INFANT HEARING SCREENING AT A COMMUNITY-BASED OBSTETRIC UNIT: A COMPARATIVE STUDY OF SCREENING TECHNOLOGY AND OUTCOMES

By

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A dissertation submitted in fulfilment of the requirements for the degree

M. Communication Pathology

In the Department of Speech-Language Pathology and Audiology

FACULTY OF HUMANTITIES

UNIVERSITY OF PRETORIA

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March 2016

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LIST OF ABBREVIATIONS

ABR	auditory brainstem response
AABR	automated auditory brainstem response
ANSD	auditory neuropathy spectrum disorder
CCW	community care worker
CHC	community health centre
CNT	could not test
DPOAE	distortion product otoacoustic emissions
EHDI	early hearing detection and intervention
ENT	ear, nose and throat
HL	hearing loss
HPCSA	Health Professions Council of South Africa
JCIH	Joint Committee on Infant Hearing
MEE	middle ear effusion
MOU	midwife obstetric unit
NGO	non-governmental organisation
NHS	newborn hearing screening
NICU	neonatal intensive care units
PCEHL	permanent congenital or early onset hearing loss
PHC	primary health care
RCW	rehabilitation care worker
SNHL	sensorineural hearing loss
TEOAE	transient evoked otoacoustic emissions
UNHS	universal newborn hearing screening
UNICEF	The United Nations Children's Fund
WCGH	Western Cape Government Health
WHO	World Health Organisation

ABSTRACT

***Objective*:** Developing countries require contextual models for universal newborn hearing screening (UNHS) to optimise screening outcomes and cost-effectiveness. Postnatal visits at community-based midwife obstetric units (MOUs) have been proposed as an alternative primary healthcare platform for UNHS in South Africa. This study evaluated the outcomes of distortion product otoacoustic emissions (DPOAEs) and automated auditory brainstem response (AABR) screening conducted by a dedicated non-professional screener at a community-based MOU in the Western Cape, South Africa.

***Methods*:** UNHS at a community-based MOU was evaluated over a 16-month period. A dedicated non-professional screener was trained to follow a two-stage screening protocol targeting bilateral hearing loss. A two group comparative design was used alternating AABR (Maico MB11 BERAphone$^{TM)}$ and DPOAE (Bio-logic AuDX I) technology on a daily basis. Infants referring the initial screen received a follow-up appointment in two days' time and were rescreened with the same technology used at their first screen. Those referring the second stage were booked for diagnostic assessments.

***Results*:** 7452 infants were screened including 47.9% (n=3573) with DPOAE and 52.1% (n=3879) with AABR technology. Mean age at first stage screen was 6.1 days. The initial bilateral referral rate was significantly lower for AABR (4.6%) compared to DPOAE (7.0%) and dropped to 0.3% and 0.7% respectively following the second stage screenings. First rescreen and initial diagnostic follow-up rates of 90% and 92.3% were obtained for the DPOAE group and 86.6% and 90% for the AABR group. Follow-up rates showed no significant difference between technology groups. Diagnostic assessment revealed a higher prevalence rate for bilateral sensorineural hearing loss among the AABR group (1/1000) compared to the DPOAE group (0.3/1000). Screening technology had no significant influence on daily screening capacity (23 AABR/day; 24 DPOAE/day).

***Conclusion*:** Postnatal visits at community-based MOUs create a useful platform for hearing screening and follow-up. AABR technology with negligible disposable costs provides opportunity for AABR screening to be utilised in community-based programmes. AABR screening offers lower initial referral rates and a higher true positive rate compared to DPOAE. Well trained non-professionals can act as dedicated screeners and contribute to programme efficiency. Renewed focus should be placed on diagnostic protocol and skill development to reach the goals of EHDI.

Keywords: developing countries; infant hearing loss; universal newborn hearing screening; community-based newborn hearing screening; midwife obstetric units; distortion product otoacoustic emissions; automated auditory brainstem response; dedicated screener, referral rate, follow-up rate, diagnostic outcomes.

1. RESEARCH PROPOSAL

1.1 Background

Infant hearing loss is described as the most common congenital sensory birth defect with a prevalence of four to six in every 1000 live births in developing countries (Olusanya & Newton, 2007). When considering the negative consequences and increased societal costs of undetected infant hearing loss the importance of universal infant hearing screening can not be over emphasised (Yoshinaga-Itano, 2004; Swanepoel, 2009). Early hearing detection and intervention (EHDI) can provide access to the critical developmental periods for language acquisition during the first year of life, offering hearing impaired children developmental outcomes comparable to those of their normal hearing peers (Yoshinaga-Itano, 2004; Joint Committee on Infant Hearing [JCIH], 2007). Although awareness has grown, South Africa is still lacking the legislation of infant hearing screening. The diverse nature of the healthcare contexts in South Africa necessitates contextually-appropriate research to guide programme development in a way that will optimise screening coverage and cost-effectiveness (Health Professions Council of South Africa [HPCSA], 2007).

1.1.1 Community-based infant hearing screening in South Africa

National surveys in the private and public healthcare sectors of South Africa revealed that approximately 90% of newborns have no prospect of having their hearing screened (Meyer & Swanepoel, 2011; Theunissen & Swanepoel, 2008). In the public health care sector, which services approximately 85% of the population, only 7.5% of hospitals offer some form of infant hearing screening whilst less than 1% offer universal screening (Theunissen & Swanepoel, 2008). To date, only one systematic government supported community-based infant hearing screening programme has been implemented where screening is provided at eight primary health care (PHC) immunisation clinics in the Western Cape (Friderichs, Swanepoel & Hall, 2012). Concerted effort is thus needed to establish hearing screening as an integrated healthcare service in order to make it available to all babies born in South Africa.

Immunisation clinics have been recommended as platform for community-based infant hearing screening programmes to supplement hospital-based programmes in developing countries (Olusanya, Luxon & Wirz, 2008; Swanepoel, Hugo & Louw, 2006). In South Africa, a significant number of births take place outside of hospitals, either at home or at birthing clinics (Swanepoel et al., 2006) and those infants born in public hospitals are often discharged from the well-baby nursery on the same day (Swanepoel, 2009). Due to the fact that immunisation clinics are well attended, it provides a means of improving the coverage rates of infant hearing screening (Swanepoel et al., 2006). Despite initial reports verifying immunisation clinics as an effective platform for infant hearing screening (Swanepoel et al., 2006; Olusanya et al., 2008), Friderichs et al. (2012) reported low coverage rates mainly attributed to the use of already burdened nursing staff as screeners. The need for dedicated screening personnel is emphasised and an alternative community-based platform, such as midwife obstetric units (MOUs), is subsequently proposed. MOUs are birthing units run by midwives in the community for primary healthcare patients. Although discharge at these units usually happens six hours after birth if both mother and baby are in good health, they return to the MOU for postnatal follow-ups focussing on navel care and feeding advice (Western Cape Government Health [WCGH], 2014a). The Road-to-Health booklet denotes postnatal visits for day three and day seven after birth but in practice the newborns often return every second day until the umbilical cord falls off. These postnatal visits seem an ideal platform for hearing screening as it would allow a younger point of entry and two to five screening opportunities before the infant reaches the age of two weeks.

A significant challenge in implementing widespread hearing screening programmes in developing countries is the general lack of manpower (Olusanya et al., 2008). The HPCSA position statement on EHDI programmes in South Africa (2007) states that nursing staff, community health care workers or lay volunteers can be utilised as screening personnel as long as they have received adequate training. The use of these role players as screeners at PHC level is cost-effective and releases the audiologist to resume the role of programme coordinator or diagnostic specialist. Although a few studies in South Africa have

investigated the use of nursing staff as screening personnel (Friderichs et al., 2012; Swanepoel et al., 2006), no studies reporting on the use of dedicated non-professional screeners could be found. Research is thus needed to explore the use of dedicated non-professional screeners and the outcomes that could be achieved in terms of coverage rates. A dearth of research also exists describing the capacity of dedicated screeners for different screening technology (e.g. amount of tests per day/month) which is essential for capacity planning of large-scale hearing screening programmes.

Currently, only two electrophysiological techniques are endorsed for infant hearing screening – otoacoustic emissions (OAEs) and automated auditory brainstem responses (AABRs) (HPCSA, 2007; JCIH, 2007). OAEs measure outer hair cell functioning in the cochlea and are recommended for screening in well-baby nurseries and community-based immunisation programmes (HPCSA, 2007). It utilises basic probe placement and 'pass/refer' criteria and can therefore be used by non-professional screeners (Swanepoel, 2009; Swanepoel et al., 2006). The Auditory Brainstem Response (ABR) is a measure of neural synchrony in the eighth cranial nerve and lower brainstem and is the technology of choice in neonatal intensive care units (NICUs). This is due to the higher prevalence of auditory neuropathy that is only detectable with a neural-based screening test such as the AABR (HPCSA, 2007). Although AABR screening can also be conducted by non-professionals (Olusanya et al., 2008) it has been found to be an ineffective screening tool for immunisation visits due to the difficult testing state of six-week old infants (Swanepoel et al., 2006). Furthermore, AABR screening has traditionally been more expensive than OAE screening due to increased disposable costs (HPCSA, 2007). Advances in screening technology have however opened up new possibilities. The MB11 BERAphone™ (MAICO Diagnostic GmbH, Germany) is a relatively new AABR hearing screening device that does not make use of disposable electrodes/ear couplers and utilises a different algorithm (Van den Berg, Deiman & Van Straaten, 2010). It is therefore potentially more cost effective with proposed advantages in test-time and ease of use, making AABR a viable option for community-based infant hearing screening especially in a MOU where infants are younger that two weeks.

1.1.2 Rationale

The World Health Organisation (WHO) (2010) acknowledges that public-private partnerships, including involvement of non-governmental organisations (NGOs), may fast-track the development and implementation of screening programmes in developing countries like South Africa. In the Western Cape, the Department of Health has agreed to pilot a community-based infant hearing screening programme at three of their MOUs. They are partnering with a local NGO, the Carel du Toit Centre Trust, who has been actively involved in community-based infant hearing screening over the past decade. As this pilot will be the first of its kind in MOU facilities in the Western Cape, research is essential to document the outcomes. Information regarding the outcomes that can be achieved through the use of different screening technology and dedicated screening personnel will be vital for policy and programme development in South Africa. Subsequently, the following research question is posed: *How do the outcomes of AABR (MB11 BERAphone®) and OAE infant hearing screening compare when performed by a dedicated screener within a community-based obstetric unit?*

1.1.3 Expected contribution

The HPCSA position statement on infant hearing screening (2007) states that evidence-based research is needed to guide the development of infant hearing screening programmes in different contexts in South Africa. The findings of this study will guide the development of a contextually appropriate service delivery model for newborn hearing screening in the public healthcare sector. The contribution will be practical in nature, informing government regarding different hearing screening technology performance, choice of screening personnel as well as the aptness of a MOU as screening platform. This will provide key information to guide further policy development for newborn hearing screening in the public healthcare sector of the Western Cape and hopefully the rest of South Africa.

1.2 Proposed methodology

1.2.1 Research objectives

The study will compare infant hearing screening technology and outcomes within a community-based obstetric unit in the Western Cape. Upon completion of the

data collection and analyses, an article will be drafted and submitted to an ISI accredited peer-reviewed journal. Table 1.1 summarises the proposed title, objectives, and journal for this submission.

Table 1.1. Proposed title, objectives and journal for submission

Proposed title	Infant hearing screening at a community-based obstetric unit: A comparative study of screening technology and outcomes
Objectives	To compare infant hearing screening outcomes at a community-based MOU in the Western Cape using AABR (MAICO MB11 BERAphone™) and distortion product OAE (DPOAE) (Bio-logic AuDX I) technology operated by a dedicated screener. a. To compare coverage rates of AABR vs DPOAE screening b. To compare referral rates of AABR vs DPOAE screening c. To determine the follow-up rate of infants seen for a second screening at the obstetric unit d. To determine the screening capacity (number of screens per day) of a dedicated screener for both AABR and DPOAE technology e. To compare the diagnostic outcomes of infants seen at tertiary level after failing a two-stage screening with either AABR or DPOAE
Journal for submission	International Journal of Pediatric Otorhinolaryngology

1.2.2 Research context

The research will be conducted at the Mitchell's Plain MOU in Cape Town. Mitchell's Plain was selected as one of three MOUs where infant hearing screening will be initiated as part of an official government supported pilot project. The unit falls under the Klipfontein/Mitchell's Plain sub-structure of the Department of Health and was selected as the main research site (from the three

MOUs) as it has the highest number of postnatal visits. Mothers who deliver at Groote Schuur Hospital, Mowbray Maternity Hospital or at home but that live within the catchment area of the Mitchell's Plain MOU can also attend the postnatal visits at the unit.

1.2.3 Research design and methods

Table 1.2 presents an overview of the study design, participant selection criteria, sampling method, expected sample size, equipment and apparatus, data collection material and procedures.

