

**Efficacy of a community-based infant hearing screening program in
the Western Cape**

by

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TABLE OF CONTENTS

FIGURES	4
TABLES.....	4
LIST OF ABBREVIATIONS	5
ABSTRACT	6
1. INTRODUCTION	8
1.1. Rationale and Motivation.....	8
1.2. Problem Statement	10
1.3. Proposed Solutions for Developing Countries.....	13
2. METHODOLOGY	17
2.1. Research objectives	17
2.2. Research design	18
2.3. Ethical considerations	18
2.4. Study population.....	22
2.4.1. Research population	22
2.4.2. Research setting.....	24
2.5. Material and apparatus	24
2.5.1. Data collection material	25
2.5.2. Data collection apparatus	25
2.6. Data collection and analysis	26
2.6.1. Hearing screening program protocol.....	26
2.6.2. Procedures for data collection	28
2.6.3. Procedure for data processing and analysis	29
3. EFFICACY OF A COMMUNITY-BASED INFANT HEARING SCREENING PROGRAM UTILIZING EXISTING CLINIC PERSONNEL IN WESTERN CAPE, SOUTH AFRICA	31
3.1. Abstract	31
3.2. Introduction	32
3.3. Methods	35
3.3.1. Research setting.....	36
3.3.2. Study population	37
3.3.3. Protocol and methods.....	37
3.3.4. Data management and statistical analysis.....	39

3.4. Results	39
3.4.1. Coverage	40
3.4.2. Referral rate	41
3.4.3. Follow-up rate	42
3.4.4. Mean age of screening and diagnosis	43
3.4.5. Diagnostic outcome of subjects	43
3.5. Discussion	45
3.5.1. Coverage	46
3.5.2. Referral rate	47
3.5.3. Follow-up rate	48
3.5.4. Mean age of screening and diagnosis	48
3.5.5. Diagnostic outcome of subjects	49
3.6. Overview and recommendations	50
3.7. Conclusion	51
4. DISCUSSION AND CONCLUSION	52
4.1. Discussion of results.....	52
4.1.1. Screening coverage	52
4.1.2. Referral rate	53
4.1.3. Follow-up rate	54
4.1.4. Mean age of screening and diagnosis	55
4.1.5. Diagnostic outcomes	55
4.2. Clinical implications and recommendations	56
4.3. Critical evaluation	59
4.4. Future research	61
4.5. Conclusion.....	61
5. REFERENCES	63
6. APPENDICES	75
APPENDIX A	76
Letter to Executive Health Director, City of Cape Town	76
APPENDIX B	79
Letter of Consent from Executive Health Director, City of Cape Town.....	79
APPENDIX C	81
Cover Letter for Informed Consent	81
APPENDIX D	90

Clinic Form for Data Collection and Informed Consent	90
APPENDIX E	93
Letter to Medical Superintendents at Tygerberg and Red Cross Children’s Hospital	93
APPENDIX F	96
Ethical Clearance from the Medical Superintendents at Tygerberg and Red Cross Children’s Hospital	96
APPENDIX G	99
Letter of Consent - Faculty of Humanities, University of Pretoria.....	99
APPENDIX H	101
Tertiary Hospital Level (Diagnostic) Data Collection Form.....	101

FIGURES

Figure 3.1: Overall outcome of phases in the screening process at primary health care clinics.....	40
Figure 3.2: Screening coverage rates at the primary health care clinics.....	41
Figure 3.3: Screening referral rates at the primary health care clinics.....	42
Figure 3.4: Follow-up return rates at the primary health care clinics and diagnostic referral hospitals.....	43

TABLES

Table 2.1: Department of Health, Expanded Program on Immunisation for 2009.....	23
Table 2.2: Apparatus used for data collection.....	26
Table 3.1: Diagnostic outcome of subjects in the “abnormal” category.....	44

LIST OF ABBREVIATIONS

IHS - infant hearing screening

UNHS - universal newborn hearing screening

EHDI - Early Hearing Detection and Intervention

PHC- primary health care

MCH- Maternal and Child Healthcare

ENT- Ear, Nose and Throat

DPOAE- distortion product otoacoustic emissions

HPCSA- Health Professions Council of South Africa

MEE- middle ear effusion

NYD- not yet determined

ABSTRACT

Apart from isolated programs in private and public health care sectors, South Africa has no existing systematic public infant hearing screening program at community level. As a result, early identification of hearing loss is certainly not being attained for the majority of infants in South Africa with far-reaching effects for individuals, families and society at large. Screening programs at primary health care immunization clinics have been proposed as an alternative to hospital-based programs in South Africa. The objective of this study was to evaluate the first systematic community-based infant hearing screening program in a developing South African community in the Western Cape.

A combined descriptive and exploratory research methodology was followed incorporating aspects of a program evaluation design. The study was of a quantitative nature and the required data were collected by means of a questionnaire and OAE testing conducted by clinic nurses on subjects. A community-based universal infant hearing screening program initiated at eight primary health care clinics in the Cape Metropolitan area was evaluated over a 19-month research period. During this time 6227 infants who were candidates for screening attended their 6, 10 or 14-week immunization visit at the relevant clinic. Clinic nurses were trained as screening personnel. A two-stage distortion product otoacoustic emissions screening protocol was utilized. The target disorder for this study was bilateral permanent congenital and early onset hearing loss and infants referring the first screen were scheduled for a 4-week follow-up visit at the clinic. Diagnostic audiological and medical evaluations were scheduled at referral hospitals when indicated. The study evaluated the efficacy of the program based on coverage, referral and follow-up rates and diagnostic outcomes according to guidelines specified by the Health Professions Council of South Africa 2007 Position Statement.

Overall coverage rate across the eight clinics was 32.4% with 2018 infants (aged 0-14 weeks) screened. The mean age of the sample at first stage screen was 3.9 weeks of age and 13.5 weeks of age for first hospital visit. Overall first stage screen referral rate was 9.5% with 62 subjects (3%) referred for diagnostic services at hospital level after a follow-up screen. The average follow-up rate for rescreens at

clinic level was 85.1% and for initial diagnostic assessments at hospital level it was 91.8%. Although minimal hearing loss was not the primary focus of the screening program the outcomes did include those subjects with fluctuating conductive hearing loss and permanent unilateral hearing loss. Prevalence rates were 4.5/1000 with significant hearing loss, including sensorineural (1.5/1000) and conductive (3/1000) losses, and 12.9/1000 for subjects with middle ear effusion.

The community-based infant hearing screening program was valuable in attaining high follow-up return rates but reaching sufficient coverage may require dedicated screening personnel as opposed to existing nursing personnel. Furthermore, consideration of an alternative community-based platform such as midwife obstetric units may improve coverage and referral rates and prevalence of permanent congenital and early onset hearing loss.

Keywords: developing countries, developed countries, universal newborn hearing screening, infant hearing loss, early hearing detection and intervention, immunization clinics, otoacoustic emissions, middle ear effusion, pilot project, coverage, referral rate, follow-up rate.

1. INTRODUCTION

The World Health Organization's definition of health is not just the absence of disease but the complete physical, mental, and social wellbeing of an individual. Therefore health beyond survival for those infants with hearing loss can only truly be accessed through early identification and intervention (Olusanya, 2005). With the advancement of technology the field of paediatric audiology has rapidly developed to deliver accountable services to the youngest and most vulnerable populations (Swanepoel, Hugo & Louw, 2006). Evidence from around the globe has shown that infant hearing screening (IHS) is 'preventative' in nature and described as a second preventative strategy in the sense that it can preclude the adverse consequences of late diagnosis and the burden of permanent hearing loss (Korver et al., 2010; Olusanya, Swanepoel, Chapchap et al., 2007; Yoshinaga-Itano, 2004). Contextually-appropriate research is essential to create awareness about the prevalence of infant hearing loss and the need for early intervention. In South Africa a great dearth of information exists on early hearing detection and intervention (EHDI), especially at community level. This poses a serious challenge in advocating the need for and implementation of IHS programs in collaboration with government (Swanepoel et al., 2006; Swanepoel, Delpont & Swart, 2004).

1.1. Rationale and Motivation

Universal newborn hearing screening (UNHS) programs are considered the gold standard in facilitating early detection and intervention for hearing impairment and has even been described as "a silent (global) revolution" (Morton & Nance, 2006). Research has shown it to be practicable, effective, cost-efficient, safe, and facilitates optimal outcomes for infants with hearing impairment (Korver et al., 2010; Olusanya 2011a; Schroeder et al., 2006). Universal screening of all infants is advocated since screening only high-risk children will only identify approximately 50% of infants with congenital hearing loss (Chu et al., 2003; Yoshinaga-Itano, 2004). As highlighted by Swanepoel et al. (2004) these UNHS programs are warranted for the following three reasons:

a) Infant hearing loss is a very common congenital sensory birth defect. A report by the World Health Organization based on studies from various countries noted that the prevalence of congenital and early onset deafness or severe-profound hearing

impairment ranged from 0.5 to 5 in every 1000 neonates and infants (WHO, 2010). The prevalence rates appear higher for developing countries (Olusanya & Newton, 2007). Pilot programs in Nigeria suggest a prevalence of 28 per 1000 live births for all degrees of sensorineural hearing impairment, which is perhaps the highest rate reported worldwide to date (Olusanya, 2011a). Annually approximately 800 000 babies are born with or acquire early onset permanent bilateral hearing loss worldwide (Olusanya & Newton, 2007; Olusanya, Wirz & Luxon, 2008). More than 90% of these are born in the developing countries of the world, of which 25% reside in sub-Saharan Africa (Olusanya, Wirz, et al., 2008). The developed countries of the world annually account for up to 53 150 permanent bilateral hearing losses which amounts to less than one third of those born in sub-Saharan Africa (Olusanya & Newton, 2007). Contextual risk factors such as HIV and malaria are common to South Africa and increase the risk for infant hearing loss. Infants born to HIV positive mothers may have a risk for a congenital hearing loss or for developing a hearing impairment shortly after birth due to the viral infection causing damage to the inner ear (Chakraborty, 2004; Yoshikawa, Ikeda, Kudo & Kobayashi, 2004). They are also at an increased risk for developing middle-ear infections due to damage to upper respiratory tract, which leads to a conductive hearing loss, and may even ultimately result in a sensorineural hearing loss (Bam, Kritzinger & Louw, 2003; Newton, 2006; Singh, Georgalas, Patel & Papesch, 2003; Yoshikawa et al., 2004).

b) Undetected hearing impairment leads to permanent language, speech and cognitive delays, with far-reaching social and economic consequences (Olusanya, Swanepoel, Chapchap et al., 2007; Schroeder et al., 2006; Yoshinaga-Itano, 2004). Reports in the United States have indicated that a deaf person's average income after high school could be 30-50% lower than that of a hearing person (Mohr et al., 2000). Furthermore, the combined expense of specialized education and loss of productivity results in an average lifetime cost for the government of more than US \$1 million (Mohr et al., 2000). Contextualized, well-monitored EHDI programs linked to existing health, social and educational systems in each country have the potential to address the inequalities caused by the developmental constraints associated with infant hearing loss (Kennedy, McCann, Campbell, Kimm & Thornton, 2005; Korver et al., 2010; WHO, 2010). Long-term economic benefits of universal screening programs for hearing loss indicate reduced costs for specialized education, social

welfare and improved lifetime productivity for individuals with hearing loss (Korver et al., 2010; Schroeder et al., 2006; Yoshinaga-Itano & Gravel, 2001).

c) No other screening program has demonstrated the same efficacy as UNHS programs to reduce the age of hearing loss identification (Kennedy et al., 2005; Yoshinaga-Itano, 2004). Research has shown that UNHS yields dramatic benefits since infants whose hearing impairment is identified before 6 months of age have significantly better language abilities than those whose hearing impairment is identified later. Furthermore, infants with hearing loss who receive early intervention within the first six months of life are likely to have linguistic, speech, and cognitive development comparable to normal hearing peers (Kennedy et al., 2005; Korver et al., 2010; Yoshinaga-Itano, 2004). A persistent language delay of 2-4 years is evident for infants identified after 6 months of age (Yoshinaga-Itano, Sedey, Coulter & Mehl, 1998).

1.2. Problem Statement

This is a privileged reality for many developed countries such as the United States and UK where UNHS programs ensure that 95% of all newborns are screened, in line with the recommendations of a Position Statement by the Joint Committee on Infant Hearing (JCIH, 2007; Kennedy & McCann, 2004; Morton & Nance, 2006). Screening technologies encompass accurate physiological techniques, namely otoacoustic emissions and/or automated auditory brainstem responses. The screening platform found to be most effective is a hospital-based program where screening is performed on the infant prior to discharge. A comprehensive document on current global newborn hearing screening issued by the World Health Organization indicates that national programs have been successfully implemented in many developed countries in line with current best practice recommendations for EHDI (JCIH, 2007; WHO, 2010).

Western models of IHS for newborns may not be appropriate for the majority of developing countries. A number of factors unique to developing countries have made the effective implementation of EHDI programs challenging (Griz, Mercedes, Menezes & Lima, 2009; Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006; WHO, 2010). The World Bank groups countries according to national income per capita, where countries in the low- and middle-income groups are classified by as developing

countries (WHO, 2008; World Bank, 2006). South Africa, a middle-income nation, is classified as a developing country although it has pockets of both developed and developing aspects (Tucci, Merson & Wilson, 2009). South Africa, which occupies the southern tip of the African continent, has a heterogeneous population of approximately 50, 586 757 million people characterised by a diverse collection of people-groups and cultures (Mcperson & Swart, 1997; Statistics South Africa, 2011, Swanepoel et al., 2006). Despite the fact that South Africa has a comparatively well-developed infrastructure there are still many challenges that remain consistent obstacles towards gaining institutional support, research funding and political advocacy for hearing screening and intervention (Mcperson & Swart, 1997; Swanepoel et al., 2004). Stearn (2007) highlights these challenges in the implementation of IHS programs in developing countries.

Firstly, limited financial resources are a key challenge. Governments are so burdened by communicable and fatal diseases, such as HIV/Aids, tuberculosis and malaria, that they are unable to wholly finance IHS programs often seeking external support (Olusanya, Swanepoel, Chapchap et al., 2007; Tucci et al., 2009). This is true for South Africa where in 2009 there was an estimated prevalence of HIV of 13.6% for females aged 15-24 and 17.8% for the general population aged 15-49 (World Bank, 2009a, 2009b). In 2010, 21.8% of woman aged 15-24 years who attended public antenatal clinics tested positive for HIV (Department of Health, 2010). As Swanepoel et al. (2006) stress, the HIV burden has reached pandemic proportions and consequently health priorities are aimed at saving lives rather than at improving quality of life for individuals with hearing loss. Furthermore, the fatality figure of chronic and non-communicable diseases is twice the number of deaths from all infectious diseases, maternal and perinatal conditions and nutritional deficiencies combined further compounding the impact on the healthcare systems of developing economies (Olusanya, Swanepoel, Chapchap et al., 2007). Another concern is inequality in the global spending for health care as striking variations in global financing are evident (Gottret & Schieber, 2006). In South Africa the majority of the population, comprising approximately 86%, are currently served by a public health sector, which only utilizes 43% of the countries' total health care expenditure. This is in stark contrast to the wealthy minority, comprising 14% of the population, which makes use of private health care services that constitute 57% of the total health expenditure (Department of Health, 2007; Schaay & Sanders, 2008).

Secondly, a significant challenge and further resource constraint in implementing widespread IHS programs in a developing country like South Africa is the general lack of manpower due to a shortage of trained paediatric audiologists (Olusanya, Wirz, et al., 2008; Swanepoel, 2006). More audiologists are needed in developing parts of the world but until enough practitioners are trained, other health care workers may be engaged in some aspects of hearing health care (Tucci et al., 2009). Therefore the use of non-specialists who have received focused training as screeners at primary healthcare (PHC) level is strongly advocated as this has been found to be cost-effective, as evident in Nigeria (Olusanya, Swanepoel, Chapchap et al., 2007). This sentiment is shared by UNICEF (2008) who advocates the use of telemedicine and training local personnel to help address the crisis of the lack of health care workers in Africa.

Thirdly, the platform for IHS used in developed countries namely hospitals prior to discharge from the well-baby nursery is not always appropriate in developing countries. A unique challenge exists in developing countries like South Africa and Nigeria whereby a significant number of births do not take place in hospitals but either at home or in clinics (Olusanya, Ebuehi & Somefun, 2009; Olusanya & Okolo, 2006; WHO, 2010). For those infants born in public hospitals in South Africa, discharge from the well-baby nursery usually occurs on the same day (Swanepoel, 2009). This would result in a high number of false-positive results for otoacoustic emission screening (Levi et al., 1997) therefore advocating the need for clinic-based screening programs to complement hospital-based screening programs in the public health sector in South Africa.

Fourthly, the perception of disability and cultural beliefs of communities towards IHS is a further barrier. Tucci et al. (2009) found that the treatment of hearing loss can be greatly influenced by the attitudes of the people residing in these countries. A fatalistic outlook on disabilities, as evident in many African families, coupled with customs and superstitious beliefs may result in a passive attitude towards early detection and intervention of hearing loss (Olusanya, Luxon & Wirz, 2004; Stearn, 2007; Swanepoel & Almec, 2008).

