

FEASIBILITY ASSESSMENT OF A UNIVERSAL NEWBORN HEARING SCREENING PROGRAMME AT RAHIMA MOOSA MOTHER AND CHILD HOSPITAL

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Neurodevelopment

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DECLARATION

I, Jacqueline Kim Bezuidenhout declare that this research report is my own work. It is being submitted for the degree of Master of Science in Neurodevelopmental. It has not been submitted before for any degree or examination at this or any other University.

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26th day of April, 2016

DEDICATION

To my amazing husband Craig, and my rays of sunshine: Matthew, Megan and Emily

ABSTRACT

Context: Universal Newborn Hearing Screening (UNHS) is not routinely performed in South African state-run hospitals. Early identification of hearing impairments and subsequent early intervention, results in improved speech and language development and overall better cognitive outcomes.

Objectives: We aim to investigate the number of neonates which could be screened for hearing deficits using the currently available staff and equipment, at a single institution over a set period of time, and to describe the outcomes of the screening test.

Design, setting and patients: A prospective feasibility assessment conducting screening hearing tests on neonates born at a secondary level hospital in Johannesburg, South Africa, during a three month period.

Methods: Hospital-based Audiologists conducted a risk factor assessment, otoscopic examinations and Distortion-Product Otoacoustic emissions (DPOAE) testing on the ears of eligible neonates. Repeat testing was carried out on neonates who presented with *refer* findings on the screening test. Testing time and challenges encountered were recorded.

Analysis: Data was entered into Microsoft Office Excel ©, and later analysed using STATA I/C version 11©.

Results: Of 2740 neonates born during the study period, 490 (17.9%) were identified for screening and DPOAE testing was conducted on 121 (4.4%). The majority (74.4%) were screened in the first 24 hours of life. Repeat testing was required in 57 (47.1%) neonates, but only 20 returned for follow-up. The presence of vernix caseosa and excessive ambient noise were factors negatively impacting on the screening process. No maternal or neonatal risk factors were found to be significantly associated with *refer* findings on the screening test.

Conclusion: The existing staff was unable to screen a significant number of neonates using DPOAE testing during the study period. Implementation of UNHS under current circumstances at this research site would likely not be feasible.

Key words: Universal Newborn Hearing Screening; feasibility study; resource-poor settings; otoacoustic emission; hearing loss.

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ABBREVIATIONS

ABR – Auditory Brainstem Response

CMJAH – Charlotte Maxeke Johannesburg Academic Hospital

DPOAE – Distortion Product Otoacoustic Emission

EHDI – Early Hearing Detection and Intervention

HIV – Human Immunodeficiency Virus

HPCSA – Health Profession Council of South Africa

IT – Information Technology

JCIH – Joint Committee on Infant Hearing

NICU – Neonatal Intensive Care Unit

OAE – Otoacoustic Emission

RMMCH – Rahima Moosa Mother and Child Hospital

SA - South Africa

USA – United States of America

UNHS – Universal Newborn Hearing Screening

WHO – World Health Organization

1.0 Introduction

1.1 Background

The presence of a hearing impairment in the newborn baby may result in devastating long-term consequences. These include communication delays, emotional disturbances, cognitive deficits and, subsequently, future employment difficulties and career limitations (1). Failure to make the diagnosis within the first six months of life results in the failure to achieve vital stages in speech and language development, and consequently, a poorer prognosis for the individual with regard to their cognitive abilities (2). An expected language delay of two to four years is associated with hearing loss that is detected in infants after the age of six months (3). It is therefore imperative to detect hearing impairments as early as possible in neonates and infants.

The incidence figures for hearing impairments in resource-poor countries are estimated at 6 per 1000 live births compared to an estimated incidence of 2-4 per 1000 in industrialised countries (1). The major relevance of detecting sensorineural hearing loss in the newborn is that it is much more prevalent than any other congenital disorder. Congenital hypothyroidism has a reported prevalence of 50 per 100 000 infants compared to the 260 per 100 000 infants affected with a sensorineural hearing loss, yet screening for congenital hypothyroidism is more commonly done (4). The aetiology of these congenital or early-onset hearing impairments are commonly genetic in origin or secondary to a perinatal insult such as congenital infections, birth asphyxia, hyperbilirubinemia or low birth weight (5). The high incidence of hearing impairment, especially in resource-poor countries, necessitates some

early form of identification so that the necessary interventions can be implemented to limit the devastating long-term complications.

Prior to 1993, in the United States of America (USA), only high risk infants were assessed for hearing loss and the Auditory Brainstem Response (ABR) was the preferred method used (6). Since the recommendation from the National Institute of Health in the USA that all infants should be screened within the first three months of life, all of the 51 states in the USA have successfully implemented Universal Newborn Hearing Screening (UNHS) programs (7).

Currently no formalised system of newborn hearing screening exists at state-run hospitals in Johannesburg, South Africa. Referrals to the audiology department for hearing screening are subsequent to follow-up in the neonatal clinics, where “high risk” individuals are identified and monitored. Risk factors for neonatal hearing loss have been identified by the Joint Committee of Infant Hearing (JCIH) in the USA, and infectious diseases more prevalent in South Africa, namely human immunodeficiency virus (HIV) and malaria, have also been identified as risk factors (8-10).

Although this system of targeted screening is viewed as a positive step toward Early Hearing Detection and Intervention (EHDI), it has been documented to have significant flaws. Studies have shown that by screening only those infants considered “high-risk”, approximately 50% of infants with hearing impediments would be missed (6). Thus, increased efforts are warranted towards ensuring that *every* baby is screened for hearing impairment and not only those with identified risk factors; particularly when the risk factors may also not be contextually relevant.

The World Health Organization (WHO) has stipulated that in order for a screening programme to be successful it needs to meet the following criteria (11):

- the condition screened for should be an important health problem for the individual and community;
- there should be an acceptable screening test and treatment available;
- early commencement of treatment should be more beneficial than if treatment is commenced at a later time. EHDI fulfils this criterion as early interventions aid the child in attaining their appropriate pre-linguistic skills;
- The cost of screening and the provision of an intervention should be economically feasible in relation to the overall medical care. This may be one of the reasons why UNHS has not as yet been successfully implemented in developing countries, as too many other life-threatening health issues such as malnutrition and poor obstetric care, compete for funds (12).

South Africa has made advances towards achieving UNHS by issuing a Hearing Screening Position Statement which is based on the year 2000 Position statement of the JCIH in the USA (13). This concept was proposed by the Professional Board of Speech, Language and Hearing Professions of the Health Professions Council of South Africa (HPCSA). The guidelines propose that (14):

- all infants should be screened by no later than one month of age,
- a full audiological examination is offered by three months of age for those infants not passing the initial screening test, and
- infants who are confirmed as having hearing loss should receive appropriate intervention by no later than six months of age.

The implementation of UNHS requires the National Department of Health to commit both economically as well as human resource-wise in terms of adequate staff numbers. Recent HPCSA data, acquired via communication with Yvette Daffue from the Information Technology (IT) department of HPCSA, shows an increase in the numbers of registered audiologists, and this may go some way towards implementing UNHS in South Africa. Professor Katijah Khoza-Shangase, Chair of the Education Committee – HPCSA Speech, Language and Hearing Board, has commented on the discussions regarding the future training of Audiology technicians. This cadre of professionals will occupy mid-level worker positions, will be larger in numbers; take a shorter time to train (240 credit programme); and therefore increase access to screening services as this will form part of their scope of practice.

1.2 Justification for this study

At present there is limited information regarding the current status of neonatal hearing screening programmes in South Africa (15). In 2008 (one year after the recommendations from the HPCSA regarding EHDI were published), Theunissen and Swanepoel reported that only 27% of public sector hospitals in South Africa were implementing any form of neonatal hearing screening (7). A recent national survey of the audiological services in the private health care sector of South Africa showed that there is significant delay in the overall diagnosis and provision of intervention for hearing loss (16).

In order to achieve UNHS in all South African hospitals, feasibility studies need to be conducted to identify potential shortcomings which will need to be modified before the

programme is implemented nationally. The results of our feasibility assessment could potentially assist future plans for implementation of UNHS.

1.3 Study Proposal

To assess the feasibility of a comprehensive Universal Newborn Hearing Screening programme at a secondary level hospital in Johannesburg, South Africa.

1.4 Study Objectives

Primary objectives:

- 1) To determine the number of babies that could be screened for newborn hearing deficits during a three month period at Rahima Moosa Mother and Child Hospital (RMMCH) with the staff and facilities available during the study period;
- 2) To determine the challenges of implementation.

Secondary objectives:

- 1) To determine the number of screened babies with “refer” findings requiring a diagnostic hearing assessment, and to determine the rate of true versus false positive results.
- 2) To analyse associated risk factors in babies with “refer” findings.
- 3) To determine the rate of follow up for babies with “refer” findings.

2. Literature Review

2.1 Prevalence of hearing loss

Hearing loss has been reported as being the most commonly diagnosed congenital abnormality (2). As compared to congenital hypothyroidism, which has an incidence of 50 per 100 000 infants, there are reportedly 260 per 100 000 infants affected with sensorineural hearing loss (4). Globally, there are an estimated 360 million people living with a hearing impairment (17). The current reported prevalence of neonatal hearing loss in resource-scarce countries is 6 per 1000 live births (1) . This is higher than that of resource-rich countries, which have a reported prevalence of 2-4 per 1000 (1). The discrepancy of neonatal hearing loss between regions can be attributed to several factors, including resource-scarce countries having a higher incidence of infectious diseases such as rubella, cytomegalovirus, measles and HIV; as well as a higher rate of premature deliveries (18). Due to the lack of audiological services and limited screening equipment, neonatal hearing losses are typically detected at a later age in children living in resource-scarce countries (19). These areas also have the additional burden of HIV, malaria and tuberculosis, thereby limiting the available budget of the health care system which can be allocated to neonatal hearing screening (12).