Table 1.2. Research design and methods

Study design	Two group comparative study using a quantitative approach.
Participant selection criteria	The target population will be all infants attending postnatal visits at the Mitchell's Plain community-based MOU in Cape Town. This may include infants born at the MOU or elsewhere (e.g. Groote Schuur Hospital, Mowbray Maternity Hospital or home births). The parent or caregiver must have signed the informed consent section on the data sheet to be included in the study (Appendix B).
Participant sampling	Non-probability purposive sampling (Hussey, 2010).
Expected sample size	The sample size will constitute the first 5000 infants attending their postnatal visits at the MOU. Hearing screening technology will be alternated on a daily basis and the aim is to screen 2500 babies with DPOAE and 2500 babies with AABR technology.
Equipment and apparatus	▪ **Bio-logic AuDX-I DPOAE** (Natus Medical Inc., CA, USA) is an automated handheld screening device that evaluates the integrity of the outer hair cells of the cochlea. ▪ **MB11 BERAphone™ AABR** (MAICO Diagnostic GmbH, Germany) is a handheld headphone unit which integrates the preamplifier and three spring-mounted stainless-steel electrodes. It screens hearing

	functioning by measuring the auditory evoked potentials of the auditory pathway. ▪ **Netbook computer** (Acer, Windows XP) is connected to the MB11 BERAphone™ via a USB cable. ▪ **MB 11 USB software** (version 2.91.0.0) is the software interface that controls the MB11 BERAphone™ and stores all test results in a database.
Data collection material	A data sheet/test form will be completed for every participant screened at the MOU (Appendix B) – it contains the informed consent, short hearing loss high-risk register as well as the screening details and results. For ethical purposes the screening results will be recorded in the participant's Road-to-Health booklet and clinical notes in the clinic file. The ear, nose and throat (ENT) and audiology departments of Red Cross Children's Hospital will provide a report to the MOU on the outcomes of the diagnostic testing (only for those participants who failed the two-stage clinic level screening).
Data collection procedures	▪ The dedicated screener will explain the details pertaining to the informed consent to the infant's mother/caregiver. The information will be available in the three main languages used by the Mitchell's Plain community namely English, Afrikaans and Xhosa (Appendix A). ▪ The dedicated screener will ask the mother/caregiver if they would like their infant, who will routinely be screened as part of an official department of health pilot programme, to participate in the study. The mother/caregiver will be asked to sign the informed consent section on the test form to demonstrate her/his willingness to participate (Appendix B). ▪ The dedicated screener will conduct a short medical case history and complete a high-risk register for hearing loss. ▪ The hearing screening technology will be alternated on a daily basis. A bilateral screening with either DPOAE or

	AABR will be performed and results will be noted on the test form, Road-to-Health booklet and clinic file. ▪ A two-stage clinic level screening protocol will be implemented. Infants who obtain a bilateral refer result will be given an appointment for a second screening to coincide with their next postnatal visit in two days time. The second screening will always be done with the same screening technology as the first screening. If a second bilateral refer result is obtained the infant will be referred directly to the tertiary hospital for diagnostic audiological and ENT services. ▪ The screener will be allowed to repeat the screening once in an attempt to improve the probe fit for OAE or impedance levels for AABR. ▪ If the screener is unable to test an infant due to restlessness, irritability or a technical fault – the outcome will be treated as a refer and an appointment will be given to coincide with their next postnatal visit in two days time. ▪ Counselling with language-appropriate pamphlets regarding normal speech, language and hearing development within the first two years of a child's life will be given to all parents/caregivers of participants – regardless of screening outcome. ▪ Daily postnatal visit statistics will be collected from the MOU on a monthly basis in order to calculate coverage rates. ▪ The screener will keep a daily screening log of the amount of tests done.
Statistical analysis	Statistical package SPSS version 20.0 will be used for the statistical analysis. Descriptive statistics: Coverage rates, referral rates and follow-up rates of DPOAE and AABR screening (%). Mean age at time of first screen. Mean amount of DPOAE and

	AABR screening tests done per day. Inferential statistics: Inferential statistics: Parametric tests such as the Chi-square and t-test will be used to determine significance of differences between the various aspects of DPOAE and AABR screening. Statistical significance: $p < .01$ will be seen as significant.

1.2.4 Ethical considerations

This study will be initiated and conducted within the framework of the ethical guidelines set out in the South African National Health Act (2007) as well as the Guidelines of Practice in the Conduct of Clinical Trials in Human Subjects in South Africa (South African Department of Health, 2000). The individual principles presented in these documents are listed and discussed below in Table 1.3 as they were applied to the proposed study.

Table 1.3. Ethical principles applied to the proposed study (South African Department of Health, 2000; South African National Health Act, 2007)

Principle	Application to study
The right, safety and wellbeing of the participants are the most important considerations and should prevail over interest of science and society. Foreseeable risks and inconveniences should be weighed against the anticipated benefit for participants and society. A study should only be initiated and continued if the anticipated benefits justify the risks.	The study poses a benefit to each participant in the sense that they will have access to early hearing detection services and if necessary, to early intervention services. Less than 10% of infants born in South Africa currently have access to early hearing detection services (Meyer & Swanepoel, 2011). Considering the high prevalence of hearing loss, 3-6/1000 live births, it is essential to make this service available to all infants born in South Africa. There are no risks involved for the participants of this study as the hearing screening tests (AABR/DPOAE) are non-intrusive and will not hurt or harm the baby. Both AABR and DPOAE hearing screening are endorsed by the HPCSA EHDI position statement (2007). Appropriate pre- and post-screening counselling will be provided to educate and empower the parents/caregivers. As the hearing screening service is being implemented as an official government pilot project, the service will be rendered to all infants regardless of their participation in this study.
Research or experimentation on an individual may only be conducted after the participant has been informed of the objectives of the research or experimentation and any possible positive or negative consequences on his or her health.	An information form (Appendix A) will be presented to all the parents/caregivers before their infant's hearing is screened. The information form will describe the purpose of the study, the fact that participation is voluntary as well as the benefit of participation. It will also ensure confidentiality and explain their right to withdraw at any stage without any negative consequences.
The healthcare provider must also, where possible, inform the individual in a language that the individual understands, and in a manner which takes into account the individual's level of literacy.	The information form will be available in English, Afrikaans and Xhosa (Appendix A) and the screener will also explain the content verbally as some parents/caregivers might be illiterate. This will be taken into consideration during the recruitment process of the dedicated screener. Preference will be given to a candidate from the community that the clinic serves and who is fluent in all three languages. This will ensure that the screener can translate and answer questions that the parents/caregivers might have. A screener from the community will also be familiar and sensitive to the culture and beliefs of the members of the community.

Freely given informed consent should be obtained from every participant prior to clinical trial participation.	The information form (Appendix A) will be used to present and explain all the details regarding the informed consent after which the screener will ask the parent/caregiver to sign the informed consent section at the top of the test form/data sheet (Appendix B) should they wish to participate.
The participant should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.	This principle is stated in the information form (Appendix A) and will also be conveyed verbally prior to commencement of the hearing screening. Should the parent/caregiver decide not to participate, their infant's hearing can still be screened (as part of a new service provided to all infants at the MOU) – their data will just not be included in the research study. Their decision will thus not have negative consequences for their infant or hinder their infant from still receiving the service.
The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).	Confidentiality will be ensured by omitting the participants' names on all data processing documentation. The researcher will implement a coding system by which each participant will be allocated a specific numbering for data processing purposes. This is also explained in the information form (Appendix A).
A preliminary study should be conducted in compliance with the protocol that has received prior institutional review board / independent ethics committee approval.	This proposal is hereby submitted to the Research Ethics Committee of the Faculty of Humanities of the University of Pretoria for approval. The proposal will also be submitted to the Research Ethics Committee of the Western Cape Department of Health for approval. Data collection will not commence prior to approval of the proposed study by both these committees. *[*Letters confirming ethical clearance and research approval have been attached as Appendix C & D]*

1.3 Research collaborations

Several research collaborations will be required in order to complete the research project. These are presented in Table 1.4.

Table 1.4. Research collaborations

Name	Role
Prof. De Wet Swanepoel	Research supervisor
Prof. James W. Hall III	Research co-supervisor
Dedicated screener (To be appointed)	Screening of infants with OAE/AABR Hearing screening administration
Western Cape Government Health ▪ ***Dr. Keith Cloete*** ▪ ***Dr. James Claassen**** ▪ ***Sr. A Mallum***	 ▪ Chief Director: Metro District Health Services (MDHS) ▪ Director: Klipfontein/Mitchell's Plain Substructure (KMPSS) ▪ Operational Manager: Mitchell's Plain MOU

** At the time when the research proposal was written, Dr. James Claassen was the director: KMPSS. He unfortunately passed away and a new director, Mrs. Patti Olckers, was appointed.*

1.4 Time line

The anticipated timing of completion of the various aspects of the research project is outlined in Table 1.5 below.

Table 1.5. Projected timeframe

Date	Tasks to be completed
March 2012	Submit final research proposal for ethical clearance.
June 2012	Obtain ethical clearance from University of Pretoria. Obtain research clearance form the Western Cape Department of Health.
July – August 2012	Pilot study
September 2012 – August 2013	Data collection. Complete literature review, theoretical discussions and methodology.
September – December 2013	Statistical analysis. Results section.
January – September 2014	Discussion and conclusion. Article submission and revision.
October 2014 – March 2015	Completion of compilation thesis for submission.

**This should only be viewed as a preliminary time frame and is subject to change.*

1.5 Projected budget

The estimated expenses of the study are presented in Table 1.6 below.

Table 1.6. Projected budget

Description of expenses	Number of units	Cost per unit	Approximate cost
Travel costs for programme coordinator to visit the site (72 visits x 50km)	3600	R 3.00	R 10 800.00
Dedicated screener (contract for 18 months)	18	R 3 000.00	R 54 000.00
DPOAE device	1	R 36 000.00	R 36 000.00
AABR device (*On loan by supplier – free for the research period)	1	-	-
Cost per baby:			
Data collection forms (A4 double sided)	5000	R 1.00	R 5 000.00
Pamphlets - milestones (A4 double sided)	5000	R 1.00	R 5 000.00
Sticker – Road-to-Health booklet	5000	R 0.50	R 2 500.00
Additional printing costs:			
Paper	5	R 45.00	R 225.00
Printer	1	R 700.00	R 700.00
Cartridges	3	R 350.00	R 1 050.00
Telephone calls	18	R 200.00	R 3 600.00
Internet usage	18	R 200.00	R 3 600.00
Printing of compilation thesis	4	R 200.00	R 800.00
UP Tuition fees:			
Masters preparatory	1	R 2 400.00	R 2 400.00
Masters tuition fees	1	R 15 000.00	R 15 000.00
Masters re-registration	3	R 2 500.00	R 7 500.00
TOTAL			**R 148 175.00**

2. RESEARCH ARTICLE

TITLE: NEWBORN HEARING SCREENING AT A COMMUNITY-BASED OBSTETRIC UNIT: SCREENING AND DIAGNOSTIC OUTCOMES

Authors: Tersia de Kock, De Wet Swanepoel and James W. Hall III
Journal: International Journal of Pediatric Otorhinolaryngology
Accepted: 26 February 2016
Publication: Volume 84 (2016) 124-131. DOI: 10.1016/j.ijporl.2016.02.031

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

2.1 Abstract

***Objective*:** Postnatal visits at community-based midwife obstetric units (MOUs) have been proposed as an alternative primary healthcare screening platform in South Africa. This study evaluated the outcomes of distortion product otoacoustic emissions (DPOAEs) and automated auditory brainstem response (AABR) screening conducted by a dedicated non-professional screener at a community-based MOU in the Western Cape, South Africa.

***Methods*:** Universal newborn hearing screening (UNHS) at a community-based MOU was evaluated over a 16-month period. A dedicated non-professional screener was trained to follow a two-stage screening protocol targeting bilateral hearing loss. A two group comparative design was used alternating AABR (Maico MB11 BERAphone$^{TM)}$ and DPOAE (Bio-logic AuDX I) technology on a daily basis. Infants referring the initial screen received a follow-up appointment in two days' time and were rescreened with the same technology used at their first screen. Those referring the second stage were booked for diagnostic assessments.

***Results*:** 7452 infants were screened including 47.9% (n=3573) with DPOAE and 52.1% (n=3879) with AABR technology. Mean age at first stage screen was 6.1 days. The initial bilateral referral rate was significantly lower for AABR (4.6%)

compared to DPOAE (7.0%) and dropped to 0.3% and 0.7% respectively following the second stage screenings. First rescreen and initial diagnostic follow-up rates of 90% and 92.3% were obtained for the DPOAE group and 86.6% and 90% for the AABR group. Follow-up rates showed no significant difference between technology groups. Diagnostic assessment revealed a higher prevalence rate for bilateral sensorineural hearing loss among the AABR group (1/1000) compared to the DPOAE group (0.3/1000). Screening technology had no significant influence on daily screening capacity (23 AABR/day; 24 DPOAE/day).

***Conclusions*:** Postnatal visits at community-based MOUs create a useful platform for hearing screening and follow-up. AABR technology with negligible disposable costs provides opportunity for AABR screening to be utilised in community-based programmes. AABR screening offers lower initial referral rates and a higher true positive rate compared to DPOAE.

Keywords: developing countries; community-based newborn hearing screening; midwife obstetric units; distortion product otoacoustic emissions; automated auditory brainstem response; dedicated screener.

Abbreviations: UNHS, universal newborn hearing screening; EHDI, early hearing detection and intervention; HPCSA, Health Professions Council of South Africa; DPOAE, distortion product otoacoustic emissions; AABR, automated auditory brainstem response; PCEHL, permanent congenital or early onset hearing loss; MOU, midwife obstetric unit.

2.2 Introduction

Infant hearing loss is the most common congenital sensory birth defect with an estimated prevalence of four to six in every 1000 live births in developing countries (Olusanya & Newton, 2007). The necessity of early hearing detection and intervention (EHDI) to contest the detrimental consequences, both individual and societal, of permanent congenital or early-onset hearing loss (PCEHL) is widely documented (Yoshinaga-Itano, 2004; Olusanya, Ruben & Parving, 2006; Joint Committee on Infant Hearing [JCIH], 2007). With at least 90% of infants with

PCEHL residing in the developing world (Olusanya, Wirz & Luxon, 2008), focus has shifted from validation of EHDI to the development of contextually feasible models of service delivery (Olusanya, 2012; Khoza-Shangase & Harbinson, 2015).