Lastly, limited prevalence data and contextual research for childhood hearing loss in developing countries makes accurate planning of IHS difficult (HPCSA, 2007; WHO, 2010). Olusanya and Somefun, et al. (2008) found that reported prevalence rates varied greatly across existing studies. Data reporting on the mean age of hearing loss detection and intervention are virtually non-existent due to the absence of systematic or routine screening programs in developing countries (Swanepoel, Hugo & Louw, 2005). This is especially true for a developing country like South Africa and Nigeria where no uniform case definition of IHS and no systematic coordinated UNHS program exists (Olusanya, Somefun, et al., 2008). Although IHS pilot studies have been conducted at various community-based sites in the public health sector throughout South Africa only one published pilot study has been reported resulting in a dearth of contextual research of this nature (Swanepoel et al., 2004; Swanepoel et al., 2006).

1.3. Proposed Solutions for Developing Countries

No other type of screening program has demonstrated the same efficacy as UNHS program to significantly reduce the age of hearing loss identification (Kennedy et al., 2005; Yoshinaga-Itano, 2004). However, in resource-poor settings where UNHS is not immediately feasible targeted newborn hearing screening should be considered (Olusanya, 2011b). UNHS studies are warranted in individual countries to establish context-specific risk factors, their performance for screening purposes as well as operational issues related to effective implementation before embarking on targeted newborn hearing screening where UNHS is not immediately practicable at any level of healthcare delivery (Olusanya, 2011b, WHO, 2010).

For those developing countries where UNHS is possible, one major challenge is the lack of contact between the majority of mothers and their babies and the healthcare system – with about half of all global births occurring at home without skilled care (WHO, 2010). As a result complementary community-based programs, especially those linked to maternal and child clinics with routine immunization programs in the first three months of life are strongly advocated (Olusanya, 2009a; Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006). The constituent interventions need not be related but are targeted at the same population at the point of delivery (Olusanya, 2009a). The integrated service delivery model not only allows for higher follow-up

return rates to the community clinic but the optimization of services in a resource poor setting (Olusanya, 2009a; WHO, 2010). Initial reports in Nigeria and South Africa support immunization programs as an effective platform for IHS. Improved coverage and first-stage referral rates were reported, and screening cost per baby and cost per child detected with permanent congenital and early onset hearing loss were also reported to be considerably lower (Olusanya, Ebuehi, et al., 2009; Olusanya, Emokpae, Renner & Wirz, 2009; Olusanya & Okolo, 2006; Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006). The reported prevalence rates from Nigeria suggest that the community-based study among infants attending routine clinics for BCG immunization would have captured a significant number of infants with postnatal hearing loss mostly missed by hospital-based UNHS programs (Olusanya, Wirz, et al., 2008). A commonly reported challenge for community-based screening programs is a loss of patients to follow-up (Griz et al., 2009; Olusanya, Swanepoel, Chapchap et al., 2007; Swanepoel et al., 2006). The challenge of high default rates is not however specific to community-based IHS programs and not uncommon in the early stages of hospital-based newborn hearing screening programs in developed countries (Korres, Balatouras, Nikolopoulos, Korres & Ferekidis, 2006; Mehl & Thomson, 2002).

This proposed community-based IHS model is specifically in line with the PHC philosophy in South Africa: this approach is the most appropriate and cost effective means of improving the population's health and is seen as the driving force in promoting equity in health care in South Africa (Department of Health, 2000, 2009a; Swanepoel et al., 2005). Since 95.5% of South African children under the age of 12 months are reported to receive vaccinations, immunisation clinics provide a means of reaching the entire population with IHS (DHIS, 2010; Swanepoel et al., 2006). Integrated approaches to child health services running simultaneously are more sustainable and cost-effective in the long run and therefore address resource constraint issues (Olusanya & Okolo, 2006).

Although there is growing awareness about the benefits of EHDI very little contextual evidence-based research on IHS has been reported to date (Swanepoel et al., 2006). The initial detection of hearing loss in South Africa is primarily passive as a result of parental concern about observed speech and language delays, unusual

behaviour or the complications of otitis media (Swanepoel, Delpont & Swart, 2007). Preliminary reports in South Africa propose that approximately 17 infants are born with or will develop hearing loss in South Africa everyday whilst 90% of these are born with no prospect of early identification (Meyer & Swanepoel, 2011; Swanepoel, Störbeck & Friedland, 2009; Theunissen & Swanepoel, 2008). An estimated 7.5% of all public hospitals in South Africa, which serve approximately 85% of the population offer some form of screening where less than 1% offer UNHS (Theunissen & Swanepoel, 2008). At present the only 'formal' screening for hearing loss in children proposed by the South African Department of Health is the use of two hearing tests, namely the Voice test and the Swart Questionnaire for babies younger than 12 months (Copley & Friderichs, 2010). In the private health sector, a report found that 39% of private health care obstetrics units in South Africa offer some form of screening and only 14% offer UNHS (Meyer & Swanepoel, 2011). Therefore, apart from isolated programs in private and public health care sectors, South Africa has no existing systematic public infant hearing-screening program at community level. This poses dire consequences considering 86% of the South African population rely on the public health system for health care and 61% of children in South Africa live in poverty (Department of Health, 2007, 2009a; Schaay & Sanders, 2008).

South Africa has taken the first step towards IHS in the form of a revised and contextually appropriate Position Statement on EHDI programs in South Africa conceptualized by the Professional Board for Speech, Language and Hearing Professions of the Health Professions Council of South Africa (HPCSA) for the year 2007. Furthermore, the South African governmental policy guidelines favour the philosophy of early detection and intervention of disabilities and autonomy of the disabled to reach their potential through documents such as the White Paper for the Transformation of the Health System in South Africa (Department of Health, 2000, 2007, 2009a) – it is only the implementation of such policy that is left wanting.

The investigation of immunization clinics as a hearing screening context is a priority if the benchmarks and quality indicators stated by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007) are to be pursued. A hearing screening program at immunization clinics needs to be assessed and well documented to provide empirical data towards the dearth of research on IHS in South Africa and also in

regard to immunization clinics as a screening platform (Swanepoel et al., 2006). This evidence-based approach is essential to further advocate the benefits and dire need for early hearing detection services with possible roll-out to more clinics in South Africa. This study therefore aims to describe the efficacy of the first systematic community-based IHS program in a developing South African community through the formation of public-private partnerships.

2. METHODOLOGY

2.1. Research objectives

The research methodology describes the process that was followed in order to determine the efficacy of a community-based infant hearing screening (IHS) program utilizing existing clinic personnel in the Western Cape.

Aims of this study:

The aims of the research project were as follows:

Main aim:

To describe the efficacy of a community-based infant hearing screening program at 8 primary health care (PHC) clinics in the Western Cape according to the benchmarks and quality indicators as stated by the HPCSA Year 2007 Position Statement on Early Hearing Detection and Intervention (EHDI) (HPCSA, 2007).

Sub aims:

1. To describe the coverage of a community-based infant hearing screening program at 8 PHC clinics in the Western Cape
2. To describe OAE screening referral rates:
 - a) referral rate of infants seen for first visit at clinic level (first stage screen)
 - b) referral rate of infants seen for second, third or fourth visit (follow-up) at clinic level (second stage screen)
3. To describe OAE screening follow-up rates:
 - a) Follow-up rate of infants seen for second, third or fourth visit at clinic level (second stage screen)
 - b) Follow-up rate of infants seen for initial diagnostic visit at tertiary hospital level
4. To describe the diagnostic outcome of infants seen at tertiary hospital level from community level in the Western Cape
5. To compare the efficacy of the different screening sites in terms of coverage, referral rates and follow-up rates

Results of sub aims 1 to 5 were compiled and described in the article titled *Efficacy of a community-based infant hearing screening program utilizing existing clinic personnel in Western Cape, South Africa* (chapter 3), which was published in the International Journal of Pediatric Otorhinolaryngology (April 2012 edition).

2.2. Research design

The research approach selected for this study was an exploratory descriptive design incorporating aspects of a program evaluation design (Babbie, 2004; Bryman & Bell, 2007; de Vos, 2002). The research design was exploratory and descriptive in nature as it investigated phenomena for which there is a dearth of contextually relevant research – coverage, referral rates, follow-up rates of infants enrolled in a screening program and the prevalence of permanent congenital and early onset hearing loss for infants at community level in the Western Cape. The research design was evaluative in that it addressed the efficacy of the hearing screening program and compared the efficacy at different screening sites according to benchmarks and quality indicators as stated by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007)

This study was of a quantitative nature since data gathered were of a numerical or categorical nature used to answer questions about the measured/dependant variables with the purpose of explaining, predicting and controlling phenomena (Leedy & Ormrod, 2005). The required data were collected by means of a questionnaire and OAE testing conducted by clinic nurses on infants at the 8 designated PHC clinics.

Furthermore in terms of the reference period the study was prospective and longitudinal including a description of the screening program findings for the first 2018 infants enrolled at the participating PHC clinics (Kumar, 1996).

2.3. Ethical considerations

In order to protect the rights and wellbeing of the participants, ethical considerations are imperative and duly need to be addressed (Leedy & Ormrod, 2005). The researcher endeavoured to uphold high ethical standards in all aspects of this research project. These are discussed below.

Respect of privacy for research participants

Leedy and Ormrod (2005) emphasize the critical and ethical importance of respecting the privacy of the participant. This confidentiality was ensured by omitting the participants' name on any data processing documentation during the research project (Strydom, 1998). A coding system was utilized in that each participant was allocated a specific numbering for data processing purposes. This was verbally explained by screening personnel in the relevant language to the participants' parents/caregivers prior to testing. Furthermore, this was clearly stated in the informed consent letter.

Informed consent

Informed consent must be acquired prior to conducting any procedure as a basic legal requisite for disclosing medical information. Failure to obtain informed consent is unethical (Olusanya et al., 2004). Leedy and Ormrod (2005) and Strydom (1998) outline the essential components in obtaining informed consent: a) providing adequate information regarding the research to the participants; b) voluntarily participation and c) participants know they could withdraw at any time during the research.

Consequently, this study obtained written informed consent from each participant's parent/caregiver, which was located on the data collection form. This form was signed by the parents/caregivers after they had been verbally informed in their mother tongue about the goal and the procedures as well as the possible consequences and benefits of the study. It is the responsibility of the researcher to convey the information in such a way that it is clear to the participant (Iacono & Murray, 2003). Therefore a letter detailing the relevant information was discussed with all participants' parents/caregivers. Due to the fact that parents/caregivers are not only English speakers these letters were available in English, Afrikaans and Xhosa. The letter ensured confidentiality (Kidder & Judd, 1986) and voluntary participation, and that the participants had the right to withdraw at any time during the research without negative consequences. Furthermore written informed consent was obtained from the Executive Health Director at the City of Cape Town and the

Medical Superintendent from Tygerberg Hospital and Red Cross Children's Hospital for those participants who required diagnostic services at tertiary hospital level.

The following procedures were pursued in order to obtain informed consent for research:

- a) A meeting was held with the Executive Director of City Health, Cape Town, Dr. Ivan Bromfield as well as his 8 City Health Sub-District Managers in order to discuss the research project
- b) A letter of permission was submitted to Dr. Bromfield regarding the details of the research project (included as appendix A)
- c) Consent for research was granted by the City of Cape Town Health Department to conduct the project (included as appendix B)
- d) A meeting was held with nurses from the identified clinics, who had already received training in IHS by the researcher and colleague Lucretia Petersen from the University of Cape Town, regarding the research project. These nurses identified possible subjects at their clinic on an ongoing basis. Neonates/infants who met the criteria were immediately enrolled in the study.
- e) The nurses at the identified clinic verbally explained the informed consent letters in the participant's mother language to the parents/caregivers whose infants were candidates. The informed consent letter outlined the goal and the procedures as well as the possible benefits of the study and was available in English, Afrikaans and Xhosa (included as appendix C)
- f) Signed consent letters were returned to the researcher once the distortion product otoacoustic emissions (DPOAE) test had been performed at the clinic (included as appendix D)
- g) For those subjects who required diagnostic services at tertiary hospital level, ethical clearance was requested (included as appendix E) and obtained (included as appendix F) from the Medical Superintendent, Dr. Carter from Tygerberg Hospital and Dr. Blake from Red Cross Children's Hospital regarding confidential information in the participant's hospital files.
- h) The University of Pretoria's Faculty of Humanities Postgraduate Committee approved the study (included as appendix G).

Beneficence and non-maleficance

The researcher has an ethical obligation to protect subjects against any form of physical and/or emotional harm (Leedy & Ormrod, 2001). In order to minimize potential emotional harm thorough information was provided to the subjects' parents/caregivers beforehand regarding the procedure as well as the potential impact of the investigation providing them with a choice and opportunity to partake or withdraw from the study (Strydom, 2002).

The collection procedures for the study were non-invasive. When the OAE test was conducted, acoustic stimuli was at a level deemed appropriate and safe according to specifications from the manufacturer, therefore not causing any discomfort or physical harm to the participant. Otoscopy, tympanometry, automated auditory brainstem response testing, diagnostic auditory brainstem response testing as well as pure tone audiometry was conducted on those subjects who required diagnostic services at tertiary hospital level. The relevant professionals informed the subjects' parents/caregivers if they detected any abnormalities in order for appropriate management to be initiated. Sedation was used on a number of subjects during this research according to necessary Ear, Nose and Throat (ENT) and audiological management. Due to the fact that this only occurred at tertiary hospital level the necessary professionals addressed this ethical point with the participant's parents/caregivers.

Upon diagnosis of a hearing loss by audiologists at tertiary hospital level, thorough counselling was done with parents/caregivers of the hearing impaired infant. Furthermore, this infant was referred into an appropriate intervention program, namely the Carel du Toit Centre Parent Guidance program and the HI HOPES family-centered home-based program.

Reliability and Validity of research

Bryman and Bell (2007) state that validity is concerned with the trustworthiness of the conclusions that are generated from a piece of research whereas reliability is defined as the replicability and consistency of measures. The integrity of the quantitative data to be collected will be ensured by the following:

- Conducting the OAE testing in more than one maternal and child healthcare (MCH) clinic increases the credibility and transferability of the data because it will be conducted in more than one setting.
- Conducting the OAE test on two separate occasions (test-retest method Bryman & Bell, 2007) increases the stability of the measurement.
- Real life settings (MCH clinic) will be implemented from a typical developing South African context, and this therefore will carry transferability toward other MCH clinics in developing contexts
- The number of screening personnel and professionals (i.e. nurses, Audiologist and Ear-Nose and Throat registrars/specialists) performing tests on each participant increase validity.
- The researcher's awareness of caregiver and community perceptions of childhood hearing loss and its detection which may be influenced by cultural tradition and religious beliefs increases the validity of the research (Olusanya & Okolo, 2006; Swanepoel et al., 2006).

Acknowledgement

To avoid plagiarism all individuals who contributed to, as well as all references that were utilized during the completion of this study, were acknowledged (Babbie & Mouton, 2001; Mouton, 2001).

2.4. Study population

2.4.1. Research population

The current study focused on the public health care sector in South Africa which serves approximately 86% of the country's citizens (Department of Health, 2007; Schaay & Sanders, 2008). During the 19-month research period (August 2008 – March 2010), 2018 infants (52.8% female) between the ages of 0 and 14 weeks attending their immunization appointments at the eight PHC clinics throughout the Cape Metropolitan area were enrolled in the study. Subjects were enrolled according to the Department of Health's Expanded Program on Immunisation for 2009 as evident in Table 2.1 (Department of Health, 2009b). This included neonates attending the clinic to obtain formula, missed BCG immunization at the hospital or routine 0-6 week developmental questionnaire. The age limit provided an opportunity

to evaluate results against international benchmarks for IHS programs (JCIH, 2007). Older infants were excluded because of the increased prevalence of otitis media with effusion and difficulty of testing due to irritability, which is associated with false-positive test results (Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006). The mean age of the sample at first stage screen was 3.9 weeks of age with 89.7% of babies 6 weeks or younger. 6 subjects included in the study were late for their immunization appointment and therefore fell slightly outside this range. The oldest subject was 16 weeks of age due to time spent in the neonatal intensive care unit at one of the tertiary hospital facilities. The City Health unpublished report for immunization for the period July 2008 – March 2009 indicated that more than 99% of infants are immunized within the first year of life allowing for sufficient coverage through IHS (City of Cape Town, 2009). This coverage is significant as the study adopted a universal screening approach whereby all infants were screened since screening only high-risk children will only identify approximately 50% of infants with congenital hearing loss (Chu et al., 2003, Davis & Wood, 1992).