2.2 Definition of hearing loss

A “disabling hearing impairment” in children under the age of 15 years is defined by the WHO as a permanent unaided hearing threshold of 31 dB hearing level or more in the better

ear (20). According to the HPCSA's EHDI position statement, the minimum criterion for screening programmes in South Africa is a bilateral permanent hearing loss of at least 40dB across the frequencies of 0.5, 1, 2 and 4 kHz (14). The shortcomings of these definitions are that children with unilateral or milder forms of hearing loss i.e. 20-30dB, are excluded from being identified as having a hearing impairment. These individuals are at risk of having language delay, but to a lesser degree compared to those with a bilateral hearing loss (1, 5). As per the HPCSA's 2007 EHDI, a unilateral pass criterion with Otoacoustic Emissions (OAE) is required to exclude a bilateral hearing loss. Congenital or early onset hearing impairments are commonly genetic in origin or secondary to a perinatal insult such as congenital infections, birth asphyxia, hyperbilirubinemia, or low birth weight (21).

2.3 Effects of undiagnosed hearing loss

2.3.1. On the individual

The domains of child development include motor (gross and fine); speech and language; cognitive; emotional and personal-social (22). The importance of detecting neonatal hearing loss is that significant developmental delay may result in any of these developmental domains, but especially in the areas of language and cognition. An expected developmental language delay of 2-4 years may occur in a child who only has the hearing loss detected after the age of six months of age (3). It is thus imperative that hearing loss is identified early and that appropriate intervention occurs in a timely manner. Further consequences of hearing loss in the child include possible stigma; social isolation; stress and maltreatment in the form of physical or emotional abuse or even neglect (23). Long term consequences may include academic failure which could result in career limitations and consequent financial difficulties

(1). The income of hearing impaired individuals is typically 40-45% less than those without a hearing disability in resource-rich countries (24).

2.3.2 On society

The societal burden of supporting a child with a specialised need such as hearing loss broadly includes additional financial burdens; specialist educational requirements; professional skills burden; and the requirement of ongoing allied medical care (25). The cost of hearing assistive devices and specialised schooling can be prohibitive, affecting the entire family, and can result in a significant reliance on social services (26). Due to the far reaching consequences of late or no detection of hearing impairment, UNHS has been mandated by several resource-rich countries.

2.4 Universal Newborn Hearing Screening

The aim of UNHS is to screen all newborns for a hearing impairment either just after the birthing process or before being discharged from the birthing facility (9). The early identification of hearing impairments will result in the appropriate intervention being implemented before six months of life (9). Early intervention for hearing impairment will result in improved language, cognitive and emotional development.

2.4.1 UNHS in resource-rich countries

UNHS has been embraced by many resource-rich countries as part of their public health prevention programme. Prior to 1993 in the United States of America (USA), only high risk

infants were assessed for hearing loss and the Auditory Brainstem Response (ABR) was the preferred method which was used when conducting the screening test (6). Since the recommendation from the National Institute of Health in the USA that *all* infants should be screened within the first three months of life, all 51 states have implemented newborn hearing screening programmes (7). The aims set forward by the American Academy of Pediatrics (AAP), according to the 2007 position statement of the JCIH, are that (9):

- all infants should be screened by no later than one month of age,
- a full audiological examination is offered by three months of age for those infants not passing the initial screening test, and
- infants who are confirmed as having hearing loss should receive appropriate intervention by no later than six months of age.

UNHS implementation is on the increase globally, as the benefits of early intervention for the individual, as well as for society, is undisputed. Of concern however, is the limited implementation of UNHS in resource-scarce countries.

2.4.2 UNHS in resource-scarce countries

At present, the total population from the 164 countries which have been classed as constituting the developing world, or resource-scarce regions, is estimated to be five billion people (18). Of this total, South Africa – which has been categorised as a resource-scarce country – has an estimated population of 54 million people, as per the statistics for the 2015 mid-year population estimates (27). There are a diversity of cultures and ethnicities making up this population with 80.2% being African, 8.8% Mixed-race, 2.5% Indian or Asian and 8.4% Caucasian (27). According to The World Bank, South Africa is classified as an upper middle

income country (28). However, despite having a relatively good infrastructure, no UNHS is occurring uniformly across all health facilities, including the private healthcare sector (16).

Infectious diseases such as HIV, tuberculosis and malaria place a major burden on the health care system and available resources in developing countries, and divert funds away from screening programmes such as UNHS (26). Other unique challenges encountered by resource-poor countries are the differing risk factor profiles such as having a large proportion of neonates being delivered in lower care-level facilities of care such as midwife-run obstetric units, which have a limited availability of audiological services (21). These factors contribute to the inadequate implementation of UNHS in resource-scarce countries.

2.4.3 UNHS in South Africa

South Africa has made advances towards achieving UNHS by issuing a Hearing Screening Position Statement which is based on the Position Statement of the Joint Committee on Infant Hearing in the USA. The concept was proposed by the Professional Board of Speech, Language and Hearing Professions of the Health Professions Council of South Africa. The guidelines recommend that (14):

- hearing screening is provided to all infants in well-baby nurseries, or upon discharge from NICU, or at the primary healthcare clinic when infants receive their immunisations at six weeks of age;
- the diagnosis of a hearing impediment must be made by three months of age, and by the latest four months of age, for those newborns who were screened at their primary healthcare clinic;

- the child should receive some form of appropriate intervention by six months of age, and by no later than eight months of age, when referred by the primary healthcare clinic;
- ongoing monitoring for a progressive hearing impairment should be continued in those individuals who are considered high risk, despite having passed their initial screening test.

UNHS is difficult to implement in resource-scarce countries, including South Africa, and a targeted approach needs to be applied to detect hearing impairments. This targeted approach aims to screen “high-risk” individuals. Although this approach is far from the ideals prescribed by resource-rich countries regarding UNHS, it provides a starting point for increasing the coverage of infant hearing screening. As resources improve, and awareness and knowledge regarding the burden of late detection of hearing loss are better understood, a gradual drive to screen all newborns for hearing impediments will hopefully be implemented.

2.5. Risk factors associated with hearing impairment

Targeted hearing screening is recommended when UNHS is unable to be implemented in resource-poor settings. The JCIH (2007) compiled a comprehensive list of aetiologies that may be associated with sensorineural hearing loss.

The JCIH identified the following as risk factors for neonatal hearing impairments, and suggests targeted screening in neonates in which the following factors are identified (9):

1. A permanent childhood hearing loss in the child’s family history.
2. Any concern from the caregiver regarding the child’s speech and language development.

3. A stay of more than five days in the NICU, or any need for assisted ventilation, or exposure to ototoxic drugs (aminoglycosides) and loop diuretics, or if there was hyperbilirubinemia severe enough to require an exchange transfusion.
4. Congenital infections especially cytomegalovirus, herpes virus, rubella, syphilis or toxoplasmosis.
5. Craniofacial abnormalities especially those involving the ear and temporal bone.
6. Physical features of syndromes associated with hearing loss such as neurofibromatosis, osteopetrosis and Usher syndrome - a genetic condition associated with hearing loss and a progressive loss of vision (29).
7. Neurodegenerative disorders such as Hunter's syndrome - a rare metabolic condition resulting in the accumulation of glycosaminoglycans in almost all tissues and organs (30).
8. Culture positive postnatal infections such as bacterial and viral meningitis.
9. A history of trauma to the head, or a systemic insult such as chemotherapy.

In addition to the above risk factors, maternal HIV and malaria infections are contextualised risk factors pertinent to the South African context (8). The current prevalence of HIV in South Africa is 6.3 million people as reported in the 2014 UNAIDS Gap Report. Of these 6.3 million affected individuals, 3.5 million are females aged 15 years and older (31). Infants born to mothers affected by HIV are at a higher risk for premature delivery, low birth weight, and an increased susceptibility for other infections which may result in meningitis (10). Maternal malaria has been included as a risk factor for congenital sensorineural hearing loss, as the treatment of malaria includes drugs that are highly ototoxic (8).

Although a targeted screening such as the one adopted by RMMCH is viewed as a positive step toward Early Hearing Detection and Intervention (EHDI), it has been documented to have significant flaws. Studies have shown that by screening only those infants considered “high-risk” approximately 50% of infants with hearing impediments would be missed (6). Thus, increased effort is warranted to ensure that every neonate is screened for hearing impairment.

2.6 Hearing impairments and current testing equipment

In order to implement a successful screening programme, objective physiological measures need to be utilized so that the results are interpreted correctly. At present, the two standard methods utilised in neonatal auditory screening are Automated Auditory Brainstem Response (AABR) and the Otoacoustic Emissions (OAE) measures (32).

2.6.1. Otoacoustic Emissions (OAE)

OAEs are low energy sound waves which are produced by movement of the hair cells of the cochlea in response to a sound stimulus (33). These sound waves can be measured by a probe that is placed at the external auditory canal, provided there is a healthy, functioning middle ear and outer ear canal (33). The OAEs are a measure of the functional integrity of the cochlea’s response to sound, and thus a good measure of the peripheral auditory system (33).

