessment at a local clinic that offers hearing services or eye tests.

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 and vision screening at his/her school/ECD centre. 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:

Mrs. Ntomboxolo Mve (Administrator: Ears and Eyes for Education (3E) project): 064 1322848

Mrs Susan Eksteen (Audiologist): 021 938 4884

Alternatively you can contact the primary investigator:

Prof De Wet Swanepoel: 012 420 4280

8) CONFIDENTIALITY

All information that you give will be kept strictly confidential. Once we have analysed 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).

The screening will take place at the school on _____ 2017

Signed at _____ on _____ of _____

Phone number of parent/guardian _____

Signature of parent/guardian _____

NB: Your child must be 4 years or older to undergo a hearing screening



APPENDIX G

Script for child's assent



EARS & EYES FOR EDUCATION

HEARING AND VISION SCREENING:

ASSENT SCRIPT

- My name is _____. I am here to make sure that you can see and hear well.
- First, we are going to test your hearing.
- Earphones will be placed on your ears [illustrate]
- Very soft sounds will then be played for you.
- You have to listen very carefully to hear them.
- When you hear the sound, you must tell me by raising your hand.
- I am then going to test your eyes.
- I am going to show you a different table every time.
- You must show me in what direction the table's legs are showing [illustrate]
- The test will not hurt, it will be fun!
- If you want to stop the test, you can tell me. I won't be upset.

If I can now test your hearing and your eyes, give me a "thumbs up". If not, you can say "no".

APPENDIX H

Data repository information

STUDY II: *Referral criteria for preschool hearing screening in resource-constrained settings: a retrospective comparison of protocols*

The dataset analysed during the current study are available in the UP research data repository. DOI: 10.25403/UPresearchdata.13651361. Researchdata.up.ac.za

STUDY III: *Community-based identification of hearing and vision loss in preschool children from low income South African communities.*

The dataset analysed during the current study are available in the UP research data repository. DOI: 10.25403/UPresearchdata.13193864. Researchdata.up.ac.za

APPENDIX I

- (1) Proof of acceptance of article
Study I**

- (2) Proof of acceptance of article
Study II**

- (3) Proof of submission of article
Study III**

Proof of acceptance of article Study I

Inbox



bulletin.submit.ask@who.int via sendgrid.net

May 10, 2019,
7:45 PM

to dewet.swanepoel, me, stefan.launer, hannah.kuper, rob.eikelboom, andrew.bastawrous

MS no: BLT/2018/227876

Title: Implementation of hearing and vision services for preschool children in low-income communities
(hearing loss theme issue)
Research

Dear Professor Swanepoel and colleagues,

Thank you for submitting a revised version of this implementation research article. I am pleased to report that it has now been accepted for publication in the Bulletin of the World Health Organization for our special theme issue on hearing loss. Many thanks for your hard work and effort.

Please note the following:

Articles are subject to editorial revision, and the right to republish in any form or language is reserved by the World Health Organization.

In the coming month, the edited version of the manuscript will be sent to you for approval. We ask that you are able to provide responses to the technical editor within 2 days of receipt. If you are unavailable during this period, please let us know which co-author will be acting as the corresponding author on your behalf.

Kaylene Selleck, our editorial assistant, will advise you of your publication date once your article is scheduled to appear online. Please do not share the contents of your accepted paper with the media until this publication date. You may be contacted by our press officer if your article is selected for a note to the media.

We do send a print version of the issue to the corresponding author of each main article, but we do not produce reprints. However, the final published text can be downloaded from our web site:

<http://submit.bwho.org>.

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Many thanks for your valuable contribution to the Bulletin.