Table 2.1: Department of Health, Expanded Program on Immunisation for 2009

Age	Vaccines, diseases against which immunized
At Birth	BCG and OPV (0)
6 weeks	OPV, RV, DTaP-IPV//Hib, Hep B and PCV (first dose)
10 weeks	DTaP-IPV//Hib and Hep B (second dose)
14 weeks	RV and PCV (second dose), DTaP-IPV//Hib and Hep B (third dose)
^a 6 months	Measles (high risk areas), Vitamin A
9 months	Measles (first dose) and PCV (third dose)
18 months	DTaP-IPV//Hib and Hep B (fourth dose), Measles (second dose)
6 years	Td vaccine tetanus, reduced strength of diphtheria vaccine
12 years	Td vaccine tetanus, reduced strength of diphtheria vaccine

BCG, bacilles calmette Guerin; OPV, oral polio vaccine; RV, rotavirus vaccine; DTaP-IPV// Hib, diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and haemophilus influenza type B combined; Hep B, hepatitis B vaccine; PCV, pneumococcal conjugated vaccine.

^aAlthough the 6-month age mark is not an official immunization milestone it has been included as it served as a follow-up appointment for subjects who displayed risk factors for hearing loss.

2.4.2. Research setting

MCH clinics within the Cape Metropolitan area were the setting for the study. Totalling approximately 100 throughout the Cape Metropolitan area, MCH clinics are part of PHC facilities that serve as immunization, health education and general healthcare centres and are primarily managed by nursing staff (Department of Health, 2009a). These clinics will be selected according to the following criteria:

- 1 community-based MCH PHC clinic per sub-district in the Cape Metropolitan area (Khayelitsha, Klipfontein, Mitchells Plain, Tygerberg, Northern, Southern, Eastern and Western) with a DPOAE machine
- PHC clinics with statistics of the highest/near-highest 6-week immunization visits
- Clinic with immunization clinics that run from Monday-Fridays
- Clinic closest to secondary or tertiary audiological and medical services or as many auxiliary medical services as possible i.e. ENT, pediatrics
- Clinic with trained screening personnel (PHC community nurses – professional, staff and enrolled)
- Clinic with quiet room for testing and secure area to lock OAE machine away
- Clinic with telephone and fax facilities and photocopy machine
- Clinic with electricity and running water

Based on these criteria the City of Cape Town Health Department identified 1 community-based PHC clinic per sub district within the Metropolitan, namely: Langa, Ravensmead, Kuyasa, Masincedane, Westridge, Wallacedene, Retreat and Dr. Ivan Toms clinic. In order to carefully monitor the quality of the program, the screening program was introduced at the 8 clinics in 3 phases over the 19-month research period, namely Ravensmead and Langa clinic in phase one (August 2008 – March 2010), Masincedane, Kuyasa and Westridge/Rocklands clinic in phase two (June 2009 – March 2010), Retreat, Wallacedene and Ivan Toms clinic in phase three (September 2009 – March 2010).

2.5. Material and apparatus

The material and apparatus that will be used for data collection and analysis are discussed independently.

2.5.1. Data collection material

At clinic level a test form was completed for every participant who was screened (included as appendix D). For ethical purposes and due to the fact that this was an ongoing health care service this information was duplicated on the participant's Road-to-Health card and clinical notes in the clinic file. At tertiary hospital level a form was completed for every participant who was seen for diagnostic testing by Audiologists and Ear-Nose and Throat registrars/specialists (included as appendix H). According to hospital policy at tertiary hospital level this information was duplicated on the participant's Road-to-Health card and clinical notes in the hospital file.

2.5.2. Data collection apparatus

Table 2.2 describes the apparatus that was used during the data collection. The clinics utilized the Biologic AuDx DPOAE as the screening instrument. The DPOAE screening parameters included the evaluation of four frequencies (5, 4, 3, and 2 kHz) using a 65/55 stimulus level (L1/L2). Three of the four frequencies were required to pass (with a ≥ 6 dB signal to noise ratio) for an overall pass result. This screening technology was chosen for a number of reasons. Firstly, based on recommendations from a pilot research project in a South African community and HPCSA Year 2007 Position Statement on EHDI it was chosen above automated auditory brainstem response testing for the ease of use and lower screening costs for these settings (HPCSA, 2007; Swanepoel et al., 2006). Secondly, the instrument is handheld, fully automated and displays the test as a "pass" or "refer" making it easy for a non-specialist, such as the clinic nurses, to use. Lastly, they are powered by inbuilt rechargeable batteries that can provide up to 10 hours of testing time, which is important considering the challenge with power failures in the Western Cape.

Table 2.2: Apparatus used for data collection

APPARATUS	RATIONALE
Clinic-based (primary level) (PHC nurses as screening personnel)	
Biologic AuDx DPOAE machine	<i>DPOAEs will be used to evaluate the integrity of the outer hair cells of the cochlea</i>
Heine Mini 2000 Otoscope	<i>To determine the condition of the external meatus and the tympanic membrane</i>
Hospital-based (tertiary level)^a (Audiologists and Ear, Nose & Throat registrars/specialists as diagnostic team)	
Red Cross Children's Hospital	Tygerberg Hospital
<ul style="list-style-type: none"> • Otoscope • High frequency tympanometer (1000Hz probe tone specific to infants 0-7months of age: Baldwin, 2006; HPCSA, 2007) • OAE system • ABR system • Diagnostic audiometer 	<ul style="list-style-type: none"> • Otoscope • High frequency tympanometer (1000Hz probe tone specific to infants 0-7months of age: Baldwin, 2006; HPCSA, 2007) • OAE system • ABR system with AABR function • Diagnostic audiometer

PHC, primary health care; DPOAE, distortion product otoacoustic emissions; OAE, otoacoustic emissions; ABR, auditory brainstem response; AABR, automated auditory brainstem response.

^aNote: only those subjects who obtained a bilateral refer result on two separate occasions with the clinic-based DPOAE required hospital-based services. Type of equipment varied between hospitals.

2.6. Data collection and analysis

The hearing screening program protocol employed and the procedures that were followed for data collection and analysis are discussed in the following section.

2.6.1. Hearing screening program protocol

Clinic nurses specifically trained in IHS at the identified clinics served as screening personnel. Screening took place in a nurse's office or a designated room in the clinic in which the ambient noise level did not interfere with proper functioning of the screening instrument. Screening was performed before immunization whenever possible and most clinics aimed to screen Monday through Fridays with the aim of 95% coverage per month (HPCSA, 2007).

The research project employed a two-stage screening protocol utilizing a DPOAE machine with repeatable protocol at both stages and bilateral refer criteria. This constituted services at clinic level. Testing protocols and parameters at tertiary hospital level depended on the relevant hospital. A test form was completed for a participant for every visit to the clinic and hospital.

The screening protocols at clinic level, based on guidelines in terms of benchmarks and quality indicators from the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007), included the following components:

- All subjects were tested bilaterally. An OAE was repeated if an infant did not pass the first attempt. If the OAE machine displayed a technical fault or a nurse was unable to test an infant (due to restlessness or irritability), a 4-week appointment was given to coincide with their next immunization visit. This was noted on the test form.
- Counseling with language-appropriate pamphlets regarding normal speech and language and hearing development within the first two years of a child's life was given to all parents/caregivers of subjects regardless of the screening outcome.
- Those neonates/infants who required a follow-up appointment due to a bilateral refer result were given a 4-week appointment to coincide with their next immunization visit. A follow-up appointment was given to avoid high referral rates to tertiary institutions (as the 'refer' may also have been due to poor probe placement or middle ear effusion (MEE)). If a second bilateral refer result was obtained the infant was referred directly to the tertiary institution for diagnostic audiological and medical services within 2-3 weeks.
- Those infants who obtained a unilateral refer result or bilateral pass result who displayed risk indicators, as listed in the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007) birth through 28 days of age, were given a 6 month follow-up to coincide with their immunization visit.
- Those infants who obtained a unilateral refer result with no risk indicators were not given a formal appointment. These mothers/caregivers were however advised by screening personnel to monitor hearing and speech and language development exceptionally closely within the first year of a child's life (based on milestone pamphlets given). They were also strongly advised to

return if the infant displayed risk indicators as listed in the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007) 29 through 2 years of age, which could be related to an acquired, late onset or progressive hearing loss.

- Those infants who obtained a bilateral pass result with no risk indicators were 'discharged' from the system. These mothers/caregivers were however advised by screening personnel to monitor hearing and speech and language development within the first year of a child's life (based on milestone pamphlets given). They were also strongly advised to return if the infant displayed risk indicators as listed in the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007) 29 through 2 years of age, which could be related to an acquired, late onset or progressive hearing loss.

Although research does indicate that a unilateral hearing loss impacts developmental and emotional outcomes of children (Bess, Dodd-Murphy & Parker, 1998) and that excluding minimal hearing loss category is not in the best interest of the child (Olusanya, Wirz, et al., 2008) a limited resources setting like South Africa requires a cost-effective program (HPCSA 2007, Swanepoel et al., 2006). Therefore identifying bilateral hearing loss is of a higher priority than the more expensive identification of a unilateral hearing loss (Lutman, 2000) although ongoing surveillance through parental monitoring and appropriate counselling is of the utmost importance. The target condition for this research study was permanent congenital and early onset hearing loss, which constituted structural abnormalities (i.e. atresia), permanent conductive hearing loss and bilateral sensorineural hearing loss. Although minimal hearing loss defined as slight/mild and unilateral hearing loss (Olusanya, Wirz, et al., 2008) was not the primary focus of the screening program the outcomes did include those subjects with fluctuating conductive hearing loss and permanent unilateral hearing loss. With no formalized hearing loss classification for children, standardization across institutions is impossible (Olusanya, Wirz, et al., 2008). Therefore testing protocols and classification of hearing loss among the relevant hospitals at tertiary hospital level performing the diagnostic testing did vary.

2.6.2. Procedures for data collection

Two sets of data were collected for each subject regarding hearing screening at clinic level: a completed brief medical case history, high-risk register, demographic

information and bilateral OAE screening outcome. Clinical otoscopic evaluation only occurred for those subjects who obtained a 'refer'. The data collection procedure was as follows:

- a) The mother/caregiver was addressed by screening personnel and asked if they would like their infant, who was routinely screened as mandated by the City of Cape Town Health, to participate in the study. Once informed consent was given the mother/caregiver signed the test form to demonstrate willingness to participate;
- b) The screening personnel then conducted a short medical case history and completed a high-risk register by using information on the Road-to-Health card and clinical notes in the clinic file of the neonate/infant.;
- c) A bilateral screening with the OAE was performed and results were recorded on the test form;
- d) Where necessary, the screening personnel conducted a clinical otoscopic examination and wrote the description on the test form;
- e) Depending on the relevant hospital's testing protocols and equipment, an automated auditory brainstem response, diagnostic auditory brainstem response or auditory steady state response test was performed on infants who failed the OAE twice with normal middle ear functioning. A qualified audiologist from one of the tertiary institutions (Tygerberg or Red Cross Children's Hospital), performed the diagnostic tests. All information at tertiary level was documented on a separate form for each participant.
- f) Follow-up evaluations were scheduled as stipulated by screening protocols above.
- g) Immunization statistics were collected from each clinic on a monthly basis.

2.6.3. Procedure for data processing and analysis

The data in this study were of a quantitative nature. Data were captured in the EHDI SA Oz eSP Database System and included all information from the participant's test form at clinic level and information for those subjects who required diagnostic services at tertiary hospital level. All information from the EHDI SA Oz eSP Database System was extracted to MS Excel 2007 and analyzed using statistical package SPSS version 17.0 and 19.0. Descriptive statistical measures were utilized to describe the sample according to coverage, referral rates, follow-up rates, prevalence of hearing loss and comparisons in coverage, referral and follow-up rates between the various clinics. Frequency distributions and other descriptive measures

such as the mean, median and standard deviation, as well as box plots and histograms were used to describe the results.

3. EFFICACY OF A COMMUNITY-BASED INFANT HEARING SCREENING PROGRAM UTILIZING EXISTING CLINIC PERSONNEL IN WESTERN CAPE, SOUTH AFRICA

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3.1. Abstract

Objective: Screening programs at primary health care immunization clinics have been proposed as an alternative to hospital-based programs in South Africa. The objective of this study was to evaluate the first systematic community-based infant hearing screening program in a developing South African community in the Western Cape.

Methods: A community-based universal infant hearing screening program initiated at eight primary health care clinics in the Cape Metropolitan area was evaluated over a 19-month research period. During this time 6227 infants who were candidates for screening attended their 6, 10 or 14-week immunization visit at the relevant clinic. Clinic nurses were trained as screening personnel. A two-stage distortion product otoacoustic emissions screening protocol was utilized. The target disorder was uni- or bilateral hearing loss and infants referring the first screen were scheduled for a 4-week follow-up visit at the clinic. Diagnostic audiological and medical evaluations were scheduled at referral hospitals when indicated. The study evaluated the efficacy of the program based on coverage, referral and follow-up rates and diagnostic outcomes according to guidelines specified by the Health Professions Council of South Africa 2007 Position Statement.

Results: Overall coverage rate across the eight clinics was 32.4% with 2018 infants (aged 0-14 weeks) screened. The mean age of the sample at first stage screen was

3.9 weeks of age and 13.5 weeks of age for first hospital visit. Overall first stage screen referral rate was 9.5% with 62 subjects (3%) referred for diagnostic services at hospital level after a follow-up screen. The average follow-up rate for rescreens at clinic level was 85.1% and for initial diagnostic assessments at hospital level it was 91.8%. Prevalence rates were 4.5/1000 with significant hearing loss, including sensorineural (1.5/1000) and conductive (3/1000) losses, and 12.9/1000 for subjects with middle ear effusion.

Conclusions: The community-based infant hearing screening program was valuable in attaining high follow-up return rates but reaching sufficient coverage may require dedicated screening personnel as opposed to existing nursing personnel.

3.2. Introduction

A growing body of research demonstrates that infant hearing screening (IHS) is 'preventative' in nature, precluding the adverse consequences of late diagnosis and the burden of permanent hearing loss (Korver et al., 2010; Olusanya, Swanepoel, Chapchap et al., 2007; Yoshinaga-Itano, 2004). The investment in early childhood, especially from a developmental perspective such as IHS, has a two-fold effect. Not only does it have an enormous impact on the child's health but it can result in important long term economic returns, which may be significantly higher than investment in formal education (JCIH, 2007; Schroeder et al., 2006). Universal newborn hearing screening (UNHS) programs are considered the gold standard in facilitating early detection and intervention for hearing loss and yield the best outcomes in terms of language and speech development (Morton & Nance, 2006; Nelson, Bougatsos & Nygren, 2008). Research evidence has shown it to be practicable, effective, cost-efficient, safe, and facilitative of optimal outcomes for infants with hearing loss (Korver et al., 2010; Olusanya, 2011a; Schroeder et al., 2006).

UNHS programs however, are a privileged reality for babies born in developed countries such as the United States and the UK (WHO, 2010). In developing countries IHS programs are rare due to socio-economic and health care barriers, limited contextual research evidence, lack of financial and/or human resources and the absence of political will (WHO, 2010). Governments are often burdened by communicable and fatal diseases, such as HIV/AIDS, tuberculosis and malaria,

which easily marginalize infant hearing loss (Olusanya, Swanepoel, Chapchap et al., 2007). This has led to a general neglect of hearing loss despite two-thirds of all persons with disabling hearing loss residing in developing countries of which at least 25% is from birth or early childhood onset (Olusanya & Newton, 2007).

Annually more than 800,000 babies are born with or acquire early onset permanent bilateral hearing loss worldwide (Olusanya & Newton, 2007; Olusanya, Wirz, et al., 2008). More than 90% of these reside in developing countries where there is virtually no prospect of early detection (Olusanya, Wirz, et al., 2008). In 2009, the World Health Organization called for a consensus on the best approaches to newborn and IHS with a demonstration of its effectiveness and cost-efficiency to justify its universal use in resource-poor countries (WHO, 2010). Olusanya (2011b) suggests that targeted newborn hearing screening is an option in less developed countries where UNHS is not immediately practicable at any level of healthcare delivery. However prior to embarking on targeted newborn hearing screening or UNHS it is recommended that each country establish context-specific risk factors, their rationale for screening as well as operational issues related to effective implementation. Contextual empirical evidence from pilot studies at community, state or national level, or even non-governmental initiatives, is necessary to demonstrate the importance and feasibility of widespread IHS (WHO, 2010). These pilot sites can provide a platform for contextual research to promote and guide improvements in service provision suited to each context and may serve as examples for future program implementation on a wider scale (HPCSA, 2007). This is important because Western models of hospital-based IHS for newborns may not be appropriate for the majority of developing countries (Griz et al., 2009; Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006).

Immunization clinic-based screening programs have been proposed as an alternative to hospital-based programs typical of developed countries for a number of reasons. Firstly, the World Health Organization recommends the co-ordination of Early Hearing Detection and Intervention (EHDI) systems with existing programs such as immunizations or well-child care in community settings to reduce costs (WHO, 2010). Adopting a horizontal (integrated) as opposed to the traditional vertical (isolated) approach to service delivery may ensure that services are mutually

beneficial, cost-efficient and effective (Olusanya, 2009a). Secondly, a significant proportion of births in most parts of the world occur outside regular hospital facilities making conventional hospital-based UNHS programs of limited value for optimal coverage (Olusanya, Ebuehi, et al., 2009; Olusanya & Okolo, 2006; WHO, 2010). Well-child clinics for routine childhood immunization are reputed for attracting babies regardless of their place of birth for a diverse range of health interventions otherwise not reached by hospital-based programs (Olusanya, 2009a; Olusanya, Ebuehi, et al., 2009). Thirdly, Olusanya and Okolo (2006) reported that prevailing cultural attitudes play a role in the success of IHS programs. Taking an apparently healthy child to a hospital for any check-up is sometimes viewed as socially and culturally inappropriate in many communities because of the notion that hospitals cater only to the sick. Furthermore, the attitude towards non-life threatening health conditions like infant hearing loss in some communities may be detrimental to the efficacy of a stand-alone IHS program (Olusanya & Okolo, 2006).