There are two types of OAE measurements: distortion-product otoacoustic emissions OAEs (DPOAE) and transient evoked otoacoustic emissions (TEOAEs). DPOAEs are produced by combining two tones of different frequencies and then measuring the response produced by the cochlear, at a third frequency, by placing a probe in the external auditory meatus (34). TEOAEs are produced by the hair cells of the cochlea in response to a series of clicks or tone-

burst stimuli of short duration, across the frequency range of 500-4000 Hz (34). Both DPOAE and TPOAE have been used in newborn hearing screening. DPOAE has the advantage over TEOAE in that it is better at detecting emissions with a frequency of more than 5000 Hz (18). High frequency loss patterns are associated with ototoxicity and noise-induced hearing loss (35, 36).

There are many benefits of using OAE testing as a screening tool, namely: the test provides objective evidence of peripheral auditory integrity; it is relatively quick to perform; it is reliable; the procedure can be performed by non-audiologists, an important advantage in resource-constrained environments such as South Africa; and it does not require sedation or co-operation on the part of the patient (37). The major disadvantage of the OAE is that it does not assess the integrity of the auditory nerve (33). This is a significant shortcoming of OAEs testing as an individual with a hearing impairment resulting from an auditory neuropathy would be able to pass the hearing screening with an OAE and thus not be identified for further intervention.

The OAE may also be negatively affected by middle ear pathology such as otitis media, perforated tympanic membrane or otosclerosis, as well as by the presence of any debris in the outer ear canal such as vernix caseosa or cerumen (37). Environmental noise may also interfere with the reliability of the OAE (33). Presence of debris in the outer ear canal has been shown to increase the number of false positives during UNHS prior to hospital discharge; and so it is an important consideration during implementation of any UNHS initiatives (38).

2.6.2. Automated Auditory Brainstem Response (AABR)

The AABR is an electrophysiological response to an acoustic stimulus that is delivered via an earphone (39). Surface electrodes placed on the scalp record the neural activity generated in the cochlea, auditory nerve and brainstem and AABR's are therefore able to provide more information with regards to an auditory neuropathy. The AABR results are less likely to be affected by outer and middle ear conditions (39). The AABR as a screening tool is safe, acceptable, reliable and valid, but the AABR has a higher fail rate when it is used in testing areas with high ambient noise levels, and when inexperienced staff perform the testing procedure (39). AABR is recommended as the screening ideal for neonates who are particularly at risk for an auditory neuropathy – as are neonates who required NICU admission (40). Neonates admitted in the NICU typically have several risk factors present such as prematurity with low birth weight, or the presence of systemic infections, therefore rendering them more susceptible to an auditory neuropathy (40, 41).

2.6.3 Tympanometry

Tympanometry is required at secondary and tertiary hospitals, to distinguish between a middle ear infection and a sensorineural hearing loss resulting in a refer result on the OAE (37). A high frequency 1000Hz probe is placed in the ear and the results are used to refer appropriately for either medical management of a middle ear infection or for further audiological investigations.

2.7 Benchmarks and quality indicators for UNHS

Certain criteria need to be enforced to maintain a suitable standard of UNHS and to ensure optimal inter-programme comparison. The quality indicators set out by the HPCSA for hospital-based screening include (14):

- with regards to universality, 95% of infants should be screened by the time of discharge or by one month of age,
- after the first year of the UNHS programme being implemented, the referral rate for audiological evaluation should ideally be less than 5%,
- a follow-up rate of more than 70%.

A systematic review by Mincarone et al. showed that there is poor standardization of UNHS reporting and screening protocols and they propose that this can be improved with the use of a checklist (42). The reference indicators include universality, timely detection and over-referral. In order to improve the quality of the services offered, regular monitoring of these indicators is required.

2.8 Implementation of UNHS in South Africa

In order for UNHS to be successfully implemented in South Africa, several factors need to be considered.

2.8.1. The availability of local resources

The estimated population of South Africa is 54 million as at July 2015 according to Statistics SA (27). The number of live births in 2014 was 1 207711. If UNHS was fully implemented, all of these newborns would have required screening. The teams of professionals who have historically been responsible for the hearing screening are the speech therapists and audiologists. According to the National Treasury Department of South Africa, the number of

speech and hearing therapists increased from 239 in 2003/04 to 363 in 2008/09 (43). This was an increase of 124 speech and hearing specialists in a five year period. This very minimal growth in the field of audiology is also demonstrated by recent data acquired from the IT department of HPCSA via email communication, which states that as from the 31 December 2015, there are 497 registered audiologists; 925 speech therapists, and a further 1510 therapists registered for both speech therapy and audiology. This results in a total of 2932 registered therapists who are qualified to screen and manage hearing impairments in South Africa. The documented increases in numbers do not correlate with the demand for the audiological services in the country; therefore UNHS has not as yet been successfully implemented.

2.8.2 Screening contexts

The HPCSA's 2007 EHDI position statement recommends that hearing screening should occur at one of three possible time points: the well-baby nursery shortly after birth, the Primary Health Care clinic when the infant is 6 weeks of age and requiring immunisations, or at discharge from NICU (14). A fourth feasible context for screening, as recommended by Khoza-Shangase et. al. is the Midwife Obstetric Unit (MOU) at the three-day neonatal follow-up visit. This study showed that a higher proportion of neonates were screened on day three of life (100%) compared to only 38.1% of those being screened hours after birth (44).

2.9 Conclusion

Hearing loss is the most common congenital condition. The undisputed benefits of early identification and referral for suitable audiological intervention warrant the application of a

UNHS service to the South African population; hence the importance of the current study which aimed at assessing feasibility of a Universal Newborn Hearing Screening Programme at Rahima Moosa Hospital, in Johannesburg, South Africa.

3. Methods

3.1 Study design

We conducted a prospective feasibility assessment. A feasibility study is one in which various parameters are evaluated prior to implementing the main study. These parameters may include the readiness of physicians to enroll patients; follow-up rates; the time required to perform the test; the number of appropriate participants and the evaluation of the outcome measures. Feasibility studies are typically used in assessing screening programmes to see if they can be implemented at a population level (45).

3.2 Study setting

The study was conducted at RMMCH, an academic secondary level hospital in Johannesburg, South Africa. In order to provide a realistic assessment of the feasibility of implementing UNHS at this institute, only the existing staff and equipment were utilized.

3.3 Study population and sample

The study population was drawn from all neonates born at RMMCH using stratified systematic sampling. Selected neonates from the postnatal wards, the neonatal unit and NICU were assessed. The postnatal wards accommodate healthy babies born via caesarean section or normal vaginal delivery. The neonatal unit cares for neonates born prematurely with birth weights <1800g; neonates with infections; neonates with perinatal asphyxia; and neonates with jaundice. Neonates admitted to NICU, mostly display complications of prematurity or neonatal encephalopathy.

The delivery rate at RMMCH is currently approximately 20-30 neonates per day. This number was too large for the current audiology team to assess, so a representative sample was taken. A total of 10 neonates was considered to be a realistic number to be screened by one audiologist daily. To avoid enrolling a biased sample, every third neonate appearing on the birth registries in the labour ward and in the Caesar theatre was added to the list of potential neonates to be screened if they met eligibility criteria. The sample was stratified to be representative of the hospital's current Caesarean section rate of 30%, by selecting 30% of the neonates to be tested from the Caesar theatre birth register and the remaining 70% from the labour ward registry. A total of 10 neonates were identified every day. This stratified, systematic sampling was done at the start of each weekday by the researcher.

Inclusion criteria

- All neonates born at RMMCH between the 01 January 2012 and 31 March 2012.
- At the time of screening, infants were to be younger than thirty days of chronological age.

Exclusion criteria

- Neonates not born at RMMCH and transferred in from other facilities.
- Any neonate whose parent/caregiver refused to provide informed consent.
- Neonates who spent more than a month in NICU were excluded as they would have exceeded the age cut-off of one month.

3.4 Study procedure

3.4.1 Identification and enrolment

Auditory screening assessments took place during weekday working hours and were conducted by the hospital's audiologists during the defined three month period. Healthy neonates were screened within the first few days of life, while neonates with complications preventing earlier screening were screened when possible within the first 30 days of life. The screening team consisted of four qualified audiologists. One audiologist was assigned to carry out the screening tests each week, on a rotational basis. No additional staff were employed to assist in the screening of these neonates, and the screening of the neonates was to be factored into their already busy schedules of ward and clinic responsibilities.

Neonates were selected from the birth registries in labour ward and Caesar theatre as per the stratified systematic sampling described above. A total of ten neonates were selected daily by the researcher; three from the Caesar theatre registry and seven from the labour ward registry.