Although awareness of the need for EHDI in South Africa has grown, legislation requiring infant hearing screening is still lacking. National surveys in the private and public healthcare sectors of South Africa reveal that approximately 90% of newborns have no prospect for hearing screening (Meyer & Swanepoel, 2011; Theunissen & Swanepoel, 2008). In the public health care sector, which services approximately 85% of the population, only 7.5% of hospitals offer some form of infant hearing screening whilst less than 1% offer universal screening (Theunissen & Swanepoel, 2008). Subsequently, the reported average age at time of diagnosis range from 23 to 44.5 months of age (Swanepoel, Johl & Pienaar, 2013; Van der Spuy & Pottas, 2008; Swanepoel, Störbeck & Friedland, 2009; Butler et al., 2013). Most infants with hearing loss in South Africa do not receive early auditory stimulation which is the foundation for optimal speech and language development (Olusanya, 2012; Yoshinaga-Itano, Sedey, Coulter & Mehl, 1998).

Due to the significant number of births taking place outside of hospitals, immunisation clinics have been recommended as platform for community-based infant hearing screening programmes to supplement hospital-based programmes in developing countries (Olusanya et al., 2008; Swanepoel, Hugo & Louw, 2006). Despite initial reports verifying immunisation clinics as a useful platform for infant hearing screening (Olusanya et al., 2008; Swanepoel, Hugo & Louw, 2006), Friderichs, Swanepoel and Hall (2012) reported low coverage rates mainly attributed to the use of already burdened nursing staff as screeners. To date, only one systematic government supported community-based infant hearing screening programme has been reported at immunisation clinics in the Western Cape (Friderichs et al., 2012). Friderichs et al. (2012) emphasised the need for dedicated screening personnel and proposed an alternative community-based platform such as midwife obstetric units (MOUs). MOUs are birthing units run by midwives in the community for primary healthcare patients. Although discharge at

these units usually happens six hours after birth if both mother and baby are in good health, they return to the MOU for postnatal follow-ups focussing on umbilical cord stump care and feeding advice (Western Cape Government Health, 2014a). A small scale study in Gauteng South Africa verified that MOU postnatal visits (also called three-day assessments) offered a practical and efficient option for hearing screening (Khoza-Shangase & Harbinson, 2015).

A significant challenge in implementing widespread hearing screening programmes in developing countries is the general lack of personnel (Olusanya et al., 2008). The Health Professions Council of South Africa (HPCSA) position statement on EHDI programmes in South Africa (2007) states that nursing staff, community health care workers or lay volunteers can be utilised as screening personnel as long as they have received adequate training. The use of these persons as screeners is cost-effective and releases the audiologist to resume the role of programme coordinator or diagnostic specialist. However, despite these recommendations, infant hearing screening conducted by audiologists is still common practice in South Africa (Khoza-Shangase & Harbinson, 2015). A few studies have investigated the use of nursing staff as screening personnel (Swanepoel et al., 2006; Friderichs et al., 2012), but there are no published reports on the use of non-professional screeners. A dearth of research also exists describing the capacity of screeners, that is, the number of tests that can be performed per day or per month, for different screening technology. Information on screening capacity is essential for programming planning.

Currently, the only techniques endorsed for infant hearing screening are otoacoustic emissions (OAEs) and automated auditory brainstem responses (AABRs) (JCIH, 2007; HPCSA, 2007). OAEs measure outer hair cell functioning in the cochlea and are recommended for screening in well-baby nurseries and community-based programmes (HPCSA, 2007). OAE measurement utilising rather simple probe placement and automated ‘pass/refer’ criteria is feasible by non-professional screeners (Swanepoel et al., 2006; Swanepoel, 2009). The AABR is a measure of neural synchrony in the eighth cranial nerve and lower brainstem. AABR is the technology of choice in neonatal intensive care units (NICUs). There is a higher prevalence of infants with auditory neuropathy

spectrum disorder (ANSD) in the NICU population. ANSD is only detectable with a neural-based screening test such as the AABR (HPCSA, 2007).

AABR screening can also be conducted by non-professionals (Olusanya et al., 2008), but it is an ineffective screening tool for immunisation visits because six week old infants rarely remain in a sleeping state required for successful recordings (Swanepoel et al., 2006). Furthermore, AABR screening with most devices is more expensive than OAE screening especially due to increased disposable costs (Boshuizen et al., 2001). New generation AABR technology, such as the Maico MB11 BERAphone™, offers several advantages for more widespread application including reduced test-time, ease of use, and negligible disposable costs (Van den Berg, Deiman & Van Straaten, 2010; Van Dyk, Swanepoel & Hall, 2015; Benito-Orejas, Ramírez, Morais, Almaraz & Fernández-Calvo, 2008; Cebulla, Hofmann & Shehata-Dieler, 2014).

In designing the current study we posed the following research question: *How do the outcomes of infant hearing screening with DPOAE and AABR using the MB11 BERAphone™ compare when performed by a dedicated screener within a community-based MOU?*

2.3 Material and Methods

2.3.1 Study design

A two group comparative design was employed to investigate infant hearing screening outcomes at a community-based MOU. A dedicated non-professional screener alternatively performed either AABR or DPOAE hearing screenings on a daily basis. Referral rates, follow-up rates and diagnostic outcomes were investigated for both technologies. The study was approved by the institutional review board of the University of Pretoria and the Western Cape Government: Health (WCGH) prior to the commencement of data collection.

2.3.2 Research context

A community-based universal newborn hearing screening (UNHS) programme was initiated at three MOUs in the metropolitan area of Cape Town (Western

Cape, South Africa) as part of a government supported pilot project. MOUs are birthing units linked to community health centres (CHCs). In addition, the MOUs offer antenatal and postnatal care encompassing all aspects of mother and baby health and well-being (WCGH, 2014a).

This study was conducted at the largest of the three units based on the number of births (approximately 3000 annual live births) and postnatal follow-up visits. The unit is the only MOU within the Mitchell's Plain health district that covers an area of approximately 5 000 ha with a population of 507 237. The socio-economic profile of the health district is characterised by an unemployment rate of 32% and 61% of households having a monthly income of R3 200 (±229 USD) or less (City of Cape Town, 2013).

2.3.3 Study population

Infants that were born either at the MOU, at home or at surrounding hospitals, together with their mothers/caregivers, attend postnatal follow-up visits at their local community-based MOU. They often return every second day until the infant's umbilical cord has fallen off. There were no exclusion criteria in this study as all infants attending the postnatal follow-up visits were offered routine screening as part of the universal screening programme. Informed consent was obtained from each parent/caregiver prior to enrolling the infant into the study. Data collection stretched over 16 months (24 September 2012 – 31 January 2014).

2.3.4 Material and apparatus

The Bio-logic AuDX-I (Natus Medical Inc., CA, USA) was used for DPOAE screening. It represented the technology typically used in existing community-based screening. The pre-set DPOAE screening parameters were used including a 65/55 dB SPL stimulus intensity level for the lower f1 frequency (L1) and the higher f2 frequency (L2). Overall pass criterion was a DPOAE to noise floor difference of ≥6 dB for three out of four f2 test frequencies (f2 of 5, 4, 3, and 2 kHz). AABR screening was done with the MB11 BERAphone^{TM} (MAICO Diagnostic GmbH, Germany) operated through a netbook computer and software that stored test results in a database. The MB11 BERAphone^{TM} is a handheld headphone unit with integrated spring-mounted electrodes that only require

application of electrode gel prior to placement. Screening settings included the use of the CE-Chirp stimulus™ at a rate of 93 stimuli per second and a stimulus level of 35dB nHL. The MB11 BERAphone™ was selected because of reduced disposable supply costs and preparation time.

2.3.5 Screening personnel

A dedicated non-specialist screener was appointed to perform hearing screening at the MOU, Monday to Friday from 7am to 3pm. The managing audiologist provided training which included a 2.5 hour theoretical session and a practical component where the screener first observed the audiologist doing screening, followed by ten supervised screens per technology. Weekly quality control and support visits continued throughout the research period. Three dedicated screeners participated in the study. Screener 1 collected the first month's data (24 September 2012 - 16 October 2012). A second screener collected data for the remainder of the period. Screener 3, the resident health promoter at the MOU, was trained to function as an auxiliary for screener 2 on sick and leave days. Both Screeners 1 and 2 were non-professionals with no formal healthcare training. They were recruited on the basis of (1) having completed high school, (2) demonstrating basic computer literacy, (3) cultural sensitivity and fluency in at least two of the three main languages of the area, (4) comfortable with handling newborns, and most importantly, (5) possessing character traits such as patience, empathy and meticulousness yet being able to function well under pressure. The job description included providing antenatal talks, hearing screening, basic counselling, data-capturing and assistance with follow-up management.

2.3.6 Protocol and methods

The MOU screening programme implemented a two-stage screening protocol at primary healthcare (PHC) level to reduce the burden of false positive referrals to tertiary hospital. A bilateral refer criteria was used as criterion for an overall refer in both stages of the screening protocol. The decision does not disregard the impact of unilateral hearing loss but it was made on the basis of cost-effectiveness and practicability. This follows recommendations by the HPCSA Year 2007 Position Statement as well as former pilot research and community-

based screening programmes for resource constrained areas (Swanepoel et al., 2006, Friderichs et al., 2012; HPCSA, 2007).

The screener completed a test form including an informed consent form signed by the parent or caregiver, demographic information, a brief medical case history, a high-risk checklist, and screening outcome for each screening session. A bilateral screening with either DPOAE or AABR was performed. The screening technology used, DPOAE or AABR, alternated from day to day with the exception of periods of equipment breakdown. Infants with a bilateral refer outcome were referred for a second screening to coincide with their next postnatal follow-up visit or in two days' time. The follow-up screening was performed with the same screening technology as the first screening. If a second bilateral refer result was obtained the infant was referred directly to the tertiary hospital for diagnostic audiological and ear, nose and throat (ENT) services.

In instances when an infant became restless or irritable, the parent/caregiver was asked to make an attempt to feed and/or calm the baby. The screener was allowed to repeat the measurement once if the screening was terminated due to the baby's state or in an attempt to improve the probe fit for OAE measurement or impedance levels for AABR. If the screener was unable to test an infant due to restlessness, irritability or a technical fault, the outcome was treated as a 'refer' and a follow-up appointment was scheduled. Counselling with language-appropriate pamphlets regarding normal speech, language and hearing development within the first two years of a child's life was given to all parents/caregivers of participants – regardless of screening outcome.

It was not possible to have access to a room in the MOU dedicated to the screening programme during the research period. As a result, screening was conducted in five different rooms in the facility with the screener repeatedly selecting the most appropriate space. Majority of the screenings took place either in the phototherapy room (51.7%) or a student doctor bedroom (39.4%), both of which were in close proximity to the postnatal visit consulting room. As a consequence ambient noise present during screening was variable, but levels were adequate for testing according to internal equipment parameters.

Waiting times for diagnostic follow-up at the tertiary hospital often were as long as six months. In an attempt to speed up the diagnostic process, a private audiologist provided follow-up services to the first six infants who yielded a refer outcome. However, the arrangement could not be sustained throughout the study as research funding was depleted.

Coverage rates for hearing screening programmes are typically reported. We do not have accurate information on the coverage rate for the MOU screening programme during the study as none of the MOU's routinely kept indicators could be used to measure the number of hearing screenings against. The conventionally used birth statistics would not suffice as babies who were born elsewhere could also access the postnatal follow-ups offered at the MOU. Similarly, the recorded data indicator for postnatal follow-up visits could not be used as it reflects the total amount of visits which includes multiple visits by the same mother and baby.

2.3.7 Data analysis

All data were captured in MS Excel 2010. Statistical package SPSS version 21.0 was used for the analysis. Descriptive statistics were applied to show basic trends in investigated variables like gender, age, referral- and follow-up rates for DPOAE and AABR screening. Inferential statistics, specifically parametric tests such as the Chi-square and t-test, were utilised to determine significance of differences between the various aspects of the two screening technologies. A significance level of 1% was applied.

2.4 Results

2.4.1 Study sample

A total of 7452 infants (51.7% male, 48.3% female) underwent hearing screening by a dedicated screener. Of the sample, 47.9% (n=3573) were screened with DPOAE and 52.1% (n=3879) were screened with AABR. Figure 2.1 summarises the screening outcomes of both groups.

No parent or caregiver refused to consent to the screening service. Table 2.1 provides a demographical overview of the sample. The mean age at first stage screen was 6.1 days (SD 8.1). However, the age of hearing screening ranged from 0 to 189 days because other hospitals referred some preterm infants to the MOU for follow-up visits post discharge.

Table 2.1. Demographics of study sample

Description	***Mean value/Percentage/Number***
Birth characteristics	
Mean gestational age	39 weeks (SD 2.1, n=7444)
Mean birth weight	3076.0 gram (SD 552.1, n=7433)
Normal vaginal delivery	72.7% (5414/7451)
Risk factors	
Preterm births[a]	11.3% (838/7444)
Low birth weight[b]	13% (969/7433)
> 5 days in NICU	0.7% (49/7451)
Mean age of mothers/caregivers at time of first screen	26.3 years (SD 6.0, n=7414)
Recorded places of birth	26
Mowbray Maternity Hospital	50.9% (3825/7512)
Mitchell's Plain MOU	38.8% (2918/7512)
Home births	1.5% (113/7512)
Born in transportation	0.4% (29/7512)

[a] Born before the 37th week of gestation (World Health Organisation [WHO], 2014). [b] <2500gram (The United Nations Children's Fund [UNICEF], 2004). The total number of infants (*n*) for each category differs due to information not being available for all infants at time of recording.

