Audiological Screening of Low-Risk Neonates at Different Times Following Birth Through the Use of Otoacoustic Emissions: A Feasibility Study

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DECLARATION

I, Shannon Leigh Harbinson, hereby declare that this submission is my own original work and that the assistance which I have received is detailed in the Acknowledgements of this report. To the best of my knowledge and belief, this submission contains no material which has been accepted for the award of any other degree or diploma at any other university or institute of higher learning, except where due acknowledgement and reference has been made in the text. I am responsible for the study and conclusions reached.

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Shannon Leigh Harbinson Date

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LIST OF ABBREVIATIONS

ABR	: Auditory Brainstem Response
CHC	: Community Health Centre
DPOAE	: Distortion Product Otoacoustic Emission
EHDI	: Early Hearing Detection and Intervention
EOAE	: Evoked Otoacoustic Emission
HPCSA	: Health Professions Council of South Africa
HREC	: Human Research Ethics Committee
JCIH	: Joint Committee on Infant Hearing
MOU	: Midwife Obstetric Unit
NICU	: Neonatal Intensive Care Unit
OAE	: Otoacoustic Emission
PCHL	: Permanent Childhood Hearing Loss
PPCHC	: Phola Park Community Health Centre
SOAE	: Spontaneous Otoacoustic Emission
TEOAE	: Transient Evoked Otoacoustic Emission
UNHS	: Universal Newborn Hearing Screening

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Abstract

Objective: To determine the feasibility of audiological screening in low-risk neonates, using Otoacoustic Emissions (OAEs), at various test times following birth. The achievability of a screening programme within the Midwife Obstetric Unit (MOU) 3-day assessment clinic at the Phola Park Community Health Centre (PPCHC) was deliberated.

Participants: Two hundred and seventy two neonates were included in this study.

Design: A prospective and longitudinal design was employed.

Methods and Materials: Case history interviews, otoscopic examinations and Distortion Product Otoacoustic Emissions (DPOAEs) were carried out at two sessions. The initial session took place within 6 hours after birth and the second session at approximately 3 days after birth at the MOU 3-day assessment clinic.

Data Analysis: Data was collected as "*pass*" and "*refer*" screening results, the number of births was compared to the number of participants at the two sessions. The number of "*pass"* and "*refer"* results per session were analysed and results per participant at the two sessions were compared to detect false-positives. The return for follow-up rate was considered.

Results: **S**creening is possible within hours of birth but is more practical and efficient at the MOU 3-day assessment clinic. During the study, 260 neonates were born at PPCHC, 38.07% of these were screened at session 1 and a total of 268 newborns were screened at session 2. The pass rate was 16.16% at session 1 and 99.25% at session 2; rendering a false-positive rate of 82.10% at session 1. Time of birth relative to discharge, resources, environmental factors, noise levels, return for follow-up rate and referral rate have been identified as factors that may impact the practicability and efficiency of screening.

Conclusion: Outcomes of the study highlight the importance of studying methodologies to ensure effective reach for hearing screening within the South African context. Based hereon, screening neonates immediately after birth is possible. However, it is recommended that

screening forms part of the MOU 3-day assessment protocol to ensure that a higher number of neonates are reached when confounding factors such as vernix have plummeted; hence decreasing false- positives.

Key words: *otoacoustic emissions, newborn audiological screening, infant hearing, protocols, universal hearing, high risk register, South Africa*

SECTION I:

PROLOGUE

Chapter 1

Introduction and Orientation

The profession of audiology has focused on childhood hearing screening for several years (Northern & Downs, 2002) and the screening for paediatric hearing impairment has subsequently become an important component of neonatal care (Parving, 2003). The Health Professions Council of South Africa (HPCSA) and the Joint Committee on Infant Hearing (JCIH) endorse, advocate and stipulate the early identification of hearing loss through the employment of objective physiologic screening measures, so that the timely diagnosis and treatment for congenital auditory impairment may occur (HPCSA, 2007; JCIH, 2007). This therefore highlights the intention of neonatal hearing screening, which is to ensure the early identification of congenital hearing impairment (Windmill & Windmill, 2006), as well as the early intervention for those identified with a hearing loss (Hyde, 2005). Screening for hearing impairment is viewed as a method of prevention and is mandated in several developed countries. Screening has also been deemed as an attainable public health programme in developing countries (Olusanya et al., 2007).

The aim of neonatal hearing screening may be achievable through the appropriate screening of all infants (Rouev, Mumdzhiev, Spiridonova & Dimov, 2004), otherwise called universal newborn hearing screening (UNHS). UNHS refers to a prevention programme in which all newborns are screened for hearing impairment, after birth, prior to discharge from the newborn nursery (Windmill & Windmill, 2006). In contrast to UNHS, targeted hearing screening denotes a selective screening method based on the presence of risk factors (de Dios & Maseres, 2005). According to Flynn, Austin, Schmidtke-Flynn, Ford and Buckland (2004)

a comparison between UNHS and targeted hearing screening procedures has indicated that universal hearing screening measures are generally preferred.

There is evidence to suggest that the lack of UNHS programmes may be detrimental to several hearing impaired children (Low, Pang, Ho, Lim & Joseph, 2005). These newborn hearing screening programmes are considered to be valid and are thus likely to result in the timeous identification of, and intervention for, congenital hearing loss - which in turn will bring about noteworthy benefit (Hyde, 2005). The primary rationale underlying UNHS and the early detection of hearing impairment is that hearing-impaired children, who are provided with suitable intervention services within the first 6 months of life, present with considerably better language skills when compared to children who receive this intervention at a later stage (Kennedy, McCann, Campbell, Kimm & Thornton, 2005). Considering the age at which the detection of, and intervention for, hearing impairment occurs, a properly implemented neonatal hearing screening programme is able to offer acceptable outcomes (Uus & Bamford, 2006). However, in the absence of an appropriate hearing screening programme, a hearing impaired child may only be identified once the child is of school going age (Hyde, 2005). UNHS has therefore been proposed as a means to speeding up the identification, diagnostic and intervention process for hearing-impaired children (Grill et al., 2006), hence the current study.

The implementation of a UNHS programme is likely to result in a reduction in the age at which individuals with a hearing impairment are identified, diagnosed and treated. Through this approach, improved speech, language and auditory outcomes - together with enhanced quality of life for the infant, as well as for their parents - may be expected (Canale et al., 2006). The early detection of, and intervention for, congenital hearing impairment can

ensure that the best possible solutions are made available, allowing these individuals to communicate effectively. This assists in facilitating maximum habilitation of the individual's ability and potential to guarantee both their involvement in society, as well as their contribution to the country's economy (HPCSA, 2007).

Neonatal hearing screening programmes are deemed as advantageous and are, therefore, accepted in many developed countries (Wada, Kubo, Aiba & Yamane, 2004). The feasibility of newborn audiological screening and the advantages associated with the early identification of, and intervention for, congenital hearing impairment have been verified through early hearing detection and intervention (EHDI) programmes (JCIH, 2007). These early hearing detection programmes have been implemented as components of the public health system in many countries (Swanepoel, Ebrahim, Joseph & Friedland, 2007) and the establishment of UNHS programmes has been on the increase internationally (Hyde, 2005).

The increase in UNHS programmes may be due to the existing evidence that UNHS is a cost-effective approach to detect congenital hearing impairment timeously and effectively (Korres, Balatsouras, Nikolopoulos, Korres & Ferekidis, 2006); and may also be attributed to reports of feasibility and value of such programmes (Olusanya et al., 2007). Neonatal hearing screening is gradually becoming a standard procedure internationally (Boone, Bower & Martin, 2005). However, it is of great consequence that the implementation of extensive neonatal audiological screening drives has mainly been limited to the developed world (Swanepoel, Hugo & Louw, 2005). This implementation has not yet been intensified in the developing world, where the developing world refers to the developing countries of Asia, Latin America, the Caribbean and Africa and 80 % of the world's population (Population Reference Bureau, 2008).

Various nations worldwide have applied UNHS programmes as a response to the US National Institute of Health policy statement of early identification of hearing loss (Navarro-Locsin, 2003). UNHS programmes have become operational in some Western countries (Olusanya & Okolo, 2006) and are legislatively mandated in many of the American states (Olusanya, Luxon & Wirz, 2005). Progress has been made in the large-scale implementation of UNHS programmes in Canada (Hyde, 2005) and, according to Lutman and Grandori (1999), Europe developed screening already in 1998. Regions in the United Kingdom have also implemented such programmes (Szyfter, Wróbel, Radziszewska-Konopka, Szyfter-Harris & Karlik, 2008) and pilot studies have been conducted in the United Kingdom (Russ, 2001).

Uilenburg, Kauffman-de Boer, van der Ploeg, Oudesluys-Murphy and Verkerk (2009) have elucidated how the effecting of UNHS in the well-baby clinic, by nursing staff, is achievable and how this has formed the foundation for national UNHS implementation in the Netherlands. In Germany, UNHS was previously only conducted in select German Federal States, but has been compulsory across all of Germany since January 2009 (Schönweiler & Schmidt, 2009). A national newborn hearing screening programme has been established and implemented in Turkey since 2003, where screening is conducted on the third day post birth (Bolat, Bebitoglu, Ozbas, Altunsu & Kose, 2009). In this programme, children identified with hearing loss are referred for treatment and rehabilitation services, this programme is working towards providing access to hearing screening services for all newborns in Turkey. In Slovakia, neonatal audiological screening commenced in 1998 and has been compulsory since 2006 (Jakubíkova, Kabátová, Pavlovcinová & Profant, 2009); and UNHS was introduced in China in 1999 (Nie, 2008).

Screening for neonatal hearing impairment forms part of standard healthcare in Cuba (Abalo et al., 2009) and UNHS is established in all hospitals with birthing facilities in Singapore (Reyes, 2008). Yu et al. (2010) have described a 2-stage procedure which is considered viable for hospital-based UNHS in Hong Kong. In India it is not considered feasible to screen all neonates for hearing impairment, hence hearing screening is therefore linked to the IMPACT India, which targets children between birth and 6 years of age (Vaid, Shanbhag, Nikam & Biswas, 2009).

Olusanya et al. (2005) reported on pilot UNHS programmes operational in Mexico, while hospital-based newborn hearing screening conducted in line with the Brazilian national health services has been deemed as feasible (Bevilacqua, Alvarenga, Costa & Moret, 2010). Oman, after piloting UNHS in limited regions, established UNHS nationally in 2002 (Khandekar, Khabori, Mohammed & Gupta, 2006). In spite of these developments, it is noteworthy that the lack of skilled and qualified hearing healthcare professionals, together with the related hearing screening infrastructure, are still unavailable or inaccessible to a great part of the world's population (Swanepoel et al., 2010). The implementation of UNHS has recently been recommended in the South African context (HPCSA, 2007). However, the manner in which this can be implemented, as well as possible limitations, have not yet been rigorously explored in this context - hence the current study.

If UNHS is valid, then it must also be established as effective and viable across geographically-varied hospital collections, with differing staffing attitudes and resources (Lam, 2006). This implies that UNHS needs to be embraced in the developing world, considering that most children with a hearing impairment are reported to live in Third World countries (Olusanya, Luxon & Wirz, 2006).

According to Olusanya, Luxon and Wirz (2004), the feasibility of newborn hearing screening programmes for developing countries seems improper in view of the diversities in the socio-economic and health standing of these countries. This may be due to the perception of hearing impairment that, although hearing loss is debilitating, it is not life-threatening when compared to various fatal childhood diseases (Swanepoel, Delport & Swart, 2004). In spite of this, a great number of developing countries are exploring practical and culturally appropriate options for early hearing screening (Olusanya & Okolo, 2006).

While the available technology for newborn hearing screening is appropriate for employment in developing countries (Berg, Papri, Ferdous, Khan & Durkin, 2006), the advantages and benefits of early detection and early intervention services for infants with a hearing impairment are not always available and easily reachable (Swanepoel, Hugo & Louw, 2006). Moreover, administrative systematisation for UNHS has not been established in several of these countries (Wada et al., 2004). Findings from ongoing infant hearing screening programmes in South Africa and in Nigeria have even proposed that hearing screening programmes be integrated into early childhood immunisation programmes in developing countries, especially where a number of births occur outside regular hospitals and clinic settings (Olusanya & Okolo, 2006). However, regardless of the numerous recommendations, Llanes and Chiong (2004) have acknowledged that the establishment of a UNHS programme in settings with such limitations may be a challenging task.

Considering Africa specifically, Tanon-Anoh, Sanogo-Gone and Kouassi (2010) have stipulated that standard audiological screening is achievable and crucial in Côte d'Ivoire. In South Africa particularly, hearing healthcare services are considered as sparse and hearing awareness as inadequate (Swanepoel, Störbeck & Freidland, 2009). However, African

children with a hearing impairment ought to have the opportunity to develop to the same potential as their peers living in First World countries do (Swanepoel & Störbeck, 2008). This notion presents as a challenge in South Africa, where the traditional service delivery model in the field of audiology is not accessible to many, especially the vulnerable population (Moodley, Louw & Hugo, 2000).

Swanepoel et al. (2004) have explained that paediatric hearing screening programmes in South Africa may not be sufficient. Yet the HPCSA affirms that South Africa has the opportunity and the responsibility to invest in hearing impaired children through the execution of extensive UNHS measures, together with the provision of timely intervention for those identified with a hearing loss (HPCSA, 2007). Hearing screening for neonates should form part of standard medical care (Habib & Abdelgaffar, 2005), yet in South Africa, many do not have access to the early detection and early intervention services for infants presenting with a hearing impairment (Swanepoel et al., 2006). According to Theunissen and Swanepoel (2008), the most commonly reported reasons for the dearth of neonatal screening programmes in South Africa is the lack of suitable screening equipment, as well as significant staff shortages.

Notwithstanding the challenges associated with the establishment and implementation of these UNHS programmes in developing countries such as South Africa, there are accessible structures that need to be explored and considered as potential platforms from which these programmes can be realised (Swanepoel et al., 2006). In South Africa, the professional board for speech, language and hearing professionals has suggested that community-based developmental hearing screening programmes be put into operation at the primary healthcare level within the district health services model (HPCSA, 2007). Structures

that may be explored include the community health centres (CHCs), where babies are followed up after being discharged from the hospital.

According to the HPCSA (2007), it is the ambition of the professional board for speech, language and hearing professions that all neonates have access to audiological screening. It has thus been suggested that UNHS protocols be successfully put into operation, allowing all newborns access to hearing screening after birth, before discharge from the newborn nursery. It has also been proposed, by this council, that the 6-week immunisation clinic be alternately employed as a neonatal hearing screening platform in South Africa. Nonetheless, the JCIH (2007) recommends the identification of a hearing loss by 3 months of age and that intervention for hearing impairment be implemented by 6 months of age. Low et al. (2005) have indicated that a UNHS programme may be the only efficient way to identify all infants presenting with a hearing impairment within the suggested time frame, thus facilitating the provision of early intervention services for hearing impairment.

Several health care professionals have come to acknowledge the benefits of neonatal audiological screening (Moeller, White & Shisler, 2006) and considerable support for UNHS has been reported in that it evidently has a positive impact on the lives of infants and their respective families (Yoshinaga-Itano, 2003). Due to the availability of objective, reliable, age-appropriate and easy to operate screening measures (Olusanya et al., 2005); and in line with the evidence that UNHS programmes result in significantly improved outcomes for neonates presenting with hearing abnormalities (Hutt & Rhodes, 2008), UNHS may be regarded as justifiable and reasonable (Hyde, 2005).

The JCIH (2007) has emphasised that newborn hearing screening is a process. The application and implementation of newborn hearing screening comprises a broader approach than the actual audiological screening. It must be an amalgamated and inclusive system (White, Behrens & Strickland, 1995). The initial stage of this complex process is the birth admission screening session, also made up of *"refer"* for follow-up screening sessions; this is followed by diagnostic testing and the provision of intervention services. A breakdown at any of these three levels jeopardises the entire endeavour and the benefits associated with the early identification of, and intervention for, hearing impairment may be lost (Windmill & Windmill, 2006). These follow-up and intervention services forming part of the newborn hearing screening process are to occur timeously and these services are to be sufficient and well co-ordinated (Low et al., 2005). Newborn hearing screening programmes should, therefore, also provide adequate facilities for these follow-up assessments and intervention services (Baroch, 2003).

In light of this, Windmill and Windmill (2006) have highlighted that all screening programmes are obligated to plan, establish and employ structures and inclusive procedures in which the initial screening process is followed by timely diagnosis, fitting of amplification devices and the provision of relevant intervention services. This is because newborn hearing screening is not ethically justifiable in the absence of relevant follow-up procedures (Hyde, 2005). This implies that, in order for newborn audiological screening endeavours to be successful, the recall of those who do not pass the initial screening measures is imperative (JCIH, 2007) and the lack of such follow up procedures presents as a potential weakness of any screening programme (Bartley & Digby, 2005). Health care professionals consequently have a responsibility to optimise the provision of this intervention to infants presenting with a hearing impairment and to provide services to their respective families (HPCSA, 2007). It is

essential that the establishment of screening protocols in hospitals and in primary healthcare centres be carefully planned and designed (HPCSA, 2007). It has been emphasised that studies exploring such implementation are required (Martineau, Lamarche, Marcoux & Bernard, 2001), hence the importance of the current study.