Emerging evidence from pilot community-based IHS programs has demonstrated the value and feasibility of this platform (Olusanya, Ebuehi, et al., 2009; Olusanya, Emokpae, et al., 2009; Swanepoel et al., 2006). A higher yield of permanent congenital and early onset hearing loss was reportedly detected at community level compared to that of the hospital-based screening programs in Nigeria (Olusanya, Emokpae, et al., 2009). Screening infants attending routine clinics for immunization potentially captured a significant number of infants with postnatal hearing loss mostly missed by hospital-based UNHS programs (Olusanya, Wirz, et al., 2008). First-stage referral rates, screening cost per baby and cost per child detected with permanent congenital and early onset hearing loss were also reported to be considerably lower for community-based screening programs in comparison to more traditional hospital-based screening programs (Olusanya, Emokpae, et al., 2009). Inclusion of a second-stage screening can significantly reduce the referral rates of an IHS program at community level (Olusanya, Ebuehi, et al., 2009; Olusanya, Emokpae, et al., 2009). Coverage rates of babies screened for a community-based IHS program have been reported to be satisfactory relative to the 95% target for UNHS and the average age of screening can be below 6 weeks of age (Olusanya, Ebuehi, et al., 2009; Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006). A commonly reported challenge for community-based screening programs is a loss of patients to follow-up

(Griz et al., 2009; Olusanya, Swanepoel, Chapchap et al., 2007; Swanepoel et al., 2006). The challenge of high default rates is not however specific to community-based IHS programs and not uncommon in the early stages of hospital-based NHS programs in developed countries (Korres et al., 2006; Mehl & Thomson, 2002).

In South Africa where less than 10% of newborns are afforded the opportunity to have their hearing screened (Meyer & Swanepoel, 2011; Theunissen & Swanepoel, 2008) community-based IHS, utilizing immunization visits, may be well suited for delivering these services. More specifically however many babies in South Africa are not born in hospitals and those who are born in public health hospitals are usually discharged within the first 12 h after birth (Swanepoel et al., 2006; Swanepoel, 2009). This leaves limited time to screen newborns and leads to unacceptably high referral rates due to residual vernix and effusion in the ear which confounds screen results (Levi et al., 1997). The only study on a community-based immunization clinic IHS program in South Africa demonstrated its potential for effective coverage with acceptable referral rates on a relatively small sample (Swanepoel et al., 2006). Community-based IHS programs were subsequently recommended as one of the proposed platforms for IHS in South Africa (HPCSA, 2007). The aim of this study was therefore to evaluate the first systematic community-based IHS program at primary health care (PHC) clinics in a developing South African community in the Western Cape.

3.3. Methods

The national health regulatory board, namely the Health Professions Council of South Africa (HPCSA), has developed a revised and contextually appropriate Position Statement on EHDI programs in South Africa for the year 2007 (HPCSA, 2007). This HPCSA Year 2007 Position Statement provides guidelines for clinic-based screening programs in the form of benchmarks and quality indicators, namely a coverage rate of 95% within the first 6 months of screening, a referral rate for audiologic and medical evaluation of less than 5% within the first year of screening, a referral rate of more than 70%, confirmation of hearing loss by 4 months of age and enrollment into an intervention program by 8 months of age (HPCSA, 2007). Based on these guidelines from the HPCSA Year 2007 Position Statement on EHDI, this study evaluated the efficacy of a community-based IHS program in the Western

Cape regarding coverage and referral rates at clinic level, follow-up rates at all levels, diagnostic outcomes and a comparison of coverage, referral and follow-up rates across clinics. The institutional review and ethics board at the University of Pretoria and City of Cape Town Health Department approved this study before any data collection commenced.

3.3.1. Research setting

The hearing screening program was implemented at eight Maternal and Child Healthcare (MCH) clinics over a 19-month research period, 5 days per week (depending on the clinic), in the Cape Metropolitan area. MCH clinics are part of PHC facilities that serve as immunization, health education and general healthcare centres and are primarily managed by nursing staff (Department of Health, 2009a). The number of these clinics throughout the Cape Metropolitan area total approximately 100. The eight clinics utilized in the current study were selected according to the following criteria: (1) one community-based MCH PHC clinic per sub-district in the Cape Metropolitan area (Khayelitsha, Klipfontein, Mitchells Plain, Tygerberg, Northern, Southern, Eastern and Western), (2) PHC clinics with the most 6-week immunization visits, (3) clinic with immunization services provided Monday through Friday, (4) clinic closest to secondary or tertiary audiological and medical services or with as many auxiliary medical services as possible, i.e. ENT, pediatrics, (5) clinic with trained screening personnel (PHC community nurses – professional, staff and enrolled), (6) clinic with quiet room for testing and secure area to lock equipment away, (7) clinic with telephone and fax facilities and photocopy machine, (8) clinic with electricity and running water. Based on these criteria the City of Cape Town Health Department identified one community-based PHC clinic per sub district within the metropolitan area. The screening program was introduced at the 8 clinics in 3 phases over the 19-month research period, namely Ravensmead and Langa clinic in phase 1 (August 2008–March 2010), Masincedane, Kuyasa and Westridge/Rocklands clinic in phase 2 (June 2009–March 2010), Retreat, Wallacedene and Ivan Toms clinic in phase 3 (September 2009–March 2010). The screening program was introduced in three phases to carefully monitor the quality of the program, in terms of coverage, referral and follow-up rates. The necessary adjustments were made to the screening program based on feedback from each phase. The total area of Cape Town is 2479 km² and is the second-most populous

city in South Africa with a population of 3,4 million people (City of Cape Town, 2006; Statistics South Africa, 2007). The City Development Index and the Human Development Index, an average of infrastructure, health, education and income indicate that Retreat, Ravensmead and Westridge/Rocklands have higher indices compared to Masincedane, Langa and Kuyasa who have lower indices and considered the poorer areas (City of Cape Town, 2006).

3.3.2. Study population

During the 19-month research period (August 2008–March 2010), 2018 infants (52.8% female) between the ages of 0 and 14 weeks attending their immunization appointments at the eight PHC clinics were enrolled in the study. 6 subjects included in the study were late for their immunization appointment and therefore fell slightly outside this range. The oldest subject was 16 weeks of age due to time spent in the neonatal intensive care unit at one of the tertiary hospital facilities. The City Health unpublished report for immunization for the period July 2008–March 2009 indicated that more than 99% of infants are immunized within the first year of life allowing for sufficient coverage through IHS (City of Cape Town, 2009). The mean age of the sample at first stage screen was 3.9 weeks of age with 89.7% of babies 6 weeks or younger. Even though the scheduled immunization visits are set at 6, 10 and 14 weeks of age, caregivers brought infants at various age intervals thus leading to the spread of infants from birth to 14 weeks and included neonates attending the clinic to obtain formula, missed BCG immunization at the hospital or routine 0-6 week developmental questionnaire. Verbal and written informed consent was obtained from each parent/caregiver by clinic nurses prior to enrolling the infant into the study.

3.3.3. Protocol and methods

The study employed a two-stage distortion product otoacoustic emissions (DPOAE) screening protocol at clinic level utilizing a DPOAE screener. A two-stage screening protocol was employed to reduce the burden of false positive referrals to tertiary hospital level. The DPOAE screening parameters included evaluation of four frequencies (5, 4, 3, and 2 kHz) using a 65/55 stimulus level (L1/L2). Three of the four frequencies were required to pass (with a ≥ 6 dB signal to noise ratio) for an overall pass result. This screening technology was chosen instead of automated

auditory brainstem response testing based on recommendations from a pilot research project (Swanepoel et al., 2006) and the HPCSA Year 2007 Position Statement on EHDI highlighting the ease of use and lower screening costs for these settings (HPCSA, 2007; Swanepoel et al., 2006). Furthermore, the instruments were chosen as they are fully automated handheld DPOAE devices (Bio-Logic AuDx) and therefore easy to use by non-specialists as they require no interpretation. They are powered by inbuilt rechargeable batteries, which is important considering the occurrence of power failures in the Western Cape.

A bilateral otoacoustic emissions refer criteria was used as criterion for an overall refer. Although unilateral hearing loss impacts developmental and emotional outcomes of children (Bess et al., 1998) for the sake of cost-effectiveness a bilateral refer criteria may be necessary in resource constrained settings (HPCSA, 2007; Swanepoel et al., 2006). Infants who referred both ears were scheduled for a follow-up screen within 4 weeks from the initial screen to coincide with their next immunization visit. If an initial screen could not be conducted due to irritability or restlessness a follow-up screening appointment was also scheduled. The follow-up screening consisted of the same protocol and if a second refer result was obtained a diagnostic audiology and ear-nose and throat specialist evaluation was scheduled at tertiary hospital level. If the follow-up screen at clinic level could not be completed due to irritability or restlessness a second or third follow-up screen was scheduled. Those infants with a unilateral refer result and bilateral pass result with risk factors for hearing loss were given a 6 month follow-up appointment to coincide with their immunization visit and caregivers were counselled regarding speech-language and hearing development and milestones.

Clinic nurses, trained and mentored in IHS before the service commenced, served as screening personnel. Nurses were trained by the program manager and colleague at their relevant clinics and received ongoing support and training from the program manager throughout the course of the screening program. Screening was conducted in a nurse's office or designated room in the clinic where ambient noise levels were adequate for testing. A test form including a brief medical case history, high-risk register, demographic information and screening outcome was completed for every visit to the clinic. A separate form was completed for every visit to the tertiary

hospital. The screening protocols at clinic level were based on guidelines from the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). Assessment protocols at tertiary level depended on the tertiary hospital's protocol.

3.3.4. Data management and statistical analysis

Data were captured in the EHDI SA Oz eSP Database System and included all information from the participant's test form at clinic level and information for those subjects who required diagnostic services at tertiary hospital level. The researcher worked with personnel from Oz Systems to contextually modify the original database. All information from the EHDI SA Oz eSP Database System was extracted to MS Excel 2007 and analyzed using statistical package SPSS version 17.0. and 19.0. The type of statistical data analysis utilized was descriptive in nature. Frequency distributions and other descriptive measures such as the mean, median and standard deviation, as well as box plots and histograms were used to describe the results.

3.4. Results

The initial DPOAE screening procedure was performed on 2018 subjects at the 8 PHC clinics. Fig. 3.1 summarizes the outcomes of the screening for all subjects in the sample group (n = 2018). The majority of subjects were successfully screened at the first stage screen. However, due to irritability and restlessness 1.5 % of all subjects (n = 31) required a follow up appointment, of which only 41.4% returned for a second stage rescreen. A rescreen for a third or fourth time was required for 0.5% of all subjects (n = 9) before a reliable referral to tertiary hospital level for diagnostic services was made. The outcome of these rescreens was included in the second stage screen results.

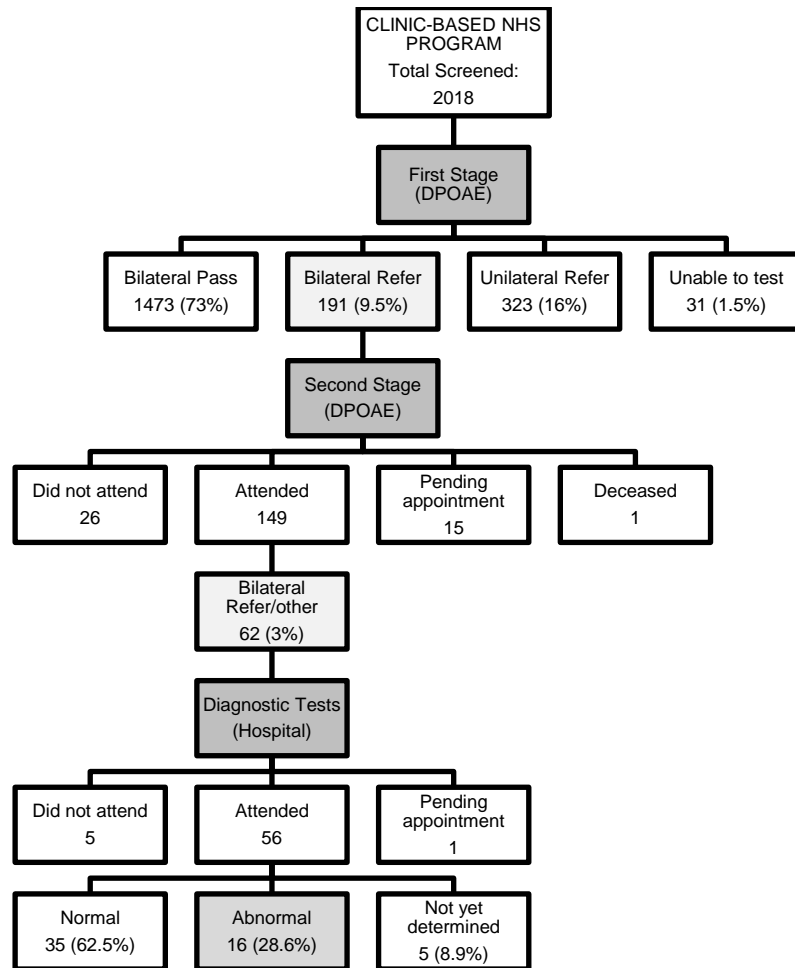


Fig. 3.1: Overall outcome of phases in the screening process at primary health care clinics

3.4.1. Coverage

Coverage rates, illustrated in Fig. 3.2, indicate the number of babies initially screened at the PHC clinic compared to the number of babies who attended their 6, 10 or 14-week immunization visit. As evident from Fig. 3.2, three of the clinics presented with coverage rates between 74.6 and 85.3% but the majority had much poorer coverage. Although 98.5% (n = 1987) of the total subjects in the sample group were successfully screened at stage one, the overall coverage rate across the 8 clinics was 32.4%.

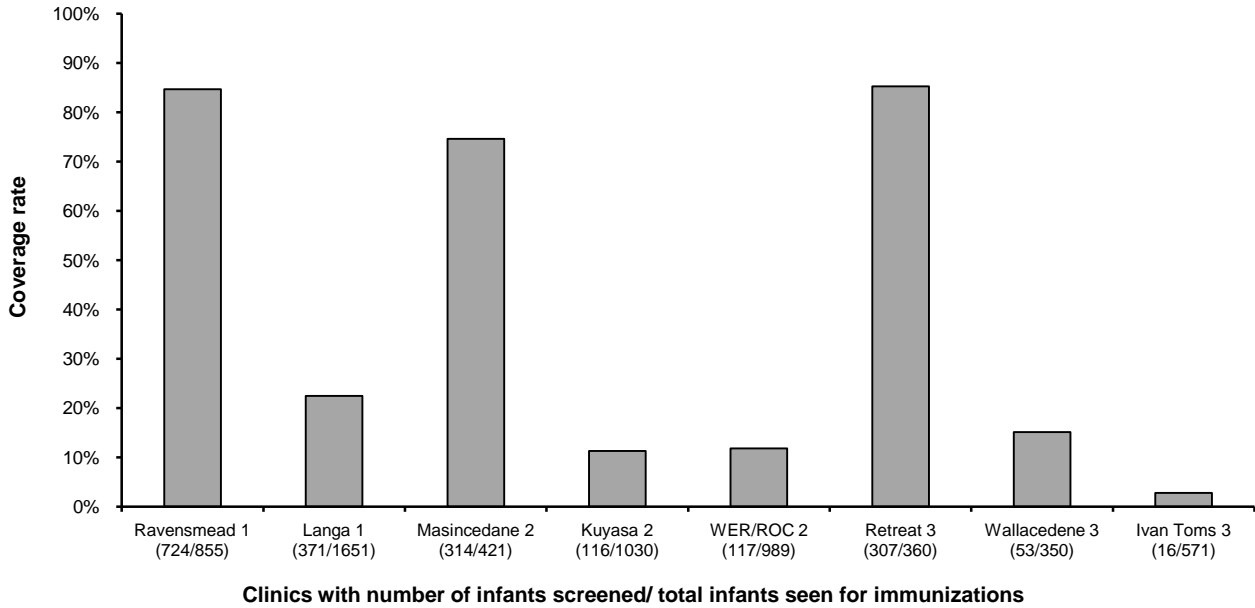


Fig. 3.2: Screening coverage rates at the primary health care clinics. (1) Clinics in phase 1; (2) clinics in phase 2; (3) clinics in phase 3.