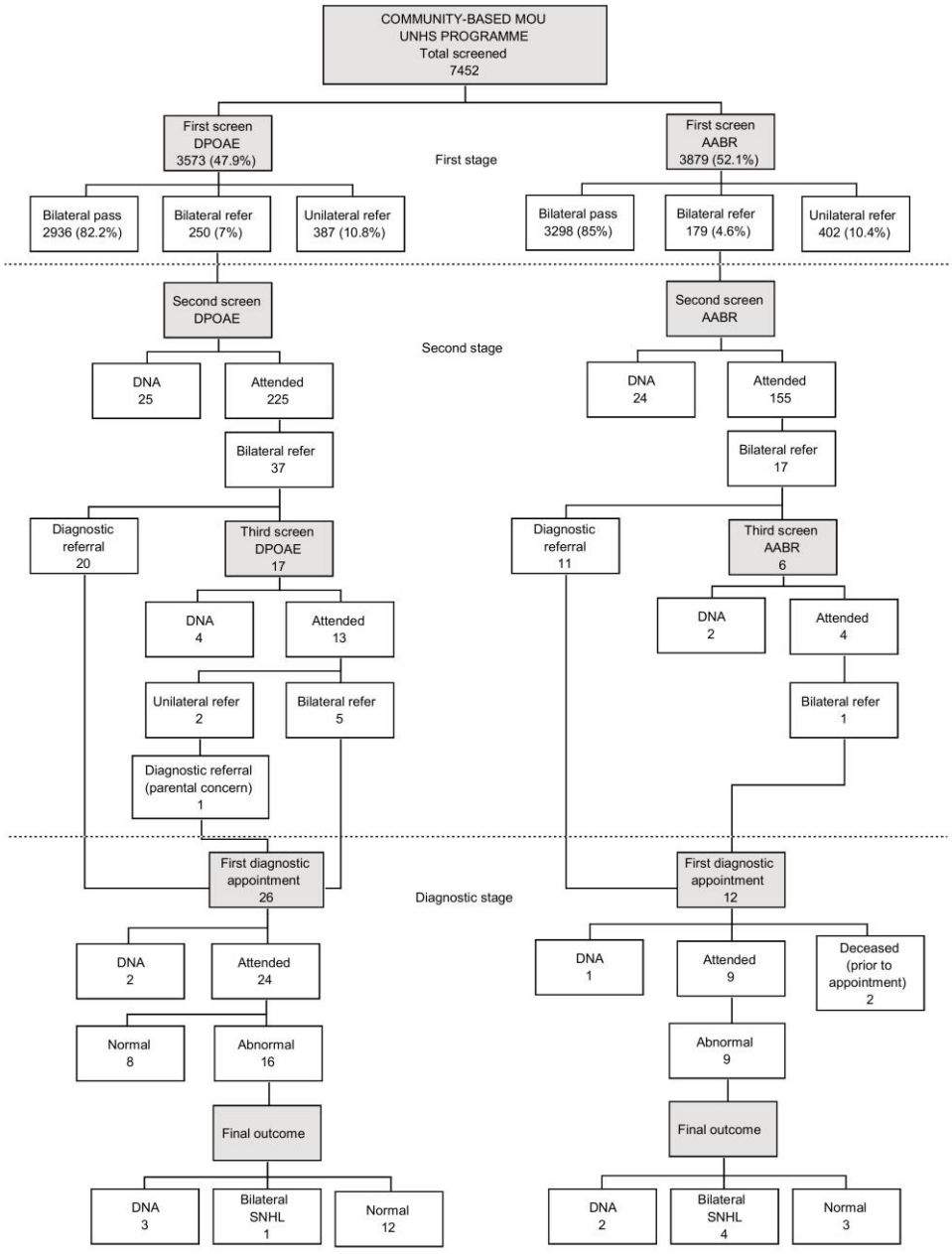

Figure 2.1. Overall outcome of stages within the screening and diagnostic process (*DNA = Did not attend; SNHL = Sensorineural hearing loss)

2.4.2 Referral rate

The bilateral first screen referral rate was 7% (250/3573) for DPOAE compared to 4.6% (179/3879) for AABR (Figure 2.1). These rates are significantly different for the techniques (Chi-square test; $p < 0.01$). Table 2.2 provides a breakdown of the bilateral refer outcomes as well as the unilateral refer rates for DPOAE and AABR.

Table 2.2. Distribution of first and second stage screening results (*CNT = Could not test)

Refer Category	***DPOAE (n=3573)***	***AABR (n=3879)***
First stage referral rate		
Bilateral refer outcome	7.0%	4.6%
Refer bilaterally for OAE or AABR	6.2%	2.4%
CNT bilateral (restless)	0.5%	1.4%
CNT bilateral (technical error)	0.1%	0.1%
CNT/Refer unilaterally for OAE or AABR	0.1%	0.7%
Unilateral refer outcome	10.8%	10.4%
Second stage/diagnostic referral rate	0.7%	0.3%

During the second stage, a sub-group of 23 infants, including 17 who referred for DPOAE and 6 who referred for AABR, received appointments for a third screen at the MOU (Figure 2.1). The main reason for a third screen was a CNT/CNT result on previous screening. The overall second stage refer rate dropped to 0.7% (26/3573) for DPOAE and 0.3% (12/3879) for AABR (Table 2.2). One infant from the DPOAE group who obtained a second stage unilateral refer result was given a diagnostic appointment because of parental concern (Figure 2.1).

Gender had no significant effect on first screen results (Chi-square test; $p > 0.01$). Age and screening technology had a significant effect on screen results (Chi-square test; $p < 0.01$). Figure 2.2 shows hearing screening outcome for DPOAE

and AABR technologies as a function of age at screening. Initial screen referral rates of newborns younger than ≤6 days (n=5437) were significantly lower (Chi-square test; $p < 0.01$) for AABR compared to DPOAE but there was no significant difference in screening outcome for the two technologies for infants older than 6 days (n=2011; Chi-square test; $p > 0.01$).

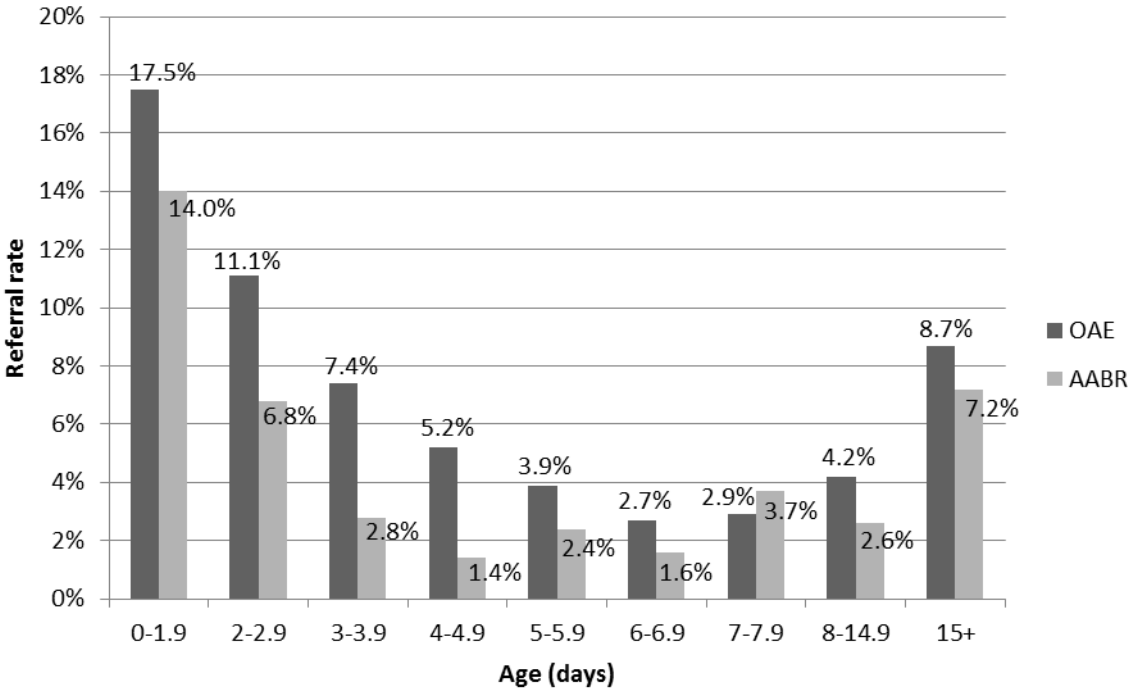

Figure 2.2. Distribution of first screen referral rate for DPOAE and AABR across age categories

2.4.3 Follow-up rate

There was no significant difference (Chi-square test; $p > 0.01$) between rescreen follow-up return rate for DPOAE (90%) and AABR (86.6), as displayed in Table 2.3. Majority of rescreens (67.4%, 256/380) coincided with the infants' second postnatal visit whilst 28.7% (109/380) returned only for hearing screening. Two infants, both from the AABR group, passed away prior to their diagnostic appointments (Figure 2.1) and were thus excluded from the diagnostic follow-up analysis (Table 2.3).

Table 2.3. Distribution of first and second stage follow-up rates

Follow-up Category	*DPOAE group*	*AABR group*	*Total sample*
First stage (MOU)			
First follow-up	90% (225/250)	86.6% (155/179)	88.6% (380/429)
Second follow-up	76.5% (13/17)	66.7% (4/6)	73.9% (17/23)
Second stage (Hospital)			
Diagnostic follow-up	92.3% (24/26)	90% (9/10)	91.7% (33/36)

2.4.4 Diagnostic outcomes

A total of 33 infants returned for a first diagnostic assessment. Among these infants, 24 had a refer outcome for DPOAE screening and 9 had a refer outcome for AABR screening (Figure 2.1). The 33 infants were grouped into a 'normal' (24.2%, 8/33) and 'abnormal' (75.8%, 25/33) category based on initial visit results. These findings are summarized in Table 2.4. All those in the 'normal' category (n=8) were within the DPOAE refer group and were discharged based on normal results elicited from repeat OAE screening (62.5%) or diagnostic ABR (37.5%).

The 'abnormal' group (n=25) received various ENT and audiological follow-ups with an average of three and a maximum of six follow-up visits. Subsequently, 15 infants were diagnosed with middle ear effusion (MEE) of which four went on to receive pressure equalising tubes. Not all these infants received complete diagnostic assessments. Final diagnostic outcomes are also summarised in Table 2.4 and Figure 2.1. Outcomes classified as normal hearing (n=15) were based on a combination of ENT confirming that the middle ears were clear and pass results on either repeat OAE screening (33.3%), freefield behaviour observation audiometry (46.7%), diagnostic ABR (13.3%), or the absence of parental concern (6.7%).

The prevalence rates of bilateral sensorineural hearing loss (SNHL) among infants undergoing diagnostic assessment were 0.3/1000 (1/3573) for the DPOAE refer group, 1/1000 (4/3879) for the AABR refer group and 0.7/1000 (5/7452) for the combined research sample. DPOAE screening resulted in a 4.2% (1/24) true positive rate of those who attended the diagnostic follow-up compared to 44.4% (4/9) for AABR screening. The prevalence rates of MEE, including unilateral and

bilateral cases, were 2.2/1000 (8/3573) for the DPOAE group, 1.8/1000 (7/3879) for the AABR group and 2/1000 (15/7452) for the total sample.

Table 2.4. Diagnostic outcomes for referred infants (*HL = Hearing loss)

Outcome Category	***DPOAE n=3573***	***AABR n=3879***	***Total sample n=7452***
Total referred for diagnostic assessment	26 (0.73%)	12 (0.31%)	38 (0.51%)
Deceased (prior to 1st visit)	-	2 (0.05%)	2 (0.03%)
Lost to follow-up (1st visit)	2 (0.06%)	1 (0.03%)	3 (0.04%)
Initial diagnostic visit			
Normal	8 (0.22%)	-	8 (0.11%)
Abnormal	16 (0.45%)	9 (0.23%)	25 (0.34%)
Conductive HL - unilateral	2 (0.06%)	1 (0.03%)	3 (0.04%)
HL unspecified - unilateral	1 (0.03%)	-	1 (0.01%)
HL unspecified - bilateral	3 (0.08%)	4 (0.11%)	7 (0.09%)
MEE - unilateral	2 (0.06%)	1 (0.03%)	3 (0.04%)
MEE - bilateral	6 (0.17%)	6 (0.15%)	12 (0.16%)
Final diagnostic outcomes			
Bilateral SNHL	1 (0.03%)	4 (0.11%)	5 (0.07%)
Lost to follow-up (diagnostic process)	3 (0.08%)	2 (0.05%)	5 (0.07%)
Normal (post follow-up)	12 (0.34%)	3 (0.08%)	15 (0.20%)

Mean age at time of referral to diagnostic services was 22 days (n=38) but long waiting lists at the tertiary facility resulted in a mean age of 106 days (15 weeks; n=33) at the time of the first diagnostic appointment (Table 2.5). The age at time of diagnosis of SNHL came to a mean of 269 days (38.4 weeks; n=5). The cases of these five infants varied greatly ranging from being diagnosed under the age of one month to being diagnosed just before the age of two years.