According to the JCIH (2007), the establishment of suitable practices is a necessary part of the foundation for newborn hearing screening programmes. Intensified research and the development of appropriate screening programmes for the detection of, and intervention for, hearing impairment in the newborn population are required. There is a pressing call for further research comparing hearing screening programmes in various contexts; that is, research is required that aims to establish whether the programme, equipment and protocols are designed to meet the specific objectives according to the context (Johnson et al., 2005). This is particularly true for developing countries, where resources are scarce and decisions are mostly financially driven. Research in this field may contribute to improved protocols and improved protocols may result in superior newborn hearing screening in terms of accuracy; as the accurateness associated with newborn hearing screening has previously been reported as moot (Wada et al., 2004).

Olusanya and Okolo (2006) have highlighted South Africa's means to realise valuable and feasible neonatal audiological screening programmes. However, in order to guide the implementation process of neonatal hearing screening programmes in South Africa, research to collate evidence concerning the efficacy and practicability of these screening programmes is required (HPCSA, 2007), hence the aim of the current study.

SECTION II:

THEORETICAL FRAMEWORK

Chapter 2

Literature Review

A hearing impairment is one of the most common forms of sensory deprivation and has been documented as a serious disability for many decades (Low et al., 2005) due to the associated negative impact of this condition (Ansari, 2004). A hearing impairment is often a chronic condition that, depending on the type and the extent of the impairment, can result in profound negative impact on speech, language and cognitive development in the paediatric population (Mackenzie & Smith, 2009).

A hearing impairment in childhood may be conductive or sensorineural, or a combination of the two, commonly referred to as a mixed hearing loss (Newman & Sandridge, 2007). A hearing loss may be bilateral or unilateral and may vary in degree from a mild hearing loss to a profound hearing loss (Prosser & Martini, 2007). A hearing impairment may be congenital, acquired, recurrent, transient, progressive or permanent in nature (Neely, 2008). A hearing-impaired individual is deprived of vital sensory input (Lam, 2006); therefore, irrespective of the type, degree and nature of a childhood hearing impairment, the presence of a hearing loss may have a devastating effect on development (Gregg, Wiorek & Arvedson, 2004).

It has previously been reported that only children presenting with a bilateral hearing impairment will demonstrate impaired speech and language skills (Kennedy et al., 2006). However, children presenting with a unilateral hearing impairment may also display difficulties and impairments in various areas of development (Cho Lieu, 2004). Significant delays and impairments in speech and language development have been reported for children

presenting with severe-profound degrees of hearing impairment (Nicholas & Geers, 2006); and a considerable number of children with minimal hearing impairment do present with delayed linguistic skills as well (Yoshinaga-Itano, Johnson, Carpenter & Brown, 2008). Even a slight congenital hearing impairment that goes undetected may inordinately influence a child's development, as most speech and language learning and development occurs between birth and the age of 36 months (Gregg et al., 2004). In cases where a child is not able to hear sounds across the speech spectrum (250 Hz – 4000 Hz) at a suitable level, it is improbable that the child would be capable of correctly producing those speech sounds (Gregg et al., 2004). Without the necessary opportunities for speech and language learning, hearing-impaired children will lag behind their normal hearing peers (JCIH, 2007).

In addition to the development of speech and language skills, there is evidence to suggest that auditory input in the early stages of life is imperative for the normal development of cognition and behaviour (Quittner, Leibach & Marciel, 2004). Developmental delays in the afore-mentioned domains may be associated with decreased education and subsequent employment levels (JCIH, 2007). Hearing impaired individuals, who are not identified timeously, are likely to display developmental delays across several domains (Quittner et al., 2004) and poor long-term prognosis for hearing impairment is thus related to an undetected hearing impairment during the early stages of life (Gregg et al., 2004). Mackenzie and Smith (2009) emphasise that hearing loss may even lead to notable social issues such as stigmatisation. However, research has shown that hearing-impaired children may develop speech and language skills equal to that of their normal hearing peers in cases where the hearing impairment is identified early (Spivak & Sokol, 2005).

Yoshinaga-Itano (2003) defines early identification as the identification of a hearing

impairment within the first 6 months of life, while the late identification of hearing impairment refers to the identification of a hearing loss after 6 months of age. Newborn hearing screening programmes are widely regarded as a suitable means to facilitate the early detection of congenital hearing impairment (Swanepoel et al., 2004). Neonatal hearing screening programmes aim to recognise significant hearing impairments timeously (Nelson, Bougatsos & Nygren, 2008) and these programmes are based on the premise of improved long-term outcomes for hearing impaired individuals (Wake, Hughes, Poulakis, Collins & Rickards, 2004). It has been documented that hearing impaired children who are identified timeously and who, as a result, receive appropriate intervention services within the first year of life display remarkably better general language abilities, phonetic repertoires, speech intelligibility, vocabulary, syntax, parental bonding as well as parental grief resolution and social-emotional development when compared to those identified with a hearing impairment at a later stage (Yoshinaga-Itano, 2003).

Neonatal hearing screening programmes are designed to provide early and effective services to the hearing impaired population (Ansari, 2004). Irrespective of the particular screening protocol employed, affected neonates that have access to newborn hearing screening services present with remarkably improved outcomes, when compared to those without access to audiological screening services (Kennedy et al., 2006).

The specific designs of neonatal hearing screening programmes may differ according to the particular context. However, performance standards are expected to be similar across programmes, as well as contexts (Hyde, 2005). Overall, neonatal hearing screening has been regarded as beneficial practice due to the associated favourable outcomes (Swanepoel et al.,

2005). There are various systems for the timeous identification of congenital hearing impairment which have been explored (Neumann et al., 2006).

The objective of UNHS is to conduct audiological screening in all neonates prior to discharge from the newborn nursery after birth (Rouev et al., 2004). However, this is not the only approach to detect hearing impairment in the neonatal population. Lahr and Rosenberg (2004) have described targeted hearing screening as another method employed in the identification of childhood deafness. Targeted hearing screening is a method based on the presence of risk factors for hearing impairment. The high-risk register forms part of the process which entails the reviewing of hospital records and birth certificates to identify those who may be at risk for a hearing impairment. Hearing screening is then conducted on the selected infants only (Lahr & Rosenberg, 2004). Both of the above-mentioned hearing screening approaches are achievable and each programme has a number of strengths, limitations and drawbacks.

Within a targeted hearing screening programme, possible risk factors for permanent childhood hearing impairment include a history of low birth weight, jaundice, perinatal hypoxia, premature birth (Roizen, 2003), a history of Neonatal Intensive Care Unit (NICU) admission, a family history of permanent childhood hearing loss (PCHL), the presence of a craniofacial anomaly at the time of birth (Lahr & Rosenberg, 2004), intrauterine infections (Morton & Nance, 2006), meningitis and septicaemia (Low et al., 2005). Apgar scores are also taken into account, as a depressed Apgar score at 5 or 10 minutes post-birth may be a risk factor for a central auditory impairment (Jiang & Wilkinson, 2006). Literature, however, clearly demonstrates that selective screening measures are not entirely practical as these measures will miss, and therefore not identify, deaf newborns without obvious risk factors

(Hyde, 2005). According to Korres et al. (2005), a reported 78% of neonates that do not pass newborn hearing screening measures are in the well-baby nursery. The high incidence of hearing impairment in children without risk factors has led to the recommendation of UNHS rather than high-risk screening alone (de Dios & Maseres, 2005).

UNHS programmes characteristically entail the screening of all neonates, prior to discharge from the newborn nursery, as well as at subsequent re-screening sessions (Hyde, 2005). This screening method has been described as both functional and effective (Watkin, 2003) and UNHS has been regarded as the most efficient method for the early identification of, and intervention for, congenital hearing impairment, with optimal outcomes (Neumann et al., 2006). This may be because UNHS methods facilitate the timeous identification of hearing loss and also because this method of screening is reported to be more accurate in comparison to a targeted screening approach (Grill et al., 2005).

Kileny and Jacobson (2000) deem UNHS as costly and unfeasible. On the other hand it has been reported by Herrero and Moreno-Ternero (2005) that comparable efficiency can be achieved by conducting hearing screening in the NICU only, or only screening those who meet the high-risk criteria for congenital hearing impairment. However, UNHS is preferred to targeted hearing screening methods by the majority of parents, hearing specialists and paediatricians (Moeller et al., 2006). Several prestigious bodies and councils also recommend universal screening over targeted screening approaches for congenital hearing impairment (Puig, Municio & Meda, 2005). Thus the general consensus emphasises a UNHS system (Hyde, 2005). The practical implementation of hospital-based UNHS programmes for neonates, both with and without audiological risk factors, is considered to be the most viable option (Pastorino et al., 2005). UNHS programmes are, therefore,

recommended over targeted hearing screening measures, which were previously endorsed (HPCSA, 2007). Nevertheless, high-risk factors should not be disregarded as significant associations between particular risk factors and the results of certain audiological screening measures do exist (Korres et al., 2005).

Making decisions on the most advantageous approach for hearing screening in infants is an intricate and challenging task (Olusanya et al., 2005). This is why research that is context-specific yields more valid results that would lead to an implementation of a screening programme that is appropriate for that context, hence the current study.

Both the otoacoustic emission (OAE) and auditory brainstem response (ABR) measures may be employed to assess the integrity of the auditory system as a component of neonatal audiological screening programmes (Dolphin, 2004). These technologies can be judged against traditional screening measures where, unless the inflexibility of an observer-based psychophysical procedure is assumed in infants younger than 6 months, behavioural observation of an infant's response to sound stimuli will engender unrepeatable and unreliable results (Cone-Wesson, 2003). It is clear that neonatal hearing impairment is not readily identifiable through routine clinical measures such as behavioural observation audiometry (Widen, Bull & Folsom, 2003) because these measures present with several limitations within the realms of validity, test time and test interpretation (Lam, 2006). Hearing screening measures in neonates are required to be safe and valid and are to entail easy application (Olusanya et al., 2005). Both the ABR and OAE audiological screening measures satisfy these criteria for application in a newborn hearing screening programme (Hayes, 2003).

Modern audiological screening measures, such as the OAE and ABR, have improved the detection of permanent hearing loss in the neonatal population (Tsui, McPherson, Wong & Ng, 2008). Both OAE and ABR measures are objective physiological audiological screening tools endorsed for employment in newborn hearing screening programmes (HPCSA, 2007). The ABR response represents neural activity that is generated in the cochlea, the auditory nerve and the brainstem in response to an acoustic stimulus. This measure also reflects the status of the peripheral auditory system (JCIH, 2007). In contrast to this, OAE technology measures the physiology of the cochlear outer hair cells and is employed to assess pre-neural function only (Dolphin, 2004). The OAE measure does not evaluate the integrity of the neural transmission of sound from the VIIIth cranial nerve to the brainstem (Bush, 2003).

When comparing OAEs with ABRs, research has shown that each of these viable screening methods has both advantages and disadvantages (Llanes & Chiong, 2004) and that both of these measures are capable of identifying even a mild hearing impairment when used for screening (Widen et al., 2003). Although both the ABR and OAE measures are quick, non-invasive and acceptable by the majority of parents (Olusanya et al., 2005), the ABR screening measure is more expensive and more time consuming when compared to the economical and rapid OAE measure (Hyde, 2005). This factor has serious implications for resource-stricken countries such as developing countries. OAE measures are easily recorded in the newborn population, they are non-traumatic, active participation in the test procedure by the child is not needed and the result obtained is objective (Saurini, Nola & Lendvai, 2004). OAEs are valuable for implementation in UNHS programmes (Balatsouras et al., 2006) and, overall, have been proven as a more useful and efficient tool for universal hearing screening programmes in the newborn population (Saurini et al., 2004), when compared to

the ABR; even though their limitation of missing neural pathology such as auditory neuropathy has been well documented.

OAEs are electroacoustic measures that can be described as weak acoustic signals detectable in the external auditory meatus of most individuals with normal hearing abilities (Cone-Wesson, 2003). OAEs are based on detecting one's physiologic response to the presentation of an acoustic stimulus (Hayes, 2003). OAEs have drawn the attention of audiologists, cell biologists and engineers (Zhang & McPherson, 2008). According to Saurini et al. (2004), there are two general types of OAEs: spontaneous OAEs (SOAEs) and evoked OAEs (EOAEs). The presence of sound stimulation is not necessary to obtain SOAEs and these are also not useful from a clinical perspective, SOAEs are not obtainable across all normal ears and are considered to present at unpredictable frequencies (Bright, 2002). EOAEs can be obtained following the presentation of external acoustic stimuli (Durante, Carvallo, da Costa & Soares, 2005). These measures are clinically useful and the validity of these measures in newborn hearing screening programmes is undisputed (Torrico et al., 2004). EOAEs are divided into a number of classes commonly labelled in accordance with the evoking stimuli (Lam, 2006); with the most frequently used being transient evoked OAEs (TEOAEs) and distortion product OAEs (DPOAEs).

Boone et al. (2005) have described TEOAEs as low intensity sounds originating from the cochlea's outer hair cells. TEOAEs can be elicited in response to wide tone bursts or clicks presented to the ear through a probe. The response is then detected by a microphone within the same probe. It is the opinion of Wroblewska-Seniuk et al. (2005) that screening for hearing impairment using TEOAEs is sufficiently specific for implementation in UNHS programmes. UNHS using TEOAEs has been described as a precise and feasible approach to

the identification of congenital hearing impairment. TEOAEs are, therefore, considered a valuable tool with regard to newborn audiological screening (Korres et al., 2003).

Saurini et al. (2004) has described DPOAEs as audio-frequency sounds which are produced by the cochlea in response to the presentation of two sound stimuli, bound together by a frequency relationship. These two tones are known as primary tones and by altering the frequency of the two primary tones, the DPOAE response can be measured over a wide frequency range. These measures can, therefore, be employed to assess cochlear status in the high frequencies (Ng & McPherson, 2005). DPOAEs are used extensively for clinical purposes and can be measured in over 98% of normal ears. DPOAEs are, however, not measurable in the presence of a hearing impairment which exceeds 40dB (Saurini et al., 2004). DPOAEs are highly reliable (Balatsouras et al., 2006) and have been reported as a method of audiological assessment which can be employed in the newborn nursery (Torrico et al., 2004).

A comparison between TEOAE and DPOAE measures has indicated that DPOAEs are certain to outperform TEOAEs in noisy test environments. This is because DPOAE measures are believed to have superior noise immunity properties (Hatzopoulos, Petruccelli, Rossi & Martini, 2006). In addition to this, DPOAE stimuli are frequency-specific, while TEOAEs are not frequency-specific; TEOAEs are elicited using broadband stimuli. Based on this, DPOAE employment in neonatal hearing screening programmes may offer a more thorough assessment, compared to the use of TEOAEs. DPOAEs may thus replace TEOAEs in neonatal hearing screening protocols (Saurini et al., 2004).

OAE measures are being widely used in newborn hearing screening protocols (Tsui et al., 2008). According to Olusanya et al. (2005), these measures have been reported as highly sensitive, meaning that they detect the majority of infants presenting with a hearing loss. These measures have also been reported to be highly specific, meaning that they exclude infants that do not present with a hearing loss. The HPCSA (2007) reported a specificity rate in excess of 98% for OAE measures. In terms of sensitivity, even a mild hearing impairment will produce abnormal OAE results (Ansari, 2004). This sensitivity, however, is only the case for peripheral hearing impairment, as OAEs only assess the auditory system up to the level of the outer hair cells in the cochlea (Hyde, 2005). OAE production is pre-neural and is unrelated to both afferent innervation as well as efferent innervation (Dolphin, 2004) and is, thus, not valuable in the identification of post-cochlear hearing disorders (Saurini et al., 2004). Infants with normal functioning cochlear outer hair cells may present with auditory neuropathy or with auditory dyssynchrony caused by dysfunction in the neural or brainstem transmission of sound. These individuals will pass the OAE screening measures, irrespective of the degree of the central hearing impairment (Berg, Spitzer, Towers, Bartosiewicz & Diamond, 2005). It is thus evident that OAE measures are not a test of hearing, hence even in the presence of a normal OAE result, hearing abilities are not definitively regarded as normal until such time as a dependable behavioural audiogram is obtained (Bush, 2003). The afore-mentioned denotes that false-negative OAE results may occur (Ngo, Tan, Balakrishnan, Lim & Lazaroo, 2006).

A false-negative test result is obtained in cases where an infant passes the audiological screening test but does, in fact, present with a hearing impairment (Herrero & Moreno-Ternero, 2005). False-negative OAE results are to be deliberated in relation to

auditory neuropathy and central auditory impairment. However, this concern may be reduced in newborn hearing screening as it has been reported that very few neonates present with auditory neuropathy, brainstem defects and auditory cortex defects (Coates & Gifkins, 2003). In addition to false-negative OAE results, the presence of false-positive OAE test results in relation to neonatal audiological screening is to be contemplated (Ciorba et al., 2007).

A false-positive test result is obtained in cases where a neonate fails the audiological test, but does not truly present with a hearing impairment (Herrero & Moreno-Ternero, 2005). During OAE testing, any factor that interferes with the transmission of sound from the earphone to the cochlea and back to the recording microphone, including the presence of fluid in the middle ear and debris in the external auditory meatus, may result in a false-positive result being obtained (Korres et al., 2005). In line with the high false-positive rate associated with OAE screening in the neonatal population, some concern has arisen regarding the implementation of UNHS programmes and early post-natal hospital discharge (Lam, 2006).

According to Torrico et al. (2004) a fundamental problem with UNHS is the time at which the screening measures are carried out. Screening neonates for hearing impairment on the day of birth does appear to be problematic due to the increased possibility of obtaining a false-positive OAE screening test result. False-positive screening results may be caused by obstruction of the external auditory meatus by vernix, which is cleared automatically after the first day of life (Korres et al., 2003). Furthermore, within 24 hours of birth, there are signs indicating ABR threshold elevation, ABR wave I latency prolongation, low amplitude OAE results, negative middle ear pressure and the presence of a conductive hearing loss (Priner,

Freeman, Perez & Sohmer, 2003). These findings are significant in neonatal audiological screening programmes, as OAE responses are absent in the presence of conductive and mixed hearing impairments (Hof, Anteunis, Chenault & van Dijk, 2005).