3.4.2. Referral rate

Although the screening protocol specified a bilateral DPOAE screening for all subjects only one ear could be screened with DPOAE in 16% (n = 323) of the sample whilst no measurements could be performed in 1.5% (n = 31) of subjects. Those subjects who could not be tested due to irritability or restlessness were scheduled for a follow-up screening appointment. As evident from Figs. 3.1 and 3.3, the overall first stage screen referral rate at clinic level was 9.5% (n = 191). The overall second stage screen referral rate for these subjects who were sent to tertiary hospital level dropped to 3% (n = 62). Referral rates varied greatly amongst the clinics from 2.6 to 23.9% at first stage screen and 0 to 18.8% at second stage screen. However in all cases, except for 1 clinic, the second stage screen referral rate dropped below 6%.

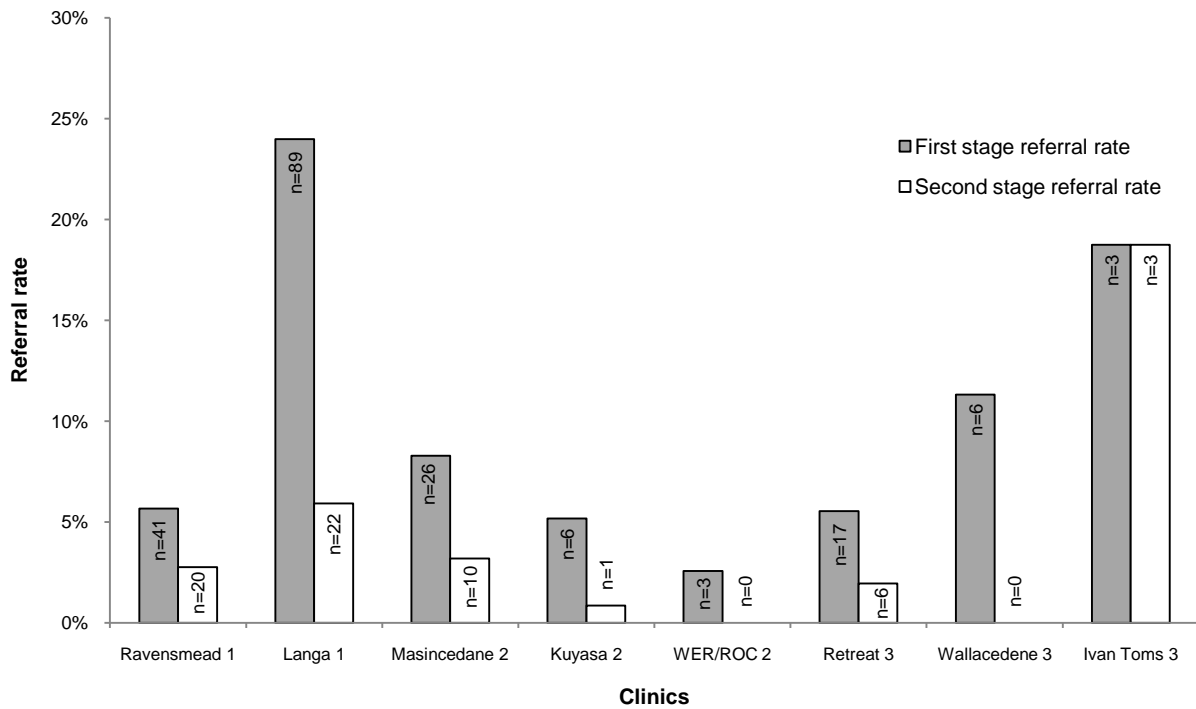


Fig. 3.3: Screening referral rates at the primary health care clinics. (1) Clinics in phase 1; (2) clinics in phase 2; (3) clinics in phase 3.

3.4.3. Follow-up rate

As evident from Fig. 3.4 the overall follow-up rate at clinic level was 85.1% and the follow-up rate of those subjects attending their initial appointment at tertiary hospital level was 91.8%. Follow-up rates varied amongst the clinics from between 50 to 100% at clinic level and 60 to 100% at tertiary hospital level. However in the majority of cases the follow-up rates at clinic and tertiary hospital level were above 80%. All subjects from Wallacedene and Westridge/Rocklands clinic passed their second stage screen and required no referral and follow-up at tertiary hospital level.

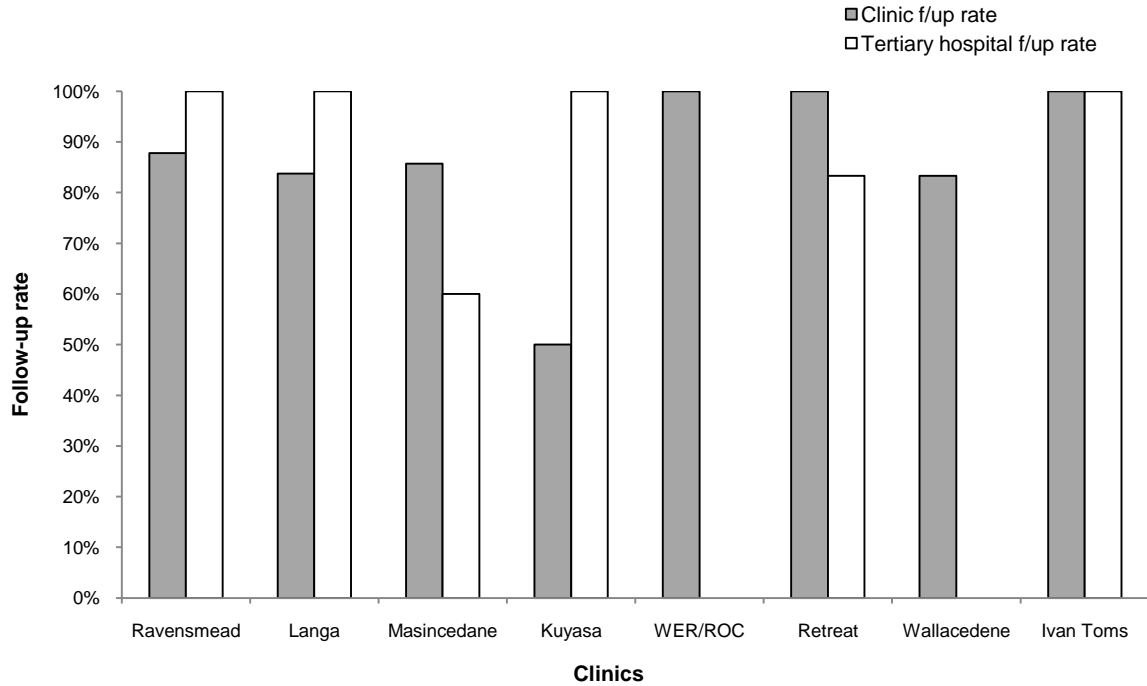


Fig. 3.4: Follow-up return rates at the primary health care clinics and diagnostic referral hospitals

3.4.4. Mean age of screening and diagnosis

The mean age at first stage screen was 3.9 weeks (SD 2.3) with 89.7% of babies 6 weeks or younger. Six subjects fell slightly outside the 0-14 week range for their first screen. The mean age of the sample at second stage screen was 8.4 weeks of age (SD 3.4) with 1 subject as an outlier at 18 weeks of age. The mean age of the sample at first tertiary hospital visit was 13.5 weeks of age (SD 6.2) with 76.4% of babies 16 weeks or younger. There were however 4 subjects who fell well outside the mean age and were between 27 and 36 weeks of age at first tertiary hospital visit. The mean number of visits for diagnostic services at tertiary hospital level was 3 visits per subject (SD 2.5) although 3 subjects had between 9 and 15 visits.

3.4.5. Diagnostic outcome of subjects

The diagnostic outcome of subjects (Fig. 3.1) who attended their tertiary hospital appointments (n = 56) were divided into a normal (62.5%), “abnormal” (28.6%) and not yet determined (8.9%) category. Those subjects whose appointments were still pending or who had been seen at tertiary hospital level but had no conclusive

diagnostic results yet were classified as ‘not yet determined’ (NYD). The outcome of subjects in the “abnormal” category was ear specific and included temporary/transient conductive or confirmed permanent sensorineural hearing loss as well as unilateral and bilateral hearing loss as evident in Table 3.1. Some subjects with middle ear effusion (MEE) had not had a diagnostic hearing test at the time of data analysis and were therefore excluded from the fluctuating conductive temporary/transient hearing loss category.

Table 3.1: Diagnostic outcome of subjects in the “abnormal” category.

Diagnostic Outcome	Number of subjects (%)	Age at first diagnosis of HL (weeks)^a
Normal and NYD	1 (.05%)	
MEE	5 (.25%)	
MEE and NYD	1 (.05%)	
Temporary/transient HL		
Conductive with MEE	4 (.20%)	
Normal and Conductive with MEE	2 (.10%)	
Confirmed permanent HL		
Sensorineural	1 (.05%)	13.6
Mixed with MEE	1 (.05%)	40.9
Normal and Sensorineural	1 (.05%)	41.6

HL, hearing loss; NYD, not yet determined; MEE, middle ear effusion. Diagnostic outcome was ear-specific indicated as a single bilateral outcome or a unilateral combination of different outcomes.

^aThe age at first diagnosis of hearing loss was only calculated for the 3 subjects with confirmed permanent hearing loss and not for those subjects with unconfirmed or temporary/transient hearing loss due to the unreliable fluctuating nature of conductive hearing loss.

The age at first diagnosis of hearing loss was only calculated for the 3 subjects with confirmed permanent hearing loss and not for those subjects with unconfirmed or temporary/transient hearing loss due to the unreliable fluctuating nature of conductive hearing loss. This was 13.6 weeks for bilateral sensorineural HL, 40.9 weeks for bilateral mixed HL (with MEE) and 41.6 weeks for unilateral sensorineural

HL. It must however be noted that the mean age at first screen at the clinic was 7 weeks and at first tertiary hospital visit was 11.9 weeks of age for this sample group.

The prevalence rates were 3/1000 (6/2018) for bilateral and unilateral fluctuating conductive hearing loss, and 1.5/1000 (3/2018) for sensorineural hearing loss, including bilateral, mixed and unilateral losses at the time of data analysis. The overall prevalence rate of significant hearing loss, including sensorineural and conductive losses, was 4.5/1000. It must be noted that although 35 subjects who were referred to tertiary hospital level were found to have normal outcomes, 13 subjects were diagnosed with MEE requiring several tertiary hospital level follow-up appointments. Therefore the prevalence rate of MEE for this research sample, including subjects from the normal and “abnormal” outcomes category was 12.9/1000 (26/2018) with 6 subjects requiring pressure equalizing tubes at a later stage.

An analysis of the subjects who obtained a bilateral refer result with risk factors for hearing loss ($n = 31$) and who were referred for diagnostic services at tertiary hospital level was conducted. Results indicated that gestational age less than 40 weeks and post natal infections (HIV positive mother and/or baby) were the most prevalent risk factors amongst the sample at 32% ($n = 10$) and 23% ($n = 7$) respectively.

3.5. Discussion

The Western Cape has limited primary and secondary Audiology and ENT services in the public health care sector (Swart, 2010). Through public-private partnerships this research program was made possible and is one of the first to implement and determine the efficacy of a systematic community-based IHS program in South Africa. The outcomes were evaluated against guidelines in the form of benchmarks and quality indicators for a clinic-based screening program according to those specified by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007).

3.5.1. Coverage

Although 98.5% of the total subjects in the sample group were successfully screened at stage one, the overall coverage rate across the 8 clinics (32.4%) and coverage at the various clinics did not meet the required benchmark of 95% as stipulated by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). The nurses were heavily burdened with a variety of tasks and struggled to effectively combine screening with other regular duties often regarded as more important. This was evident with Kuyasa clinic (11.26%) where the burden of attending to HIV and TB patients accounted for lower coverage rates. Often times they were short staffed at the clinics, such as Ivan Toms clinic (2.8%) that functioned on skeleton staff for over a year due to budget cuts and challenges with post allocations. A high turnover of clinic staff also accounted for lower coverage rates at Langa clinic (22.47%). These factors were the main reasons for poor coverage, as previously reported in other developing countries also with similar challenges (Olusanya, Swanepoel, Chapchap et al., 2007). Missed screening opportunities due to incorrect or inconvenient immunization times and shortage of immunization stock were also found to contribute to a lower coverage rate (Corrigall, Coetzee & Cameron, 2008). Some clinics managed to maintain high coverage rates which approximate the 95% benchmark (HPCSA, 2007). Those clinics with higher coverage rates in the study had a dedicated day set aside in the week for screening and/or dedicated screening personnel with focused training who took ownership of the program. Retreat clinic combined the hearing screening with an existing newborn program held every Thursday afternoon. This accounted for the highest coverage rate of 85.27% as they had a dedicated day and specific clinic staff to perform the screening. Ravensmead (84.67%) and Masincedane clinic (74.58%) screened three days or more per week but had allocated one member of staff to perform the screening. The screening staff rotated biweekly or monthly to ensure preservation of their screening skill. Furthermore, these clinics had the lowest number of babies coming to the clinic for immunization which meant they had more time to perform screening. Immunization rates were lowest for Ravensmead, Masincedane and Retreat clinic and highest for Kuyasa, Ivan Toms and Westridge/Rocklands clinic. With buy-in and financial support from government, the allocation of dedicated screening personnel could effectively address the shortage of health care workers in resource poor-settings (Olusanya, Wirz, et al., 2008).

3.5.2. Referral rate

Referral rates usually decrease over time in well-monitored screening programs especially with the use of a two-stage screening protocol (Mehl & Thomson, 2002; Olusanya, Ebuehi, et al., 2009). Although the overall first stage screen refer rate of 9.5% at clinic level ($n = 191$) did not meet the required benchmark of 5% (HPCSA, 2007), the overall second screen referral rate of 3% to tertiary hospital level ($n = 62$) was well within this target. These outcomes were similar to earlier community-based UNHS studies performed where first-stage referral rates went from 14.3% to 4.1% in Nigeria and 14% to 3% in South Africa (Olusanya, Emokpae, et al., 2009; Swanepoel et al., 2006). Although the program employed a bilateral refer criteria for first and second stage screen, 5 subjects did not adhere to this criteria but were still referred to tertiary hospital level. This was due to the fact that these subjects displayed significant risk factors for hearing loss or had an existing automated auditory brainstem response appointment at tertiary hospital level.

Referral rates varied greatly between the clinics. This may be attributed to the fact that the screening program was implemented over the course of 19 months in 3 phases. Therefore those clinics introduced in the latter phases of the program did not have the same time and experience in screening compared to the earlier clinics (Olusanya, Wirz, et al., 2008). This was evident for one of the clinics with first and second stage referral rates of 18.8% who was introduced in the last phase of the program. This clinic had the lowest coverage rate due to consistently being short staffed, which meant screening personnel had less opportunity to practice screening and may not have been as competent (Mayekiso, Moonilal, Slotema & Sparg, 2010). Other factors that could potentially have influenced the referral rates include noisy clinic waiting rooms (Brass & Kemp, 1994) and infants with MEE resulting in higher false-positive rates (Swanepoel et al., 2006). Furthermore, referral rates are usually minimal when a two-stage hearing screening protocol with a combination of otoacoustic emissions and automated auditory brainstem response is utilized (Olusanya, Swanepoel, Chapchap et al., 2007). However due to financial reasons, a two-stage DPOAE hearing screening protocol for this study was deemed the most feasible and was recommended by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007; Olusanya, Swanepoel, Chapchap et al., 2007).

3.5.3. Follow-up rate

The overall follow-up rate at clinic level (85.1%) and follow-up rate at the tertiary hospital level (91.8%) was well within the required benchmark of 70% (HPCSA, 2007). This is contrary to many previous studies where loss of patients to follow-up was reported as one of the most significant challenges (Griz et al., 2009; Olusanya, Swanepoel, Chapchap et al., 2007; Swanepoel et al., 2006). The dedicated monitoring of the screening program by a screening coordinator may have been partly responsible for the high follow-up return rates (Corrigall et al., 2008; HPCSA, 2007). The monitoring included telephone call reminders, home visits by community health workers to recall subjects who did not attend their follow-up appointments, training of administrative personnel dealing with clinic folders and visual reminders in the clinic folders for rescreens. The screening personnel's knowledge of the community's language and culture may have also played a role in the high follow-up return rates in his/her ability to address negative or superstitious perceptions of hearing loss (Olusanya, Emokpae, et al., 2009). Data management and tracking systems are also critical for long-term sustainability and efficacy of a screening program and the post-neonatal care pathways (JCIH, 2007; HPCSA, 2007; Olusanya, Ebuehi, et al., 2009; Watkin & Baldwin, 2011). Although no national database registry for IHS currently exists in South Africa, the study utilized an electronic internet-based database (EHDI SA Oz eSP Database System) for management and statistical analysis as part of a larger pilot research program in South Africa.