Each of these pre-identified neonates was assigned a study number by the researcher and the list of neonates requiring testing was given to the allocated audiologist. As this was a feasibility study, the audiologist would perform testing on as many babies as possible from the list. The audiologist would commence screening in numerical order as per the list of identified neonates. In the event that the audiologist was unable to locate a patient who may have been discharged or if the caregiver refused screening, the audiologist would proceed to the next neonate numerically on the list. The study protocol was explained to one or both parents and they were provided with an information sheet containing pertinent information about the testing (Appendix A). Written informed consent was obtained prior to testing (Appendix B). This informed consent was only obtained immediately prior to the screening, so that there would be no possibility of a caregiver consenting to the screening and the neonate not being assessed due to time constraints or equipment malfunction. The neonates' clinical history was obtained in all cases prior to testing. This was obtained both verbally from the parent and by obtaining information documented in the neonate's hospital file. Testing was initially conducted in a side room outside the postnatal ward, but due to noise interference was later moved to the audiology department. For those neonates who had been admitted to the neonatal unit, screening was carried out in the neonatal ward. Neonates admitted to NICU were screened only after being discharged from NICU as the high ambient noise levels would have interfered with the screening process.

3.4.2 Measurements

Each neonate who was screened first underwent an otoscopic examination, performed by the audiologist, to assess patency of the ear canal as this could potentially impede the screening procedure and impact the result. Thereafter, Distortion Product Otoacoustic Emission

(DPOAE) testing was conducted on both ears, giving either a “pass” or “refer” result. The machine used was a Natus Bio-logic AuDX® (Appendix C).

- A “pass” result was obtained if the patient passed the DPOAE test across three or more of the five tested frequencies (1000kHz, 2000kHz, 3000kHz, 4000kHz and 5000kHz) at 25-30 decibels hearing level, in both ears.
- A “refer” result implies that the patient did not pass the hearing screening test across three or more of the five tested frequencies (1000kHz, 2000kHz, 3000kHz, 4000kHz and 5000kHz) at 25-30 decibels hearing level, in both ears. A “refer” result could be the result of an actual hearing deficit, or due to noise interference.

The staff member conducting the screening test would record the results of the test; indicate the time taken to screen the neonate; what the challenges had been encountered during the testing process; and what the plan of action would be (See data capture sheet, Appendix D). Babies receiving a “pass” result were discharged without a planned follow-up, unless follow-up was clinically indicated. Newborns receiving a “refer” result were rescreened within a month of initial screening. The re-screening procedures included an otoscopic examination, a tympanogram, and a repeat DPOAE. The tympanogram was only performed on babies who had not passed the initial screening test, as the equipment was located in the Speech and Hearing Department and neonates were required to attend the department for testing. Neonates who were too ill to leave the ward were thus unable to be tested for a tympanogram. The tympanogram would possibly provide helpful information pertaining to conduction deficits in those who had *referred* on the initial DPOAE. If the results of the re-screening procedures were still inconclusive, the infant was referred for diagnostic ABR performed at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

3.4.3 Study data sheet

A study data sheet was completed by the staff member for each neonate that was screened (Appendix D). Information on this form was verified by the researcher, by retrieving information from the hospital file and from asking the caregiver questions. The study data sheet comprised three sections which included general information of the baby; the presence of risk factors; and the findings on clinical assessment.

- **General information** provided information regarding the demographics of the babies being screened and included:
 - type of delivery,
 - birth weight,
 - HIV exposure,
 - Apgar scores,
 - ward where the neonate was located.
- **A risk factor assessment** was completed for each neonate screened. The following items were included:
 - a family history of permanent childhood hearing loss,
 - admission to NICU, and if so, was assisted ventilation required,
 - exposure to ototoxic drugs such as aminoglycosides or loop diuretics,
 - hyperbilirubinemia requiring exchange transfusion,
 - congenital infections such as: cytomegalovirus, herpes, toxoplasmosis, rubella, syphilis, HIV and malaria ,
 - the presence of craniofacial abnormalities.

- **Examination Findings**

The data sheet captured information from the initial screening as well as the re-screening procedure, if this was required.

- Otoscopy examination was vital to provide information regarding the presence or absence of vernix, or if there were anatomical defects present such as a narrow ear canal. Additional information pertaining to the otoscopic examination could be indicated.
- Data indicating which frequencies, ranging from 1000 kHz-5000 kHz, had been tested and passed, as well as the duration taken to complete testing, were captured.
- In addition, data indicating the challenges perceived by the screening team that may have resulted in “refer” results were also captured.

3.5 Statistical analysis

Data was entered into Microsoft Office Excel ©, and later analysed using STATA I/C version 11© (46). Numerical data was described in terms of median, and interquartile range. The outcome variables were the total number of neonates screened, and the number of those screened who received a pass or refer result. Chi square tests were used to identify associations between risk factors and unsuccessful hearing assessments. Odds ratios with 95% confidence intervals were used to quantify significant associations. P-values less than 0.05 were considered statistically significant (47).

3.6 Ethical considerations

The study adhered to the Singapore Statement on Research Integrity guidelines in terms of research into human subjects (48). Therefore, ethical approval to conduct this research trial was obtained from the Committee for Research in Human Subjects at the University of Witwatersrand (Medical). HREC number M111119 (Appendix E).

Informed consent was signed by the parents or legal guardians of all participants enrolled onto the trial. Access to the Excel database was limited to the researcher.

All neonates screened were assigned a unique study identification number to ensure confidentiality. This number was assigned to the individual on the day of the initial screening and was the only form of identification used if the baby was brought back for repeat DPOAE.

Appropriate counselling and referral would be provided to the caregivers of a baby found to have a hearing impairment.

4. Results

4.1 Study Population

During the study period, 2740 neonates were born at RMMCH. A total of 490 neonates were identified and assigned study numbers during the three month period over which the study was conducted. Of the sample group, two mothers refused consent for their infants to be screened. One hundred and twenty one neonates were screened, representing 24% of the identified neonates. A total of 369 neonates (75.3%), were identified for potential screening but did not receive a hearing assessment. Thus, of the 2740 neonates born at RMMCH during the three month study period, 4.4% underwent screening.

Eight (7%) of the 121 neonates that were screened were assessed in the neonatal unit whilst the remainder (n=113, 93.4%) were screened in the postnatal wards. Seventy-nine (65.3%)

neonates were born via normal vaginal delivery, with two (1.7%) requiring assisted delivery, and 40 (33%) were born via caesarean section. This distribution of delivery patterns was in accordance with the hospital's anticipated caesarean section rate of 30%. During the three month screening period there were 855 caesarean section deliveries, making up 31.2% of the total deliveries. Of the 121 study participants screened, 90 (74.4%) were HIV unexposed, 29 (24%) HIV exposed, and two (1.6%) were born to mothers who had, at the time of screening, not yet been tested for HIV. These sample population demographics are depicted in Table 4.1.

Table 4.1 Sample population demographics

	Neonates screened (N=121)
Birth weight (gram) n (%)	
<2500g	16 (13.2%)
≥2500g	105 (86.8%)
Type of delivery n (%)	
NVD	79 (65.3%)
Caesarean section	40 (33%)
Assisted delivery	2 (1.7%)
HIV exposure n (%)	
Yes	29 (24%)
No	90 (74.4%)
Unknown HIV status	2 (1.6%)
ICU admission after birth n (%)	
Yes	2 (1.7%)
No	119 (98.3%)
APGAR Scores	
1 minute Apgar ≤5	6 (5%)
1 minute Apgar >5	115 (95%)
5 minute Apgar ≤5	0
5 minute Apgar >5	121 (100%)

10 minute Apgar ≤ 5	0
10 minute Apgar >5	121 (100%)

Birth weights ranged from 1700g to 4080g with a median of 2915g, as depicted in Figure 4.1.

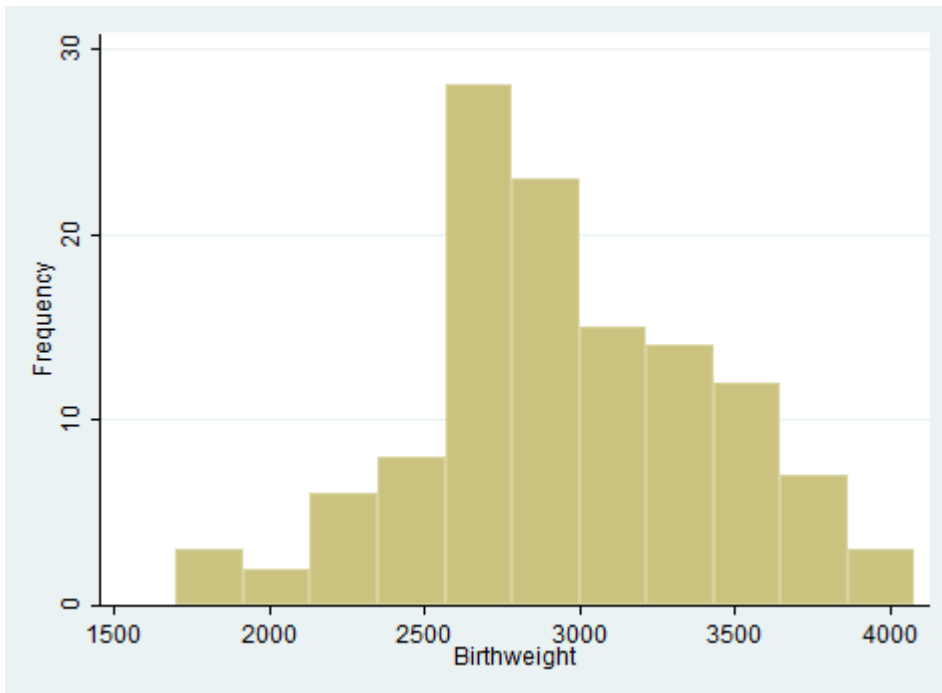


Figure 4.1 Distribution of birth weights

Ninety one (75.2%) of the 121 neonates were screened in the first 24 hours of life. A further 21 (17.4%) were screened at 24-48 hours of life, and seven (5.8%) were screened at 48-72 hours of life. The remaining two (1.6%) were screened on day seven of life.