Bartley and Digby (2005) have suggested that OAEs stabilise 48 hours post birth and, according to Korres et al. (2003), the ideal day for conducting hearing screening in neonates is on the third or fourth day after birth. The short postnatal stay of hospital-born infants is, however, noteworthy and does not allow for this testing time consistently to be observed. Healthy newborns are discharged from the newborn nursery within hours of birth (Low et al., 2005). A false-positive rate of 8% is reportedly typical for OAE screening in neonates at birth (Watkin, 2003). It has, however, been suggested by Shoup, Owen, Jackson and Laptook (2005) that re-screening within a few hours is effective in decreasing the frequency of false-positive OAE test results obtained through UNHS. The false-positive rate has been reported at 1% in cases where re-screening is conducted prior to discharge from the newborn nursery (Watkin, 2003). Ciorba et al. (2007) have highlighted that false-positive test results may have a negative impact on UNHS programmes. In line with this, a reduced false-positive OAE screening result rate will lead to a decrease in the ensuing negative impacts associated with neonatal audiological screening (Mathur & Dhawan, 2007).

The timing of the initial screening session is of relative interest. It has been suggested that, for UNHS purposes, OAEs be performed as late as possible after birth, but before discharge from the newborn nursery (Torrico et al., 2004). It has been proposed that hospital-based newborn hearing screening, prior to discharge from the newborn nursery, is possible and practical in the United Kingdom (Wessex Universal Neonatal Hearing Screening Trial Group, 1998) and 98% of newborns in the United States of America undergo audiological

screening after birth, prior to hospital discharge (Johnson et al., 2005). UNHS may thus still be practical, even in the case of early post-natal discharge (Korres et al., 2003). This has given rise to a principled responsibility to pursue various methods for the timeous identification of, and intervention for, congenital hearing impairment especially in developing countries, such as South Africa (HPCSA, 2007). Reasons for delays in the identification of, and intervention for, congenital hearing impairment must be explored and addressed in order to verify that UNHS is effective and beneficial (Weichbold, Nekahm-Heis & Welzl-Mueller, 2006a).

Poulakis, Barker and Wake (2003) have proposed that the presence of false-positive screening results may lead to additional and unwarranted evaluations of the infant which may, in turn, cause parental anxiety. According to Hyde (2005), this anxiety is the principle disadvantage of UNHS. Anchored in the possibility of maternal anxiety, many critics have refused to recommend neonatal audiological screening (Korres et al., 2003).

It is remarkable that the technological improvements in the OAE equipment employed in neonatal audiological screening programmes have already contributed to a decrease in the number of false-positive test results obtained (Méndez Colunga et al., 2005). Lahr and Rosenberg (2004) have also recommended that, in order to facilitate a parent's understanding of the importance of the audiological screening their newborn has undergone and to minimise parental anxiety, parents are to be provided with ample culturally and educationally relevant information in the newborn nursery. A reduction in parental anxiety may be accomplished through ensuring that parents recognise the meaning of being recalled for additional screening (Crockett, Wright, Uus, Bamford & Marteau, 2006). This can be achieved through an explanation of the procedures and results, the availability of pamphlets on audiological

screening and on hearing impairment; and can be reinforced by well-trained screening personnel (Hyde, 2005).

Realising and sustaining optimistic parental attitudes forms a fundamental aspect of a feasible and valid neonatal hearing screening programme (Ng, Hui, Lam, Goh & Yeung, 2004). This is significant because, notwithstanding the negative reports regarding UNHS, many audiologists, parents, educators and physicians maintain their support for, and encouragement of, universal programmes for the early identification of newborns presenting with a congenital hearing impairment (Olusanya et al., 2007). UNHS has gained this support as it is the most effective way to identify a congenital hearing impairment timeously (Lin, Huang, Lin, Lin & Wu, 2004) and is the avenue through which access to quality intervention may be made available (Yoshinaga-Itano, 2004). It is, however, essential to consider that the low incidence of detected neonatal hearing impairment, as well as the lack of funding for such initiatives, has an impact on programme continuation (Kanne, Schaefer & Perkins, 1999).

Specific research needs to be conducted in order to ensure that practice surrounding early hearing detection programmes can receive support (Gravel et al., 2005). Due to the high number of home-births, the Western approach to newborn hearing screening prior to discharge from the newborn nursery, within 6 hours of birth, may not be suitable for application in South Africa (Olusanya & Okolo, 2006). Alternate screening platforms, for this context, therefore need to be considered (Swanepoel et al., 2006). In identifying the most advantageous and appropriate screening approach, as suggested by Clarke, Iqbal and Mitchell (2003), the main aim of the current study was to determine the feasibility of audiological screening in low-risk neonates, using OAEs, at different times following birth.

SECTION III:

EMPIRICAL RESEARCH

Chapter 3

Research Design and Methodology

Terre Blanche and Durrheim (2006) define scientific research as a scientific activity that is objective, plausible and experimental. According to Durrheim (2006), research designs ought to stipulate a sequence of activities aimed to allow applicable and authentic suppositions to be extracted from the research.

This chapter will consider the chosen research design as the strategy for resolving the research question and will detail the methodological technique applied to attain, evaluate and scrutinise the research information.

Objectives of the Study

The objectives of this study are as follows:

Primary objective of the study.

The primary objective of the present study was to determine the feasibility of audiological screening in low-risk neonates, using OAEs, at different times following birth.

Specific objectives of the study.

The specific objectives of the current study were:

1. To investigate the practicability and efficiency when OAE screening takes place within 6 hours after birth, prior to discharge from the newborn nursery.
2. To investigate the practicability and efficiency when OAE screening takes place at 3 days after birth at the Midwife Obstetric Unit (MOU) 3-day assessment clinic.

3. To compare the findings of the OAE screening obtained across the two differing test times.
4. To identify the factors that may influence feasibility and efficiency at each test time.

Design of the Study

This research project has employed a quantitative research design. This has been appropriate for the purposes of this study as it provides precise quantitative information, with the research results reasonably independent of the researcher (Johnson & Onwuegbuzi, 2004). Quantitative research designs entail the utilisation of standardised measures, with fixed categories, to which numbers are assigned. For the purposes of this study, the standardised measures have been the audiological screening measures (otoscopic examinations and OAEs) and the fixed categories have referred to the screening results obtained (*"pass"/"refer"*). Each observation can only fall into a single category and this implies mutual exclusivity (Breakwell & Rose, 2006). Kumar (2005) has described this research design as restrictive in terms of the degree of enquiry since this design is reported to involve a pre-established and inflexible methodology. A quantitative research design is suitable for this project as this design boasts a larger sample size, is focused on a particular form of measurement and organisation of variables. This design is also somewhat analytical in nature and allows for the development of theories (Kumar, 2005). The primary benefit of this research design lies in the possibility of obtaining results which can be generalised (Patton, 2002).

Within the quantitative research design application for this research project, a longitudinal approach has been adopted. A longitudinal design, or within-subject design,

involves the collection of data from the same sample of participants at two or more points in time. The time period between data collection sessions, as well as the number of sessions, may vary - the study may be limited to a couple of days or may span over several years (Breakwell & Rose, 2006). For the objective of this study, there were two data collection sessions: one on the day of birth and then one at the MOU 3-day assessment clinic, with approximately 3 days between the sessions.

This project was non-experimental and may be labelled as a cohort study. Dawson and Trapp (2004) describe a cohort study as one that studies a group of participants where the group is followed for a period of time. For the purposes of the current study, the events of interest transpired following the commencement of the project, thus making this a prospective study (de Vaus, 2001). A cohort study is advantageous as it allows for the control of many sources of bias in relation to both participant selection as well as to measurement and it is also able to provide clear evidence. Although this design may be susceptible to challenges such as poor follow-up of participants, participant attrition and migration (Dawson & Trapp, 2004), it has remained appropriate for the intention of the present research project as part of a quantitative longitudinal design.

Research Site

The research was conducted at the Phola Park Community Health Centre (PPCHC) in Thokoza, Gauteng, South Africa. Thokoza is on the East Rand and is one of three townships in the Kathorus area, approximately 30km from Johannesburg (Federico, 2004). It was appropriate to conduct a study within the Gauteng province as 21.4% of the country's population live in the Gauteng province (Statistics South Africa, 2009). The researcher was

employed as an audiologist at PPCHC during the time of the study. The time period over which this study was conducted was from 30 August 2009 to 30 September 2009.

The research site was suitable for the purposes of the current study as it is safe for mothers and babies - with availability of 24 hour security and armed response, this may have an impact on the willingness of mothers to bring their newborns back to the clinic for follow-up testing. The site was suitable in terms of noise levels as well, as there were no nearby construction sites or roadworks. Electricity failures were also backed up by generators.

The MOU department at PPCHC is run by midwives. Dippenaar (2004) has described the South African context where midwives care for 77% of pregnant women and are, therefore, an integral part of the healthcare system. It has been stated that low-risk pregnancies are managed well by midwives (Dippenaar, 2004). In line with this, the MOU department at PPCHC refers any high-risk pregnancy to the hospital system and, as a result, only low-risk pregnancies and births are attended to at the CHC. Hence all the neonates attended to at the clinic are considered to be low-risk. District Hospital settings do offer a 24 hour service for obstetric complications, as well as deliveries of the majority of high-risk pregnancies and births (Department of Health, 2002).

Description of Participants

Participants in this study are described as follows:

The sample.

For the purposes of a research project, a sample refers to the subset of a population, where research results are obtained from the sample (Howell, 2004). Inferences may then be

made regarding population parameters based on the scores obtained from the sample studied (Myers & Well, 2003). For the purposes of this research project, the target population refers to the low-risk neonatal population in South Africa, while the accessible population refers to all neonates at PPCHC in Thokoza that were easily accessible to the researcher. The sample for this study has, therefore, been recruited from the accessible population - the neonates at PPCHC at the time of this study. The sample for this study was comprised of 272 neonates at PPCHC, 149 males and 123 females. The demographic profile of the participants in this study is detailed below in Table 1.

Table 1:

Demographic Profile of Participants (N=272)

Factor	**Number**	**Mean**	**Range**	**SD**
Gender	Male= 149	N/A	N/A	N/A
	Female=123	N/A	N/A	N/A
Age at session 1 (hours)	N/A	4.240	0.5 - 6	1.318
Age at session 2 (days)	N/A	3.918	3 - 7	1.075

Key: N/A= Not applicable

The sample for this study (*N*=272) is further divided into three distinct groups: the first group (*n*=99) is comprised of the neonates tested at session 1, the second group (*n*=173) is comprised of newborns tested only at session 2 and the third group (*n*=95) is comprised of neonates tested at both session 1 and session 2.

Sampling procedure.

According to Kumar (2005), sampling can be described as the selection of a small group of participants from a relatively larger group. The fundamental principle in sampling is that, if a somewhat small number of participants is selected, it can make available, with an amply high degree of probability, a reasonably accurate representation of the target

population. The precision of research findings relies significantly on the method by which the sample is selected (Kumar, 2005). However, even the most meticulously composed sample will rarely absolutely represent the population from which it is selected; there will always be an amount of sampling error (Rubin & Babbie, 2004). Therefore, the intention of any sampling design is to curtail, as much as possible, the disparity between the sample and the population from which it is drawn (Kumar, 2005).

The sampling method employed for the current study was non-probability sampling. This sampling method is also referred to as accidental sampling or as convenience sampling (Rubin & Babbie, 2004) and relies on the availability and accessibility of participants (Kemper, Stringfield & Teddlie, 2003). This particular method is frequently employed as it is thought to be economical and is often suitable for the type of research being conducted. Research projects which make use of convenience samples are usually able to present valuable and indispensable findings, particularly in research projects where the researcher is cautious with regard to over-generalisation of the research findings (Rubin & Babbie, 2004).

Participation in this research project was based on the willingness of parents to have their neonates participate in the study, as well as on the basis of inclusion criteria. All parents approached regarding the study agreed to have their newborns participate in this study, possibly due to the fact that this might have been viewed as part of required medical assessments. There were no parents that decided not to have their newborns participate in the current study.

Inclusion criteria.

According to Atkins, Siegel and Slutsky (2005), the target population for newborn

hearing screening programmes is to be clearly defined. For the purposes of this research project, low-risk newborns of either gender, of any race and of any culture were included as participants in this study. Participants were required to be well, full term neonates, born by normal vaginal delivery. A full term neonate is one that is born at 38-42 weeks gestation (Harrison, 2008). Participants were required to present with an unremarkable prenatal and perinatal history, as reported in the participant's clinic file. Meeting the above-mentioned criteria was not challenging during the current study as babies that presented with any prenatal or perinatal complications were discharged immediately from the clinic setting and referred to the hospital system. Also newborns born at PPCHC were born by normal vaginal delivery; no caesarean sections were performed at the clinic. In order to participate in this study, the neonates were required to be available for audiological screening on the day of birth, prior to discharge from the newborn nursery and/or approximately 3 days after birth at the MOU 3-day assessment clinic.

As highlighted by Pastorino et al. (2005), all neonates are to be included in a UNHS programme. Based hereon all newborns available were offered the newborn hearing screening during the time of the study and there were no exclusion criteria. However, babies that were identified as being at risk for hearing loss were handled differently. As the current study is focused on low-risk neonates, risk-factors which are documented to put the neonate at risk for congenital hearing impairment were collated and documented to ensure that analysis of data would be appropriately conducted. Neonates identified as having risk-factors for hearing loss were still included in the current study. High-risk factors may include a history of low birth weight (Roizen, 2003) where low birth weight refers to a newborn weighing less than 2500g (DeCherney, Nathan, Goodwin & Laufer, 2006). High-risk factors also include jaundice, perinatal hypoxia, premature birth (Roizen, 2003); a newborn born

before the 37th week of gestation is considered to be a preterm or premature neonate (DeCherney et al., 2006). A family history of PCHL or the presence of a craniofacial anomaly at the time of birth are considered as high risk factors (Lahr & Rosenberg, 2004), as are intrauterine infections (Morton & Nance, 2006), meningitis, septicaemia (Low et al., 2005) and a depressed Apgar score at 5 or 10 minutes post birth (Jiang & Wilkinson, 2006). It is, however, noteworthy that present risk indicators may not be recognised accurately by parents or by professionals (Weichbold, Nekahm-Heis & Welzl-Mueller, 2006b). Sood and Kaushal (2009) have also described how many hearing-impaired newborns do not present with any risk-factors.

Newborns older than 7 days at session 2 were not included in this study. The rationale for this is that the aim of UNHS is to identify congenital hearing loss (Lin et al., 2004), where congenital hearing loss, is a hearing loss present at birth (Madell & Flexer, 2008). A postnatal hearing loss is a hearing loss which is acquired after the perinatal period (Weichbold et al., 2006b), where the perinatal period refers to the period from 28 weeks complete gestation to day 7 after delivery (Mangate, 2004). Based on this, the 7 day cut-off was applied in an attempt to differentiate postnatal hearing loss from congenital hearing loss.

Test Protocol

The test protocol for this research project is described below.

Materials.

The materials which were employed for the purposes of this research project included a document of information and informed consent for the participant's parent (Appendix A), a case history checklist form (Appendix B) and a data collection form (Appendix C). A Heine

mini 2000 otoscope and a GSI AUDIOscreener were utilised for the purposes of this study and a sound level meter was employed to monitor noise levels during the hearing screening.

The participant information leaflet was designed to assist the parents of potential participants to make a decision regarding the participation of their newborn in the current study. The informed consent document was then signed by those parents who subsequently decided to have their neonate participate in the study. Schenker, Wang, Selig, Ng and Fernandez (2007) have described informed consent as a voluntary process where consent is given by a responsible proxy for a child's participation in a study.

The case history form is a document designed with the objective of obtaining information and relevant details pertaining to the participants of a study (Madell & Flexer, 2008) and was utilised to determine whether participants met the stipulated criteria for participation in the study at hand. Case history information is to be obtained prior to any screening taking place (Madell & Flexer, 2008) and only parents that had already decided to have their newborn participate in this study were interviewed for case history information. The process of obtaining a case history presents a valuable opportunity to establish a rapport with the mother/family of the participant; this in turn may result in an increased readiness on behalf of the mother to accept the screening results as well as any further recommendations that may be made (Madell & Flexer, 2008).

Madell and Flexer (2008) describe how a case history includes subject areas that are pertinent and relevant to the evaluation at hand. For the purpose of this screening, the required information was obtained through an interview with the mother as well as from the participant's clinic file. The case history form included biographical information so that the

researcher was able to collect data accurately. This information incorporated the date and time of birth of the participant. Details pertaining to the mother's pregnancy with the participant were included in this interview and were aimed at determining whether the pregnancy was a healthy one, whether any complications existed as well as to determine the age of the mother. Younger than 15 years and older than 35 years are regarded as the limits of maternal age (Norwitz & Schorge, 2006). Details regarding the birth of the participant formed a significant aspect of the case history, specifically the duration of labour, description of any complications, the Apgar score as well as the participant's birth weight. Questions regarding postnatal conditions and a family history of hearing impairment were included in the case history with the aim of establishing whether any risk factors were present. It was important to identify and document any possible risk factors for congenital hearing impairment which the participants presented with.

The data collection form, specific to this study, included a date and time of birth for each participant, the bilateral otoscopic examination result and bilateral DPOAE screening result for each participant at each screening session and a note column where place of birth and gender were recorded. The form was completed by the investigator and these results were analysed by the investigator once all the research data had been collected.