3.5.4. Mean age of screening and diagnosis

The mean age of the sample at first stage screen was 3.9 weeks of age with 89.7% of babies 6 weeks or younger. Six subjects included in the study were late for their immunization appointment and therefore fell slightly outside the 0-14 week range for their first screen. The oldest subject was 16 weeks of age due to time spent in the neonatal intensive care at one of the tertiary hospitals. The mean age of the sample at second stage screen was 8.4 weeks of age with 1 subject as an outlier at 18 weeks of age. This was because the subject was 13 weeks of age at the first stage screen. The mean age of the sample at first tertiary hospital visit was 13.5 weeks of

age with 76.4% of babies 16 weeks or younger. This is in line with recommendations by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007) for diagnostic evaluations before 4 months of age for infants from clinic-based screening programs. The 4 month benchmark for screening programs at PHC clinics has been specified to allow sufficient time across three immunization visits (6, 10 and 14 weeks) for rescreens and diagnostic assessments. Four subjects were well outside the mean age however (between 27 and 36 weeks of age) at the first tertiary hospital visit. This was attributed to poor parental compliance regarding clinic and tertiary hospital follow-up appointments as also reported by Olusanya (2009b) in a hospital-based UNHS screening program in Nigeria. It was apparent that some of the subjects went to live with family members in rural communities in another province far from the initial screening and diagnostic services in the Cape Metropolitan area.

3.5.5. Diagnostic outcome of subjects

An average of three visits was necessary to the tertiary hospital before a final diagnosis was recorded although 3 subjects had between 9 and 15 visits. The most important reason was due to persistent MEE as diagnosed by ENT Surgeons, which resulted in a delay in ascertaining accurate air conduction hearing thresholds. Furthermore, 2 of the subjects had a disability (cleft palate and Trisome 21), which also resulted in a delay in diagnosis of potential hearing loss due to associated MEE and difficulty in testing. The tertiary hospitals also mostly rely on natural sleep to test babies' diagnostically, which may contribute to the poor success rate and multiple visits required.

The mean age at first diagnosis of confirmed permanent hearing loss was approximately 32 weeks, with a range of 13.6-41.6 weeks of age. Although this is significantly lower than previous findings in the Western Cape of 23 months of age (Van der Spuy & Pottas, 2008), it is higher than the recommended benchmark of 4 months of age for clinic-based screening programs (HPCSA, 2007). It must also be noted that the mean age at first screen at the clinic was 7 weeks and at first tertiary hospital visit was 11.9 weeks of age for this sample group. Factors that may have contributed to the delay in diagnosis of hearing loss are poor parental compliance, long hospital waiting lists for diagnostic tests and persistent MEE. Park and

colleagues (2005) report that 20% of delayed diagnoses of hearing loss was due to middle ear infections.

The prevalence rate of MEE for this research sample was 12.9/1000 (26/2018) with 6 subjects requiring pressure equalizing tubes at a later stage. This rate may have been higher if the project had utilized a unilateral refer criteria (Boudewyns et al., 2011). It must be noted that although 35 subjects were found to have normal outcomes, 13 subjects had MEE requiring several tertiary hospital level follow-up appointments. Therefore, although not the primary target population, the research project was preventative in identifying and treating MEE that could potentially have led to chronic otitis media with effusion and consequently a hearing loss later in life (Doyle, Kong, Strobel, Dallaire & Ray, 2004). Once data analysis was completed it became evident that the subject with bilateral mixed hearing loss was diagnosed with bilateral permanent sensorineural hearing loss once the recurrent MEE dissipated. This highlights the necessity to closely monitor MEE cases since they may mask a sensorineural hearing loss (Boudewyns et al., 2011).

3.6. Overview and recommendations

Screening coverage and overall referral rate for diagnostic evaluation are two key measures in the effectiveness of UNHS programs (Olusanya, Ebuehi, et al., 2009). Poor coverage rates at the clinic could have accounted for the low overall prevalence rate of 4.5/1000 compared to outcomes in other developing countries for community-based UNHS programs like Nigeria with a yield of 22.5 per 1000 with permanent congenital and early onset hearing loss (Olusanya, Emokpae, et al., 2009; WHO, 2010). The use of a two-stage DPOAE screening protocol may not have offered the same specificity and sensitivity as the transient-evoked otoacoustic emissions/automated auditory brainstem response combination utilized by Olusanya and Emokpae, et al. (2009). Furthermore, other unilateral losses would have been missed for the most part due to the bilateral refer criterion. However due to practical and financial reasons, targeted bilateral hearing loss criterion for this study was deemed the most feasible and was recommended by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). Another factor which could have influenced the low prevalence rates were subjects who defaulted initial and follow-up screening appointments, as well as those with pending appointments and NYD outcomes at the

time of data analyses. This is illustrated in the outcomes where all subjects with hearing loss (except one) were screened at phase 1 clinics.

The importance of a program coordinator monitoring quality and providing on-going support and training was demonstrated by the high follow-up return rates achieved in this pilot investigation. In contrast to this, utilizing already burdened clinic nursing staff as screeners may explain the poor coverage rates in this study. Dedicated screening personnel may be necessary to ensure sufficient coverage rates at clinics are achieved. In addition to dedicated screening personnel an alternative platform such as the midwife obstetrics units in the Western Cape may also improve coverage and referral rates. These units are dedicated birthing facilities alternative to domiciliary delivery in Cape Town which offer pre- and post-natal support to mothers (Van Coeverden de Groot, Davey, Smith, Vader & van der Merwe, 1978). Of particular interest are the 3 and/or 7 day post-natal visits where UNHS could effectively take place. Coverage rates may increase as midwife obstetric units personnel focus specifically on maternal and infant care and referral rates may be low due to the fact that infants are 3 or 7 days old when screened.

3.7. Conclusion

The community-based UNHS model in this study was partly effective with confounding variables intrinsic to the model resulting in varied coverage and referral rates and a low yield of permanent congenital and early onset hearing loss. Findings emphasize the need for dedicated screening personnel in community-based UNHS programs and also for consideration of an alternative community-based platform such as midwife obstetric units which may improve coverage and referral rates. The high follow-up return rate attained in this study demonstrates the value of community-based programs and also emphasize the importance of a dedicated EHDI services coordinator.

4. DISCUSSION AND CONCLUSION

4.1. Discussion of results

Reports of studies documenting large-scale infant hearing screening (IHS) programs in developing countries are limited (Olusanya & Roberts, 2006; Tucci et al., 2009; WHO, 2010). Due to the fact that infants in developing countries are exposed to an array of additional environmental risk factors for hearing loss not apparent in developed countries, the incidence for hearing loss is expected to be higher (Olusanya & Newton, 2007; Swanepoel 2010). This necessitates evidence-based research in the form of IHS pilot programs to address this dearth of information and gain legislative support (HPCSA, 2007). Previous research in South Africa and Nigeria has verified the efficacy of immunization clinics as a context for hearing screening at community level (Olusanya & Okolo, 2006; Swanepoel et al., 2006). Through public-private partnerships this study was realized and is one of the first to implement and determine the efficacy of a systematic community-based IHS program in South Africa. The outcomes of the study were evaluated against guidelines in the form of benchmarks and quality indicators for a clinic-based screening program according to those stipulated by the Health Professions Council of South Africa (HPCSA) Year 2007 Position Statement on Early Hearing Detection and Intervention (EHDI) (HPCSA 2007). The study findings are discussed according to these benchmarks in the subsequent sections.

4.1.1. Screening coverage

Screening coverage and overall referral rate for diagnostic evaluation are two key measures in the effectiveness of universal newborn hearing screening programs (Olusanya, Ebuehi, et al., 2009). Although 98.5% of the total subjects in the sample group were successfully screened at stage one, the overall coverage rate across the 8 clinics (32.4%) and coverage at the various clinics did not adhere to the required benchmark of 95% as specified by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). The low coverage can be attributed to a number of factors commonly reported in other developing countries (Olusanya, Swanepoel, Chapchap et al., 2007). The nurses were heavily burdened with a variety of tasks and struggled to effectively combine screening with other regular duties often regarded as more of a priority. Often times they were short-staffed at the clinics, which resulted in

hearing screening being neglected due to the nurses having to attend to essential clinic tasks. Missed screening opportunities due to incorrect or inopportune immunization times and shortage of immunization stock were also found to contribute to a lower coverage rate (Corrigall et al., 2008). A few clinics managed to maintain high coverage rates which approximate the 95% benchmark (HPCSA, 2007) and coverage rates reported in developed countries like the USA and UK (Kennedy & McCann, 2004; Morton & Nance, 2006). As evident from reports of community-based IHS programs from Nigeria and South Africa where coverage rates were above 95%, those clinics had dedicated screening personnel and allocated days (Olusanya, Ebuehi, et al., 2009; Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006). It must be noted that initial coverage rates in Nigeria were poor due to low attendance observed when mothers were initially referred to a single screening site (Olusanya, Wirz, et al., 2008). However once the number of screening sites were increased the coverage improved significantly to 100%. Similarly, coverage rates improved in Malaysia over three years from 89% to 90% due to dedicated personnel, enough portable OAE machines and the committed OAE coordinator (Asma et al., 2008).

4.1.2. Referral rate

Referral rates have been known to decline over time as the program coordinator and screening personnel gain more experience in their respective settings (Olusanya, Ebuehi, et al., 2009). Although the overall first stage screen refer rate of 9.5% at clinic level did not adhere to the required benchmark of 5% (HPCSA, 2007), the overall second screen referral rate of 3% to tertiary hospital level was well within this target. These findings are comparable to studies performed in Nigeria and South Africa where a two-stage referral criterion within a well-monitored program resulted in a decrease in referral rates over time (Mehl & Thomson, 2002; Olusanya, Ebuehi, et al., 2009; Olusanya, Emokpae, et al., 2009; Swanepoel et al., 2006). Referral rates varied greatly between clinics. This may be attributed to the fact that the screening program was implemented over the course of 19 months in 3 phases. Therefore those clinics introduced in the final phases of the program did not have the same time and experience and therefore were not as competent in screening compared to the earlier clinics (Mayekiso et al., 2010; Olusanya, Wirz, et al., 2008). Other factors that could potentially have influenced the referral rates include an

unsuitable test environment such as the clinic waiting rooms where ambient noise was high (Olusanya, Swanepoel, Chapchap et al., 2007) and infants who presented with middle ear effusion (MEE) resulting in higher false-positive rates (Swanepoel et al., 2006). Furthermore, referral rates can also be affected by the choice of screening technology and protocol (Olusanya, Ebuehi, et al., 2009). Developed and other developing countries like Nigeria have found the use of a two-stage transient evoked otoacoustic emission/ automated auditory brainstem response protocol associated with possibly the most favourable combination of specificity, sensitivity and acceptability (Olusanya, Ebuehi, et al., 2009; Olusanya, Swanepoel, Chapchap et al., 2007). Due to financial reasons, a two-stage DPOAE hearing screening protocol was chosen as it was deemed the most feasible and was recommended by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007).

4.1.3. Follow-up rate

The overall follow-up rate at clinic level (85.1%) and follow-up rate at the tertiary hospital level (91.8%) was well within the required benchmark of 70% (HPCSA, 2007). These findings are contrary to poor follow-up return rates from other developing countries like Nigeria (Olusanya, 2009b, Olusanya, Wirz, et al., 2008) and Brazil (Griz et al., 2009). The dedicated monitoring of the screening program by a program coordinator may have contributed to high follow-up return rates (HPCSA, 2007). Furthermore, the screening personnel's knowledge of the community's attitudes and beliefs towards childhood deafness and other disabilities may be responsible for high follow-up return rates (Olusanya, Emokpae, et al., 2009). Olusanya (2009b) states screening protocol and effective tracking system is essential for high follow-up return rates. Post-neonatal pathways assure timely follow-up after newborn hearing screening to ensure improved quality of life for those children with permanent hearing impairment (Korver et al., 2010; Watkin & Baldwin, 2011). The study utilized an electronic internet-based database (EHDI SA Oz eSP Database System) for quality monitoring and statistical analysis as part of a larger pilot research program in South Africa.

Follow-up return rates could further improve by addressing socio-economic and demographic factors such as mother's income and educational level, and location of residence relative to the follow-up appointments (Griz et al., 2009). Culturally-appropriate public education and reduction in the number of visits from screening to

diagnosis as far as possible should minimize loss to follow-up and facilitate improved outcomes on program costs and performance in many countries (Olusanya, Emokpae, et al., 2009). Communication between practitioners and implementation of monitoring systems and checks and balances may also improve the efficacy of early intervention programs (Krishnan, 2009).

4.1.4. Mean age of screening and diagnosis

The mean age of the sample at first stage screen of 3.9 weeks of age and at first tertiary hospital visit of 13.5 weeks of age were in line with recommendations by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007) for diagnostic evaluations before 4 months of age for infants from clinic-based screening programs. However the mean age at first diagnosis of confirmed permanent hearing loss of approximately 32 weeks was higher than the recommended benchmark of 4 months of age for clinic-based screening programs (HPCSA, 2007). This is contrary to a community-based program in Nigeria where the age of diagnosis of permanent congenital and early onset hearing loss was 52 days (Olusanya, Emokpae, et al., 2009). Furthermore, UNHS programs in developed countries like the USA and UK has shown to significantly decrease the age of identification and diagnosis of hearing loss to 3 months of age as stipulated by the JCIH (2007). Factors that may have contributed to the delay in diagnosis of hearing loss are persistent MEE (Park, Warner & Sturgill, 2005) and lengthy hospital waiting lists for diagnostic tests due to limited human resources (Griz et al., 2009). Poor parental compliance was also noted as a significant factor as reported in a study by Olusanya (2009b).

4.1.5. Diagnostic outcomes

The overall prevalence rate of significant hearing loss, including sensorineural and conductive losses, was 4.5/1000 which was below reported prevalence rates of permanent congenital and early onset hearing loss for developing countries (Olusanya, 2011a; Tucci et al., 2009; WHO, 2010). Factors that may have accounted for low prevalence rates are poor coverage rates and the exclusion of automated auditory brainstem response technology in the two-stage screening protocol (Olusanya, Emokpae, et al., 2009). Furthermore, subjects who defaulted initial and follow-up screening appointments, as well as those with pending appointments and

'Not Yet Determined' (NYD) outcomes at the time of data analyses could have influenced the low prevalence rates (Olusanya, Ebuehi, et al., 2009).

The prevalence rate of MEE for this research sample was 12.9/1000 with 6 subjects requiring pressure equalizing tubes at a later stage. Literature emphasizes the need to closely monitor MEE due to the fact that it may mask a sensorineural hearing loss and could potentially lead to chronic otitis media with effusion and consequently a hearing loss later in life (Boudewyns et al., 2011; Doyle et al., 2004). This was evident for this study where some subjects had numerous visits to the tertiary hospital before a final diagnosis was recorded.

4.2. Clinical implications and recommendations

Limited data exists for community-based IHS pilot programs in developing countries. This study aimed to challenge this dearth of information by demonstrating practical ways to improve the efficacy of such a program. These are described below.

Program coordinator

The importance of a program coordinator was demonstrated by the high follow-up return rates achieved in this pilot investigation. On-going support and training of screening personnel is essential to ensure a highly effective screening program. Furthermore quality control measures, such as adequate supply of consumables, availability of standby/back up instruments, overnight charging of instruments daily to ensure uninterrupted usage and several unscheduled visits by program coordinator are key to achieving this (Olusanya, Ebuehi, et al., 2009). As highlighted by the JCIH Year 2007 Position Statement (JCIH, 2007) audiologists are central to each component of the EHDI process from identification, evaluation and auditory habilitation for infants with hearing loss. Therefore as the professionals concerned with infant hearing loss, audiologists can and should effectively serve in the capacity of program coordinator supervising the EHDI program (HPCSA, 2007).

Screening personnel

A major finding from a pilot study done in Nigeria is that community health workers with focused training can successfully screen infants for hearing loss (Olusanya, Wirz, et al., 2008). India has successfully decentralized hearing screening services

by using health care workers to screen in the community (Sharma, 2001). This supports the view that non-specialists, such as nurses or community workers could play an important role in the provision of basic community-oriented hearing services and address the shortage of health workers in resource-poor settings (Olusanya, Wirz, et al., 2008). However it was found that utilising already burdened clinic nursing staff as screeners was not effective and may explain the poor coverage in this study. This is due to the fact that the number of infants seen at these clinics is significantly higher those at clinics in developed countries due to the higher birth rates evident for developing countries. The World Bank indicates that the crude birth rate (per 1,000 people) for South Africa is almost twice that of the USA and UK (World Bank, 2010). Dedicated screening personnel may be required to ensure satisfactory coverage rates at clinics and sustainability of the screening program.

Midwife Obstetrics Units as alternative screening platform

The World Health Organization (2010) emphasizes the need for context-specific adaptations of existing practices in the developed world to facilitate the development of effective and culturally appropriate early identification programs in developing countries (Olusanya, 2011a). Olusanya (2011b) suggests that targeted newborn hearing screening is an option in less developed countries where UNHS is not immediately practicable or feasible. However prior to embarking on targeted newborn hearing screening or UNHS it is recommended that each country conduct pilot studies to establish context-specific risk factors, a rationale for screening as well as operational issues related to effective implementation (Olusanya, 2011a, 2011b).

The screening program in this study was integrated with existing well established routine immunization clinics previously reported as a successful platform for screening (Olusanya, 2011a). Although results indicated that this model was not entirely effective as demonstrated by the poor coverage and referral rates and low prevalence of permanent congenital and early onset hearing loss, the horizontal (integrated) approach to service delivery allowed services to be mutually beneficial and cost-efficient (Olusanya, 2009a, Theunissen & Swanepoel, 2008). Considering only 28% of public sector hospitals in South Africa provide speech therapy and/or audiology services of which less than 1% offer universal screening, there is a need

for an alternative community-based platform in the Western Cape such as midwife obstetric units (Theunissen & Swanepoel, 2008).