4.2 Screening results

Fifty-seven of the 121 participants (47.1%) had a refer result at the first screening, whilst the remainder were discharged from the program because they passed the screening bilaterally. Of the 57 due to come back for repeat DPOAE, only 20 (35.1%) returned for follow-up. Upon repeat DPOAE, 18 of the 20 (90%) passed and therefore were subsequently discharged and two (10%) required ABR as per research protocol. Of the neonates requiring ABR, one neonate was a term baby, born vaginally, with a birth weight of 3.27 kg, and had no associated

risk factors. On the initial screening test, the audiologist indicated that noise and vernix caseosa contributed towards the challenges experienced. At the repeat DPOAE, the otoscopic examination was normal and the challenge faced was that the baby had been crying during the second assessment. The caregiver did not return with the infant for the third follow-up.

The second neonate who referred on two DPOAEs was a low birth weight infant of 2.48 kg, who was delivered by vacuum delivery, and had no associated risk factors. Vernix caseosa and noise were identified as challenges experienced during the initial screening. This neonate did not pass the repeat DPOAE and, as per our protocol, should have been referred to CMJAH for an ABR. However, at the time of our study the ABR machine at the CMJAH was not functional and hence this neonate underwent a third DPOAE, which was successfully passed.

Ultimately only 83 neonates were successfully screened, as 38 individuals were lost to follow-up. Figure 4.2 depicts the outcomes of the screening process in a flow diagram.

Neonates identified

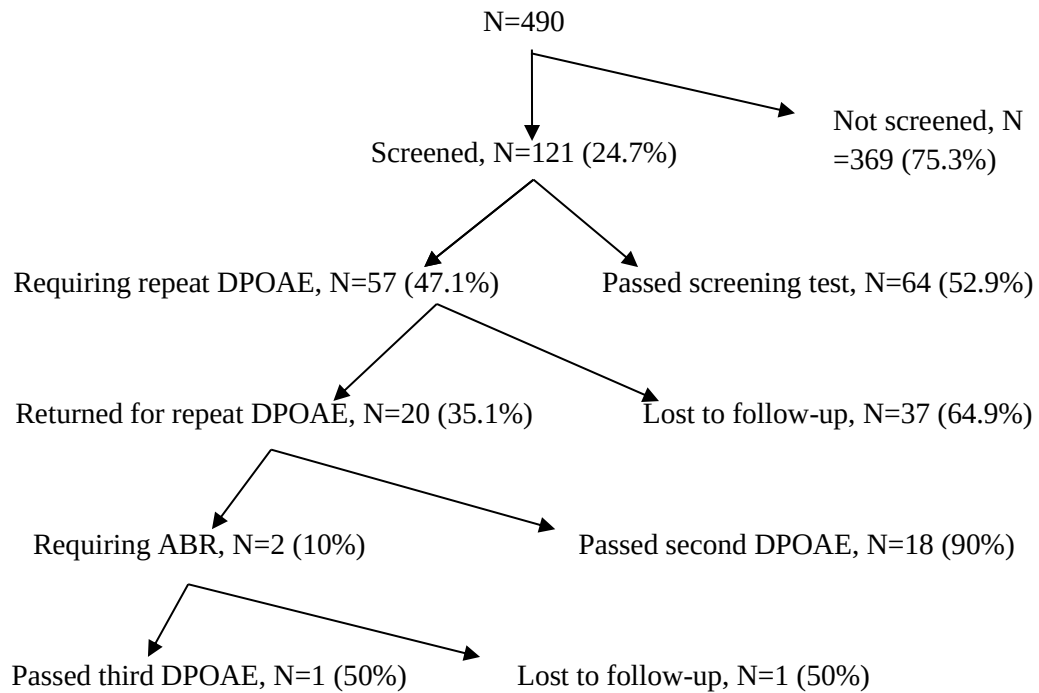


Figure 4.2 Flow diagram showing the screening outcomes

4.3 Risk factor assessment

The assessment of the presence of risk factors showed that 2 of the 121 neonates screened (1.7%) had been admitted to NICU, and both babies required assisted ventilation. The first neonate had an NICU stay of six days and passed the initial DPOAE which was conducted on day 7 of life. The second neonate was admitted to NICU for eight days and was considered high risk for a possible hearing deficit as several risk factors were identified, namely:

- a positive family history (the maternal uncle) of permanent childhood hearing loss

- the presence of a congenital syphilis infection
- requiring intermittent positive pressure ventilation in NICU for six days
- postnatal exposure to aminoglycoside antibiotics.

In this neonate, the initial DPOAE result was that of a bilateral ‘refer’, but upon retesting after discharge from NICU, the results were a bilateral ‘pass’.

Other risk factors identified in the screened population, included a family history of hearing loss recorded in ten (8.3%) neonates. Four of the neonates with a positive family history had a refer result on their initial DPOAE and the caregivers were requested to return for follow-up testing. Only one infant was brought back for a second DPOAE, which was passed successfully, and the remaining three infants were lost to follow-up.

Exposure to ototoxic medications in the form of aminoglycosides was recorded in three neonates in the screened cohort (2.5%). One of these neonates with ototoxic drug exposure required a repeat DPOAE, which was successfully passed.

One neonate born at full term with a birthweight of 2.8kg had a raised bilirubin level of 332 $\mu\text{mol/l}$ at 72 hours of life. According to the NICE guidelines for neonatal jaundice, phototherapy was all that was required as the management (49). Although the initial DPOAE generated a ‘refer’ result, the infant passed the repeat DPOAE.

No neonates in the screened cohort presented with craniofacial abnormalities.

Table 4.2 displays the risk factors according to the two groups – those that passed the initial DPOAE (n=64) and those requiring a repeat test (n=57).

Table 4.2 Outcome groups on initial DPOAE screening and recorded risk factors

	'Passed' screening test N=64	Requiring repeat DPOAE, N=57	Total screened N=121
Admitted to NICU n (%)	1 (1.5%)	1 (1.7%)	2 (1.6%)
Family history of permanent hearing loss n (%)	6 (9.3%)	4 (7%)	10 (8.2%)
Exposure to ototoxic drugs n (%)	2 (3.1%)	1 (1.7%)	3 (2.4%)
Hyperbilirubinemia n (%)	0 (0%)	1 (1.7%)	1 (0.8%)
Congenital infection n (%)	0 (0%)	1 (1.7%)	1 (0.8%)

Risk factors were not significantly associated with *referring on* or passing the DPOAE.

4.4 Otosopic examination results

Otosopic examinations revealed that 86 (71.1%) neonates had vernix caseosa in their external auditory canal, and 39 (32.2%) were subjectively considered to have narrow ear canals. Other findings included: the presence of blood in the right ear canal (n= 1), a pre-auricular skin tag (n= 1), and an ear canal that collapsed during testing (n= 1).

Of the 86 neonates identified with vernix caseosa in the auditory canal, 50 (89.3%) required a repeat DPOAE compared with seven of the 35 neonates (20%) who did not have the substance in the external auditory canal (OR: 4.0, 95% CI: 1.75-9.16, p= 0.0001).

The occurrence of a narrow ear canal was a subjective finding identified on otoscopic examination by the audiologist in 39 cases; 18 (46.2%) of which required a repeat DPOAE versus 39 (47.6%) of those without a narrow canal (OR: 0.86, 95%CI: 0.46-1.61, p= 0.88).

4.5 Challenges identified by the assessor during the screening procedure

The audiologists conducting the testing recorded challenges encountered which made the screening process more difficult. These challenges did not necessarily result in a refer result, but were any factors that may have contributed towards a prolonged testing time. The assessors documented their starting time when commencing the screening and upon completion would again document the time; therefore giving a record of the time required to screen each newborn. The mean time taken to screen each neonate was 11 minutes 17 seconds, with the longest duration being 40 minutes and the shortest screening time being 5 minutes. The median time taken to screen was 10 minutes. Thirty four neonates had a screening time of longer than 11 minutes, and 11 (32%) of these neonates had no identifiable challenges contributing towards their prolonged testing time.

Challenges included equipment failure, noise interference, and vernix caseosa in the external auditory canal.

- Equipment failure was identified as a challenge by the assessors in five (4.1%) cases, two of which required repeat DPOAE. Only one patient requiring repeat testing returned and subsequently passed the DPOAE.
- Noise interference was identified in 39 (32.2%) cases and 27 (69.2%) of these required a repeat DPOAE (OR: 2.25, 95%CI 1.14-4.44, $p=0.001$). Half of these children, (14/27, 52%) also had a finding of vernix caseosa in their ears.
- Vernix caseosa was identified by the audiologists as a challenge in 40 (33.1%) neonates, with 39 (97.5%) neonates requiring a repeat DPOAE (OR: 0.015, 95%CI: 0.002-0.1155, $p<0.0001$). The presence of vernix caseosa was documented as an

examination finding in 86 (71%) infants, but was identified as a challenge complicating testing in only 40 (33%) infants.

- Other challenges identified included crying (n=4, 3.3%), the screening session being interrupted (n=1, 0.8%), and a baby that was hiccupping during the testing procedure (n=1, 0.8%).

These challenges, as well as the initial screening results are depicted in Table 4.2.