Test procedures.

The test procedures are detailed below.

Ethical considerations.

Ethical considerations are a significant component of research projects as a study may be viable from a practical perspective, but may essentially be unfeasible as it would be

deemed as unethical (Barrett, 2006). The principle of informed consent has become reputable as the foundation of ethical practice (Schenker et al., 2007). The researcher, therefore, ensured that the parents of participants had full access to information regarding the screening process. This was achieved through the divulging of possible risks and benefits of the screening process, prior to soliciting a decision to participate that was given voluntarily and without restraint as is prescribed by the HPCSA (2007). Ethical merit necessitates that the parents of research participants fully understand the manner and intention of the research being conducted and that the parents are given the opportunity to make un-coerced decisions to have their newborns participate in the study (Long, 2007). Based on this notion, the researcher ensured she obtained informed consent from the families of participants prior to conducting any screening measures on their babies.

There has been much deliberation regarding the ethical aspects of research in developing countries, such as South Africa, as the chief motivation for participation in research projects may be access to otherwise unavailable healthcare services (Macklin, 2004). To avoid this, for the duration of the current study, the neonatal audiological screening services at PPCHC were not limited to research participants, but were made available to all newborns at the centre.

All newborns in whom hearing impairment was suspected, and subsequently identified, had access to the readily available follow-up services at PPCHC. These services included a diagnostic assessment, the necessary intervention for the hearing impairment and the requisite counselling services. From an ethical standpoint, screening is only justifiable in cases where the associated and necessary treatments are readily available to, and affordable for, those who do not pass the screening (Olusanya et al., 2004).

Schenker et al. (2007) have reported that the presence of language barriers in developing countries may pose a challenge to the provision of screening services. The researcher therefore attempted to minimise this challenge as far as possible through the employment of a trained interpreter. An interpreter was employed as it was essential to make certain that effective communication takes place between the researcher and the families of participants in the study as is prescribed by the HPCSA (2007). Olusanya et al. (2004) highlights the importance of parental knowledge regarding infant hearing screening. The researcher therefore conveyed information about all aspects relating to the screening process and the research project to parents in a truthful manner. The ethical principle of veracity, which encourages professionals to be truthful and not to mislead the participant's family (Fried, 2003), was therefore adhered to as well. Additionally, the welfare of participants and their respective families was considered by the researcher at all times throughout this study. Leedy and Ormrod (2001), stipulate that the researcher has an obligation to protect the participants from harm.

It has been reported that, in developing countries, ethical concern regarding the risk of exploitation exists, where participants are merely used for the purposes of the research with a complete lack of consideration for the wellbeing, needs and dignity of the participants (Emanuel, Wendler, Killen & Grady, 2004). Thus, to ensure ethical merit, the dignity, wellbeing and rights of the research participants and their families are to be respected (Diekema, 2006) and this was adhered to during the research process for the current study. In accordance with the stipulations given by the JCIH (2007), the participants in research projects and their respective families also have the right to confidentiality regarding all aspects of the screening being conducted.

The maintenance of confidentiality is highlighted as a key criterion for ethical practice. The investigator is accountable for maintaining participant confidentiality (Green & Thorogood, 2004). Hearing screening and assessment results are to be awarded the same protection as all other academic and healthcare data (HPCSA, 2007). To guarantee confidentiality throughout this study, research numbers were allocated to the participants as an alternative to recording names and clinic file numbers. Parents of participants were also informed in advance of the details which may be included in the research report, as well as of the parties and authorities that may be awarded access to the research data.

With regard to ethical approval, the investigator is responsible to ensure that the study has the approval of the applicable ethics committees. The researcher also has a duty to present detailed information regarding the research proposal and the research results to the authorities concerned (Green & Thorogood, 2004). The researcher ensured that this was done.

Obtaining ethical clearance.

Formal ethical clearance was obtained for this research project as it involves human participants (Appendix D). This clearance was obtained from the Human Research Ethics Committee (HREC) of the University of the Witwatersrand (Protocol Number M090836) and this research project did not commence until the required ethical clearance had been granted. Ethical considerations were continually scrutinised throughout the course of the research project. In line with the guidelines proposed by Long (2007), it was at no stage pre-supposed that the ethical aspects of the research project entailed no further deliberation from the investigator following the attainment of ethical clearance.

A positive attitude, optimism and support from the institution concerned towards neonatal audiological screening are imperative (Korres et al., 2006). For the purposes of this project, written permission to conduct this research at the MOU department of PPCHC was obtained from both the facility manager at PPCHC and from the head of the MOU department at this centre. (Appendix E).

Recruitment of participants.

Regarding the recruitment of participants, consent had been obtained from the facility manager at PPCHC, as well as from the head of the MOU department at this centre, for the investigator to approach the mothers of potential participants directly. The researcher introduced the concept of UNHS and OAEs as well as the process thereof to the parents of prospective participants at the PPCHC MOU section. This explanation was provided verbally, a trained interpreter was employed to ensure complete understanding as language barriers may confound such communication (Chen, 2006). Following verbal explanations, information leaflets were issued. These leaflets contained written explanations of the procedure as well as the rights of participants and the rights of their parents. Participation was then considered and informed consent subsequently obtained from the parents of potential participants. Participants were issued with a research number, which was then used in place of the participant's name or clinic file number.

The collection of case history information.

Following the attainment of informed consent for participation in the study, case history information per participant was obtained using a case history checklist. The case history information was drawn from the participant's clinic file by the researcher and from interviews with the participant's mother. All relevant information was recorded on the case

history form. In the presence of a language barrier, the services of a trained interpreter were employed in order to ensure the gathering of adequate case history details and to facilitate clear communication between the investigator and the parents of the research participants (Schenker et al., 2007).

Audiological screening.

In order to investigate this area of enquiry for this project, there were two newborn hearing screening test sessions. The initial screening session (session 1) took place at PPCHC in the MOU department's newborn nursery, within 6 hours of the participant's birth, before discharge from the birth facility. The second screening session (session 2) also took place at PPCHC as part of the MOU 3-day assessment clinic, approximately 3 days after the participant's birth.

Tattersall and Young (2006) have suggested that, in the case of a healthy infant obtaining a "*pass"* result during the initial screening process, no additional testing is necessary. Despite this suggestion, for the purposes of this study, irrespective of the result obtained at the initial screening session, all neonates were booked for re-screening at the MOU 3-day assessment clinic. (See figure 1).

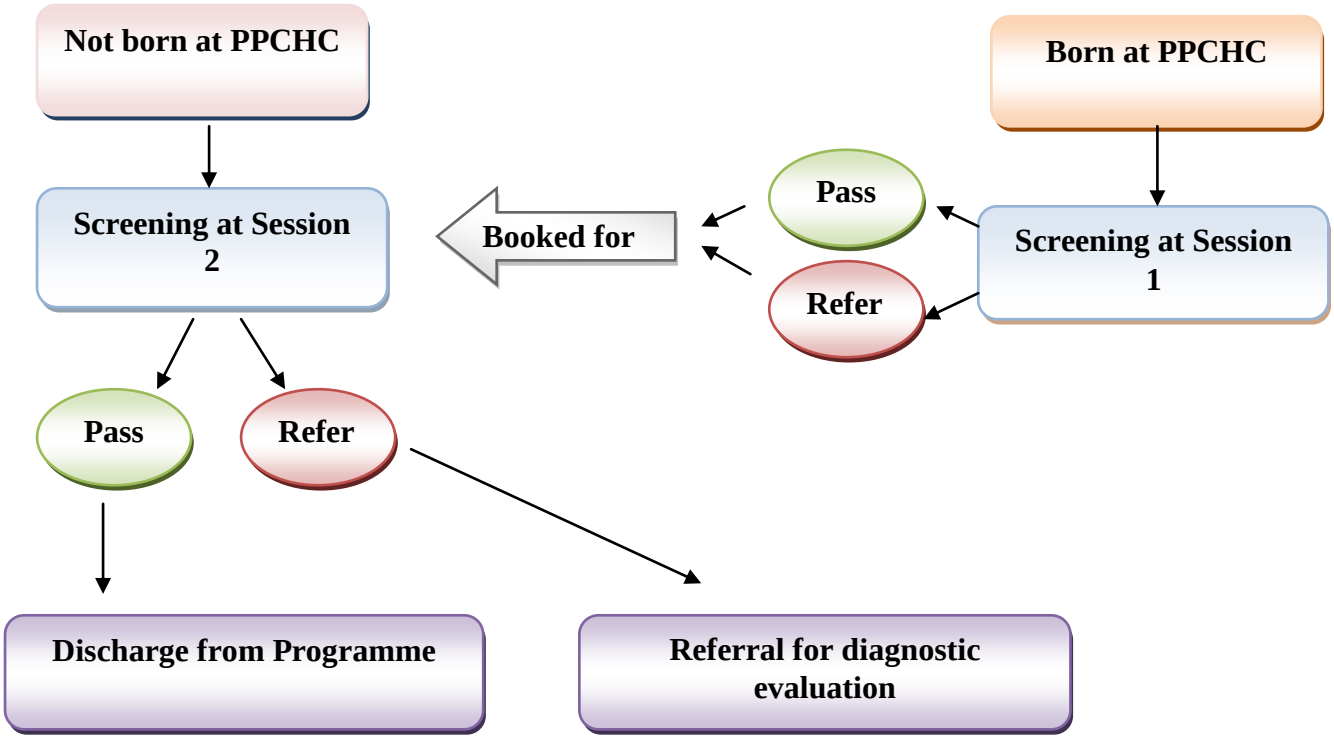

Figure 1: Procedure for Audiological Screening

At each audiological screening session, an otoscopic examination was carried out in both ears on each participant. A Heine mini 2000 otoscope was used for this purpose. An otoscopic examination is a subjective procedure deemed to be useful in the assessment for the presence or absence of middle ear effusion and to examine the external auditory meatus in order to assist with the selection of an appropriate probe tip (Jones & Kaleida, 2003). In the past, specialists have purposely highlighted the diagnostic worth of the otoscopic examination, claiming that the appropriate utilisation of this procedure may lead to improved diagnosis of middle ear pathology (Orji & Mgbor, 2007). Although the otoscopic examination is a subjective measure, it is also a cost-effective and a highly-rated diagnostic tool (Olusanya, Okolo & Adeosun, 2004). The otoscopic examination therefore ought to form part of standard paediatric audiological evaluations. There should be objective and subjective components of paediatric audiological assessments (Psarommatis, Valsamakis, Raptaki, Kontrogiani & Douniadakis, 2007).

For the otoscopic examination during this study, a "*pass"* result represented a clear external auditory meatus with no foreign bodies or debris in the external auditory canal, no obvious middle ear pathology and a visibly intact and healthy tympanic membrane. The otoscopic examination is a key stage in the newborn hearing screening process, as middle ear pathology has an adverse effect on the detectability of OAE responses and the presence of cerumen or vernix in the external auditory meatus is frequently implicated in failed hearing screenings (Hof et al., 2005).

Following the otoscopic examination, a DPOAE screening was conducted in both ears of each participant. In order to obtain a DPOAE response, a small probe is inserted into the participant's external auditory meatus (Tattersall & Young, 2006). To enhance the probe fitting, the tester may remove and clean the probe tip and then re-test immediately (Nicholson & Widen, 2007) and this was done from time to time in the current study.

The GSI AUDIOscreener was employed to obtain the DPOAE measures for this study. This tool is a portable, hand-held screener with automatic operations for quick and simple screening and is designed for UNHS purposes. This screener incorporates calibration within the test-ear, which promotes total screening accuracy (Viasys Healthcare, 2009). The test parameters were set according to the default screening protocol setting "Quick DPOAE" and three frequencies (2000Hz, 3000Hz and 4000Hz) were assessed for each ear per participant. The criteria for an overall "*pass"* result were based on passing at least two of the three frequencies tested.

The hearing screening test results can be obtained in only a few seconds as DPOAE screening devices conveniently feature pass-fail algorithms (Hyde, 2005). Screening

methodologies that include automated response detection are preferable to the screening methodologies that require operator interpretation. Therefore, to decrease tester error, a programmed OAE machine with pass/fail criteria is recommended (Coates & Gifkins, 2003) and was employed for the purposes of the current study. The audiological screening results obtained, per participant, across the two screening sessions were recorded by the investigator, using the data collection form. The screening results were recorded across the "*pass"*/"*refer"* category. The term "*refer*" was used in place of the term *"fail"* with the aim of emphasising that not passing the screening session indicates necessity for follow-up testing to confirm or exclude the presence of a hearing impairment (Widen et al., 2003).

The overall "*pass"* criteria for the purposes of this research project were a normal otoscopic examination on the left and right ear, as well as a bilateral "*pass"* result for the DPOAE screening. It has been suggested that newborns that do not pass the initial hearing screening session can be re-tested prior to hospital discharge (Shoup et al., 2005). It has been implied that test repetition may result in a reduction in the high "*refer"* rates from UNHS (Korres et al., 2006). Thus the overall specificity of a screening protocol can be increased by testing infants twice (Shoup et al., 2005). In line with this, for the purposes of this study, participants not obtaining a "*pass"* result were re-screened immediately.

All neonates who do not pass the birth admission audiological screening session and any follow-up screening sessions are to undergo thorough audiologic and medical examinations in order to verify the presence of a hearing impairment before the infant is 3 months of age (Prieve, 2007). Therefore, for the purpose of the current study, in the case of a neonate not passing the second screening session, the neonate was referred for a full audiological assessment. Following each screening session, time was taken by the

investigator to explain the results of the screening to the parent of the participant and to answer any questions the parent had regarding the screening process or result.

The results were given to parents in the form of "*pass"* or "*refer"* directly after each session. A "*pass"* screening result was explained to parents as a clean, clear ear canal with a visible eardrum and a "*pass"* OAE result, as given by the OAE machine. The researcher explained a "*refer"* screening result as meaning that follow-up testing is needed to confirm or exclude the presence of a hearing loss, because a "*refer"* result may indicate the presence of a hearing loss. It was also explained to parents that, in these cases, the Audiology Department at PPCHC will provide counselling, in-depth tests and the necessary intervention, thus ensuring early detection of hearing loss and early intervention for their newborn. At the time of providing an explanation of the screening results to parents of participants in this study, the researcher explicated that any factor that interferes with the transmission of sound from the earphone to the inner ear and back to the machine, including the presence of fluid in the middle ear and debris in the external auditory meatus, may cause an inaccurate OAE "*refer"* result to be obtained (Kemp, 2002). The examiner also clarified that the OAE only measures up to the inner ear and does not test hearing from the inner ear to the brain, so a "*pass"*result does not automatically mean that the neonate can hear.

OAE responses can be obtained in a non-soundproofed environment (Durante et al., 2005). Therefore, for the initial testing session, within 6 hours of birth, audiological screening took place in the post-delivery room, in the MOU department at PPCHC. Screening was conducted while the neonate was lying in an open crib. The participants need not be asleep for the OAE testing, as an OAE can be obtained in various states of arousal (Lustig, Niparko, Minor & Zee, 2003). Screening during the second test session took place in

the Rehabilitation department at PPCHC, which is off the same corridor as the MOU department. Noise levels in both testing environments were controlled and monitored and kept at an absolute minimum.

Clark, Kemp and Bankaitis (2003) have emphasised that infection control measures are not to be neglected. According to Bankaitis and Kemp (2003), infection control can be defined as a methodical endeavour to manage the environment with the aim of reducing exposure to pathogenic micro-organisms. For this study, standard infection control measures were implemented. The tester washed her hands before and after every participant was tested, hands were washed with antibacterial liquid soap and dried using paper toweling. The probes and speculi were sterilised before and after each use, using Milton's sterilising fluid, as these items come into contact with cerumen (Bankaitis & Kemp, 2003). Cerumen is deemed to be infectious material when contaminated by blood or mucous. Cerumen should, therefore, be handled as an infectious substance as one is unable to determine the content of cerumen by means of visual scrutiny (Bankaitis & Kemp, 2008). For this reason, gloves were worn by the tester when handling objects contaminated by cerumen (Bankaitis & Kemp, 2003).

Validity and Reliability

The concepts of validity and reliability are widely applied in various forms of research (Golafshani, 2003). According to Rubin and Babbie (2004), validity and reliability are inter-related notions, but these notions are, however, not synonymous. Validity refers to whether the means of measurement in a research project are precise and whether they fundamentally measure that which they propose to measure (Bell, 2005). In addition to this, validity purports that the results of the research project, as well as the conclusions drawn by

the investigator, are verifiable by both the researcher as well as by others (Kumar, 2005). On the other hand, Bell (2005) defines reliability as the constancy of research results over time and the accurate representation of the population which is under study. Embodied in the notion of reliability is the concept of replicability of results (Golafshani, 2003). The goal of any research project should be to maximise these concepts as far as possible (de Vaus, 2001).

For the purposes of the current study, a trained interpreter was employed when indicated in order to obtain an accurate case history for each participant (HPCSA, 2007). This contributed to the validity and reliability of the data obtained for the case history. To ensure that an accurate case history was obtained, information obtained during the interview was cross- checked with the detail recorded in the participant's clinic file. The researcher deemed the perusal of the clinic file as an adequate method for cross-check. In terms of test procedures, the employment of an otoscopic examination, conducted prior to the OAE screening, ensured an accurate interpretation of the OAE result obtained and thus added to the aspects of validity and reliability. The OAE screening measure, which is considered as accurate and objective (Hyde, 2005), contributed to reliability and validity, as these screening measures are reportedly both reliable and sensitive (Kemp, 2007). In an attempt to ensure validity and reliability throughout this study, the appropriate screening equipment was utilised and protocol strictly adhered to (Eiserman et al., 2008). Protocols also remained constant between participants; and calibration of the OAE machine was ensured. Furthermore, it has been suggested that, in order for OAE measures to be reliable, ambient noise levels should not exceed 50 to 55dB A of noise (Rhoades, McPherson, Smyth, Kei & Baglioni, 1998). This recommendation does differ from the suggestion by Olusanya (2010) that screening is valid up to 68dB A; while Kemp (2002) has recommended a test environment with background noise below 40dB. For the purposes of the current study, the

guideline proposed by Rhoades et al. (1998) was adhered to. Noise levels in both of the test environments were measured using a sound level meter to ensure that the environment remained appropriate for audiological screening; that is between 50 to 55dB A of noise.