Table 2.5. Distribution of infants' ages and waiting times at various stages of the follow-up process

	Age (days) at screen referral (n=38)	*Age (days) at 1st diagnostic session (n=33)*	*Waiting time (days) screen referral to 1st diagnostic session (n=33)*	*Age (days) at diagnosis (n=5)*
Mean (SD)	22 (28.2)	105.9 (43.4)	84.7 (44.5)	269 (279.9)
Minimum	3	29	11	29
Maximum	138	191	176	718

2.4.5 Screening personnel

Only the data of screener 1 and 2 were considered in this section as screener 3 conducted limited screening and did not screen on consecutive days. Screener 1 completed 200 DPOAE and 174 AABR screens with bilateral refer rates of 14.5% for DPOAE and 5.2% for AABR screening. Screener 2 performed 3301 DPOAE and 3635 AABR screens and yielded bilateral refer rates of 6.5% for DPOAE and 4.6% for AABR screening. The difference in referral rates between the two screeners was statistically significant for DPOAE screening (Chi-square test; $p < 0.01$) but not for AABR screening.

No statistically significant difference was noted in the amount of screens per day between the two technologies (t-test; $p > 0.01$) as shown in Table 2.6.

Table 2.6. Screening capacity of dedicated screener with DPOAE & AABR technology

	DPOAE	***AABR***
Mean tests per day (SD)	24 (9.1)	23 (7.0)
Maximum tests per day	51	43
Number of test days	155	182

2.5 Discussion

2.5.1 Referral rates

Two-stage screening protocols reportedly reduce referral rates (Friderichs et al., 2012; Van Dyk et al., 2015; Olusanya, Ebuehi & Somefun, 2009). The current study supports this conclusion. Initial referral rates of 7% for DPOAE and 4.6% for AABR decreased to 0.7% and 0.3% after the second stage. These values are well below the national benchmark of 5% (HPCSA, 2007) and the international benchmark of 4% (JCIH, 2007). Initial and second stage DPOAE referral rates were lower than the 9.5% and 3% respectively reported in a preceding immunisation-linked hearing screening programme that employed a similar protocol (Friderichs et al., 2012). The reduction might be attributed to the younger point of entry on the MOU postnatal visit platform (mean age 6 days compared to 3.9 weeks at first screen).

Comparative studies reporting referral rates for OAE and AABR screening in hospital-based settings in South Africa (TEOAE 37.9%; AABR 16.7%; Van Dyk et al., 2015), Spain (TEOAE 8.2%; AABR 0.35%; Granell et al., 2008) and Turkey (TEOAE 10.5%; AABR 2%; Konukseven et al., 2010), demonstrate lower AABR referral rates, similar to findings in this study.

To date, AABR has not been recommended for primary health care contexts due to high disposable costs, test time and difficulty in obtaining results in infants beyond the newborn period (Swanepoel et al., 2006; Olusanya, Emokpae, Renner & Wirz, 2009). However, advances in technology, like the MB11 BERAphone™, combined with the younger point of entry achieved in this study, demonstrated that cost-effective infant hearing screening with AABR is feasible and well-suited for countries with limited resources. Reduced initial referral rates not only result in cost and time savings but also in fewer caregivers attending additional appointments and experiencing stress related to their infant's hearing status (Granell et al., 2008; Olusanya, 2011; Cebulla & Shehata-Dieler, 2012).

If a unilateral refer criteria was to be implemented, as is standard practice in many countries, the programme would be severely pressured with initial referral rates

rising to 17.8% for DPOAE and 15% for AABR. This would result in approximately three times the amount of second stage rescreens with a causal sequence on the diagnostic referral rate and first screen coverage.

Consistent with previous reports (Khoza-Shangase & Harbinson, 2015; Van Dyk et al., 2015), the least optimal time to screen was within the first 48 hours after birth for both technologies. Lowest initial referral rates were at the age of 4 days for AABR (1.4%) and 6 days for DPOAE (2.7%). Screening between 3 and 14 days after birth with AABR and 5-14 days of age with DPOAE resulted in referral rates meeting a ≤5% benchmark (HPCSA, 2007). Referral rates of both technologies increased post two weeks of age, as infants are typically more difficult to test and transient middle ear effusion might be more prevalent (Friderichs et al., 2012; Swanepoel, Hugo & Louw, 2007). MOU postnatal follow-up visits present a very useful platform for screening that results in lower referral rates compared to earlier (<48h) or later (immunisation-linked) screening (Khoza-Shangase & Harbinson, 2015; Friderichs et al., 2012). Additionally, this study highlights that AABR technology could significantly reduce initial referral rates and allow more efficient screening at an earlier age on this platform.

2.5.2 Follow-up rates

Internationally, loss to follow-up is one of the greatest challenges experienced in newborn hearing screening programmes with follow-up rates in the region of 50% often being reported (Granell et al., 2008; Olusanya, Emokpae et al., 2009; Scheepers, Swanepoel & Le Roux, 2014). In contrast, follow-up rates in the current study were encouragingly high for both technology groups. The first MOU follow-up was 90% for infants with a DPOAE refer and 86.6% for infants with an AABR refer. Diagnostic follow-up rates for DPOAE refer outcomes (92.3%) and AABR refer outcomes (90%) surpassed the target of 70% for community-based screening programmes (JCIH, 2007; HPCSA, 2007). These findings are in agreement with an earlier immunisation-linked screening programme that had follow-up rates of 85.1% for clinic level and 91.8% for diagnostic follow-up (Friderichs et al., 2012). Friderichs et al. (2012) ascribed high follow-up rates to the dedicated monitoring of the programme by a screening coordinator which included strategies such as telephone calls and reminders in folders. Contributors

to higher follow-up rates in our study may have included the facilitative platform offered by the MOU postnatal visits, the use of a dedicated screener and shorter time between initial screen and follow-up. The dedicated screener was well trained in providing thorough information counselling at the point of first screen referral. 67% of repeat screens happened in conjunction with the babies' second postnatal follow-up visit and was achieved without any reminders. Strategies only had to be implemented for the remainder; reducing time spent and related costs. The dedicated screener contacted parents/caregivers on the same day that they defaulted on their infant's follow-up appointment to establish the reason for not attending. Concerns or misconceptions could be addressed and a suitable follow-up date rescheduled. Lastly, as follow-ups took place within a few days of the initial screen, the majority of infants were still within the newborn period and mothers/caregivers were cooperative.

In the current study follow-up rates deteriorated with additional screening or diagnostic appointments. For example, five babies who received a second diagnostic appointment were lost to follow-up after having attended their first appointment. This highlights the importance of following protocols and obtaining complete and accurate results as early as possible.

2.5.3 Diagnostic outcomes

The prevalence rate for bilateral SNHL was 1/1000 for those screened with AABR and 0.3/1000 for those screened with DPOAE. Both rates were lower than the 1.5/1000 reported for an earlier immunisation linked programme that implemented a two stage DPOAE protocol (Friderichs et al., 2012). However, the rate in the earlier study included unilateral and mixed losses of permanent nature (Friderichs et al., 2012). A universal community-based programme in Nigeria, employing a two stage OAE/AABR protocol, resulted in a 22.5/1000 yield of PCEHL (uni-/bilateral). The high yield was attributed to the large percentage (55%) of screened infants who were born outside of hospital settings without skilled attendance, a factor that influences the incidence of PCEHL (Olusanya, Emokpae et al., 2009). In contrast, only 1.9% of births in our sample took place without skilled attendance.

The low yield obtained in this study is partially attributed to loss to follow-up. If the ideal scenario of 100% attendance was achieved for all screening and diagnostic follow-ups, the prevalence rates are estimated to increase to 0.6/1000 for the DPOAE group and 2.3/1000 for the AABR group. Secondly, variability in the applied diagnostic protocols could have added to the low yield. Diagnostic ABR measurements were only employed in eight of the 33 initial evaluations (5 DPOAE group; 3 AABR group). Repeat screening at diagnostic level, absence of bone conduction measures and use of freefield behavioural observation audiometry instead of ear specific visual reinforcement audiometry were noticed. All these factors have been described as potential pitfalls in the audiological assessment of young infants (Gravel & Seewald, 2001).

Standardised implementation of a diagnostic test battery, aligned with international best practice, as well as skill development in the areas of audiological diagnosis and management of young infants (1-6 months) are required to reach the goals of EHDI (JCIH, 2007; Hall & Swanepoel, 2010; Teixeira & Joubert, 2014). Implementation of clinical peer review and quality assurance systems have been facilitative in many countries (Kuttva, Radomskij & Raglan, 2009). Furthermore, strengthening district level audiology and ENT services could alleviate pressure on tertiary level and improve timeous access to diagnostic services. These factors should be addressed prior to pursuing more stringent screening criteria.

2.5.4 Dedicated screening personnel

Screener experience reduced DPOAE referral rates as evident from the 14.5% achieved by screener 1 who worked a month compared to 6.5% by screener 2 who worked for 15 months. Interestingly, AABR referral rates were not influenced by screener experience. Although previous studies showed that AABR (MB11 BERAphone™) test time is still longer than OAE screening (Van Dyk et al., 2015; Konukseven, Ḋincol & Genc, 2012), this study showed comparable daily capacity for both technologies with an average of 24 DPOAE screens per day and 23 AABR screens per day. This is higher than the reported average of 13 OAE screens per day in a community-based programme in Nigeria but corresponds to the stated capacity of 20 screens per day (Olusanya, Emokpae et al., 2009). The

only difference being that their screener was supported by an administration assistant whilst the screener in this study worked alone. Daily number of screens is dependent on access to infants which is an important benefit of community-based programmes (Olusanya, Emokpae et al., 2009). It was also an observed benefit of the MOU postnatal visit platform over the immunisation clinics within the Cape Town area.

The appointment of a dedicated non-professional screener positively influenced consistent screening services, follow-up rates, follow-up administration, electronic data-capturing, equipment maintenance, and provision of antenatal information regarding UNHS. These benefits contribute to an efficient and cost effective screening programme (Friderichs et al., 2012). They cannot be expected in screening programmes relying on existing nursing personnel with high caseloads.

The current study showcased that the role of dedicated screeners could be fulfilled by non-professional individuals with character and experience being more important than qualification. Quality of training and regular supervision are vital.

2.6 Conclusion

Postnatal follow-up visits at community-based MOU facilities create a useful platform for access to UNHS and facilitate high follow-up rates. AABR technology with negligible disposable costs and improved test time provides opportunity for AABR protocols to be utilised in community-based screening programmes. Benefits hereof include significantly lower initial referral rates, higher true positive rates, more efficient screening at an earlier age and the ability to identify neural hearing losses. This however needs to be seen in the light of the MOU context evaluated in this study with infants mostly younger than two weeks of age. Well trained and managed non-professionals can successfully be utilised as dedicated screeners and positively impacted programme efficiency and administration. This may be valuable in settings where UNHS feasibility has been poor due to overburdened nursing personnel. Alongside the development of contextual UNHS models, timeous access to diagnostic services as well as diagnostic protocol and skill development coherent with international best practice should be fostered.

2.7 Acknowledgments

The authors would like to thank and acknowledge the following contributors: 1) Western Cape Government: Health, the Carel du Toit Centre and Irene Watt for their support and contributions to this project; 2) The DG Murray Trust for funding the research; 3) Maico Germany for providing the MB11 BERAphone™ on loan basis; 4) Lebone Medical Supplies for the technical assistance. None of the contributors were involved in any part of the research design, analysis or interpretation of the data.

2.8 Conflict of interest statement

The authors have no conflict of interests to declare.

3. DISCUSSION AND CONCLUSION

Access to newborn hearing screening services are limited in South Africa (Theunissen & Swanepoel, 2008; Meyer, Swanepoel, Le Roux & Van der Linde, 2012). In the Western Cape, public-private partnerships have been a catalyst in the process of model development and building context specific evidence in the field of newborn hearing screening. This research was developed upon recommendations of the first systematic infant hearing screening programme in the Western Cape (Friderichs et al., 2012) and intended to further inform model development to support sustainable implementation. A new PHC screening context was explored and outcomes for two screening technologies were compared and evaluated against benchmarks and quality indicators for clinic-based screening programmes as provided by the HPCSA Year 2007 Position Statement on EHDI (HPCSA 2007).

3.1 Discussion of results

3.1.1 Referral rates

Choice of screening protocol and technology is known to influence a screening programme's referral rates (Olusanya, Ebuehi et al., 2009). Similar to previous findings (Friderichs et al., 2012; Olusanya, Ebuehi et al., 2009; Van Dyk et al., 2015), the current study demonstrated the value of two-stage screening protocols in reducing referral rates. Initial referral rates of 7% for DPOAE and 4.6% for AABR decreased to 0.7% and 0.3% after the second stage. These values are well below the national benchmark of 5% (HPCSA, 2007) and the international benchmark of 4% (JCIH, 2007). Initial and second stage DPOAE referral rates were lower than the 9.5% and 3% respectively reported in a preceding immunisation-linked hearing screening programme that employed a similar protocol (Friderichs et al., 2012). The reduction might be attributed to the younger point of entry on the MOU postnatal visit platform (mean age 6 days) compared to the immunisation platform (mean age 3.9 weeks).

Various studies comparing OAE and AABR screening referral rates in hospital-based settings have reported significantly lower referral rates for AABR – these include South Africa (TEOAE 37.9%; AABR 16.7%; Van Dyk et al., 2015), Spain

(TEOAE 8.2%; AABR 0.35%; Granell et al., 2008) and Turkey (TEOAE 10.5%; AABR 2%; Konukseven et al., 2010). The findings of the present study is in agreement with previous results but importantly, was demonstrated within a PHC context for the first time in South Africa.

To date, AABR has not been recommended for community-based UNHS due to high disposable costs, test time and difficulty in obtaining results in infants beyond the newborn period (Swanepoel et al., 2006; Olusanya, Emokpae et al., 2009). However, advances in technology, like the MB11 BERAphone™, combined with the younger point of entry achieved in this study, successfully addressed these barriers. Reduced initial referral rates not only result in cost and time savings but also in fewer caregivers attending additional appointments and experiencing stress related to their infant's hearing status (Cebulla & Shehata-Dieler, 2012; Granell et al. 2008; Olusanya, 2011). The study demonstrated that cost-effective infant hearing screening with AABR is feasible and well-suited for countries with limited resources.