Table 4.3 DPOAE screening test results for the cohort of 121 neonates

Initial test result, n (%)	
Pass	64 (53%)
Refer	57 (47%)
Difficulties encountered during testing, n (%)	
Vernix	40 (33%)
Noise interference	39 (32%)
Equipment	5 (4.1%)

4.6 Other challenges identified during the study

During the three month testing period, 121 neonates out of a total of 2740 live birth deliveries (4.4%) were screened. Several challenges were encountered during the testing period:

- High patient-assessor ratio – a team of four audiologists were available to conduct all the screening tests. However, one of the audiologists resigned during the study period and the diminished team was unable to test all the newborns. Prior to the decrease in the staff complement, the audiologist on duty would see, on average 12 neonates per week. This decreased in the third month of testing, to 7 neonates per week (Figure 4.3).

- Technical difficulties were encountered with the OAE machine in the second week of screening, and the machine was sent in for repairs. The repair process took three weeks to complete. Only one neonate was screened during this period and screening could only recommence once an OAE machine had been loaned from the Wits audiology department in the fourth week of testing. Another technical difficulty encountered was that at the time of the screening, the ABR machine at CMJAH was also being repaired. This resulted in the two neonates who should have had an ABR after not passing the DPOAE on two occasions, requiring a third DPOAE.

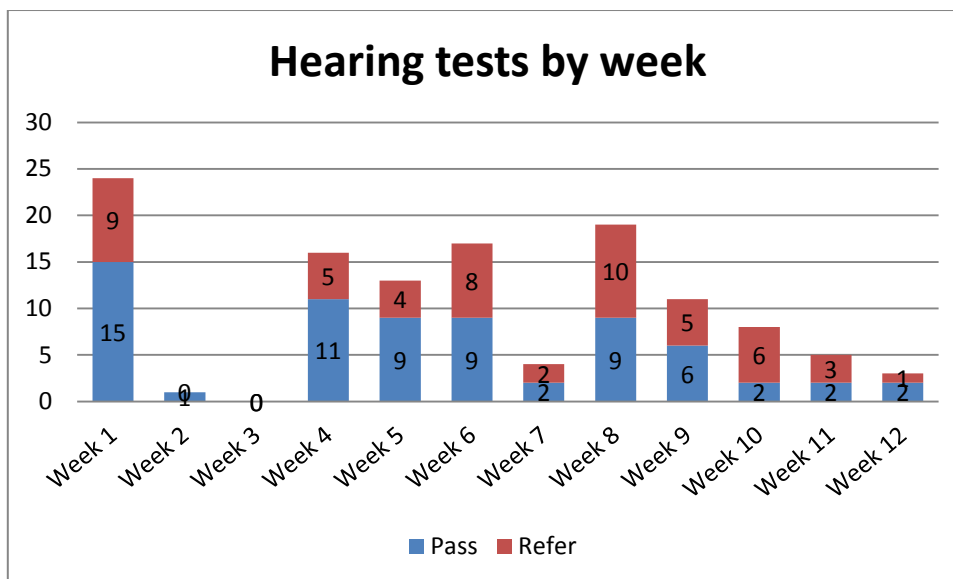


Figure 4.3 Bar diagram indicating the number of neonates screened per week and the number of ‘refers’ per week

5.0 Discussion

The study results will be discussed in this section. Challenges encountered will be described, and recommendations for clinical practice will be made.

This study highlighted many of the challenges present in our setting that are preventing the implementation of UNHS. A comprehensive set of standards has been stipulated by the JCIH (2007) for evaluating the efficacy of EHDI. These benchmarks include (9):

- A minimum of 95% of all neonates are screened by one month of age,
- The referral rate of those not passing their initial screening test should be less than 4%.
The return rate of those who require further diagnostic evaluation after failing the initial screening, should be at least 95%,
- By three months of age, 90% of infants who failed the screening tests should have a thorough diagnostic evaluation. Infants with confirmed hearing loss should receive amplification, if the family elects to amplify, within a month of confirmed diagnosis.

These benchmarks of quality for UNHS are difficult to achieve in developing countries (12).

5.1. Main findings

The implementation of a UNHS programme at RMMCH, a secondary institute, is not attainable in the current setting with the available staff and equipment. The primary objective of this study was to assess the number of newborns that could be screened in a three month period at RMMCH utilising the currently available staff, equipment, and facilities. Determining the number of neonates who could be screened during this feasibility assessment enabled us to assess if a UNHS programme could be successfully implemented at RMMCH

and what challenges would need to be addressed prior to the initiation of the programme. During the specified study period, 2740 neonates were born at the facility and only a very small number of them – 121 (4.4%) had an initial DPOAE. The final number of neonates who were successfully screened was only 83 in total (3%), as 38 neonates were lost to follow up prior to receiving a final result.

When the study was initiated we had anticipated screening ten neonates a day through a five day work week, for a continuous three month period. However, at the end of the study period, 490 neonates had been identified for screening, with only 83 neonates having been screened. This was significantly less than what we had anticipated. Several factors which contributed to this poor screening coverage included factors that prolonged the screening time such as vernix, high ambient noise levels and equipment failure. Other factors included the high ‘refer’ rate and inadequate number of screening staff. Our primary objective was to assess the number of neonates that could be screened at RMMCH in a three month period. With only 3 % of identified neonates being screened, leads one to presume that UNHS, cannot as yet, be successfully implanted in this setting, and that targeted screening should be considered.

Targeted screening for hearing loss is an option which needs to be considered in settings in which adequate screening numbers cannot be attained. The American Joint Committee on Infant Hearing has recommended targeted newborn hearing screening, in resource-scarce countries, for infants considered to be at high risk of hearing loss (9). This may be acceptable as an interim measure, but it has been reported that targeted screening misses up to 50% of infants with hearing impairments, therefore this is a poor alternative (50).

The role of UNHS is to detect hearing impairment and provide intervention for children requiring hearing amplification before the major speech and language milestones have been missed. Children with a disability – like hearing loss – in a resource-scarce country, are at high risk of experiencing malnutrition and physical abuse (23). Access to social services is also limited. The detection of a disability is a priority, especially if intervention is available (50). The other issue with such targeted screening is that the targeted screening programmes whose risk factors have been stipulated by the JCIH – an organisation based in a resource-rich nation – may not identify risk factors which are prevalent in resource-scarce countries e.g. infectious diseases, non-elective caesarean delivery, maternal hypertension and malnutrition (21). Research determining risk factors which are more relevant for targeted screening in a developing country is needed. The WHO Report on Newborn and Infant Hearing Screening recommends UNHS, utilising either OAE or ABR, be the goal of both developed and developing countries (5).

5.2 Challenges encountered during screening

Several challenges were identified by the professionals conducting the screening tests. Identified challenges will be discussed.

5.2.1 Staff

The primary challenge encountered in our study was the limited, although enthusiastic, number of audiologists available to perform the screening tests. The team was initially comprised of four audiologists, three of whom held senior positions within the department and one who was completing her community service year. During the second month of screening, one of the audiologists resigned, thus reducing the team to only three. The audiologists worked

according to a pre-planned schedule as to who was assigned to conduct the weekly screening tests, but with their team being reduced by 25% they needed to redistribute their resources so as to cover all of their clinic as well as ward duties. With 2740 neonates being delivered during the three month screening period, 228 neonates would need to be screened per week, and 45 neonates would require screening daily during a five-day work week. Audiologists employed in the state sector, do not currently receive financial remuneration for any overtime work and so screening had to take place during regular working hours. A greater number of audiologists and/or speech therapists would be required to meet screening targets successfully as therapists need to see to other work commitments on a daily basis. An alternative to these professionals being solely responsible for carrying out the screening tests would be to involve the nursing staff. This would alleviate the problem of the audiologists being required to conduct screening afterhours as most nursing staff work in shifts and so would be available for afterhours testing. In Lagos Nigeria, a two week training period for non-specialist staff in the use of TEOAE screening was deemed feasible. The study reported that 98.7% of all eligible newborns were screened before being discharged from the hospital (51). A similar study was conducted in South Africa, where clinic nurses were trained to screen infants, attending their primary health care clinics, with DPOAE. Although this community-based infant hearing screening program was successful in achieving a high follow-up rate for those requiring repeat testing, it only managed to screen 32.4% of infants eligible for screening (52).

5.2.2 Equipment

Our testing equipment – the OAE machine – was another challenge encountered which contributed towards the limited number of neonates being screened. In the second week of screening, the OAE machine malfunctioned and was sent to the manufacturer for repair. The

repair of the occluded probe tip, took three weeks to complete. We were without an OAE machine for 2 weeks, during which no neonates were screened. However an identical model OAE machine was loaned to us from the Wits Audiology department and screening could resume using the loaned machine. This technical complication was unexpected, but highlights the fact that in order for a unit to have a successful UNHS programme, there should be two machines available so that screening is not interrupted should there be a fault with one of the machines. There were no further equipment failures during the study, however in five cases the screener felt that the equipment was contributing to the refer result. Of these five cases, two neonates required a repeat OAE with one of the neonates passing on the second attempt and the other being lost to follow-up.

Another challenge encountered was that in our protocol we had indicated that if a neonate had received a refer result on two occasions the next step would be to have an ABR carried out at CMJAH. Of the 20 babies that returned for repeat OAE, two required an ABR, however, at that time the ABR machine at CMJAH was undergoing repairs. This resulted in one infant having a third OAE which was successfully passed, and the other infant was lost to follow-up.