Factors such as the representativeness of the selected sample may influence the external validity of a study (Rubin & Babbie, 2004). In this study, the sample size was selected based on statistical reasoning and is, therefore, sufficient to represent the population from which it was drawn - thus contributing to validity.

Data Analysis and Statistical Procedures

The data analysis and statistical procedures for the current study are detailed below.

Neuman (1997) describes data analysis as the identification and establishment of data trends by means of arranging and classifying the information obtained. This study entailed the collection of categorical data, used for classification purposes, where categorical data can be defined as the frequency of observations falling into various categories (Howell, 2004). The categories pertaining to this project were those of "*pass"* and "*refer*".

In order to determine the feasibility of audiological screening in low-risk neonates, using OAEs, at different times following birth, various statistical tests were conducted. Statistics can be defined as summarising data in a sample from which observations have been extracted and numerical values calculated (Howell, 1999).

In the analysis of the data collected as part of the current study and with the aim of determining the feasibility of audiological screening in low-risk neonates, using OAEs within

6 hours of birth, prior to discharge from the newborn nursery; cross-tabulations were employed. Cramer (1994) has indicated that cross-tabs is short for cross tabulations or contingency tables and Howell (1999) has defined a contingency table as a two- dimensional table wherein each observation is simultaneously categorised, based on two variables. In addition to cross-tabs, the matched pair's t test was also utilised in this investigation. The matched pair's t test is employed to assess whether the difference between the two paired population means is equal to 0. The null assumption is that it is equal to 0 (Bowers, 2008).

To investigate the practicability and efficiency of OAE screening in newborns approximately three days after birth at the MOU 3-day assessment clinic, cross-tabs and the matched pair's t test were again utilised.

In a comparison between the findings obtained across the two differing screening sessions, the matched-pairs t test was used. The matched pair's t test can be employed in the event of the same individual being tested twice, or in the event of participants being matched in pairs (Welkowitz, Cohen & Ewen, 2010).

In order to determine the factors which may influence feasibility at each test time, descriptive and correlation statistics were applied. Descriptive statistics describe and comment on the data obtained and allow the opportunity for comparison of results to be made among subjects (Rosenthal & Rosnow, 1991). Correlation statistics were used to describe the relationship between the otoscopy and OAE result. Howell (1999) defines correlation as the relationship that exists between variables and the correlation coefficient as the degree of that relationship. Correlation coefficients range from -1 to +1: the closer the coefficient is to each of these limits, the stronger the relationship is. Howell (1999) describes the standard

correlation coefficient as Pearson's r. This applies principally to variables distributed along interval or ratio scales of measurement. For the purposes of this study, dummy variable coding has been employed as a method for handling nominal variables (Powers & Xie, 2008). Binary coding has been adopted, where 0 indicates a "*refer"* result and 1 indicates a "*pass"* result. These are dichotomous variables (Hardy, 1993). Dichotomous variables are also known as binomial variables, where only two possible categories or values exist (Argyrous, 1997). In the current study, both the dependent variables (test results 0, 1) and independent variable (test procedures) are dichotomous, where the independent variable refers to the variables that can be controlled by the researcher and the dependent variables refer to the data obtained (Howell, 1999). The Phi correlation coefficient is appropriate for application as a measure of association in cases where both variables are dichotomous (Cramer, 1994). For the Phi coefficient; the standard Pearson's r correlation procedure is applied for calculation purposes, with the answer labelled as Phi, as it is a special case of Pearson's r (Howell, 1999). Levin and Fox (1994) have highlighted that a 2 x 2 table is a criterion for Phi coefficient application.

The number of neonates presenting with "*refer"* findings were analysed unilaterally and bilaterally using descriptive statistics.

SECTION IV:

PRESENTATION,

ANALYSIS & DISCUSSION

OF FINDINGS

Chapter 4

Results

A sample of 272 low-risk neonates was screened for hearing impairment during the current study, across the two screening sessions. This sample was comprised of 149 male participants and 123 female participants. Figure 2 illustrates the number of males and females that formed the sample for the current study.

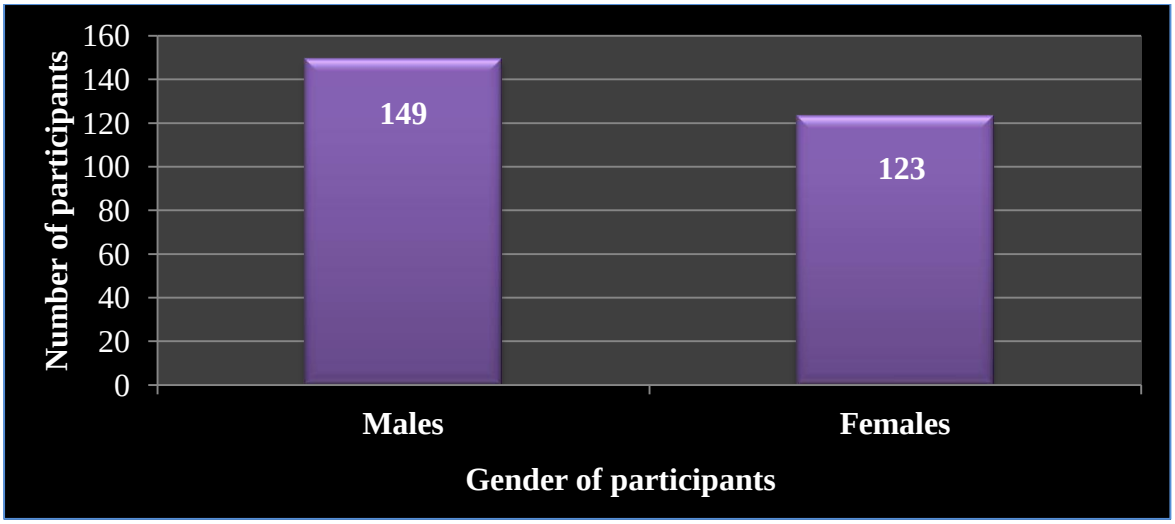

Figure 2: Comparison of the Number of Male and Female Participants in the Current Study (*N*=272)

For the current study, risk factors for hearing impairment were noted during the collection of data. Only one of the neonates was identified as having a positive family history for PCHL. Table 2 depicts the risk factors for hearing loss that were identified and documented in the current sample.

Table 2

Occurrence of Risk Factors in the Sample Screened (N=272)

Possible risk factors for hearing loss	**Participants identified with the risk factor**
Low birth weight	0
Jaundice	0
Perinatal hypoxia	0
NICU admission	0
Family history of PCHL	1
Craniofacial anomaly	0
Depressed APGAR score	0
Premature birth	0

The Practicability and Efficiency of OAE Screening within 6 Hours after Birth

The first objective of the current study was to determine the practicability and efficiency of neonatal audiological screening when OAE screening takes place within 6 hours after birth, prior to discharge from the newborn nursery. In terms of practicability, aspects taken into account included the availability of participants, Asma et al. (2008) defines the coverage rate as the percentage born during the study that were tested, available resources in the form of staffing, the working hours of the audiologist and the time-frames of discharge from the newborn nursery, as well as the test equipment. In terms of efficiency, aspects taken into consideration included the results obtained for the otoscopic examination and for the otoacoustic emission, as well as the referral rate. The time taken per screening measure also forms part of the evaluation of the efficiency of OAE screening within 6 hours after birth.

During the time of the current study, 260 neonates were born at PPCHC. However, only 99 (38.07%) of these newborns, 49 male and 50 female, were screened at session 1. The 99 newborns screened at session 1 were available for screening at session 1; that is that the time period between the neonate's birth and discharge from the newborn nursery fell within normal working hours, when the audiologist was on duty to perform the screening. It is notable that the 99 newborns screened at session 1 comprised all the participants approached

to participate in the study, as no participants declined the screening services as part of the current study. A total of 161 newborns were missed at the first screening session, as these neonates were born over weekends or during the night. The time period between these neonates' births and their discharge from the newborn nursery did not fall within normal working hours when the audiologist was on duty to perform the screening and this is depicted in Figure 3 below.

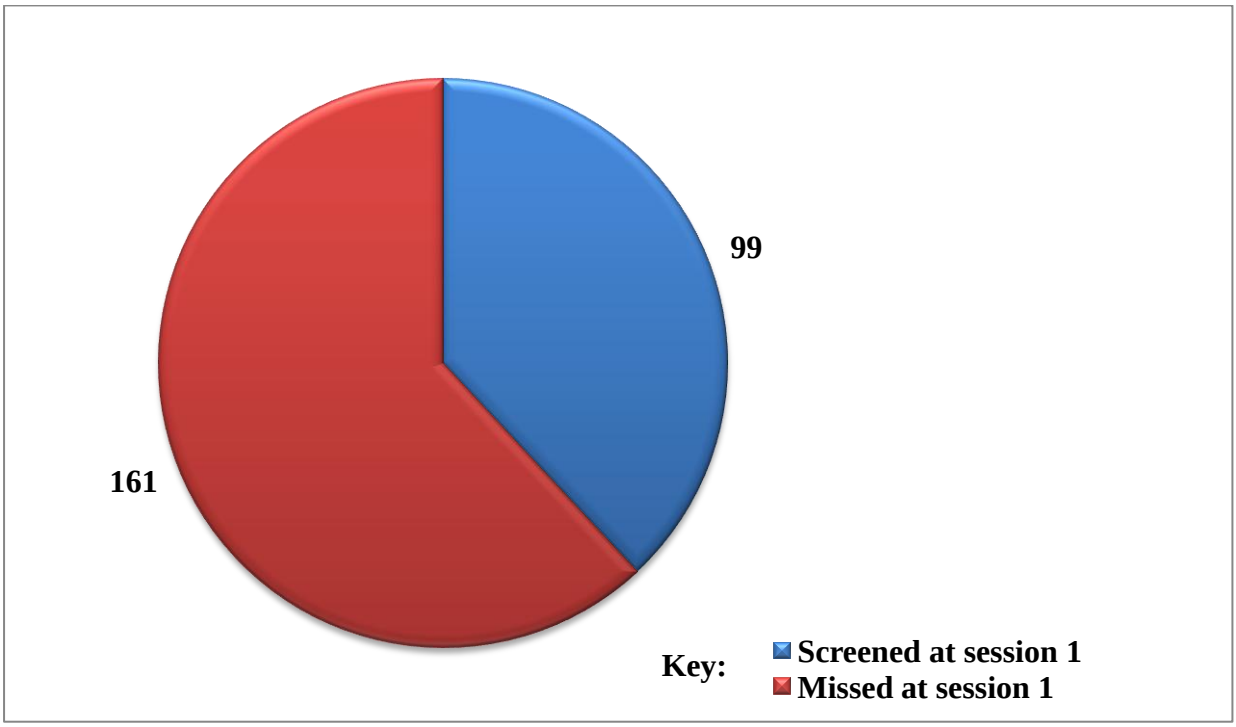

Figure 3: The Number of Participants Screened and Missed at Session 1, of the 260 Born at PPCHC

In terms of staffing resources for the purposes of the current study, there was only one audiologist on duty at the facility. As far as equipment is concerned, a Heine mini 2000 otoscope and a GSI AUDIOscreener were used to conduct the screening on all participants, in both ears. The equipment was in good working order and had been calibrated prior to the commencement of the study.

In evaluating the efficiency of OAE screening at session 1; the screening results obtained have been taken into account. Out of the 99 participants screened at session 1, 16 newborns obtained an overall "*pass"* result for the audiological screening and the remaining 83 participants obtained an overall "*refer*" result; this equates to an 83.83% refer rate. With the overall "*pass"* criteria for the purposes of the current study being a normal otoscopic examination bilaterally as well as a bilateral "*pass"* result for the DPOAE screening, the results for both the otoscopic examination as well as for the DPOAE screening at session 1 are detailed in Table 3 below.

Table 3

Summary of the Screening Results Obtained During Session 1 of the Current Study.

Procedure & Result obtained	**Unilateral**	**Bilateral**	**Total ears**	**Total participants examined**
Otoscopic Examination- "*Pass*"	7	17	41	99
Otoscopic Examination- "*Refer*"	7	75	157	
DPOAE- "*Pass*"	9	16	41	
DPOAE- "*Refer*"	9	74	157	

Of the 99 participants screened at the first session of the current study; 75 newborns presented with bilateral "*refer*" results for the otoscopic examination and 74 newborns presented with bilateral "*refer*" results for the DPOAE procedure. Seventeen neonates presented with a bilateral "*pass"* result for the otoscopic examination and 16 neonates presented with a bilateral "*pass*" result for the DPOAE screening measure. There were 7 participants that presented with a unilateral "*pass"* result for the otoscopic examination and 9 participants presented with a unilateral "*pass"* result for the DPOAE screening measure. In the 7 cases, the laterality of the ear in which the "*pass"* result for the otoscopic examination

and DPOAE screening was obtained correlated. There were 2 newborns that obtained a bilateral "*pass"* result for the otoscopic examination, yet obtained a unilateral "*refer"* result for the DPOAE screening. In the current study, there were no neonates that obtained a "*refer"* otoscopic examination result and a "*pass"* DPOAE screening result. This data is detailed in Table 4 below.

Table 4

Breakdown of Screening Results Obtained During Session 1

Detailed results obtained	**Number of participants**
Number of bilateral "*refer*" result for Otoscopic examination and DPOAE screening	74
Number of bilateral "*pass*" result for Otoscopic examination and DPOAE screening	16
Number of unilateral "*pass*" result for Otoscopic examination and DPOAE screening on the left ear	4
Number of unilateral "*pass*" result for Otoscopic examination and DPOAE screening on the right ear	3
Number of bilateral "*pass*" result for Otoscopic examination, unilateral "*refer*" result for DPOAE screening	2
Total number of newborns screened at session 1	99

According to Hall (2000) the OAE, when used as part of a UNHS programme, has a fairly short test time. The time taken to conduct the hearing screening on each participant is recognised as an aspect in the evaluation of the efficiency of OAE screening within 6 hours after birth, prior to discharge from the newborn nursery. However, this aspect was not formally measured as part of the current study and did not seem to be problematic - i.e. the time taken with each neonate was appropriate for a screening session.

The Practicability and Efficiency of OAE Screening 3 Days after Birth

The second objective of the current study was to determine the practicability and efficiency of OAE screening when it is conducted approximately three days after birth at the

MOU 3-day assessment clinic. Similar aspects and factors that were investigated in session 1 were examined in session 2 as well. With regard to practicability, facets such as participant availability as well as human and equipment resource availability were considered. Efficiency was considered based on the otoscopic examination and otoacoustic emission screening results obtained, the rate of referral as well as the time required per screening measure.

During the time of the current study 260 neonates were born at PPCHC. It is noteworthy that a total of 268 neonates, 147 males and 121 females, were included at the second screening session, 173 more than at session 1. This indicates that 8 newborns not born at PPCHC were included at the second screening session; this is shown in Table 5 below.

Table 5

Difference Between Total Births at PPCHC and Number of Newborns Screened at Session 2

Total births at PPCHC	**Number screened at session 2**	**Difference**
260	268	8

For session 2 of the current study, there was still only one audiologist on duty at PPCHC from 08:00 to 16:30 on weekdays. As screening was conducted as part of the MOU 3-day assessment programme, during scheduled times daily, no newborns were missed due to discharge time-frames or due to the audiologist's working hours.

In the evaluation of the efficiency of audiological screening at session 2 of the current study, of the 268 participants screened at session 2, 266 participants obtained an overall "*pass"* result. Two participants did obtain an overall *"refer"* result for the audiological

screening, which equates to an overall "*refer"* rate of 0.74% for the audiological screening results obtained during session 2. The audiological screening results obtained during the second screening session are detailed in Table 6 below.

Table 6

Summary of the Screening Results Obtained During Session 2.

Procedure & Result obtained	**Unilateral**	**Bilateral**	**Total ears**	**Total participants examined**
Otoscopic Examination-"*Pass*"	1	267	535	268
Otoscopic Examination-"*Refer*"	1	0	1	268
DPOAE-"*Pass*"	2	266	534	268
DPOAE-"*Refer*"	2	0	2	268

There were no neonates that presented with bilateral "*refer"* results for both the otoscopic examination as well as for the DPOAE screening measure during session 2. There was 1 participant that presented with a unilateral "*pass"* result for both the otoscopic examination and the DPOAE screening measure. In this case, the laterality of the ear in which the "*pass"* result for the otoscopic examination as well as the DPOAE result were obtained correlated. There was 1 newborn that obtained a bilateral "*pass"* result for the otoscopic examination, yet obtained a unilateral "*refer"* result for the DPOAE screening. It is worth noting that both the DPOAE "*refer"* results obtained were unilateral. There were no neonates that obtained "*refer"* otoscopic examination results and "*pass"* DPOAE screening results. This information is detailed in Table 7.