If a unilateral refer criteria was to be implemented, as is standard practice in many countries, the programme would be severely pressured with initial referral rates rising to 17.8% for DPOAE and 15% for AABR. This would result in approximately three times the amount of second stage rescreens with a causal sequence on the diagnostic referral rate and first screen coverage.

Consistent with previous reports, the first 48 hours were the least optimal time to screen for both technologies (Van Dyk et al., 2015; Khoza-Shangase et al., 2015). Day three (48h to <72h after birth) offered improvements of 51% and 37% in AABR and DPOAE referral rates respectively. Ideal age for screening, where initial referral rates were lowest, related to the age of 4 days for AABR (1.4%) and 6 days for DPOAE (2.7%). However, the referral rate benchmark of ≤5% (HPCSA, 2007) was met between the ages of 3 to 14 days for AABR and 5 to 14 days for DPOAE. Important to note is that the period between the ages of 2 to 6 days displayed the greatest significance with AABR referral rates being 38% to 73% lower compared to DPOAE. Referral rates of both technologies increased post two weeks of age, as infants are typically more difficult to test and transient middle

ear effusion might be more prevalent (Friderichs et al., 2012; Swanepoel et al., 2007). MOU postnatal follow-up visits present a very useful platform for screening that results in lower referral rates compared to earlier (<48h) or later (immunisation-linked) screening (Friderichs et al., 2012; Khoza-Shangase et al., 2015). Additionally, this study highlights that AABR technology could significantly reduce initial referral rates and allow more efficient screening at an earlier age on this platform.

3.1.2 Follow-up rates

The community level (DPOAE 90%, AABR 86.7%) as well as tertiary hospital level (DPOAE 92.3%, AABR 90%) follow-up rates for both technology groups surpassed the target of 70% for community-based screening programmes (HPCSA, 2007). Type of technology and age of mothers/caregivers had no influence on the follow-up rate. These rates are similar to the follow-up rates (85.1% clinic level, 91.8% tertiary level) reported in the immunisation-linked screening programme that preceded the current one (Friderichs et al, 2012).

The high follow-up rates stand in stark contrast to many international reports that describe loss to follow-up as one of the greatest challenges experienced in NHS programmes in developing and developed countries alike (Scheepers et al., 2014; Olusanya et al., 2009; Granell et al., 2008). Interestingly, the high follow-up rates in the current study was achieved without a multi-level data management and tracking system, which is perceived as one of the most important facilitators in follow-up management (Olusanya, 2009; Scheepers et al., 2014). The addition of such a system would however contribute to the long term sustainability and efficacy of the programme (JCIH, 2007; HPCSA, 2007).

Aligning follow-up appointments with existing healthcare visit schedules contribute to high follow-up rates (HPCSA, 2007). The postnatal visit platform was instrumental in facilitating the high follow-up return rates in the study. 67% of repeat screens happened in conjunction with the babies' second postnatal follow-up visit at the MOU and was achieved without any reminders. Strategies only had to be implemented for the remainder; reducing time spent and related costs. The importance of thorough information counselling at the point of first screen referral;

follow-up phone calls to establish the reason for not attending; as well as limiting the number of follow-up visits in the process between screening and diagnosis; have all been identified as important contributors to follow-up compliance in the programme.

3.1.3 Diagnostic outcomes

The goal of the diagnostic phase in the EHDI process is to establish whether a permanent hearing loss is present (HPCSA, 2007; JCIH, 2007; British Columbia Early Hearing Program [BCEHP], 2012). A test-battery approach, guided by best practice protocols, is required to ensure an accurate diagnosis (BCEHP, 2012; Hall & Swanepoel, 2010; Teixeira & Joubert, 2014). Analysis of diagnostic results in the current study revealed great variability in the applied protocols. Diagnostic ABR measurements were only employed in eight of the 33 initial evaluations (5 DPOAE group; 3 AABR group) of which five were cases seen by the private audiologist contracted during the initial phase of the research. The desired ear-specific and frequency-specific hearing information (BCEHP, 2012) could seldom be derived from results. These factors together with loss to follow-up, may have attributed to the relatively low yield, 0.3/1000 for the DPOAE group and 1/1000 for the AABR group, obtained in this study.

A community-based UNHS programme in Nigeria, employing a two stage OAE/AABR protocol, resulted in a 22.5/1000 yield of PCEHL (uni-/bilateral). The high yield was attributed to the large percentage (55%) of screened infants who were born outside of hospital settings without skilled attendance - a factor that influences the incidence of PCEHL (Olusanya, Emokpae et al., 2009). In contrast, only 1.9% of births in our sample took place without skilled attendance.

Despite achieving a younger average age at time of screen referral (22 days), the average age at first diagnostic appointment (15 weeks/3.5 months) and at confirmation of hearing loss (37.9 weeks/8.7 months) were higher than the preceding immunisation-linked programme (11.9 weeks and 32 weeks respectively) (Friderichs et al., 2012). This falls outside the recommended benchmark of diagnosis by the age of four months for clinic-based screening programmes (HPCSA, 2007) and highlights the growing burden on tertiary level

services with waiting lists remaining between four to six months. Natural sleep could often no longer be used for diagnostic ABR sessions and difficulties encountered with available sedation options frequently required more than one session to obtain conclusive results.

Implementation of evidence-based protocols for diagnostic assessment, skill development and timeous access to diagnostic services are required to reach the EHDI goals (JCIH, 2007; Hall & Swanepoel, 2010; Teixeira & Joubert, 2014).

3.1.4 Screening personnel

The use of already overburdened nursing personnel as screeners has been reported to result in low coverage rates (Friderichs et al., 2012). This programme is the first in South Africa to report on the outcomes of screening performed by a dedicated non-professional screener. Screener experience reduced DPOAE referral rates as evident from the 14.5% achieved by screener 1 who worked a month compared to 6.5% by screener 2 who worked for 15 months. Interestingly, AABR referral rates were not influenced by screener experience.

Daily screening capacity of a screener within a certain context is important to inform programme planning. The dedicated screener's daily average for DPOAE and AABR screening was almost equal and showed no significant difference (24 DPOAE/day; 23 AABR/day). This is higher than the reported average of 13 OAE screens per day in a community-based programme in Nigeria but correlates well to their stated capacity of being able to do 20 screens per day (Olusanya, Emokpae et al., 2009). The only difference being that their screener was supported by an administration assistant whilst our screener worked alone. Daily number of screens is dependent on access to infants which is an important benefit of community-based programmes (Olusanya, Emokpae et al., 2009). It was also an observed benefit of the MOU postnatal visit platform over the immunisation clinics within the Cape Town area.

The appointment of a dedicated non-professional screener positively influenced consistent screening services, follow-up rates, follow-up administration, electronic data-capturing, equipment maintenance, and provision of antenatal information

regarding UNHS. Additionally, fewer equipment breakdowns were experienced compared to previous contexts where multiple lesser experienced staff used a single device. These benefits contribute to an efficient and cost effective screening programme (Friderichs et al., 2012).

The introduction of a simple uniform (scrubs with embroidery) positively influenced the level of respect with which mothers/carers treated the screener and bridged the initial hurdle of not being seen as professional or taken seriously. An important consideration when employing a dedicated screener is to plan for vacation and sick leave from the outset. In this programme the resident health promoter was trained as back-up screener.

3.2 Clinical implications and recommendations

3.2.1 Choice of screening technology

Recommendations to date uniformly suggested OAE technology for community-based screening programmes for reasons such as ease of use, cost and screening duration (Swanepoel et al., 2006; HPCSA, 2007; JCIH, 2007; Olusanya, Emokpae et al., 2009). The current study was the first to compare the outcomes of OAE and new generation AABR (MB11 BERAphone^{TM}) technology within a community-based UNHS programme. AABR technology with advances in terms of screening time and disposable costs (as demonstrated with the MB11 BERAphone^{TM}) provides opportunity for AABR protocols to be applied in community-based NHS programmes. In addition to the known advantage of being able to detect neural hearing losses, this study highlighted additional advantages of AABR screening namely: (1) significantly lower referral rates, (2) a higher true-positive rate and (3) acceptable referral rates at a younger age compared to OAE screening. Furthermore, a similar daily capacity (average number of screens per day) is possible for both technologies.

With UNHS not yet implemented at all hospitals and NICUs in South Africa (Theunissen & Swanepoel, 2008), community-based screening programmes cater for a wide range of infants and are not restricted to ‘well-babies’. A recommendation is made for the consideration of AABR screening within the

community-based context, especially if the programme is implemented on a platform where infants are mostly younger than two weeks.

Despite all the benefits, purchasing an AABR screening device requires around two-and-a-half to three times the capital expenditure compared to an OAE screening device. This has made it difficult to convince government, ever facing budget cuts, to follow this recommendation. However, research modelling the screening costs over a couple of years, taking into account the disposable costs, number of equipment breakdowns (e.g. probe replacements), number of screening and diagnostic follow-ups required as well as the true positive rate – will inform decision making more accurately in terms of cost-effectiveness.

A national survey of NHS services in the private healthcare sector of South Africa reported that only one in four programmes in NICUs implement AABR screening (Meyer et al., 2012). Additionally, challenges related to follow-up default have also been reported in private sector NHS programmes (Scheepers et al., 2014). The results of the current study, demonstrating the benefits of AABR screening, can thus also prompt the private healthcare sector to consider AABR as first line screening tool.

3.2.2 Screening personnel

Despite the fact that the EHDI position statement (HPCSA, 2007) makes allowance for the use of trained screeners, majority of NHS programmes in South Africa still relies on audiologists as primary screeners (Khoza-Shangase et al., 2015). In the light of the scarcity of audiologists (Swanepoel, 2006; Fagan & Jacobs, 2009), non-audiologist screeners will be essential in achieving the goal of universal screening coverage in South Africa. This study demonstrated that a well-trained and managed non-professional can successfully act as screener.

The job description in this study included providing antenatal talks, hearing screening, basic counselling, data-capturing and assistance with follow-up management. When recruiting non-professional screeners attention should be given to the following: (1) good communication skills in the primary language/s of the community they will serve, (2) literacy skills, (3) basic computer literacy, (3)

cultural sensitivity, (4) comfortable with handling newborns, (5) character traits such as patience, empathy, meticulousness and the ability to function well under pressure.

The role of hearing screener will be fulfilled by different role players (i.e. nurses, community care workers [CCWs], rehabilitation care workers [RCWs], non-professionals, retired professionals etc.) depending on the context and needs of the programme. Using non-professionals, as opposed to nursing personnel or audiologists, will impact the cost-effectiveness of the programme. The study demonstrated enhanced programme efficiency due to the screener being dedicated to the task. Quality of training is key and in South Africa a curriculum guideline is yet to be developed to ensure uniformity of training by screening coordinators.

The role of a programme coordinator is however emphasised (Friderichs et al., 2012) – providing theoretical and in-service training, regular quality assurance visits and being available to answer questions or to assist with trouble shooting.

3.2.3 Postnatal visits at community-based obstetric units as screening platform

The postnatal visit platform at community-based MOUs provides access to a steady flow of newborns, predominantly under the age of two weeks. The advantages of these factors combined with the employment of a dedicated screener become clear when viewing the side-by-side comparison offered in Table 3.1. It shows the outcomes achieved in two UNHS programmes in the Western Cape – one linked to immunisation visits (Friderichs et al, 2012) and the current study, linked to the postnatal visit platform.

Table 3.1. Comparison of immunisation-linked and postnatal visit-linked UNHS programmes in the metropolitan area of Cape Town

	Immunisation-linked programme (Friderichs et al., 2012)	**Postnatal visit-linked programme (Current study)**
Screening sites	8 Primary Healthcare clinics	1 Midwife Obstetric Unit
Screening personnel	Existing nursing personnel	Dedicated non-professional screener
Research period	19 months	16 months
Total infants screened	2018	7451
Mean age at 1st screen	3.9 weeks	6 days
Coverage rate	32%	Could not be determined
Referral rates: 1st stage	9.5% (OAE)	7% (OAE) 4.6% (AABR)
2nd stage	3% (OAE)	0.7% (OAE) 0.3% (AABR)
Total referred for diagnostic assessments	62	38
Follow-up rates: 1st stage	85.1%	88.6%
2nd stage	91.8%	91.7%
Prevalence of MEE	12.9/1000	2.2/1000
Prevalence of PCEHL	1.5/1000	0.3/1000 (OAE group) 1/1000 (AABR group)

A single dedicated screener and screening device out-performed screening at eight immunisation clinics with a screening device per site. Apart from the vastly greater number of infants reached and lower referral rates, the screening programme in the MOU required the screening coordinator to manage a single site and screener compared to eight sites with ever changing screening personnel. This reflects the efficiency and cost-effectiveness of integrating NHS into postnatal visits at MOUs.