Midwife obstetric units are dedicated birthing facilities alternative to domiciliary delivery which offer pre- and post-natal support to mothers. They are situated in suburbs with a high population density in Cape Town linked by telephone to the base hospital and staffed by midwives and nursing staff. The concept of the midwife obstetric unit is particularly suited to Africa and indeed to any developing country (Van Coeverden de Groot et al., 1978). This context is of particular importance due to the 3 and/or 7 day post-natal visits where universal newborn hearing screening could effectively take place. Coverage rates, and consequently prevalence of permanent congenital and early onset hearing loss, may improve as midwife obstetric units personnel focus specifically on maternal and infant care and therefore may have more time to perform the hearing screening. Furthermore, referral rates may be low due to the fact that infants are 3 or 7 days old when screened. This is significant as previous research has shown that older infants may present with higher false-positive results due to irritability during testing and higher prevalence of otitis media with effusion (Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006).

Although first and second stage screening could be performed at the MOU, the PHC immunization clinic may serve as a suitable follow-up facility for those infants who are older than 7 days. This integrated service will require excellent communication between MOU's and PHC clinics, as well as tertiary hospitals to ensure that no infants are lost to follow-up. This proposed community-based IHS model for the Western Cape is represented graphically in Fig. 4.1.

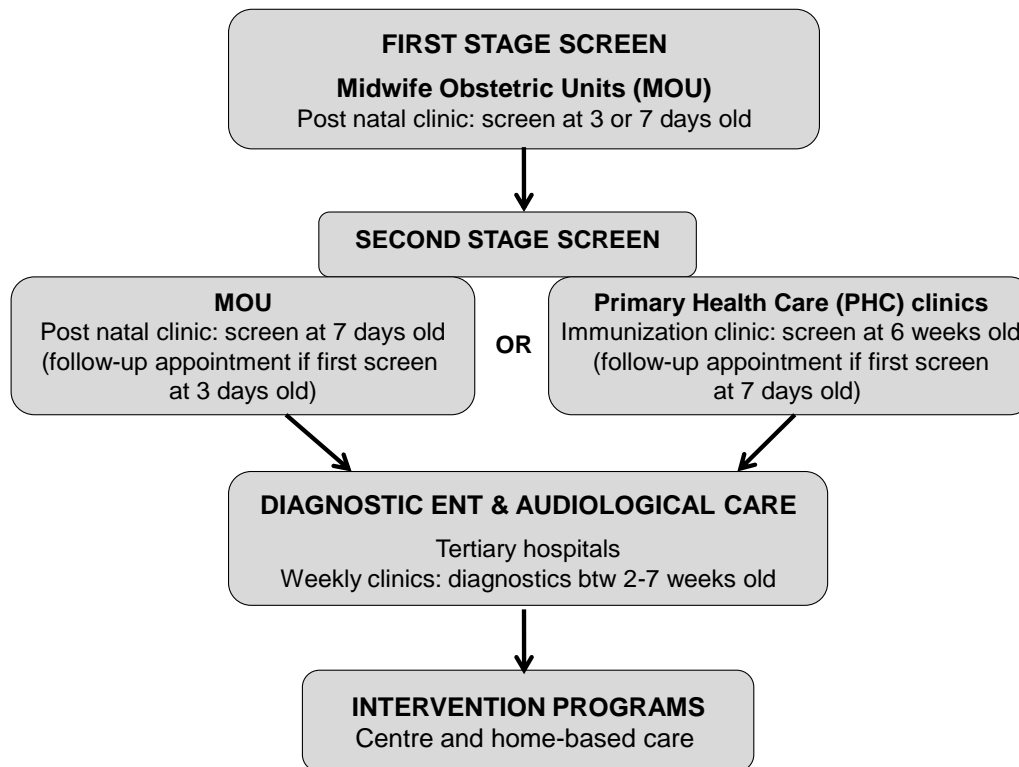


Figure 4.1: Proposed community-based IHS model for the Western Cape

4.3. Critical evaluation

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

Strengths of study

Apart from isolated programs in private and public health care sectors, South Africa has no existing systematic public infant hearing-screening programs at community level. Therefore a dearth of information exists about the efficacy of a systematic community-based screening program and consequently the prevalence of infant hearing loss at community level in South Africa. This research project attempted to address this shortage by describing the efficacy of a systematic community-based screening program according to benchmarks and quality indicators for a community-based screening program by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). Although results indicated that this model was not entirely effective as demonstrated by the poor coverage and referral rates and low prevalence of permanent congenital and early onset hearing loss, it provided valuable information

to guide the development of contextual EHDI services in the Western. First of all, it is the first study that assessed the feasibility of a systematic IHS program on district level in South Africa according to objective benchmarks of the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). Secondly, it emphasized the potential feasibility of community-based nurses as screening personnel, which will hopefully motivate local government in other provinces to contemplate incorporating hearing-screening programs at community level. Thirdly, it investigated the feasibility of a horizontal (integrated) health care service utilizing existing infrastructure to facilitate a self-sustaining hearing-screening program at community level in the Western Cape. The key to this sustainability was found through capacity building and empowerment of local health care members. Fourthly, it further advocates the need for infant hearing-screening programs throughout South Africa and serves as a pilot study for similar studies elsewhere in the country in line with the recommendations by the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). Fifthly, although prevalence rates of permanent congenital and early onset hearing loss were lower than previous research for developing countries (Olusanya, 2011a; Tucci et al., 2009) outcomes on the prevalence of MEE contributes to knowledge on this subject and the appropriate management and monitoring thereof when screening. And lastly, the high follow-up return rate attained in this study demonstrates the value of community-based programs when managed by a dedicated program coordinator.

Limitations of study

The low coverage rates negatively influenced the accuracy of prevalence rates of permanent congenital and early onset hearing loss. Although not evaluated in this study, it reinforced the need for dedicated screening personnel (Olusanya, Wirz, et al., 2008; Swanepoel et al., 2006) as the nurses were too burdened by other clinic tasks considered as more important than screening. Furthermore, due to the cut off period for data collection and analysis the diagnostic outcomes for certain subjects had not been determined which may also have influenced the accuracy of prevalence rates of permanent congenital and early onset hearing loss. The high turn-over and shortage of staff due to City Health's budget cuts may have also resulted in an inaccurate representation of referral and coverage rates, and

consequently prevalence rates of permanent congenital and early onset hearing loss.

4.4. Future research

This study provided important information on the use of immunization clinics as a platform for community-based IHS programs in South Africa. Reported results created potential for future research regarding a number of aspects.

Firstly, further longitudinal pilot studies need to be conducted throughout South Africa exploring alternative platforms for community-based IHS programs based on guidelines from the HPCSA Year 2007 Position Statement on EHDI (HPCSA, 2007). For the Western Cape this would be the feasibility of the MOU's in conjunction with PHC clinics to assess whether coverage and referral rates and prevalence of permanent congenital and early onset hearing loss improved. Secondly, further pilot studies need to be conducted at community level to assess whether the use of dedicated screening personnel significantly improves coverage rates and consequently prevalence of permanent congenital and early onset hearing loss. Thirdly, it is essential to explore post-neonatal care pathways in the form of an effective national tracking system to further reduce infants who get lost to follow up (Olusanya, 2011a; Olusanya, Swanepoel, Chapchap et al., 2007; Watkin & Baldwin, 2011). Fourthly, it would be essential for those communities with limited resources to explore the option of a targeted newborn hearing screening program (Olusanya, 2011b) with the aim of advocating for UNHS at local provincial level. However, prior to embarking on targeted newborn hearing screening or UNHS it is recommended that each community conduct pilot studies to establish context-specific risk factors, a rationale for screening as well as operational issues related to effective implementation (Olusanya, 2011a, 2011b).

4.5. Conclusion

The community-based UNHS model in this study was partly effective. Follow-up return rates were high, whilst coverage and referral rates varied and the yield of permanent congenital and early onset hearing loss was low. The findings of this study emphasize the need for dedicated screening personnel in community-based

universal IHS programs supervised by a program coordinator, preferably an audiologist. Furthermore, it calls for consideration of an alternative community-based platform such as midwife obstetric units which may improve coverage and referral rates and prevalence of permanent congenital and early onset hearing loss. The high follow-up return rate achieved in this study demonstrates the value of community-based programs and also emphasizes the importance of a dedicated EHDI services coordinator.

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6. APPENDICES

APPENDIX A

Letter to Executive Health Director, City of Cape Town

September 2008

Dear Dr. Bromfield

RE: PERMISSION TO CONDUCT RESEARCH AT PRIMARY HEALTH CARE CLINICS IN THE CAPE TOWN METROPOLITAN AREA RELATED TO THE IVAN TOMS INFANT HEARING SCREENING PROGRAM

We would like to gain permission for research to be conducted at the 8 primary level care sites in relation to the Ivan Toms Infant Hearing Screening Program. The various research projects are still to be defined but will address some the following components:

- Evaluating statistics generated from the relevant 8 sites for the purpose of determining the prevalence and incidence of infant hearing loss and otitis media in the Western Cape
- Evaluating the efficacy of a systematic community-based infant hearing screening program in the Western Cape
- Evaluating the efficacy of training nursing staff to act as screening personnel
- Evaluating the perception of parent/caregivers of infants who receive a OAE screening test
- Explore the opportunities and barriers to the implementation of systematic universal infant hearing screening

Please note that all research personnel will obtain ethical clearance from their relevant academic institutions. Parents/caregivers and nursing personnel will give informed consent for information to be used for research. There are no financial obligations related to participation in the research to the parents/caregivers of infants being screened and nursing staff. There are also no medical risks associated with the research.

Participation is strictly voluntary and parents/caregivers of infants being screened and nursing personnel may decide to withdraw their consent at any time without any negative consequences. Information regarding research or the parents/caregiver, infants being screened and nursing personnel's right as participants will be provided upon request at any time during the research process. All information and test results will be treated with confidentiality and the information will be destroyed should they wish to withdraw from the research project. According to international regulations, a copy of the raw data will be stored in electronic format for 15 years before it will be destroyed. The stored data may be used in future research projects, but should this happen, the relevant parties' permission in this regard, will be requested. The information and results gathered will be available in the format of a conference presentation as well as in a possible journal publication. All participants will have access to all data obtained in this project.

Furthermore, all research conducted will not interfere with service delivery. The time span for research will be for a minimum of three years and reports will be submitted to the City of Cape Town on an annual basis for review.

You are most welcome to contact us at any stage if you require more information at 021 938 5303.

Kind regards,



Ms. Niki Friderichs
Audiologist and Researcher
The Carel du Toit Centre, Cape Town



Ms. Lucretia Petersen
Audiologist and Researcher
The University of Cape Town



Dr. De Wet Swanepoel
Audiologist and Researcher
The University of Pretoria



APPENDIX B

Letter of Consent from Executive Health Director, City of Cape Town



CITY OF CAPE TOWN | ISIXEKO SASEKAPA | STAD KAAPSTAD



Civic Centre
12 Hertzog Boulevard
Cape Town 8001
P.O. Box 2815, 8000
Ask for: **Dr I Bromfield**
Tel: 021 400 2100
Cell: 084 629 5364
Fax: 021 421 4894

Isiko loLuntu
12 Hertzog Boulevard
Cape Town 8001
P.O. Box 2815, 8000
Cela: **Orh I Bromfield**
Umxeba: 021 400 2100
Cell: 084 629 5364
Hekoi: 021 421 4894

Burgersentrum
Hertzog-boulevard 12
Kaapstad 8001
Posbus 2815, 8000
Vra vir: **Dr I Bromfield**
Tel: 021 400 2100
Sel: 084 629 5364
Faks: 021 421 4894

E-mail: ivan.bromfield@capetown.gov.za
Website: <http://cityweb.capetown.gov.za>
Ref:
Filename: fcbd-civic-039Home@bosman1\My Documents\Novallwdocs\City Healthletters\Permission - Infant hearing Screening programme.doc

CITY HEALTH

2008-11-10

To Niki Friderichs
Audiologist and Researcher
Carel du Toit Centre for Hearing Impaired Children

Lucretia Petersen
Audiologist and Researcher
University of Cape Town

Dr De Wet Swanepoel
Audiologist and Researcher
University of Pretoria

Dear Ms Friderichs, Ms Petersen and Dr Swanepoel

PERMISSION TO CONDUCT RESEARCH AT PRIMARY HEALTH CARE CLINICS IN THE CAPE TOWN METROPOL RELATED TO THE DR TOMS INFANT HEARING SCREENING PROGRAMME

I hereby give permission for you and relevant others to conduct research at the eight identified sites. I also grant permission for you to access the necessary clinic files in order to obtain immunization and hearing/middle ear related information. The identity of the babies, parents/caregivers and nursing personnel will not be revealed and all information is to be treated in the strictest of confidence.

Yours sincerely

**DR IVAN BROMFIELD
EXECUTIVE DIRECTOR: CITY HEALTH**

APPENDIX C

Cover Letter for Informed Consent

English, Afrikaans and Xhosa

Date:

Dear Parent/Caregiver,

RE: YOUR CHILD'S OAE TEST RESULTS TO BE USED FOR RESEARCH

The City of Cape Town Health Department has agreed to pilot a community-based infant hearing screening project whereby every child being immunized receives a free hearing test at selected clinics in the metropolitan area. We are members of the staff of the Division of Communication Pathology at the University of Pretoria and are conducting research to decide the best method to screen the hearing of infants. If children cannot hear, their speech and language does not develop 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, then they can be provided with assistance. The results will help us to describe the efficacy of a community-based infant hearing screening program in the Western Cape as well as to decide on the nature of hearing screening programs that must be set up at other clinics in South Africa.

What is the screening test?

The test which we will be using to screen your child's hearing system is called an otoacoustic emission (OAE). The OAE test gives us information on your child's inner ear. We will also be screening the hearing of a number of other infants.

What does screening with OAE involve?

This screening test involves gently putting a tube (probe) fitted with a soft tip in your child's ear canal. The probe produces a sound and has a microphone which will record the response of your child's inner ear. The other end of the probe is connected to the screening machine which will tell us whether your child's ears are working as they should or whether we need to screen your child again. Your child may sleep, be awake or feed while this screening test is being done. We will test both ears.

How long is the test?

This test will not hurt or cause your child any discomfort. It is quick and will be completed in less than one minute (provided your child is quiet).

When will the results be available?

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

What happens if my child passes the test?

If your child passes the test, it means that their inner ear is functioning as it should. However, 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, (for example your child does not begin to speak at the age of 1 to 2 years, or your child has frequent ear infections), please speak to your clinic nurses immediately. They will then refer your child to either Red Cross Children's Hospital or Tygerberg 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.

What happens if my child does not pass the test?

If your child does not pass the OAE test in both ears, you will also be informed. You will need to bring your child in to the clinic in 4 weeks time so that his/her hearing may be screened again. If your child does not pass the second OAE screening in both ears, he/she will be referred to either Red Cross Children's Hospital or Tygerberg 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, then appropriate plans will then be made to manage your child's hearing loss and language development.

What will be required of you?

You will be required to give written permission for your child's hearing screening results to be used for research. The OAE test will be conducted in the position which is the most comfortable for your child and none of the procedures are invasive or will result in any discomfort. Your child does not need to do anything – just sit quiet and relax. There will be no payment for participation in this study and no known risks to participating in the study. If you become worried about the test results, the nurse will offer counselling, answer your questions, and make appropriate referrals for you. You may also contact the researchers if questions arise at any time after the screening.

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, including those at Red Cross and Tygerberg Hospitals, 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 the final thesis report but no identifying information will be used at any time. Coded data will be stored for a minimum of 15 years according to University of Pretoria Regulations.

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 using OAEs 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.

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

Sincerely,



Ms. Niki Friderichs
M.Communication Pathology Student



A handwritten signature in black ink, appearing to read 'De Wet'.

Professor De Wet Swanepoel
Lecturer / Project Supervisor

Professor Brenda Louw

HEAD: Department of Communication Pathology

Datum:

Geagte Ouer/Versorger,

INSAKE: GEBRUIK VAN JOU KIND SE OAE TOETS RESULTATE VIR NAVORSING

The City of Cape Town Gesondheidsdepartement het ingestem om 'n loodsstudie rakende die uitvoering van 'n gemeenskapsbaseerde baba gehoor siftingsprojek te doen by gekose klinieke in die metropool. Dit beteken dat elke baba wat geïmmuniseer word, ook 'n gratis gehoortoets sal ontvang. Ons is personeel van die Departement Kommunikasiepatologie, Universiteit van Pretoria en gaan navorsing doen oor die beste manier om die gehoor van babas te sif. As kinders nie kan hoor nie, kan spraak en taal ontwikkeling 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 help om die effektiwiteit van 'n gemeenskapsbaseerde baba gehoor siftingsprojek in die Wes-Kaap te beskryf sowel as om te bepaal hoe om ander gehoorsiftingsprojekte in Suid Afrika te implementeer.

Wat is die siftingstoets?