Table 7

Breakdown of Screening Results Obtained During Session 2

Detailed results obtained	**Number of participants**
Bilateral "*refer*" result for Otoscopic examination and DPOAE screening	0
Bilateral "*pass*" result for Otoscopic examination and DPOAE screening	266
Unilateral "*pass*" result for Otoscopic examination and DPOAE on the left ear	0
Unilateral "*pass*" result for Otoscopic examination and DPOAE on the right ear	1
Bilateral "*pass*" result for otoscopic examination, unilateral "*refer*" result for DPOAE	1
Total newborns screened at session 2	268

In terms of efficiency, the follow-up rate is to be taken into account. In the current study, of the 99 newborns that were screened at session 1, 95 participants returned for follow-up screening at session 2, as part of the MOU 3-day assessment clinic. This equates to a follow-up return rate of 95.95%.

As in session 1, although not measured, the amount of time required to conduct the hearing screening on each neonate is acknowledged as a factor in the assessment of efficiency of OAE screening. This did not seem to be problematic in that the time taken with each neonate was appropriate for a screening session.

Comparison of Findings across the 2 Screening Sessions

The third objective of the current study was to compare the findings of the neonatal audiological screening obtained across the 2 different screening sessions.

During the time of the current study, 260 newborns were born at PPCHC. During session 1 of the current study only 99 newborns were screened, but 268 newborns were screened at session 2. This difference is depicted below in Figure 4.

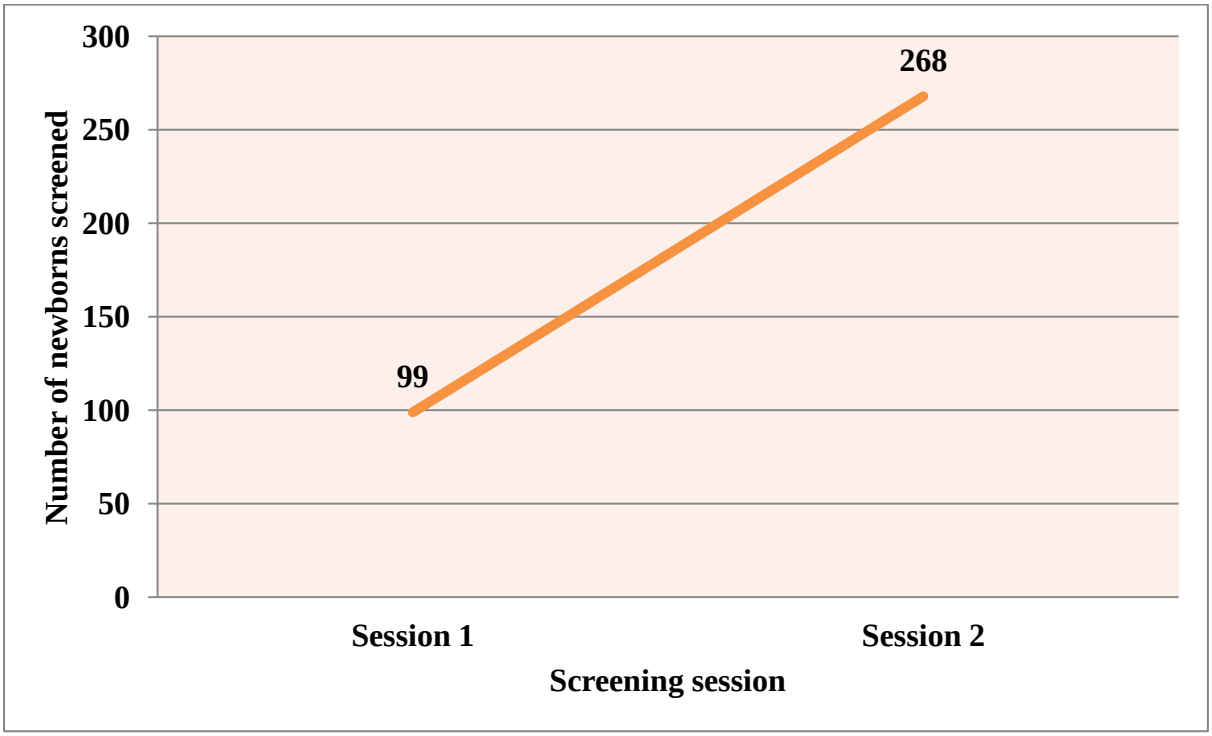

Figure 4: Comparison of the Number of Participants Screened at Session 1 and Session 2

A total of 161 neonates were missed at the first screening session as these neonates were born over weekends or during the night and, due to discharge time-frames, the audiologist was not on duty to perform the screening. There were 268 newborns tested at session 2 as screening at session 2 was not affected by time of birth and discharge being outside of working hours. Audiological screening at session 2, as part of the MOU 3-day assessment clinic, was the final screening session where referrals for diagnostic assessments were made. There were 2 participants that did not pass the screening at session 2. One obtained a unilateral *"refer"* result for the otoscopic examination and the DPOAE screening

and the other participant obtained a unilateral DPOAE *"refer"* result. These neonates were referred for further testing.

In the current study, a total of 95 participants underwent screening at both sessions. The screening results for each of these participants has been captured across the 2 screening sessions and compared. It is notable that the majority of these participants (73.68%) obtained bilateral "*refer"* results for the otoscopic examination and DPOAE screening at session 1 and then obtained bilateral "*pass"* results for the otoscopic examination and DPOAE screening at session 2. There was a single participant who obtained an overall "*refer"* result at both sessions and 16 participants who obtained an overall *"pass"* result at both sessions. A total of 78 participants obtained a *"refer"* result at session 1 and a *"pass"* result at session 2. It is notable that there were no participants that obtained a *"pass"* result at session 1 and a *"refer"* result at session 2. This is depicted in Table 8 below.

Table 8

Contingency Table to Compare the Results, Within Participants, Obtained at Session 1 and Session 2

Table of S2_Overall by S1_Overall				
		S1_Overall		
		0	1	Total
S2_Overall				
0	Frequency	1	0	1
	Col Pct	1.27	0	
1	Frequency	78	16	94
	Col Pct	98.73	100	
Total	Frequency	79	16	95
Frequency Missing = 177				

Key:

S1= Session 1
S2=Session 2
Col Pct=Column Percentage
0 =Overall "Refer" result
1= Overall "Pass" result

It is notable that there were no participants that obtained a *"pass"* result at session 1 that did not present for screening at session 2, but there were 3 participants with bilateral *"refer"* results at session 1 that did not present for re-screening at session 2.

In comparing the feasibility and efficiency of audiological screening at various times following birth, the number of "*refer"* results obtained across the 2 sessions has been taken into account. With regard to the otoscopic examination results, of the total "*refer"* results obtained, 99.36% of these were obtained during session 1; while only 0.63% were obtained at session 2. This indicates a considerably higher "*refer"* rate for otoscopic examinations at session 1 compared to session 2, approximately 3 days later. This detail is depicted in Table 9 below.

Table 9

Summary of Otoscopic Examination Results Obtained at Session 1 and Session 2

Otoscopic examination	**Ears examined**	**Clear "*Pass*"**	**Visible vernix "*Refer*"**	**Total examined**
Session 1	198	41	157	99
Session 2	536	535	1	268
Total per category	734	576	158	367

In comparing the feasibility and efficiency of audiological screening at various times following birth, the number of DPOAE "*refer"* results obtained across the 2 sessions has been taken into account. Of the total "*refer"* results obtained; 98.77% of these was obtained during session 1, while only 1.22 % was obtained at session 2. Thus the refer rate for DPOAE screening at session 1 is notably increased when compared to the rate at session 2. This is depicted in Table 10 below. These findings do correlate with the otoscopic examination findings and it is thus apparent that a significantly larger number of "*refer"*

results for both the otoscopic examination as well as the DPOAE screening are obtained at session 1 when compared to session 2.

Table 10

Summary of DPOAE Screening Results Obtained at Session 1 and Session 2 in the Current Study

DPOAE result per ear	**Ears examined**	**"*Pass*"**	**"*Refer*"**	**Total examined**
Session 1	198	37	161	99
Session 2	536	534	2	268
Total per category	734	571	163	367

Figure 5 below represents a summary of the outcomes for the 2 screening sessions in the current study.

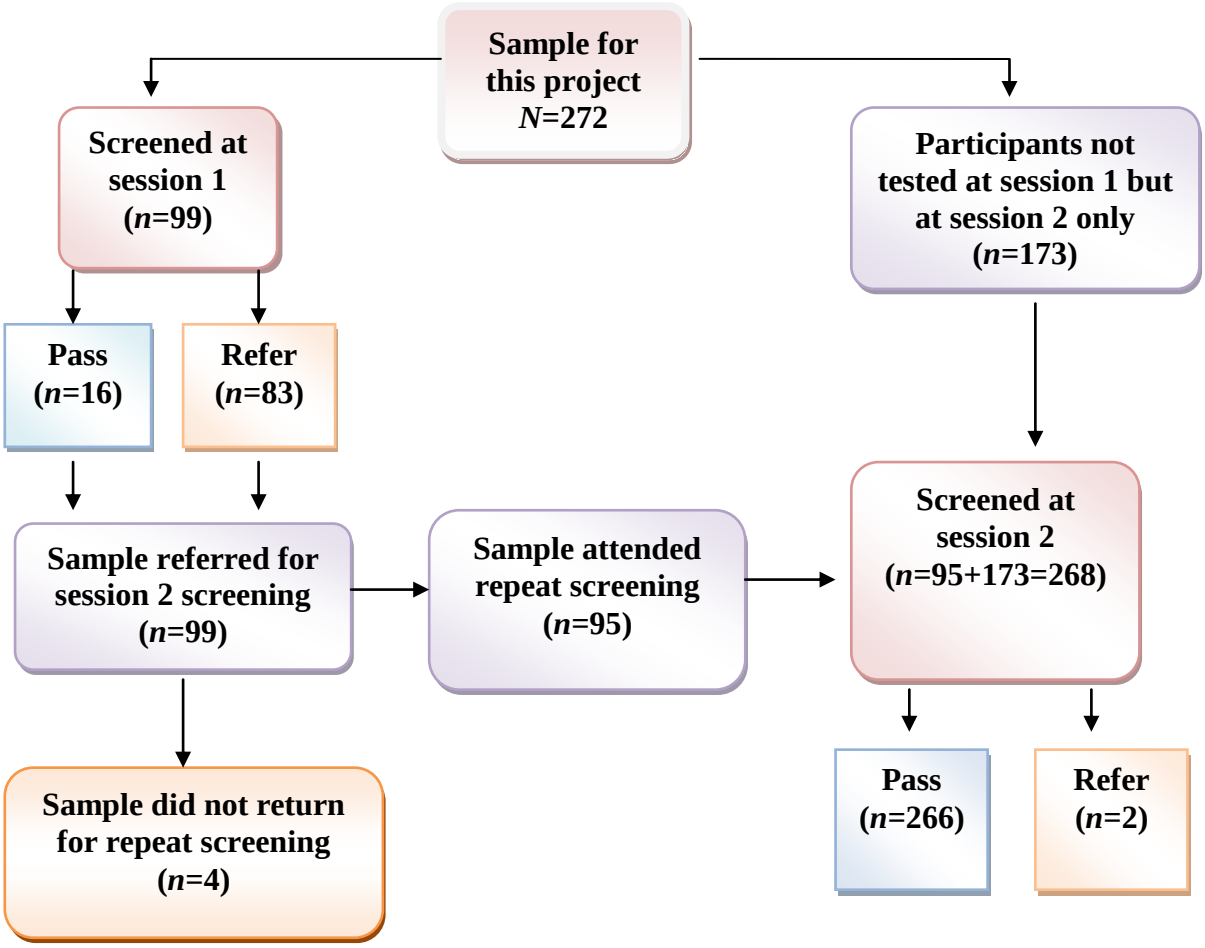

Figure 5: Summary of Screening Outcomes in the Current Study.

In a comparison of the test environments for session 1 and session 2 of the current study, the environments for both test sessions were controlled for noise and ambient noise levels did not exceed 55dB A of noise - as suggested by Rhoades et al. (1998). In terms of equipment, the same otoscope and screener were used to conduct screening in all participants. The GSI AUDIOscreener that was employed to obtain the DPOAE measures at both sessions included automated response detection and is a recommended screening tool (Coates & Gifkins, 2003). These factors did not, therefore, play a role in the comparison of OAE screening at session 1 and at session 2.

Factors Influencing the Feasibility and Efficiency of Screening at each Test Time

The fourth objective of the current study was to identify factors that may influence the feasibility and efficiency of the screening at each test time. Throughout the course of the current study, the researcher took note of factors that may have an impact on the feasibility and efficiency of newborn audiological screening at session 1 and session 2. These factors are listed below in Table 11.

Table 11

List of Factors that may Affect the Feasibility and Efficiency of Screening at Each Test Time

Factor	**Session affected**	**Effect on practicability or efficiency**
Time of birth relative to working hours	1	Practicability
Time of discharge relative to working hours	1	Practicability
Staff resources	1 & 2	Practicability
Equipment	1 & 2	Practicability
Environment	1 & 2	Practicability
Noise levels	1 & 2	Practicability
Referral rate	1 & 2	Efficiency
Return for follow-up rate	2	Efficiency

The time of birth of the neonates, as well as the time of discharge from the newborn nursery, have been identified in the current study as factors, as they may have an impact on whether or not a newborn will undergo screening at session 1. This is because the audiologist is only available to conduct screening during normal working hours (Monday to Friday 8:00 to 16:30). This means that several newborns may be missed at the session 1 screening due to birth in the evenings and/or over weekends. These factors do not, however, appear to have any bearing on the feasibility or efficiency of neonatal audiological screening at session 2, where screening takes place during scheduled times as part of a normal working day. One of the participants born within normal working hours was born before the study commenced and, although counted here, this participant was only included for screening from session 2. This information is detailed in Table 12 below.

Table 12

Comparison of Infants Born at PPCHC and Discharged Within Normal Working Hours and Outside Normal Working Hours

Time period before discharge from clinic after birth	**Number of participants**
Within normal working hours (Monday-Friday 8:00-16:30)	100
Outside of normal working hours (Monday-Friday 8:00-16:30)	160
Total number of participants	260

Resources, in terms of staff and equipment, have also been identified in the current study as a factor that may have an impact on the practicability of newborn hearing screening at both test times. In terms of human resources, during the course of the current study there was only one audiologist on site at PPCHC. This has a significant bearing on the practicability of neonatal hearing screening at both session 1 as well as at session 2. With regard to equipment, there was only one portable otoscope and OAE screening machine available for use.

In terms of test environment in the current study, the availability of testing space may have an impact on the practicability of neonatal audiological screening at both screening sessions. It would be best if the screening can take place in a designated space that is controlled and private. In terms of environmental noise, this is often a factor for consideration (Salina, Abdullah, Mukari & Azmi, 2010). However, in the current study, this did not have an impact on the practicability of OAE screening at session 1 or at session 2 as it was measured and controlled by the tester. In the current study, the first screening session took place in the post-delivery room in the MOU department with the neonate lying in an open crib; the second hearing screening session took place in the rehabilitation department at PPCHC. For the purposes of the current study, ambient noise levels did not exceed 55dB A of noise - as suggested by Rhoades et al. (1998). This was achieved through the utilisation of a sound level meter to monitor noise levels during the hearing screening at both session 1 and session 2.

The test environment may have a noteworthy impact on the time required to carry out the testing (Salina et al., 2010). According to Ahmad, Mohamad, Mansor, Daud and Sidek (2011), the site of the neonatal audiological screening can even result in a high failure rate. Testing in the study by Chan and Leung (2004) was affected by ambient noise such as the waiting room noise and noise from the announcement system. In the current study, both rooms utilised for the screening sessions were at the end of the passage, away from the waiting rooms and thus away from the noise. There was also no announcement system in operation at PPCHC during the current study. In addition to this, PPCHC is surrounded by an open field on one side, a community vegetable garden on the other side and two quiet roads on the other two sides. The socio-economic status of the Thokoza township means that

there are fewer cars and people generally walk to the clinic. These factors lead to less traffic noise and reduced environmental noise in general.

The number of "*refer*" results obtained in the current study has been identified as a factor that may influence the efficiency of OAE screening at session 1 and at session 2. A "*refer*" rate of 83.83% at session 1 for the current study is related to a reduced efficiency of screening results at session 1. The "*refer*" rate at session 2 for the current study was much lower than at session 1 at 0.74%.

In the current study, the return for follow-up rate has been identified as a factor that may influence the efficiency of audiological screening at session 2, approximately 3 days after birth as part of the MOU 3-day assessment clinic. Out of the 99 newborns screened at session 1, 95 newborns screened returned for follow-up audiological screening at session 2. This is a return for follow-up rate of 95.95%.

Stevens (1999) details the level of significance as 5% where there is a 5% chance of making a Type I error or saying that there is a difference between groups when, in reality, there is not. It is notable in Table 13 that $p < 0.0001$, which indicates a very small chance that the differences are due to things other than group membership, where group membership refers to whether or not newborns were tested at session 2. The matched pair's t test indicated statistically significant differences between session 1 and session 2 findings ($p<0.0001$).

Table 13

Matched Pair's t Test Results

t Test					
The TTEST Procedure					
Difference: S1_Overall - S2_Overall					
N	Mean	Std Dev	Std Err	Minimum	Maximum
95	-0.8211	0.3853	0.0395	-1	0
Mean	95% CL Mean		Std Dev	95% CL Std Dev	
-0.8211	-0.8996	-0.7426	0.3853	0.3373	0.4495
DF	t Value	Pr > |t|			
94	-20.77	<.0001			

Key:

S1= Session 1
S2=Session 2

Using the Phi correlation coefficient, a correlation between the OAE and otoscopy results have been computed. This is in order to determine and describe the link between the otoscopic examination and OAE results. It can be noted that there is no Phi, as the results obtained are the same when the right ear is considered. It is evident in the table below that 1 participant obtained a *"refer"* OAE result in the right ear at sesssion 2, while all the other 267 participants obtained *"pass"*results for the otoscopic examination and OAE screening measures. This is detailed in Table 14.