Yours sincerely,

Dr Rhona MacDonald
Bulletin of the World Health Organization

Proof of acceptance of article Study II

Inbox



LSHSS <em@editorialmanager.com>

Mar 17, 2021, 8:07 PM
(13 days ago)

to me

CC: hstorkel@ku.edu, ishss@asha.org, "Robert H Eikelboom" rob.eikelboom@earsceince.org.au, "Stefan Launer" stefan.launer@sonova.com, "Hannah Kuper" hannah.kuper@lshtm.ac.uk, "De Wet Swanepoel" dewet.swanepoel@up.ac.za

Ref.: Ms. No. LSHSS-21-00008R1

Referral criteria for preschool hearing screening in resource-constrained settings: a retrospective comparison of protocols.

Language, Speech, and Hearing Services in Schools

Dear Dr. Eksteen,

I am pleased to accept your manuscript for publication in Language, Speech, and Hearing Services in Schools.

If you haven't already selected the open access option, please consider doing so now. Choosing the open access publishing option can increase readership, online attention, and citation levels. ASHA assesses an article processing charge (APC) of \$2,000 for the open access option. You can find out more about Open Access by visiting <https://academy.pubs.asha.org/asha-journals-author-resource-center/manuscript-submission/open-access/>

Thank you for the opportunity to review and publish your work.

Sincerely,

Dr. Lisa Davidson

Editor

Language, Speech, and Hearing Services in Schools

****Attention NIH-funded authors****

ASHA now deposits to PubMed Central, on behalf of authors, any articles that have received NIH funding. These articles are made publicly available via PMC—in their final, published form—6 months after publication. All NIH-funded articles published in ASHA's journals from the first issues of 2015 forward have been deposited to PMC.

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Proof of submission of article Study III

Inbox



BMC Pediatrics

Jan 12, 2021,
23:23PM
(67 days ago)

to me

From: **BMC Pediatrics - Editorial Office** <em@editorialmanager.com>
Date: Tue, 12 Jan 2021, 23:23
Subject: Confirmation of your submission to BMC Pediatrics - BPED-D-21-00039 - [EMID:906d7f62477254dd]
To: Susan Eksteen <susaneeksteen17@gmail.com>

BPED-D-21-00039

Community-based identification of hearing and vision loss in preschool children from low income South African communities.

Susan Eksteen, MA; Robert H Eikelboom, PhD; Hannah Kuper, PhD; Stefan Launer, PhD; De Wet Swanepoel, PhD
BMC Pediatrics

Dear Mrs Eksteen,

Thank you for submitting your manuscript 'Community-based identification of hearing and vision loss in preschool children from low income South African communities.' to BMC Pediatrics.

The submission id is: BPED-D-21-00039
Please refer to this number in any future correspondence.

During the review process, you can keep track of the status of your manuscript by accessing the following website:

<https://www.editorialmanager.com/bped/>

If you have forgotten your password, please use the 'Send Login Details' link on the login page at <https://www.editorialmanager.com/bped/>. For security reasons, your password will be reset.

Best wishes,

Editorial Office
BMC Pediatrics
<https://bmcpediatr.biomedcentral.com/>

****Our flexible approach during the COVID-19 pandemic****

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BMC Pediatrics

Feb 02, 2021,
3:13 PM
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to me

From: **BMC Pediatrics - Editorial Office** <em@editorialmanager.com>

Date: Tue, 02 Feb 2021, 03:13

Subject: AU - Author Information about Handling Editor - [EMID:e9b9aecff750b96]

To: Susan Eksteen <susaneeksteen17@gmail.com>

Community-based identification of hearing and vision loss in preschool children from low income South African communities.

Susan Eksteen, MA; Robert H Eikelboom, PhD; Hannah Kuper, PhD; Stefan Launer, PhD; De Wet Swanepoel, PhD
BMC Pediatrics

Dear Mrs Eksteen,

To update you on your submission's status, your manuscript is being handled through peer review by Prof. Juliana Jalaludin who is the Handling Editor of your manuscript.

Your manuscript: "Community-based identification of hearing and vision loss in preschool children from low income South African communities."

BMC Journal: BMC Pediatrics

If you have any queries, please use the 'CONTACT US' link to get in touch with the Journal Editorial Office or 'Send E-mail' from your Action links.

Best wishes,

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