A new model for community-based NHS in the metropolitan area of the Western Cape is subsequently proposed (Figure 3.1). Following the vision of the Western

Cape's Healthcare 2030 strategic framework, NHS is embedded into the district health services with a strong focus on patient-centred quality care (WCGH, 2014b). On the PHC platform, messages regarding the importance of EHDI and prevention of hearing loss can be included in antenatal care. Postnatal visits at MOUs serve as primary screening platform for initial and follow-up screening whilst a role change is suggested for immunisation clinics. Instead of offering NHS screening, immunisation clinics can monitor screening coverage, follow-up compliance and speech-language and hearing developmental milestones. Any concerns are to be referred to the local audiology referral point. The home and community based care (HCBC) platform hosts various functions such as (1) monitoring of NHS coverage and follow-up compliance during routine CCW home visits; (2) targeted home visits to parents/caregivers who failed to attend their infant's follow-up screening or diagnostic appointment and (3) family-based early intervention, often provided by NGO partners, once an infant has been diagnosed with hearing loss. District hospital audiology services can potentially offer a professional follow-up service to allow families access to a professional within two weeks of their infant's second 'refer' outcome at the MOU, whilst awaiting their tertiary level diagnostic appointment. This gives opportunity for the audiologist to address the parents/caregivers' questions and/or concerns, to obtain a detailed case history, to assess middle ear functioning and to act as case manager for the family.

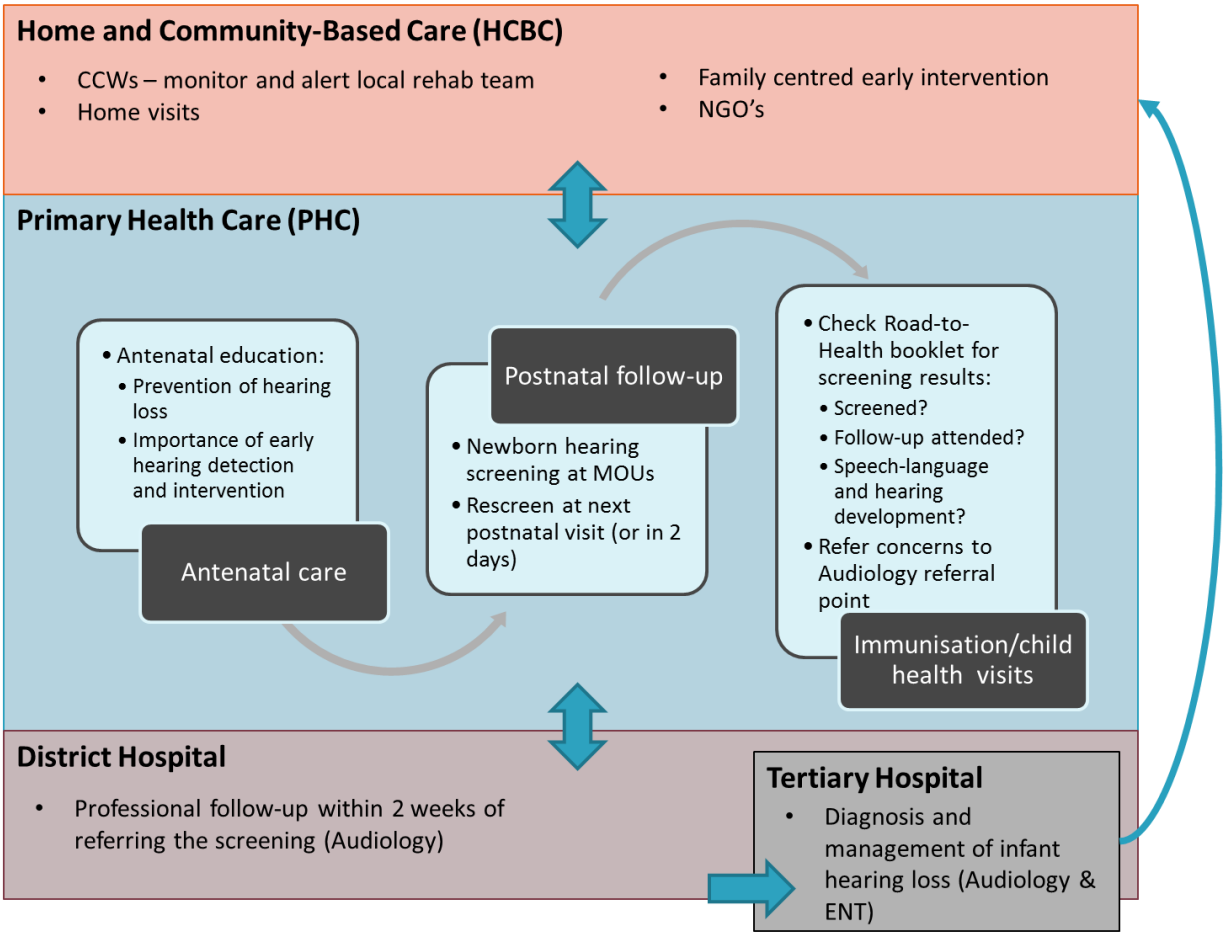

Figure 3.1. Proposed model for community-based NHS in the Western Cape

The proposed model is currently being demonstrated as part of a larger paediatric speech and hearing services project in a sub-district within Cape Town.

3.2.4 Diagnostic protocol and skill development

Due to the status of no or very limited UNHS programmes in South Africa (Theunissen & Swanepoel, 2008; Meyer et al., 2012) and the resultant late diagnosis of hearing loss (Swanepoel et al., 2013; Van der Spuy & Pottas, 2008; Butler et al., 2013), majority of audiologists are not experienced in the audiological assessment and management of young infants (i.e. newborn to six months old). This study calls for a renewed focus on the diagnostic audiological assessment and management that are required post the screening stage. Development and implementation of evidence-based practice guidelines together with skill development should be prioritised in all departments and practices offering paediatric audiological services (Teixeira & Joubert, 2014).

3.3 Critical evaluation

3.3.1 Strengths of the study

The study was based on the first government supported UNHS programme that has been aligned with postnatal visits at community-based obstetric units in South Africa. As such, the study firstly provides important information on the use of postnatal visits at MOUs as platform for community-based NHS programmes. The new contextual model for NHS will guide further roll-out in the Western Cape and hopefully beyond. Secondly, the study was the first in South Africa to demonstrate the potential of non-professionals to act as screeners in UNHS programmes as well as the positive influence they can have on programme efficiency. Thirdly, it emphasised the viability and benefits of implementing AABR technology (such as the MB11 BERAphone^{TM}) as first line screening tool in community-based UNHS programmes. Lastly, the study highlighted the importance of clinically sound and timeously available diagnostic services to follow the screening process. EHDI programmes can only reach the desired outcomes if the screening, diagnostic and intervention components function effectively (JCIH, 2007; HPCSA, 2007).

From a statistical perspective, one of the strengths of the study was the relatively large sample size. Among other things, it allowed plotting the distribution of referral rates for DPOAE and AABR across age categories and allows better generalisation of the research findings (Leedy & Ormrod, 2001). Furthermore, the MOU where the study was conducted is the largest community-based MOU in the metropolitan area of Cape Town based on number of births and postnatal visits per month. The constant flow of infants allowed the researchers to investigate the screening capacity of a single dedicated screener per day (number of screenings per day).

3.3.2 Limitations of the study

The greatest limitation of this study related to the fact that accurate coverage rates could not be determined. To address this in future, programme coordinators will engage with MOU management to instate a new routinely kept data indicator relating to the number of first postnatal visits. Additionally, not all areas and provinces have MOUs as described in this study which may limit the application of

some of the findings. However, postnatal follow-up services should be available to all mothers and newborns. Studies exploring these postnatal service platforms in all provinces across South Africa would provide valuable information to guide NHS programme development and implementation. Lastly, the fact that the UNHS programme in this study implemented a bilateral refer criteria limited the comparability of the referral rate results – not only to other international programmes but also to international benchmarks.

3.4 Future research

This study opened multiple opportunities for further research:

- The study highlighted the importance of conducting studies in all provinces across South Africa in order to determine the most suitable platforms for community-based UNHS programmes. Although all provinces might not have community-based MOUs functioning exactly like the ones in the Western Cape, postnatal follow-up visits (also called 'three day assessments') should be offered. Exploring these platforms within each province will assist in accelerating roll out of NHS in the public sector.
- NHS studies to date have mainly focussed on metropolitan areas which are easily accessible and generally speaking, better resourced. However, model development and research in rural healthcare contexts will be essential in order to reach UNHS coverage in South Africa.
- A study comparing the use of dedicated non-professional screening personnel to the use of existing nursing personnel within MOUs would be insightful. Within the MOU context, nursing personnel providing postnatal care are only focussed on maternal and infant care. It might be possible for existing nursing personnel to act as screeners depending on the size of the MOU and the number of postnatal visits per month. Viability of expecting additional duties such as data capturing and follow-up management should also be monitored and reported on.
- Majority of hospital-based NHS programmes in South Africa utilise audiologists as screeners. Research evaluating the use of dedicated non-professionals or existing nursing personnel as screeners within hospital-

based screening programmes would provide valuable information to guide future development.

- Studies exploring context specific risk factors for hearing loss in South Africa will assist in obtaining comprehensive information on the unique characteristics of infant hearing loss in the country.
- Longitudinal studies that track infants who passed their NHS with unilateral pass results or bilateral pass results but with known high risk factors would be insightful. It will guide protocol development for screening as well as monitoring post-screening.
- A South African study exploring the 'cost of not screening' would be valuable for advocating the legislation of UNHS. Existing NHS programmes should also document the cost of screening (per baby screened and per baby identified with hearing loss) as no South African data currently exists. This will be essential in guiding the selection of cost-effective protocols and the planning of large scale role out.

3.5 Conclusion

Integrating UNHS with postnatal follow-up visits at MOUs create a community-based model that facilitates optimal access to NHS as well as high follow-up rates. AABR technology with negligible disposable costs and improved test time provides opportunity for AABR protocols to be utilised in community-based screening programmes. Benefits hereof include significantly lower initial referral rates, higher true positive rates, more efficient screening at an earlier age and the ability to identify neural hearing losses. This however needs to be seen in the light of the MOU context evaluated in this study with infants mostly younger than two weeks of age. Furthermore, the study showcased that well trained and managed non-professionals can successfully be utilised as screeners. The dedicated screeners improved programme efficiency and administration. This may be valuable in settings where UNHS feasibility has been poor due to overburdened nursing personnel. Alongside the development of contextual UNHS models, timeous access to diagnostic services as well as diagnostic protocol and skill development coherent with international best practice should be fostered.

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5. APPENDICES

APPENDIX A

Cover Letter for Informed Consent:

English, Afrikaans and Xhosa

Date:

Dear Parent/Caregiver,

RE: YOUR CHILD'S HEARING SCREENING RESULTS AS PART OF A RESEARCH PROJECT

The Western Cape Department of Health has agreed to pilot a community-based infant hearing screening project whereby infants attending their postnatal visits at selected Midwife Obstetric Units (MOUs) receive a free hearing screening test. We are researchers at the Department of Communication Pathology at the University of Pretoria and are conducting research at Mitchell's Plain MOU to compare the outcomes of different hearing screening technologies. If children cannot hear, their speech and language does not develop normally and this will impact on their ability to learn, and to attend school. It is therefore important to know as soon as possible whether they can hear or not. If they cannot hear, they can be provided with assistance. The results will help us to develop guidelines for community-based infant hearing screening programmes in order to assist government to make this important service available to all babies born in South Africa.

How will my child's hearing be screened?
The tests that are used to screen babies' hearing systems are called otoacoustic emissions (OAEs) and automated auditory brainstem responses (AABRs). Your child's hearing will be screened with one of these tests depending on the day that you visit the clinic. Both tests are approved by the Health Professions Council of South Africa (HPCSA). With both tests a soft sound is presented into your baby's ear but different responses are measured to give an indication of the functioning of your baby's hearing system. The tests will not hurt or harm your baby.

How long is the test?
The session, including the test and administration, will vary between 5 and 15 minutes depending on your baby's state. It is best if your baby is asleep or in a quiet state while the screening test is being done. We will test both ears.

When will the results be available?
Immediately after the test your child's test results will be shared with you. You may ask the person conducting the test any questions about the results.

What happens if my child does not pass the test?
If your child does not pass the hearing screening test in both ears, you will be informed and you will need to bring your child in to the clinic in two days' time so that his/her hearing may be screened again. If your child does not pass the second hearing screening in both ears, he/she will be referred to Red Cross Children's Hospital for an in-depth hearing evaluation (at no cost to you) to determine whether there is a hearing loss. If a hearing loss exists, appropriate plans will then be made to manage your child's hearing loss and language development.

What happens if my child passes the test?
Even if your child passes the hearing screening test it is important to continue monitoring him/her as hearing loss may sometimes develop as your child grows. Therefore please read the information pamphlet provided very carefully. If you become aware of your child having difficulty hearing in the future, please speak to

your clinic nurses immediately. They will then refer your child to Red Cross Children's Hospital for a hearing test. You must try to do this as soon as you become concerned. It is important to find out whether there is a hearing loss as early as possible, so that assistance can be provided and to help your child's language development.

Confidentiality
A record of your child's hearing screening results will be stored on a computer database. This information will only be made available to the audiologists who may be involved in testing your child's hearing (if applicable) and to the researchers. All information will be treated as confidential and your child's name will not be used since each participant will be assigned an identifying code which will be used for all data processing. Results may be published in a journal article and thesis report but no identifying information will be used at any time.

Voluntary participation
We would like to invite you to participate in this study. You may withdraw at any time after the study has begun and you do not have to provide an explanation for withdrawing from the study. If you withdraw, your child's treatment will not be affected in any way. Your child's hearing will still be screened if you wish, but the results will not be used in this study.

If you agree to have your child's hearing screened as part of this study, please sign the informed consent area on your child's test form. Please note that all data will be stored for 15 years at the University of Pretoria for research and archiving purposes.

For any further information, you can contact me at 021 938 5303.