Table14

Phi Correlation Coefficient Result When Considering OAE and Otoscopic Examination Results on the Right Ear for Session 2.

Table of S2_Oto_R by S2_OAE_R				
		S2_OAE_R		
		0	1	Total
S2_Oto_R				
1	Frequency	1	267	268
	Col Pct	100	100	
Total	Frequency	1	267	268
Frequency Missing = 4				
No phi since they are the same				

Key:

S1= Session 1
S2=Session 2
Col Pct=Column Percentage
0 =Overall “Refer” result
1= Overall “Pass” result

Chapter 5

Discussion

The HPCSA has highlighted that, in order to guide the implementation process of UNHS in South Africa, research data concerning the efficacy and practicability of these screening programmes is required (HPCSA, 2007) - hence the importance of the current study. With the aim of identifying the most feasible and efficient newborn hearing screening approach, as suggested by Clarke et al. (2003), the main objective of the current study was to determine the feasibility of audiological screening in low risk neonates, using OAEs at different times following birth. Sun et al. (2009) have proposed that an efficient and organised newborn hearing screening programme could contribute to the avoidance of developmental delays and could contribute to society's alleviation of healthcare-related burdens. The current study was conducted in accordance with the suggestion made by Swanepoel et al. (2006) where they state that alternate screening platforms for UNHS need to be considered. For the purposes of this study, newborn hearing screening as part of the MOU 3-day assessment clinic was considered and evaluated.

In the current study, the sample comprised 272 newborns and there were no exclusion criteria for the purposes of this study. The study was focused on low-risk newborns, as the newborns enrolled in the clinic system are considered to be low-risk. Any newborns presenting with prenatal or perinatal conditions are referred to the hospital setting and would thus not be available for testing at the clinic or for participation in the current study. In light of this, noted risk factors for hearing impairment that were identified during the current study were collated and documented so that data could be analysed accordingly. In the current study; 1 newborn was identified as having a positive family history for PCHL. Lahr and

Rosenberg (2004) have listed this as a risk factor for hearing impairment. It is noteworthy that no other risk factors for hearing impairment were identified during the data collection of the current study. This is consistent with what would be considered appropriate in low-risk neonates and indicates that the current sample is representative of the general low-risk neonatal population.

The first objective of the current study was to determine the practicability and efficiency of neonatal audiological screening, when OAE screening takes place within 6 hours after birth, prior to the newborn being discharged from the newborn nursery. During the time of the current study, 260 neonates were born at PPCHC, yet only 99 of newborns underwent screening at session 1, a mere 38.07%. There were no newborns whose parents refused screening at session 1; yet 161 newborns were missed at the first screening session.

Factors contributing to the reduced number of participants at session 1 may include the time of birth, as the audiological screening at session 1 only took place at the centre during normal working hours, being on a Monday to Friday (8:00 to 16:30). Many newborns were born outside of this time frame, were discharged within 6 hours of birth and were thus not screened. The findings from the current study are consistent with reports by Ng et al. (2004) from a study they conducted at The University of Hong Kong, Queen Mary Hospital, where neonates were discharged without screening due to the time of birth and discharge outside of normal working hours. The study conducted by Abdullah et al. (2006) reported that 10.8% of newborns were missed at the session 1 screening while, in the current study, 61.92% were missed at session 1. This is significantly higher and has serious implications for the current context. The reasons for this, as documented by Abdullah et al. (2006), included discharge during weekends, absent screening personnel and neonates that were

unintentionally overlooked. Although this is similar to the findings from the current study, a marked difference between the study by Abdullah et al. (2006) and the current study exists. In the current study, newborns were discharged within 6 hours of birth; in the study by Abdullah et al. (2006) neonatal screening at session 1 took place within 24 hours of birth. The longer hospital stay meant that fewer newborns were missed due to working hour limitations in the study by Abdullah et al. (2006) when compared to the current study. In spite of these findings, it is notable that Lim and Daniel (2008) have reported that screening prior to discharge after birth offers the greatest coverage. Nonetheless, this is a significant factor which reduces practicability of neonatal audiological screening using OAEs within 6 hours of birth.

Adelola, Papanikolaou, Gormley, Lang and Keogh (2010) refer to a newborn hearing screening programme where the screening takes place in the maternity ward within 48 hours of birth from Monday through Friday. Adelola et al. (2010) has described how the screening is conducted at the bedside and in the presence of the neonate's mother. In that programme, the missed babies are sent for session 2 screening at the outpatient department. In a private healthcare setting, the minimal period for hospital stay post-birth is 24 hours and this is sufficient time to allow for universal newborn hearing screening to be conducted (Swanepoel et al., 2007). In addition to this, it is possible for screening to be conducted from Monday through to Saturday in these contexts; again due to the availability of resources (Swanepoel et al., 2007). This is a great contrast to the structures surrounding UNHS for the current study in a government clinic where newborns are discharged from the clinic 6 hours post-birth and where the audiologist is only available to conduct the screening during normal working hours. This implies that the practicability for session 1 in the current study is compromised. This has significant implications for implementing UNHS in CHC settings across South

Africa, where similar protocols are followed in terms of discharge times and the availability of audiologists or other screening staff.

EHDI co-ordinators are to be attentive to circumstances under which infants may be lost to the UNHS system. These may include home/out-of-hospital births and hospital missed screenings when infants are discharged prior to the hearing screening being conducted (JCIH, 2007). This is especially considerable for efficiency of screening at session 1 in the current study, where newborns are discharged within 6 hours of birth and where the audiologist conducting the screening is only available during normal working hours. Spivak (1998) has emphasised that a course for managing home births, early hospital discharge as well as private births needs to be instituted so that high coverage and consistent services can be delivered; and it is the opinion of the current researcher that this is crucial in a developing country like South Africa where not all births are hospital births.

In terms of resources related to staffing, there was only one audiologist on site to conduct the neonatal audiological screening. The audiologist did adhere to normal working hours and this resulted in several newborns being missed at the initial screening session. This was proven to have a negative impact on the practicability of neonatal audiological screening at session 1. Theunissen and Swanepoel (2008) have stated that the most commonly reported grounds for the lack of neonatal screening programmes is the shortage of suitable screening equipment, as well as personnel shortages. Widen et al. (2003) have also explained that trained nursing staff and volunteers are able to conduct newborn hearing screening tests; which is consistent with the statement made by Hayes (2003) that newborn hearing screening can be conducted by trained volunteers. Hayes (2003) has, however, stipulated that an audiologist's supervision is required in this event. The notion of newborn hearing screening

being conducted by non-audiological staff is supported by the study conducted by Ferro, Tanner, Erler, Erickson and Dahr (2007) where Newborn Hearing Screening programmes in Illinois were compared. In their study, hearing screening was commonly conducted by the nursing staff.

Throughout areas such as Latin America, the availability of hearing healthcare professionals is limited, especially in rural communities (de Garcia, Gaffney, Chacon & Gaffney, 2011). In the study by Chan and Leung (2004), the screening was conducted by enrolled nurses who had received training on OAE testing. These nurses conducted automated OAE screening and performed standard nursing duties as well. In contrast to this, in the current study, screening was only carried out by a qualified audiologist. This is the standard protocol in South Africa generally; and it was also a result of time and resource limitations. Chan and Leung (2004) report that UNHS programmes, where screening is conducted by nurses, is a practical option; and Olusanya, Wirz and Luxon (2008) have reported similar findings in that community health workers - with concentrated and direct training - are able to conduct effective neonatal audiological screening. In the current study, in the event of the audiologist being ill for a day, the programme would be gravely affected as no other screening staff was available; a finding that can be generalised to a majority of clinics in South Africa as similar staffing and scope of practice conditions apply.

Hall (2000) has stated that universal newborn hearing screening through the use of OAE measures can be recorded dependably by non-audiologic personnel. In the current study, if screening was conducted by trained nursing staff, this would have meant that screening could have been conducted 7 days a week and 24 hours a day. Thus the number of newborns missed at session 1 would have been greatly reduced. This is inconsistent with the

findings stated by Eiserman et al. (2008) in that OAE measures are only practicable for implementation as part of UNHS programmes when the testing is conducted by qualified hearing healthcare professional. Albuquerque and Kemp (2001) have recommended that, if babies are discharged at any time, 24 hours screening services should be available 7 days a week.

In terms of resources as it relates to test equipment, there was only one otoscope and OAE screening machine available for use at session 1 for the purposes of this study. This does have a bearing on practicability, especially if the equipment became faulty or malfunctioned. For the purposes of the current study, the otoscope was in good working order and the GSI AUDIOscreener was in good working order and had been calibrated. The same equipment was used to screen all newborns and this, therefore, contributes to practicability of screening at session 1. The test environment for session 1 was controlled for noise and a dedicated test space was allocated for testing. These factors contributed to improving the practicability of neonatal audiological screening at session 1. This highlights the importance of having a dedicated noise controlled test environment, as well as functional equipment, for a successful implementation of UNHS.

In determining the efficiency of screening at session 1 for the current study, the audiological screening results obtained at that session have been considered. Of the 99 participants screened at this session, an overall "*refer"* rate of 83.83% was obtained. In light of such a high "*refer"* rate, it is essential to consider the possibility of false-positive results where a neonate does not pass the hearing screening but does not truly present with a hearing impairment (Herrero & Moreno-Ternero, 2005). In the case of neonatal audiological screening, false-positive screening results have been reported as a major concern (Lam,

2006). False-positive results may be obtained when the transmission of sound from the earphone to the cochlea and back to the recording microphone is interrupted (Korres et al., 2005). Screening newborns on the day of birth is of particular concern due to the presence of vernix in the external auditory meatus (Korres et al., 2003). Based on this fact, the high "*refer"* rate at this screening session is not unexpected. Albuquerque and Kemp (2001) have stated that, when newborns are discharged from the birthing facility within 6 hours of birth, OAEs will render an unacceptably high false-positive rate; a finding supported by the results of the current study. Hall (2000) has stated that the higher the "*refer*" rate is, the lower the OAE specificity is; and this therefore has a negative impact on the efficiency of screening at session 1 for the current study. This does highlight the pitfalls of screening at this time and reduces the efficiency of screening at this session. These findings are not consistent with the American Academy of Paediatrics (1999) where it has been stated that OAEs render a 5-20% "*refer*" rate in the first 24 hours post-birth. The findings in the current study are also not consistent with the results reported by Abdullah et al. (2006) where, at session 1 within 24 hours of birth, a "*refer*" rate of 19.7% was obtained. The reason for this inconsistency may be attributable to the time difference between 6 hours for the current study and the 24 hour discharge time-frame for the study by Abdullah et al. (2006). Current study findings provide evidence that, within the South African context, screening prior to discharge (which is often within 6 hours of birth) might not be the best time and might also be more detrimental than beneficial due to the impact of false-positive findings on the mother's well-being.

The second objective of the current study was to determine the practicability and efficiency when OAE screening takes place approximately 3 days after birth as part of the MOU 3-day assessment clinic. Coverage is an important aspect of a newborn hearing screening programme (Stevens & Parker, 2009). During the time of the current study 260

neonates were born at PPCHC, but it is, however, noteworthy that a total of 268 neonates were included at the second screening session. This implies that newborns born outside of PPCHC presented to the clinic and were included at the second screening session. Place of birth may influence the outcomes of a UNHS programme as this has an impact on the number of newborns that can not be tested at session 1 - purely because they may not have been born at PPCHC. Olusanya and Somefun (2009) have emphasised that a sizeable percentage of neonates with hearing impairment in numerous developing countries are born outside of hospital settings. This accentuates the necessity for community-oriented UNHS, which will lead to early detection and intervention. In terms of coverage, Akhtar, Datta, Alauddin and Kamal (2010) have stated that, in order to identify all newborns with a hearing loss, all newborns need to be screened. In developing countries many newborns with sensorineural hearing loss are born at home and, therefore, session 2 testing may be more practical as these newborns can then be included in the screen as well (Olusanya & Somefun, 2009). Based hereon it is evident that screening newborns for hearing loss at the MOU 3 day assessment clinic is practicable, as more newborns can be tested during this time-frame. In the current study, there were newborns that were born at home or on the way to the clinic. Thus, even in the presence of early discharge from the newborn nursery from various institutions and even in the case of births outside of the hospital (home based), newborns can still undergo hearing screening in the first few days of life. This contributes to the efficiency as well as the practicability of screening at this time. It has been recommended by Lim and Daniel (2008) that a screening protocol be developed where neonates born at home or outside of the healthcare facility can be screened and perhaps even be run in conjunction with other programmes. In line with this recommendation, the current study has proven the feasibility of the implementation of audiological screening as part of the MOU 3-day assessment clinic.

For the purposes of the current study, only one hearing healthcare professional was on duty at PPCHC. However the impact of this staffing limitation was less influential at the second screening session as newborn screening was only conducted during scheduled times of the day and there was thus no impact of discharge time and birth times. The MOU 3-day assessment clinic is where medical check-ups on both the mother and baby take place; and so the attendance is higher since the neonate will be undergoing a medical examination as well as a hearing screening. This highlights the importance of scheduling a hearing screening at the same time as a routine medical check-up. This will ensure that attendance is less costly for the parents in that it is cost effective to come for a single appointment to see several professionals than to present for appointments on different days.

Ng et al. (2004) conducted a study at the Tsan Yuk hospital, which is a university teaching hospital situated in Hong Kong. Ng et al. (2004) reported a high default rate for follow- up screening between days 21 and 30 after birth. This default rate may be due to migration as well as parents being unwilling to return to the birthing facility for only a hearing test. Ng et al. (2004) have stated that the ideal time for screening would be when the neonate and mother present for a routine medical check up. The findings of the current study support this and this again highlights the value of the MOU 3-day assessment clinic, where both the mother and child present for a post-birth medical check up.

Bartley and Digby (2005) have reported that OAEs stabilise after day 2 post-birth and this may explain the decrease in the number of "*refer"* results obtained at the second screening session in the current study. In a study conducted by Vaid et al. (2009), 1238 well newborns were screened. In their study, a "*refer*" rate of 11.14 % was reported when newborn hearing screening was conducted at 3 days post-birth. This finding is consistent

with the results reported by Doyle, Burggraaf, Fujikawa and Kim (1997) where 200 well newborns were tested at 5 to 120 hours post-birth. These authors have reported that the OAE "*pass*" rate increases in infants older than 24 hours. The findings of the current study are consistent with this as a "*refer*" rate of 0.74% was obtained at session 2.

In terms of efficiency, the follow-up return rate was taken into account. In the current study, 95 of the 99 neonates screened at session 1, returned for follow-up screening at session 2. This equates to a follow-up return rate of 95.95% and indicates that session 2 is efficient as a platform for UNHS.

The third objective of the current study was to compare the findings of the neonatal audiological screening obtained across the 2 differing test times. Two hundred and sixty newborns were born at PPCHC. At session 1 of the current study, only 99 newborns were included. However 268 newborns were included at session 2. Screening for session 1 of the current study only took place at PPCHC and this meant that only newborns born at PPCHC could be included. However, newborns born outside of PPCHC could be included at the second screening session and this positively influences the practicability of screening at session 2. Of the 99 participants included at session 1, only 4 did not attend the second screening session. A total of 95 participants were screened at both session 1 and session 2, which implies that screening at session 2 is more practical, based on the increased number of participants available at this test time.

With regard to the audiological screening results in the current study, of the "*refer"* results obtained for the otoscopic examination, 99.36% were obtained at session 1 while only 0.63% were obtained at session 2. A total of 98.77% of the DPOAE "*refer"* results were

obtained during session 1 and the remaining 1.22% were obtained at session 2. The audiological screening results from session 2 indicate an overall "*refer"* rate of 0.74%. This is significantly lower than the "*refer"* rate obtained during screening at session 1 and implies that several false-positive results may have been obtained during the audiological screening at session 1. This reduces the efficiency of session 1 as a platform for UNHS. The JCIH (2007) has stated that less than 4% of newborns should fail audiological screening at session 1 and at session 2 before being referred for diagnostic tests. In the current study, session 1 does not meet the stipulated criteria and this implies that session 1 may not be a feasible test time; and might actually be a costly exercise in an already resource-stricken environment.

Abdullah et al. (2006) highlights the fact that audiological screening before 24 hours of age does result in a high false-positive rate. Consistent with the findings obtained in the current study, Stevens and Parker (2009) have outlined how the "*pass"* rate for OAE neonatal screening is reduced in the first 24 hours after birth. It has also been stipulated by Wada et al. (2004) that the accuracy of newborn hearing screening seems to improve with time: a stipulation realised in the findings of the current study when the results from session 1 and session 2 are compared. This highlights the value and reliability of screening at a time outside of the first 48 hours post-birth, when vernix no longer has an impact on the findings and at a time when parents are still eager to return to the clinic for follow-up visits.

In agreement with this, Torrico et al. (2004) have suggested that screening should not take place within the first 24 hours of birth. Sun et al. (2009) conducted a study in which various time intervals for in-patient UNHS were compared and results have indicated that testing on day 3 was more effective than screening on day 1 or 2 post-birth. These findings and notions are in line with the findings of the current study, where session 2 was conducted

on days 3 to 7 post-birth. It has been found by Bartley and Digby (2005) that a major shortcoming in OAE screening in neonates is the minimised occurrence of OAEs in the first few hours following birth and that the OAE results may not stabilise until 48 hours post-birth. This emphasises the importance of neonatal audiological screening at the MOU 3-day assessment clinic, as it relates to the current study.