Technical issues encountered with both the OAE machine and the ABR equipment were major challenges impacting on the successful implementation of our study. Although these physiological forms of testing are the approved screening methods, alternative methods may be utilised in resource-poor settings (5, 14). Behavioral Observation Testing was shown to have a high sensitivity and specificity as well as being quick and inexpensive to perform; although its specificity and sensitivity has been found lacking when compared to objective electrophysiologic measures (53). This method involves observing the infant's behavioural response to a sound stimulus. Historically, this form of testing was associated with infants

aged six to nine months, which may be too late considering the 2007 JCIH guidelines on detecting hearing impairments recommend that hearing loss be identified by three months of age (32). Behavioural observation testing could be of limited use in the interim for developing countries.

5.2.3 Noise levels

Ambient noise level was another challenge that was encountered. We had initially arranged for all the neonates in the postnatal wards be screened in a side room just outside of the ward. The room is off a passage connecting the two postnatal wards and we did not anticipate this passage being so noisy. After the first week of testing, we decided to move the area for screening to the speech therapy department. This change in location for screening meant that all neonates needed to be transported in their cribs from the second floor postnatal ward to the third floor speech therapy department, and the mothers needed to be ambulant to accompany their neonates. This resulted in neonates born via caesarean section only being able to be screened on day two of life, once their mothers had been discharged from the ward and were ambulant.

High ambient noise levels were identified by the audiologists as being a noteworthy challenge and resulted in a statistically significant number of children requiring a repeat DPOAE. The ideal hospital ward should be a setting of rest for a patient, especially in a postnatal ward where mothers and babies are rooming-in together. The reality is that the ambient noise levels typically range between 61.0-90.5 dB in a hospital setting (54). According to the World Health Organization, an ideal ambient noise level in a hospital ward is 30dB (55). A dedicated testing area with ambient noise levels not exceeding 50-55dB is required so as to minimize the

number of false positive test results (56). False positive “refer” results may cause the caregivers undue stress and result in the caregivers having to return to the hospital for a repeat screening test.

5.2.4 Vernix caseosa

Vernix caseosa is a physiological substance produced by the foetus in utero and consists of water (81%), lipids (9%) and proteins (10%) (57). The vernix caseosa has several functions, most importantly; it acts as an epidermal barrier in utero. Despite the high water content of vernix, it has a high viscosity as the water is thought to be contained within the corneocytes of the foetal skin (57). Due to the sticky nature of vernix, it can be quite difficult to remove from a neonate’s ear. Vernix caseosa was identified as a significant challenge in the assessment of hearing in our study. Otoscopic examination revealed 86 (71%) neonates having vernix in their ears, but in only 40 (46%) was this identified as a challenge by the screener. Forty five percent of neonates with vernix caseosa present in the external auditory canal required repeat DPOAE. The presence of vernix caseosa was a statistically significant finding and, in an ideal testing scenario, time should be taken to try and remove the vernix caseosa prior to conducting the DPOAE. The removal of vernix caseosa and other debris in the ear canal of neonates has been shown to improve the pass rates when conducting OAEs (58, 59). Cleaning the ear canal would prolong the testing time but would ultimately result in fewer false positives requiring a repeat OAE.

Khoza-Shangase et al recommend that in order for more neonates to be assessed and for confounding factors such as the presence of vernix caseosa to be minimised, screening should

take place on day three of life at the Midwife Outpatient Unit. Their findings show that more neonates were screened and fewer false positive findings were present on day three of life compared to within a few hours post delivery. This could be attributed to the vernix caseosa being removed from the outer ear canal (44). This would be difficult to implement in our facility as our neonates who are born vaginally are typically discharged within a couple of hours from delivery. Similar findings were reported by Tsui et al who described delaying diagnostic ABR by up to 50 days post delivery of the neonate, improved the specificity of the hearing assessment. This was again postulated to be secondary to the spontaneous removal of vernix in the ear canal or the improvement of any other middle ear pathology, such as middle ear effusions (60). The disadvantages of delaying the hearing screening are that there could potentially be a delay in the detection of hearing loss, as well as the potential emotional stress to the caregivers as they await the hearing assessment (60). The possible anxiety experienced by the caregivers from delaying the assessment needs to be weighed against the potential anxiety caused by a false positive result on hearing screening, which may inhibit the bonding between mother and child (18).

5.2.5 Early discharge of neonates from the ward

Screening neonates born afterhours via normal vaginal delivery was an anticipated difficulty, as these mothers are typically observed for six to eight hours post-delivery and then discharged home. A possible solution to this would be if the audiologists had a larger team who could then screen at two time intervals during the day, or if alternate health care professional were trained to conduct the screening test.

The second group of neonates who were not screened was those that were born over the weekends and were discharged home before being enrolled into the study. This limitation, set by the non-availability of staff to conduct screening over the weekend, was a major factor when assessing the feasibility of UNHS.

5.3 Refer results

Repeat testing was required for 57 (47%) neonates, however only 20 infants returned for repeat DPOAE. This referral rate of 47% after initial screening is much higher than the HPCSA's recommendation of <5% (14), which is in agreement with the guidelines from the JCIH that less than four percent of all newborns should fail the initial screening and be referred for repeat screening (9). No significant risk factors were found within the group requiring repeat DPOAE. The target referral rate is a means of applying quality-control to the screening program (5). The high refer rates may have been attributed to inappropriate testing circumstances with excessive ambient noise interference, the presence of vernix and the faulty DPOAE machine. The high referral rate of 47% also contributed to increasing the burden of work for the under-resourced screening team.

There were no infants found to have a hearing impairment and therefore the rate of true versus false positive results could not be determined.

5.4 Risk factors

A recent South African study by Le Roux et al retrospectively reviewed 264 pediatric patients who had received cochlear implants, and assessed the diagnosis and associated risk factors. They reported that a positive family history of hearing loss, admission to NICU, and prematurity were significant risk factors for profound hearing loss (19). Although these risk factors were present in the screened cohort, no neonates were found to have impaired hearing. The infant who defaulted on the third OAE, had no significant risk factors on history, and was a well term neonate who had delivered vaginally.

5.5 Loss to follow-up

After the initial screening, 57 neonates were due to come back for a repeat OAE with only 20 (35%) returning for follow-up. In addition to this, of the two that required an ABR, only one returned for follow-up. An information sheet was explained and given to the mother or caregiver when they were counseled after the first DPOAE had not been passed. The importance of repeat testing may not have been made clear to the mothers and this lack of understanding could have contributed to the poor follow-up rate.

The time during which pregnant mothers wait in the antenatal queue is being utilised at some clinics to counsel the mothers and educate them about various health issues such as the importance of breastfeeding and knowing their HIV status. An ideal time to adequately counsel the mothers regarding the importance of the screening test would be at an antenatal visit. Expectant mothers' knowledge regarding their babies care was improved by short sessions of antenatal education, as was demonstrated by Weiner et al in Vientiane, Laos (61).

Another possible reason for the poor follow-up rate may be due to financial limitations as these families may not have been able to afford the cost of travel to return to the hospital. The

associated costs and lack of knowledge of the caregivers were found to be the two most common reasons for defaulting follow-up appointments for rescreening in a South African study (62). Improved counselling and communication, as well as proactive reminders decreases the loss to follow-up rate. The return rates would most likely improve if the follow-up screening, or diagnostic testing, was on the same day as the visit to the local clinic for immunisations, or on the same day as the neonatal follow-up appointment (63). Community-based screening programmes in the Western Cape have been found to be effective in improving the rate of follow-up (52). In the Western Cape study, Friderichs et al utilised clinic nurses to screen infants at their routine clinic immunisation visits. A two-stage DPOAE screening process was implemented, which was similar to the screening process utilised by our study except that the timing of administration differed. If the initial DPOAE was a refer result, a second DPOAE was administered four weeks later at the 14 week immunisation clinic visit. If this was again a refer result, the infant would be referred for a diagnostic ABR. This method of screening was highly effective in improving follow-up rates, but the disadvantage was that dedicated screening personnel were required to implement the screening test.

With such a high rate of false positives being detected and resulting in unnecessary follow-up for the patients, the importance of having an ideal testing scenario for the initial screening test is emphasised. Ideally, what would be required is a testing environment with low ambient noise levels, reliable equipment, and staff trained to perform the necessary testing. A study in Greece demonstrated that by conducting OAE testing at birth and again prior to discharge of the neonate, unnecessary high referral rates were prevented (64). This was possible in the study setting as neonates typically stay at least four days in hospital post delivery (64).

5.4 Study limitations

- The main limitation of the current study was that the time period used for data collection was limited to three months due to the fact that this was a study in partial fulfillment of a degree where limited time period was available. It is believed that a longer time frame where other variables could have come into play might have influenced the findings of the study.
- The second limitation is that the study was in one hospital in Johannesburg where resources are significantly better than in a number of other hospitals in the country; therefore generalizability of the findings is limited.
- The last limitation; which also has implications for generalization of the findings; is the small sample size, although this would not have altered the primary study outcome which was to assess the number of neonates who could be successfully screened.

It is important therefore that current findings be interpreted with these limitations in mind; and that future studies consider these in their study design.