Sincerely,

Ms. Tersia de Kock
Audiologist
M.Communication Pathology Student

Professor De Wet Swanepoel
Project Supervisor

Professor Bart Vinck
HEAD: Department of Communication Pathology

University of Pretoria | Telephone : 00 27 12 420-2357 | dewet.swanepoel@up.ac.za
Pretoria, 0002 | Facsimile : 00 27 12 420-3517 | www.up.ac.za

Datum:

Geagte Ouer/Versorger,

INSAKE: U KIND SE GEHOORSIFTING RESULTATE AS DEEL VAN 'N NAVORSINGSPROJEK

Die Wes-Kaapse Departement van Gesondheid het ingestem om 'n loodsstudie rakende die uitvoering van gemeenskapsbaseerde baba gehoorsifting te doen by geselekteerde verloskundige eenhede (beter bekend as MOUs – "Midwife Obstetric Units"). Dit beteken dat elke baba wat die eenheid besoek vir 'n opvolg afspraak na die geboorte, ook 'n gratis gehoorsiftingstoets sal ontvang. Ons is navorsers by die Departement Kommunikasiepatologie, Universiteit van Pretoria, en gaan navorsing doen by die Mitchell's Plain MOU. Ons wil graag die uitkomste vergelyk wanneer ons babas se gehoor met verskillende tegnologieë sif. As kinders nie kan hoor nie, kan spraak- en taalontwikkeling nie plaasvind nie en beïnvloed dit hul vermoë om te leer en skool te gaan. Dit is daarom belangrik om spoedig te weet of babas kan hoor of nie. Hulp kan dadelik verskaf word as babas nie kan hoor nie. Die resultate van hierdie studie sal ons help om riglyne saam te stel vir die ontwikkeling van gemeenskapsbaseerde baba gehoorsiftingsprogramme. Dit sal die staat bemagtig om in die toekoms hierdie belangrike diens beskikbaar te maak aan alle babas wat in Suid Afrika gebore word.

Hoe sal my kind se gehoor gesif word?
Die toetse wat gebruik word om kinders se gehoorsisteme mee te sif word oto-akoestiese emissies (OAEs) en ouditiewe breinstamresponse (OBR) genoem. Jou kind se gehoor sal met een van hierdie twee toetse gesif word afhangend van watter dag julle die kliniek besoek. Beide toetse word aanvaar en aanbeveel deur die HPCSA (Health Professions Council of South Africa). Met beide toetse word 'n sagte klank in jou baba se oor gespeel maar die respons word op verskillende maniere gemeet om 'n aanduiding te gee van die funksionering van jou baba se gehoorsisteem. Die toetse is nie seer nie en sal nie enige ongemak veroorsaak nie.

Hoe lank neem die toets?
Die totale sessie, insluitend die toets en administrasie, sal wissel tussen 5 en 15 minute afhangend van jou kind se toestand. Dit sal die beste wees indien jou baba slaap of in 'n baie rustige toestand is tydens die toetsing. Ons sal beide ore toets.

Wanneer sal die resultate beskikbaar wees?
Die resultate word dadelik aan jou meegedeel. Jy kan die persoon wat die toets uitvoer enige vrae vra rakende die resultate.

Wat sal gebeur indien my kind nie die gehoorsifting slaag nie?
Jy sal ingelig word indien jou kind nie die gehoorsifting in albei ore slaag nie. Dit is dan belangrik om jou kind oor 2 dae weer terug te bring na die kliniek toe sodat die gehoorsiftingstoets herhaal kan word. As jou kind die tweede sifting in albei ore nie slaag nie, sal hy/sy na die Rooikruis Kinderhospitaal verwys word vir 'n volledige gehoorevaluasie (gratis) om te bepaal of jou kind 'n gehoorverlies het. Sou daar 'n

gehoorverlies bestaan, sal toepaslike besluite geneem word om jou kind se gehoorverlies en taalontwikkeling aan te spreek.

Wat beteken dit as my kind die gehoorsifting slaag?
Indien jou kind die gehoorsifting slaag is dit steeds belangrik om sy/haar gehoor te monitor aangesien gehoorverlies ook kan ontwikkel soos wat kinders ouer word. Dit is daarom belangrik om die inligtingspamflet goed deur te lees. Sou jy in die toekoms bewus word daarvan dat jou kind gehoorprobleme ervaar moet jy dadelik met jou klinieksuster daaroor praat. Hulle kan dan jou kind verwys na die Rooikruis Kinderhospitaal vir ‘n gehoortoets. Reël so ‘n afspraak sodra jy bekommerd raak. Dit is belangrik om gehoorverlies so gou moontlik te identifiseer sodat hulp verskaf kan word en jou kind se taal kan ontwikkel.

Vertroulikheid/Konfidensialiteit
Rekord van jou kind se gehoorsifting sal bewaar word op ‘n rekenaardatabasis. Hierdie inligting sal slegs beskikbaar gemaak word aan die oudioloë wat moontlik betrokke kan wees by toekomstige gehoortoetse (indien van toepassing) en aan die navorsers. ‘n Unieke kode word aan elke deelnemer toegeken vir dataverwerking en jou baba se naam sal nie bekend gemaak word nie - alle inligting sal as streng vertroulik hanteer word. Die resultate van die studie kan moontlik in ‘n finale verslag en/of joernaalartikel gepubliseer word maar geen identifiseerbare inligting sal daarin bevat word nie.

Vrywillige deelname
Ons wil u uitnooi om deel te neem aan die studie. U kan op enige stadium besluit om te onttrek van die studie en hoef nie ‘n rede te verskaf nie. Sou u onttrek, sal dit nie u kind negatief affekteer nie. U kind se gehoor sal steeds gesif kan word, sou u dit so verkies, maar die resultate sal dan nie vir die studie gebruik word nie.

Indien u instem om u kind se gehoor te sif as deel van hierdie studie, moet u asseblief die gedeelte rakende ‘ingeligte toestemming’ op u kind se toetsvorm onderteken. Neem asb kennis dat alle data vir ‘n periode van 15 jaar by die Universiteit van Pretoria gestoor sal word vir navorsings- en argiefdoeleindes.

Vir enige verdere navrae kan u my gerus skakel by 021 938 5303.

Byvoorbaat dankie,

Me. Tersia de Kock
Oudioloog
M.Kommunikasiepatologie Student

Professor De Wet Swanepoel
Studieleier

Professor Bart Vinck
HOOF: Departement Kommunikasiepatologie

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Date:

Dear Mzali,

SICELA IMVUME YOKWENZA UPHANDO NGOKU TESTA NGOKUVA KOMNTWANA WAKHO

Sisebenzisana norulumente sivumelene ukuba umama amzise umntwana azokujongwa kwakhona. Emva kokuba ezelwe sijonge indlebe zomntwa. Ukujongwa kwendlebe akubhatali. Singamalungu eDepartment of Communication Pathology eUniversity of Pretoria. Senza uphando lokuva abantwana ukuba bayeva kakuhle. Ukuba abeva sinika uncedo.

Yintoni iscreening test
Umntwana wakho wofumana uvavanyo kwaba matshini OAE (otoacoustic emissions) okanye AABR (automated auditory brainstem respons). Abamatshini balungile bobabini (Health Professions Council of South Africa). Abamathsini benza izandi ngaphakathi endleni yomntwana. Zitesite ukuva komntwana ngaphakathi endlebeni.

Athatha ixesha elingakanani latest
Le test ayibuhlungwanga. Ayakhawuleza ngaphantsi komzuzu. Uba umntwalulele.

Zibuya nini iziphumo
Zibuya kwangoko, zixelelwa wean mzali.

Kwenzeka ntoni ukuba umntwana uphumelele itest
Ukuba umntwana uphumelela kuthetha ukuthi uyeva. Ngamanye amaxesha umntwana uye engeva xa ekhula. So funda eliphepha linencukacha ukuba uyamazi umntwana wakho akeva kukhuhle okanye umntwana akakathethi ena 1 or 2 eminya ka okanye indlebe yakhe iyavuza nceda thetha nonesi kwiclinic ekufutshane nawe. Bazakumthumela eRed Cross.

Kwenzeka ntoni umntwana xa engaphumelelangaitest
Xa umntwana engaphumelelanga uzakwaziswa. Kufuneka use umntwana eclinic intsuku ezimbini ezizayo ukwenzela aphinde agonywe undlebe kwakhona. Ukuba neyesibini akaphumelelanga uzakusiwa eRed Cross.

Yintoni ezakufuneka kuwe
Kuzakufuneka ipermission yakho ukuba kwenziwe uphando ngokungeva oko. Ukuzubakho mali ibhatalwayo. Okokuba ngaba awusafuni kuba nathi kwakhona unga ndixelela.

Amfihlo
Azakugcinwa emfihlakalweni kwi computer zonke iziphumo.

Anzebenziswano
Siyakumemo ukuba uzekulenzebenziswano.

Ukuba uyavuma ukuba umntwana eze kolugonyo bhala kwiphepha elo linikiweyo.

Ukuba ufuna inkcazelo ethe vetshe nantsi inumber 021 938 5303.

Nkosi Kakulu,

Ms. Tersia de Kock
Audiologist
M.Communication Pathology Student

Professor De Wet Swanepoel
Project Supervisor

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APPENDIX B

Informed Consent on Data Collection/Test Form

INFANT HEARING SCREENING PROGRAMME

INFORMED CONSENT FROM PARENT/CAREGIVER FOR RESEARCH: I hereby agree that the details of the study have been explained to me and I give consent for my child's (child in my care) hearing screening results to be used for research. I understand that our personal details will not be used or published and that I can withdraw from the study at any stage.

Signature: **Date:**

PARENT/CAREGIVER

PARENT/CAREGIVER'S DETAILS

Folder nr:_____
Name:_____
Surname:_____
D.O.B: d d / m m / y y y y
Address:_____
_____
Tel nr:_____
Alternative tel nr:_____

INFANT'S DETAILS

Baby's folder nr:_____
Baby's name:_____
Surname:_____
D.O.B: d d / m m / y y y y
Gender: Male / Female
Place of birth: MOU / Mowbray Maternity Home / Groote Schuur / Karel Bremer Other / Transferred to:_____

HEARING PREVIOUSLY SCREENED? ☐ **YES** ☐ **NO**

GROOTE SCHUUR HOSPITAL	TYGERBERG HOSPITAL	OTHER _____	DATE _____	**RESULT** L _____ R _____

TODAYS DATE: d d / m m / y y y y	**SCREENER'S NAME:**	
OAE / AABR	**POST-NATAL VISIT NR:** 1 / 2 / 3 / 4 / 5+	**1ST / 2ND TEST**
INFANT'S AGE:	days / weeks	

RISK FACTORS RELATED TO HEARING LOSS

BIRTH WEIGHT: grams	**GESTATIONAL AGE:** weeks	**APGAR:** /10 /10
Birth: NVD (normal) / C-section		

1. Is there a history of hearing loss in **children** in the family ?	YES	NO
2. Any of the following illnesses or problems **during pregnancy**? (Please X all applicable and specify)		
- Cytomegalovirus / Toxoplasmosis / German measles (Rubella)		
- Herpes Simplex / Syphilis / Malaria / Other childhood diseases		
- High blood pressure / Diabetes / TB		
3. Any ototoxic medication taken **during pregnancy** ?	YES	NO
- Please specify		
4. Any problems **during or after birth**? (Please X all applicable options and specify)		
- NICU >5 days / Ototoxic medication		
- Severe jaundice [NNJ] (hyperbilirubinaemia) requiring exchange transfusion (had to give baby blood?)		
- Stigmata or syndrome / Craniofacial anomalies		
- Certain viral infections / Meningitis (bacterial?)		
Additional comments:		

SCREENING RESULTS

RIGHT EAR		LEFT EAR	
☐ **PASS**	☐ **REFER**	☐ **PASS**	☐ **REFER**
☐ **NOT DONE**	☐ **TECHNICAL FAULT**	☐ **NOT DONE**	☐ **TECHNICAL FAULT**

FOLLOW-UP DATE (After 1st screening)

d d / m m / y y y y

REFERRAL (After 2nd screening)

TYGERBERG HOSPITAL	RED CROSS CHILDREN'S HOSPITAL	APPOINTMENT DATE: d d / m m / y y y

APPENDIX C

Ethical Clearance:

Research Ethics Committee of the Faculty of Humanities of the University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Office of the Deputy Dean

2012-05-02

Dear Prof Swanepoel

Project:	Infant hearing screening at a community-based obstetric unit: a comparative study of screening technology outcomes
Researcher:	de Kock T
Supervisor:	Prof de Wet Swanepoel
Department:	Communication Pathology
Reference Number:	22095102

Thank you for the application that was submitted for review.

The application was **approved (with comments)** by the **Postgraduate Committee** on 17 April 2012, and approved by the **Research Ethics Committee** on 26 April 2012. 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 proposal and ethical clearance.

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

We wish you success with the project.

Sincerely

Prof John Sharp
Chair: Postgraduate Committee &
Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: john.sharp@up.ac.za

APPENDIX D

Research Approval:

Provincial Health Research Committee of the Western Cape Government
Department of Health

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
healthres@pgwc.gov.za
tel: +27 21 483 9907; fax: +27 21 483 9895
1st Floor, Norton Rose House, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: RP 82/2012
ENQUIRIES: Dr Sikhumbuzo Mabunda

51 Sterling Crescent
Parklands
7441

For attention: Tersia de Kock and Prof De Wet Swanepoel

Re: Infant hearing screening at a community-based obstetric unit: A comparative study of screening technology and outcomes

Thank you for submitting your proposal to undertake the above mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries.

Mitchells Plain MOU	**Ms Z Xapile**	**(021) 391 5820**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (healthres@pgwc.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely

DR NT Naledi pp
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 6/11/2012

CC **DR G PEREZ** **ACTING DIRECTOR: KLIPFONTEIN/MITCHELLS PLAIN**