Die toets wat ons gaan gebruik om jou kind se gehoor sisteem te sif word 'n OAE genoem. Die OAE toets gee vir ons inligting oor jou kind se binne oor. Ons beplan om die gehoor van ander babas wat immunisasie ontvang, te sif.

Wat behels die OAE sifting

'n Toestel met 'n sagte proppe word sagkens in jou baba se oorkanaal geplaas. Die toestel maak 'n klank waarop jou kind se binne oor reageer en 'n mikrofoon neem dan daardie respons op. Die toestel dui aan of jou kind se binne oor funksioneer en of ons die sifting weer moet herhaal. Die toets word uitgevoer terwyl jou baba slaap, wakker is (rustig) of gevoed word. Ons toets albei ore tydens die sifting.

Hoe lank neem die toets?

Die prosedure is vinnig en kan in minder as 'n minuut voltooi word (solank jou kind rustig is). Die toets sal nie seer wees of ongemak veroorsaak nie.

Wanneer is die resultate beskikbaar?

Die resultate word dadelik aan jou meegedeel. Jy kan die suster wat die toets voltooi enige vrae vra rakende die resultate.

Wat beteken dit as my kind die gehoorsifting slaag?

Dit beteken dat jou kind se binne ore normaal funksioneer. Gehoor verlies kan egter ontstaan soos wat kinders ouer word. Dit is daarom belangrik om die inligtingspamflet goed deur te lees. Sou jy bewus word dat jou kind gehoorprobleme ervaar in die toekoms, (bv. nie begin praat teen die ouderdom 1 – 2 jaar nie; as jou kind gereeld oorinfeksie het ens.), moet jy dadelik die kliniek suster kontak. Hulle kan dan jou kind verwys na of Red Cross Children's Hospitaal of Tygerberg Hospitaal

vir 'n gehoortoets. Reël so 'n afspraak sodra jy bekommerd is. Dit is belangrik om gehoorverlies so gou moontlik te identifiseer sodat hulp verskaf kan word en jou kind se taal kan ontwikkel.

Wat beteken dit as my kind nie die gehoorsifting slaag nie?

Jy sal ingelig word as jou kind nie die gehoorsifting slaag in albei ore nie. Dit is dan belangrik om jou kind oor 4 weke terug te bring na die kliniek toe sodat sy/haar gehoor weer gesif kan word. As jou kind die tweede sifting in albei ore nie slaag nie, sal hy/sy na òf Red Cross Children's Hospitaal òf Tygerberg Hospitaal verwys word vir 'n volledige gehoorëvaluasie (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 taal ontwikkeling te behandel.

Wat word van jou verwag?

Daar word verwag dat jy geskrewe toestemming sal gee dat jou kind se gehoorsifting resultate gebruik kan word vir navorsing. Die OAE toets is nie indringend of ongemaklik nie. Jou kind hoef niks te doen nie – behalwe om rustig te wees. Daar is geen betaling wat verskaf word vir deelname aan die studie nie. Geen risiko's verbonde aan deelname aan die studie is bekend nie. Die suster sal berading aanbied, vrae beantwoord en die toepaslike verwysings maak indien jy bekommerd is oor die resultate. Jy kan ook die navorsers kontakte as daar enige vrae is na die sifting.

Vertroulikheid

Rekord van jou kind se gehoorsifting sal bewaar word op 'n rekenaar databasis. Hierdie inligting sal slegs beskikbaar wees vir die oudioloë wat betrokke kan wees by toekomstige gehoortoetse, insluitende Red Cross Children's Hospitaal en Tygerberg Hospitaal, en die navorsers. 'n Unieke kode word aan elke deelnemer toegeken vir data prosessering en jou baba se naam sal nie bekend gemaak word nie - alle inligting sal as vertroulik hanteer word. Die resultate van die studie kan moontlik in 'n finale tesis gepubliseer word maar geen identifiseerbare inligting sal daarin bevat wees nie. Die kodeerde data sal vir 'n minimum van 15 jaar gestoor word volgens die Universiteit van Pretoria se regulasies.

Vrywillige deelname

Ons wil u uitnooi om deel te neem aan die studie. U kan ter enige tyd onttrek van die studie en hoef nie 'n rede te verskaf nie. Sou u onttrek, sal dit nie u kind se behandeling affekteer nie. U kind se gehoor sal steeds gesif kan word, sou jy verkies, maar die resultate sal nie in die studie gebruik word nie.

As jy instem om jou kind se gehoor te sif as deel van hierdie studie, moet jy asseblief die ingeligte toestemmings brief teken op jou kind se toetsvorm.

Vir verdere navrae, kan jy my skakel by 021 938 5303

Byvoorbaat dankie,



Ms. Niki Friderichs
M.Kommunikasiepatologie Student



A handwritten signature in black ink, appearing to read 'De Wet'.

Professor De Wet Swanepoel
Studieleier

Professor Brenda Louw
HOOF: Departement Kommunikasiepatologie

Date:

Dear Mzali,

DIFUNA: UMWANA WAKHO NDIMNXLONGELA UKUFUNDA

Isixeko saseKapa sivumelene ukuba sibambisane ukuba kugonywe abantwana simahla, lelokuba umntwana uyeva kakuhle kwiclinics ezikhethiweyo. Singamalungu eDivision of Communication Pathology eUniversity of Pretoria. Senza uphando lokuva abantwana ukuba bayeva kakuhle. Ukuba abeva sinika uncedo.

Yintoni iscreening test

Le test sizakuyisebenzisa for ukuqonda ukuba umntwana uyeva kuthiwa yi OAE. OAE test isinika inkcazelo yokuba indlebe yomntana injani ngaphakathi.

Aquka ntoni iscreening nge OAE

Le screening test iquka ukufakwa kombobo endlebeni yomntwana. Lombobo uzisa isound unayo ne microphone urecodisha ukuva komntana endlebeni.

Athatha ixesha elingakanani latest

Le test ayibuhlungwanga. Ayakhawuleza ngaphantsi komzuzu.

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 eliphapha linencukacha ukuba uyamazi umntwana wakho akeva kukhuhle okanye umntwana akakathethi ena 1 or 2 eminya ka okanye indlebe yakhe iyavuzwa nceda thetha nonesi kwiclinic ekufutshane nawe. Bazakumthumela eTygerberg or Red Cross.

Kwenzeka ntoni umntwana xa engaphumelelangaitest

Xa umntwana engaphumelelanga uzakwaziswa. Kufuneka use umntwana eclinic kwiveki ezi4 ezizayo ukwenzela aphinde agonywe undlebe kwakhona. Ukuba neyesibini akaphumelelanga uzakusiwa eTygerberg or Red Cross.

Yintoni ezakufuneka kuwe

Kuzakufuneka ipermission yakho ukuba kwenziwe uphando ngokungeva oko. Ukuzubakho mali ibhatalwayo.

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. Niki Friderichs
M.Communication Pathology Student



Professor De Wet Swanepoel
Lecturer / Project Supervisor

Professor Brenda Louw
HEAD: Department of Communication Pathology



APPENDIX D

Clinic Form for Data Collection and Informed Consent



DR. IVAN TOMS INFANT HEARING SCREENING PROGRAM

KUYASA CLINIC	DR IVAN TOMS CLINIC	RAVENSMEAD CLINIC	WALLACEDENE CLINIC
LANGA CLINIC	RETREAT CLINIC	MASINCEDANE CLINIC	WESTRIDGE ROCKLANDS

PATIENT DETAILS

Folder number: _____ - _____
 Name: _____ Gender: M / F
 D.O.B: d d / m m / y y y y
 Address: _____
 CONTACT NUMBERS: _____

_____ weeks/ months

1ST / 2ND OAE TEST

TODAYS DATE: d d / m m / y y y y	SCREENER'S NAME:
*BIRTH WEIGHT: _____ grams	*GESTATIONAL AGE: _____ weeks
*APGAR: /10 /10	

CASE HISTORY

* RISK FACTORS RELATED TO A HEARING LOSS	YES	NO
- Is there a history of hearing loss in children in the family		
- Any of the following illnesses or problems during pregnancy :		
- Cytomegalovirus		
- Toxoplasmosis		
- German measles or any other childhood diseases		
- Herpes Simplex		
- Syphilis		
- Malaria		
- Any ototoxic medication taken during pregnancy		
- Any problems during or after birth :		
- Ototoxic medication administered		
- NICU [>5 days]		
- Severe NNJ or hyperbilirubinaemia (requiring exchange transfusion)		
- Craniofacial anomalies		
- Presence of a stigmata or syndrome		
- Certain viral infections		
Additional comments: _____		



OAE SCREENING RESULTS

RIGHT EAR		LEFT EAR	
<input type="checkbox"/> PASS	<input type="checkbox"/> REFER	<input type="checkbox"/> PASS	<input type="checkbox"/> REFER
<input type="checkbox"/> NOT DONE	<input type="checkbox"/> TECHNICAL FAULT	<input type="checkbox"/> NOT DONE	<input type="checkbox"/> TECHNICAL FAULT

OAE FOLLOW-UP DATE

d d / m m / y y y y

HEARING PREVIOUSLY SCREENED

GROOTE SCHUUR HOSPITAL	TYGERBERG HOSPITAL	OTHER _____
---------------------------	-----------------------	----------------

COMMENTS

INFORMED CONSENT FROM PARENT/CAREGIVER FOR RESEARCH	
Signature:	Date:
PARENT/CAREGIVER'S PERCEPTION	<input type="checkbox"/> <input type="checkbox"/>

REFERRALS

TYGERBERG HOSPITAL	RED CROSS CHILDREN'S HOSPITAL
	Appointment date
AUDIOLOGY & ENT	d d / m m / y y y y
SPEECH THERAPY	d d / m m / y y y y
OTHER:	d d / m m / y y y y



APPENDIX E

Letter to Medical Superintendents at Tygerberg and Red Cross Children's Hospital

11 May 2009

Attention: Dr. Carter, Medical Superintendent Tygerberg Hospital

**RE: PERMISSION TO ACCESS HOSPITAL FILES FOR RESEARCH AND CONTINUED
SERVICE DELIVERY**

The City of Cape Town Health Department has agreed to pilot a community-based infant hearing screening project, namely the Ivan Toms Infant Hearing Screening Program, whereby every child being immunized receives a free OAE test at selected clinics in the metropolitan area. As Audiologist from the Carel du Toit Centre I have assumed the role of program manager and am currently doing my Masters with the University of Pretoria on the efficacy of this community-based infant hearing screening program. I have partnered with the Medical Research Council and University of Cape Town to enable me to effectively run and research this program.

I would therefore like to request direct access to the hospital files of children participating in the Ivan Toms Infant Hearing Screening Program in terms of all audiological and middle ear related information at tertiary level. The identity of the infants and parents/caregivers will not be revealed and all information is to be treated in the strictest of confidence.

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

Sincerely,



Ms. Niki Friderichs

M.Communication Pathology Student



Professor De Wet Swanepoel
Lecturer / Project Supervisor

Professor Brenda Louw

HEAD: Department of Communication Pathology

University of Pretoria

Telephone : 00 27 12 420-2357

brenda.louw@up.ac.za

Pretoria, 0002

Facsimile : 00 27 12 420-3517

www.up.ac.za

11 May 2009

Faculty of Humanities Department of
Communication Pathology

Attention: Dr. Blake, Senior Medical Superintendent Red Cross Children's Hospital

**RE: PERMISSION TO ACCESS HOSPITAL FILES FOR RESEARCH AND CONTINUED
SERVICE DELIVERY**

The City of Cape Town Health Department has agreed to pilot a community-based infant hearing screening project, namely the Ivan Toms Infant Hearing Screening Program, whereby every child being immunized receives a free OAE test at selected clinics in the metropolitan area. As Audiologist from the Carel du Toit Centre I have assumed the role of program manager and am currently doing my Masters with the University of Pretoria on the efficacy of this community-based infant hearing screening program. I have partnered with the Medical Research Council and University of Cape Town to enable me to effectively run and research this program.

I would therefore like to request direct access to the hospital files of children participating in the Ivan Toms Infant Hearing Screening Program in terms of all audiological and middle ear related information at tertiary level. The identity of the infants and parents/caregivers will not be revealed and all information is to be treated in the strictest of confidence.

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

Sincerely,



Ms. Niki Friderichs

M.Communication Pathology Student



Professor De Wet Swanepoel
Lecturer / Project Supervisor

Professor Brenda Louw
HEAD: Department of Communication Pathology



APPENDIX F

Ethical Clearance from the Medical Superintendents at Tygerberg and Red Cross Children's Hospital



Departement van Gesondheid
Department of Health
iSebe lezeMpilo



Verwysing
Reference
Isalathiso

Navrae
Enquiries
Imibuzo

Telefoon
Telephone
Ifowuni

Dr M.A. Mukosi

021-938 5966

Tygerberg Akademiese Hospitaal en
Mitchellsplein & Tygerberg Mondgesondheidsentrums

Tygerberg Academic Hospital and
Mitchells Plain & Tygerberg Oral Health Centres

Isibhedlele Sase Tygerberg Kwakunye Ne
Mitchells Plain Neziko Lamazinyo Lase Tygerberg

Privaatsak X3/ Private Bag X3
Tygerberg, 7505

Date: 18th December 2009

Ref: Your Research / Clinical trial No 99050839.: Efficacy of a Community-Based Infant Hearing Screening Programme in the Western Cape.

Dear Mrs N Friderichs

PERMISSION TO CONDUCT YOUR RESEARCH/CLINICAL TRIAL AT TYGERBERG HOSPITAL

In accordance with the Provincial Research policy and Tygerberg Hospital Notice No. 40/2009, permission is hereby granted for you to conduct the above-mentioned research/clinical trial here at Tygerberg Hospital.

DR PTA CARTER
CHIEF DIRECTOR: TYGERBERG HOSPITAL

Attention Ms. Friderichs and co-researchers

**PERMISSION TO ACCESS HOSPITAL FILES FOR RESEARCH AND
CONTINUED SERVICE DELIVERY**

I hereby grant Ms. Friderichs direct access to the hospital files of children participating in the Ivan Toms Infant Hearing Screening Program to obtain audiological and middle ear related information. The identity of the infants and the parents/caregivers will not be revealed and all information is to be treated in the strictest of confidence.



Dr. Blake

Senior Medical Superintendent
Red Cross Children's Hospital

1 December 2009

Date

APPENDIX G

Letter of Consent - Faculty of Humanities, University of Pretoria



100
1908 - 2008



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Postgraduate Committee

18 September 2009

Dear Prof Swanepoel,

Project: Efficacy of a Community-Based Infant Hearing Screening Programme in the Western Cape
Researcher: N Friderichs
Supervisor: Prof DW Swanepoel
Department: Communication Pathology
Reference number: 99050839

Thank you for the well prepared application you submitted to the Postgraduate Committee, Faculty of Humanities

I have pleasure in informing you that the Postgraduate Committee formally **approved** the above study on 17 September 2009. The approval is subject to the candidate abiding by the principles and parameters set out in her application and research proposal in the actual execution of the research.

The Committee requests that you convey this approval to Ms Friderichs

We wish you success with the project.

Sincerely

Prof. David Medalie
Acting Chair: Postgraduate Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: david.medalie@up.ac.za

Postgraduate Committee Members: Prof S Africa; Prof PJ Botha; Dr C Carbonatto; Prof E Dreyer; Dr A Gildenhuys; Prof AE Goslin; Ms H Kirstein; Prof L Kriel; Prof D Medalie (Acting Chair); Dr S Ouzman; Prof I Pikirayi; Prof MMME Schoeman; Prof JS Sharp (Chair); Prof GJ Swart; Prof R Vally; Prof H van der Mescht; Prof A Wessels; Ms P Winst



APPENDIX H

Tertiary Hospital Level (Diagnostic) Data Collection Form



Tertiary Hospital Level Data Collection Form
Dr. Ivan Toms Infant Hearing Screening Program

Hospital folder number.....									
D.O.B.....				d	d	m	m	y	y
Date of evaluation.....				d	d	m	m	y	y
Follow-up Audio&ENT date.....				d	d	m	m	y	y

*** TYMPANOMETRY**

1000Hz probe tone	
226 Hz probe tone	
Right ear	Left ear
Normal/Type A	Normal/Type A
Abnormal	Abnormal
Type B	Type B
Type C	Type C

*** OAE**

Right ear	Left ear
Pass	Pass
Refer	Refer
Not done	Not done
Technical fault	Technical fault

*** AABR**

Right ear	Left ear
Pass	Pass
Refer	Refer
Not done	Not done
Technical fault	Technical fault

*** ABR/ASSR**

Right ear	Left ear
Normal range	Normal range
Abnormal/hearing loss	Abnormal/hearing loss
Not done	Not done
Technical fault	Technical fault

*** VRA/PLAY AUDIOMETRY**

Right ear	Left ear
Normal range	Normal range
Abnormal/hearing loss	Abnormal/hearing loss
Not done	Not done
Technical fault	Technical fault

*** EAR-, NOSE & THROAT EXAMINATION**

Right ear	Left ear
Normal	Normal
MEE	MEE
OM	OM

*** ENT MANAGEMENT**

None	
Pressure equalizing tubes	
Comments	