6.0 Conclusion

Conducting a Universal Newborn Hearing Screening programme was not feasible at RMMCH, a secondary level hospital in Gauteng South Africa. The most important limitations to the feasibility were the insufficient number of audiologists available to provide screening, the high rate of false positive test results, and the unacceptably high rates of loss to follow-up. Two modifiable factors, namely the presence of vernix caseosa in the external ear canal and high ambient noise levels were found to have significantly impacted on the testing process. Further research is required to determine the constituents for a successful screening programme in the South African context.

7.0 Recommendations

- A local screening programme should be developed that is appropriate and feasible for the South African context.
- UNHS is currently not feasible in our secondary level hospital and so targeted screening for those considered at high risk of a hearing impairment should be implemented as an interim measure.
- Further research needs to be conducted to better define risk factors in the context of resource-constrained countries.
- To improve the overall refer rates to an acceptable level i.e. < 5% as per HPCSA EHDI guidelines, necessary steps should be taken to improve the testing environment. This entails limiting the ambient noise levels and removing any debris or vernix caseosa from the neonate's ear prior to testing.
- Research into the possibility of training nursing personnel, who are available afterhours, in the use of the OAE machine in order to implement screening. Another possibility is the future training of Audiology technicians.

- Public awareness, especially for the expectant mothers and medical personnel, needs to be improved with regards to the importance of hearing screening. This can be implemented as part of the essential education available to mothers in the antenatal clinics.

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**Information Sheet for feasibility assessment of Universal Newborn
Hearing Screening programme at Rahima Moosa Mother and Child
Hospital**

Dear Parent/Caregiver

Hello. My name is Dr Jacqui Bezuidenhout and I am a doctor working in the Paediatric department. We are conducting a study at Rahima Moosa Mother and Child Hospital, looking at the number of newborn babies born with hearing problems and would like to include your baby.

Hearing is essential for normal speech and language development, and if left untreated, can result in the child not reaching their full potential. For the best outcome, babies with hearing losses should be fitted with a hearing aid by six months of age.

We will be using a machine called an otoacoustic emission device which sends a sound wave into the ear which tells us how the inner ear is functioning. It is completely painless and can be completed within a few minutes. If the baby passes the tests you will not need to have any further testing of the ears, but if the baby does not pass the test we will need to retest the baby within a month. If the baby again does not pass the test, we will refer the baby to Charlotte Maxeke Johannesburg Academic hospital for further testing. If a hearing deficit is found, and depending on the type and severity of hearing loss present, a suitable hearing assistive device will be provided by Rahima Moosa Mother and Child hospital's speech and hearing department.

With your permission, we would like to use information from your baby's file including if available, your HIV status. This information is going to help us in understanding which babies are more at risk of having hearing losses. The information will be kept confidential, and you or your child's identity will not be revealed to anyone. The results of this study will be shared with other doctors and audiologists looking after babies with hearing losses.

Although there will be no financial benefit in participating in this study, your baby if detected to have a hearing loss will benefit from early intervention and provision of an appropriate hearing assistance device. You are free to withdraw from the study at any time if you change your mind and this will not affect your child's hospital care in any way.

There are no risks associated with the use of an OAE machine to test for hearing losses, but should you feel any anxiety or distress if your child has an inconclusive result or a definite hearing problem, psychological counseling will be provided by our psychologists.

Should you have any questions, please feel free to contact the researcher, Dr J Bezuidenhout at Rahima Moosa Hospital on 011 470 9144

Thank you

Appendix B – Consent form

Consent Form for Universal Newborn Hearing Screening at Rahima Moosa Mother and Child Hospital

Dear Parent/Caregiver

Hello. My name is Dr Jacqui Bezuidenhout and I am a doctor working in the Paediatric department. We are conducting a study at Rahima Moosa Mother and Child Hospital, to determine if it would be possible to offer hearing tests to all newborn babies here.

Hearing is essential for normal speech and language development, and if left untreated, can result in the child not reaching their full potential. We will be using a machine called an otoacoustic emission device which sends a sound wave into the ear which tells us how the inner ear is functioning. It is completely painless and can be completed within a few minutes. If the baby passes the tests you will not need to have any further testing of the ears, but if the baby does not pass the test we will need to retest the baby within a month. If the baby again does not pass the test, we will refer the baby to Charlotte Maxeke Johannesburg Academic hospital for further testing. If a hearing deficit is found, and depending on the type and severity of hearing loss present, a suitable hearing assistive device will be provided by Rahima Moosa Mother and Child hospital's speech and hearing department.

With your permission, we would like to use information from your baby's file including if available, your HIV status. This information is going to help us in understanding which babies are more at risk of having hearing losses. The information will be kept confidential, and you or your child's identity will not be revealed to anyone. The results of this study will be shared with other doctors and audiologists looking after babies with hearing losses.

Although there will be no financial benefit in participating in this study, your baby if detected to have a hearing loss will benefit from early intervention and provision of an appropriate hearing assistance device. You are free to withdraw from the study at any time if you change your mind and this will not affect your child's hospital care in any way.

There are no risks associated with the use of an OAE machine to test for hearing losses, but should you feel any anxiety or distress if your child has an inconclusive result or a definite hearing problem, psychological counseling will be provided by our psychologists.

Should you have any questions, please feel free to contact the researcher, Dr J Bezuidenhout at Rahima Moosa Hospital on 011 470 9144

Thank you.

A. I, (name of mother/caregiver) hereby give consent to my child..... (name of patient), having his/her ears tested.

Signature of parent/caregiver:.....

Signature of witness:.....

Date signed:.....

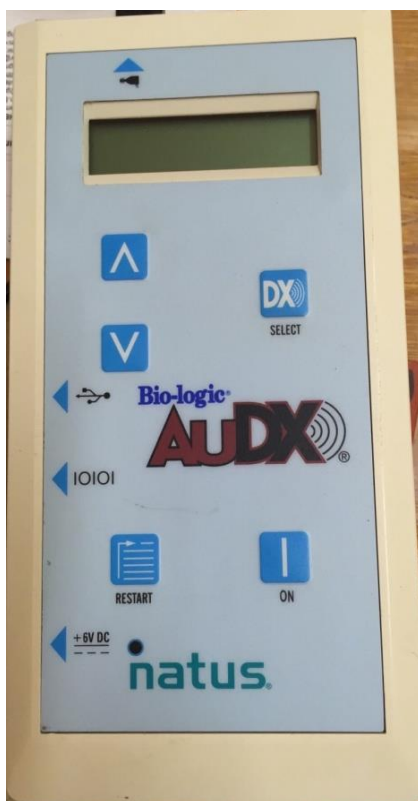
B. I (name of parent/caregiver) hereby do not give consent for my child (name of patient) to have his/her ears tested.

Signature of parent/caregiver:

Signature of witness

Date signed:

Appendix C – Image of DPOAE machine utilized for screening at RMMCH



Appendix D – Data collection form

Rahima Moosa Hospital - Otoacoustic emission (OAE) Screening Form

General information

Study no		Location	Ward 7 ☐ 8 ☐ 16 ☐	Date exam	of / / 2012
Mode of delivery	☐ NVD ☐ C/S ☐ Assisted	HIV exposed?		☐ Yes ☐ No ☐ Unknown	
Apgar scores	1' 5' 10'	Birth weight (g)			

Risk Factor assessment

Family history of permanent childhood hearing loss?	☐ Yes ☐ No							
Admitted to NICU?	☐ Yes ☐ No							
	Duration of NICU stay? (Days)							
	Assisted ventilation?		☐ Yes ☐ No					
Exposure to ototoxic drugs (aminoglycosides/loop diuretics)?	☐ Yes ☐ No							
Hyperbilirubinaemia requiring exchange transfusion?	☐ Yes ☐ No		Highest bilirubin documented _____					
Congenital infections?	CMV	Herpes	Toxo	Rubella	Syphilis	HIV	Malaria	None
Craniofacial abnormalities?	☐ Yes ☐ No							

A. Initial Screening

1. Otoscopic examination

	Vernix	Narrow canal	NAD		
Right					
Left					

2. OAE

	Right	Left
1000kHz		
2000kHz		
3000kHz		
4000kHz		
5000kHz		

Plan and outcome

Time taken	Start time:..... End time:.....			Examiner's initials:
Challenges	Vernix	Equipment	Noise	Other (Specify)
Plan	Discharge		Repeat OAE	Other (specify)

B. Repeat Screening

1. Otoscopy

	Vernix	Narrow canal	NAD		
Right					
Left					

2. Tympanometry

	<u>Right</u>	<u>Left</u>
Ear canal volume	cm ³	cm ³
Static compliance	cm ³	cm ³
Pressure	daPa	daPa
Type		

3. OAE

	<u>Right</u>	<u>Left</u>
1000kHz		
2000kHz		
3000kHz		
4000kHz		
5000kHz		

Plan and outcome

Time taken	Start time:..... End time:.....			Examiner's initials:
Challenges	Wax	Equipment	Noise	Other (Specify)
Plan	Discharge		ABR	Other (specify)

C. ABR result

Appendix E – HREC clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Jacqueline Bezuidenhout

CLEARANCE CERTIFICATE

M111119

PROJECT

Feasibility Assessment of a Universal Newborn
Hearing Screening Programme at Rahima
Moosa Mother and Child Hospital

INVESTIGATORS

Dr Jacqueline Bezuidenhout.

DEPARTMENT

Department of Paediatrics

DATE CONSIDERED

25/11/2011

M1111190DECISION OF THE COMMITTEE*

Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 16/01/2012

CHAIRPERSON
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Tim De Maayer

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...