The results of the current study are similar to the results obtained from the research conducted in Sweden by Hergils (2007). In that study, 14 287 newborns at two maternity wards were screened over two sessions. Session 1 took place on the day of birth and session 2 took place at 3 days post-birth. The results of their study indicate that screening on the day of birth is less effective than screening on day 2 or 3 after birth (Hergils, 2007). This is consistent with Gabbard, Northern and Yoshinaga-Itano (1999), who have also reported a significant difference in OAE screening within the first 24 hours after birth and thereafter.

In terms of staffing resources, there was only one audiologist on duty at PPCHC for the duration of the current study. This implies that the same audiologist conducted the hearing screening at both session 1 and at session 2. Therefore no differences in the results obtained at session 1 and session 2 could be due to staffing changes. Equipment resources also did not change between session 1 and session 2. The equipment was calibrated and in good working order, therefore changes in the screening results could not be attributable to equipment factors. In terms of environmental noise, the noise levels were controlled in both test rooms for session 1 and session 2; therefore factors such as noise levels did not have any bearing on the results obtained. Clearly these conditions are not generalisable to a general clinical setting, as they were controlled under specific research conditions and have a bearing on the findings obtained in the current study.

The fourth objective of the current study was to identify factors that may influence the feasibility and efficiency of the screening at each test time. The time of birth of the neonates and the time of discharge from the newborn nursery may affect the practicability of screening at session 1. Newborns that were born and discharged over a weekend or outside of working hours were not screened at session 1, as the audiologist was not available to screen them during this time. This resulted in reduced practicability of screening at session 1 for the current study. However, these neonates were able to attend screening at session 2 and this, therefore, positively influences the feasibility and practicability of screening at session 2.

With regard to the environment in which the audiological screening was conducted, the practicability of OAE screening at various time frames after birth may be influenced. Headley, Campbell and Gravel (2000) have proposed that OAE screening can be influenced by the testing environment. Furthermore, Olusanya (2010) has stated that newborn hearing screening instrumentation was initially designed for use in developed countries and set out to determine the effects of ambient noise levels on OAE screening implementation in sub-Saharan Africa. Findings of their study show that, in hospital, noise levels total 61.0-90.5 dB A; noise levels in CHCs total 55.8-82.5 dB A. Olusanya (2010) has suggested that OAEs are valid in environments with noise levels up to 65dB A. Noise levels were controlled in the current study and were, therefore, not a factor that influenced practicability and efficiency at either session 1 or session 2.

In a study by John, Balraj and Kurien (2009), OAE screening was conducted during normal working hours but finding a quiet test room and the use of non-portable equipment were documented as challenges. The current study is not consistent with this, as test rooms were allocated for the purpose of testing and the equipment was portable. Thus these

challenges were not identified in the current study, but may very well be a reality in most other clinical settings.

Declau, Boudewyns, Van den Ende, Peeters and van den Heyning (2008) highlight that several UNHS programmes report difficulty in getting referred neonates to return for follow-up screening and to complete the programme. Tann, Wilson, Bradley and Wanless (2009) have stated that the follow-up rate is recognised as a significant barrier to UNHS success in many countries. In contrast to this, Chan and Leung (2004) report that an advantage associated with community-based UNHS programmes is a good return rate for follow-up. This is evident in the current study where only 4 neonates did not return for follow-up screening at session 2 as part of the MOU 3-day assessment clinic.

With regard to protocol, Chan and Leung (2004) reported that the decreased rate of incomplete audiological screening tests in their study may be attributed to the time taken by the testers to prepare the neonates for testing and may also be attributable to the competence of the tester in handling the newborns. In the current study, it is noteworthy that there were no incomplete tests and this is, therefore, not a factor that influences practicability and efficiency in the current study. Equipment may have a bearing on the practicability of OAE screening in neonates at various time frames following birth. It has been reported that OAEs are practical for implementation in UNHS programmes when a qualified audiologist conducts the testing and when appropriate equipment is used and protocol followed (Eiserman et al., 2008). This was adhered to in the current study for both session 1 and session 2. The same audiologist, equipment and protocol meant that these challenges were eliminated in the current study. In terms of protocol, in the study by Chan and Leung (2004), no otoscopic examination was conducted. In contrast, in the current study, otoscopic examinations were

carried out bilaterally and an otoscopic examination failure resulted in an overall session failure. There was only one otoscope and OAE screener for session 1 and session 2 in the current study and this could have a negative impact the efficiency of screening at session 1 and session 2 should the equipment become faulty. However, as there was only one professional available to conduct the screening, having only one set of equipment does not pose as a challenge.

The number of stages that the protocol entails may influence screening referral rates; the more stages there are, the smaller the referral rate would be, as false-positive results are reduced with further screening (Tann et al., 2009). The current study employed a two-stage screening programme; all newborns were asked to return for follow-up screening at session 2 as part of the MOU 3-day assessment clinic, irrespective of the results obtained at the initial audiological screening session. It was noted that the number of "*refer*" results obtained did decrease over time and this, therefore, indicates how significant the timing of the screening is in terms of practicability and efficiency in UNHS.

In the study by Chan and Leung (2004), only babies without an external auditory meatus were excluded from the study. However, in the current study, although the main focus was on low- risk neonates, there were no strict exclusion criteria and any identified risk factors were documented for analysis. Hall (2000) describes how the majority of neonates that present with risk factors for hearing impairment are not well and have possibly already been admitted to an in-hospital NICU. In addition to this, not many of these neonates would be born at a CHC. In terms of risk factors, it is notable that NICU history, a family history of hearing loss and craniofacial anomalies identify almost 60% of children with PCHL (Hall, 2000) and Kaye (2006) has reported that at least 50 % of congenital hearing impairment is

associated with genetic risk factors. Korres et al. (2005) have reported that a family history for PCHL is a frequent risk factor for hearing loss in the well newborn. The findings of the current study are consistent with that report, as the one risk factor identified in the current study was related to a positive history of PCHL.

The follow-up rate for UNHS programmes is a vital factor when the efficiency of the programme is considered. Asma et al. (2008) has described how parents return to their hometowns post delivery and thus miss follow-up appointments. Asma et al. (2008) has also proposed that the return rate at session 2 as part of neonatal audiological screening programmes is poor due to parents not being adequately informed of the importance of the audiological screening, as well as poor advice on follow-up. Shulman et al. (2010) conducted research in the United States of America where 55 territorial and state UNHS programmes - and site visits with 8 state programmes - were conducted to identify whether programmes were reaching their goals and also to identify barriers to follow-up efficiency. An urgent challenge that was highlighted in this study was that many newborns with a positive screening result did not return for follow-up screening. This was not a major factor in the current study as only 4 newborns screened at session 1, that obtained a positive screening result, did not return for follow-up screening, whilst the other 79 did. Transport limitations, language barriers and financial constraints have been identified as factors that affect the accessing of audiological screening services (Shulman et al., 2010), additionally the migratory nature of the population in the South Africa context may also be an influencing factor.

Hollenbeck (2008) has highlighted the vital role that nurses play in advocating for UNHS and supporting families during this process. Goedert, Moeller and White (2011) have

explained that midwives can play an essential role in ensuring that each newborn has access to hearing screening, which implies that their knowledge on the subject needs to be enriched with training. Midwives and nurses did not play a vital role in the current study and can, therefore, not be considered as a factor.

The effectiveness of several UNHS programmes in the United States has been restricted by aspects such as poor rates of screening as well as follow-up screening (Kennedy & McCann, 2004). In spite of the protocol employed, it is challenging to track the neonates that do not pass the initial hearing screening session and have them return for follow-up testing (Gravel et al., 2005). Olusanya and Akinyemi (2009) report that a significant challenge in both developed and developing countries is return for follow-up screening for newborns that fail the initial audiological screening. The JCIH (2000) states that successful follow-up can be negatively affected by the lack of ample tracking information due to a change in the name or address of the neonate's mother. Tracking enhances the capacity to identify neonates who are lost to follow-up at any phase of the EHDI programme (JCIH, 2000). UNHS follow-up can also be affected negatively in cases where some mothers provide invalid, incorrect or fictitious contact details or refuse to provide any contact details (Isaacson, 2000). This was not a factor in the current study as no contact details were recorded for the mothers and no tracking systems were in place.

Olusanya and Akinyemi (2009) have reported in their study that many may not return for follow-up screening sessions but they surmise that this is probably not associated with educational levels, as 83% of those that did not return for follow-up screening or for a diagnostic evaluation had at least a secondary education level. In contrast to this, Hubley (2006) reported that informed parental education contributes to the transformation of health-

seeking behaviour in developing countries, notwithstanding the challenges of poor education and literacy levels. Also, in the study by Olusanya and Akinyemi (2009), the services were offered at no charge so there is unlikely to be a link between ability to pay for the service and compliance. In Lagos, Nigeria, a community-based neonatal hearing screening pilot programme reported that more than half of the participants did not return for follow-up in spite of incentives being offered - i.e. transportation and services being free of charge (Olusanya et al., 2008). No incentives were offered in the current study and all parents were asked to bring back their newborns for follow-up screening. A total of 95 out of 99 newborns did return for the follow-up screening and this is, therefore, not consistent with the above findings.

Mukari, Tan and Abdullah (2006) issued questionnaires to 314 parents who did not return their babies for follow-up after obtaining a fail result at the initial screening session. One hundred and fifty eight of the 314 parents (50.32%) responded. The results thereof suggest that four factors contributed to the poor rate of follow-up. These included poor communication between the parents and the screeners, ineffective protocol for setting up follow-up appointments, poor parental awareness on the subject of hearing impairment and the necessity for early intervention, as well as transport problems. Vohr, Carty, Moore and Letoureau (1998) have also found that grounds for the attrition rate include ineffective communication between the hospital and the community-based medical service. However Olusanya and Akinyemi (2009) found that the only factor that correlated with screening follow-up compliance was that the mothers who gave birth outside of hospital were more likely to return for follow-up screening than those who gave birth in hospital settings. It has been reported by Olusanya and Akinyemi (2009) that mothers in an inner-city environment typically opt for traditional birthing attendants and, thereafter, demonstrate increased

keenness in making use of modern healthcare services to make certain that their newborns are not unjustifiably disadvantaged. This may elucidate why these mothers demonstrate improved compliance with follow-up screening in comparison with mothers that gave birth in hospitals (Olusanya & Akinyemi, 2009). It is noteworthy that only 8 newborns not born at PPCHC presented for screening at the MOU 3-day assessment clinic.

Barriers to UNHS programmes identified in the study by Shulman et al. (2010) included insufficient screening equipment as well as the lack of standard screening protocols. Olusanya and Akinyemi (2009) have indicated that it may be problematic for mothers to keep follow up screening appointments as a result of various constraints and that it may, therefore, be more effective to link follow-up screening protocols with another routine clinic visit. This has been adhered to in the current study where session 2 screening is part of the MOU 3-day assessment clinic, where mothers are already required to present for a full check-up both for themselves as well as for their newborns. By doing this, no additional appointment needs to be scheduled for the sole purposes of the audiological screening. This is consistent with the findings by Konradsson, Kjaerboel and Boerch (2007) who describe a 2 year project in Copenhagen (Denmark) at the Hvidovre and Frederiksberg hospitals. The authors have described how most hearing screening occurred when the neonates returned to the hospital at 4 -10 days after birth for metabolic screening procedures. This protocol is similar to the current study as the neonates are returning to the healthcare facility for other programmes and not solely for audiological screening measures.

According to Folsom et al. (2000), within hearing screening protocols, predictors of non-compliance may include socio-economic factors such as young maternal age, where there are more than 2 children at home (parity) as well as race (being non-white). These are

considerable and Ahmad et al. (2011) have reported that, in a UNHS programme, a high default rate can reduce the effectiveness of the programme and ultimately decrease the rate of detection of hearing impairment in the neonatal population. This, however, did not play a role in the current study due to the high return rate.

Lim and Daniel (2008) have proposed that the size and geographical distribution of the population to be screened may have an impact on the ease with which one can recall participants to a central site. This has a massive impact on the design of the UNHS programme, especially in rural and community contexts. It has been proposed by Lim and Daniel (2008) that the best screening coverage can be obtained at the initial screen at the birthing facility, after birth but before discharge from the newborn nursery. This was not observed in the current study where the better coverage rate was obtained at the session 2 screening.

Swanepoel and Almec (2008) have described how parental knowledge and attitudes regarding hearing impairment are critical to the success of the programme, especially in developing countries where cultural belief factors play a part. In a study by Swanepoel and Almec (2008), 100 South African mothers, who were part of the public health system, were surveyed and results have shown that 99% of these mothers indicated they wanted to have their newborns' hearing assessed after birth. Olusanya and Akinyemi (2009) report that UNHS programmes, like any other early childhood health interventions, require parental support and participation in order to realise adequate uptake of the service. Olusanya and Akinyemi (2009) have suggested that public health campaigns on the advantages of UNHS be extended to spouses, as spouses may have an influence on maternal health-seeking behaviour - as the societies in developing countries are often paternalistic. In the current

study, the prenatal educational sessions have been identified as the ideal platform for this information on hearing impairment and audiological screening to be shared with mothers. Olusanya et al. (2008) have highlighted that follow-up rates can be increased through improving parental education as well.

Due to the number of newborns that may be missed at session 1 compared to those tested at session 2, session 1 screening may not be deemed as feasible and practical. With regard to the primary objective of this study, from the results obtained, it has been ascertained that the MOU 3-day assessment clinic is a feasible and practical platform for the application of audiological screening using OAEs in low-risk neonates within the South African context.

Orji and Mgbor (2007) have highlighted the value of the otoscopic examination in the diagnosis of middle ear pathology and Hof et al. (2005) has described how middle ear pathology and the presence or vernix or cerumen in the ear canal may have adverse effects on the detectability of OAEs; and thus result in failed hearing screening. Based hereon, the correlation of the otoscopic examination and the OAE has been considered. The results have indicated that the otoscopic examination results and the OAE results matched when the right ear was considered. The correlation between the OAE and otoscopic examination results highlights the efficiency of the screening protocol employed at the sessions considered in the current study.

SECTION V:

EPILOGUE

Chapter 6

Limitations, Implications and Conclusion

The purpose of this chapter is to outline the limitations and short comings of the current study.

Limitations of the Test Protocol

Although the protocol followed for the current study was well deliberated and carefully designed, there were nonetheless some limitations to this protocol.

- High frequency tympanometry did not form part of the protocol. The inclusion of high frequency tympanometry to the test protocol may have contributed some valuable information to the current study, as there is a correlation between middle ear function and the OAE response (Margolis, Bass-Ringdahl, Hanks, Holte & Zapala, 2003).

- Newborns that obtained "*refer*" results at the second screening session were referred for diagnostic testing to confirm the hearing status. The results thereof did not, however, form part of the current study; and the researcher believes this would have added some valuable information with regard to the efficiency aspect of the current study.

- The time taken to conduct the otoscopic examination and OAE measures was not properly documented in the current study, due to time constraints. This information may have been valuable in the comparison between the 2 screening sessions.

- The overall results may not be generalisable to real clinical situations because this was a controlled research environment: noise levels were controlled and equipment was available and in good working order.

Limitations of the Current Study

Although the current study was well deliberated and carefully designed, there were nonetheless some limitations of the study.

- One of the shortcomings of this study is that the rate of false-negative results at session 1 and at session 2 has not been established or even considered. The investigator did not consider those neonates who passed the hearing screening but did present with hearing impairment, e.g. cases of auditory neuropathy; an implication for further studies to include ABR in their protocols.

- Detailed background information on the mothers and participants may have provided information on their willingness to return for follow-up testing, as well as on the likelihood that they would return. Through this, factors that may influence follow-up could have been established. However, in the current study, this was not carried out sufficiently for results to be analysed and conclusions drawn. In addition to that, in the current study, there was no tracking system in place to ensure follow-up.

- For the purposes of the study at hand, when a *"refer"* result was obtained, the neonate was re-screened immediately. This was done because it has been implied that test repetition may result in a reduction in the high "*refer"* rates from UNHS (Korres et al., 2006). The number of re-tests of this nature, for the purposes of this study, were not tallied for the purposes of this study but may have provided valuable information.

- The sample size of the current study is limited, but the results of the study still have implications for UNHS in community settings in South Africa.

- The audiological screening results obtained for the current study were obtained through screening that was conducted in a very controlled environment, where the noise levels were monitored and kept at a minimum. This may not be realistic for application in other programmes and settings.

- In the current study, language barriers were overcome through the use of an interpreter and it is reasonable to assume that this service may not be available in other contexts and for other programmes.

Significance of Results and Conclusion

Research strives to contribute to a scientific body of knowledge and aims to enhance health services and health outcomes (Green & Thorogood, 2004). In the current study, a community-based newborn hearing screening programme has been considered in terms of efficacy and practicability. Research in this field is important as the drive behind the execution of extensive neonatal hearing screening programmes has not yet reached developing countries where more than half of the world's hearing impaired children reside

(Olusanya et al., 2006). It is noteworthy that Olusanya and Somefun (2009) have reported that need exists for the establishment of community-oriented primary ear care services in the developing world. The general performance of UNHS as part of a community-based programme is analogous with traditional hospital-based UNHS programmes (Olusanya, Ebuehi & Somefun, 2009). From a moral standpoint, lessening the unnecessary discrepancies in health care, including those between children with an early detected hearing impairment and those with a later identified hearing impairment, is a matter that requires deliberation (Braveman & Gruskin, 2003).

White (2003) has stated that the developing world has seen massive growth in the detection of hearing loss and UNHS programmes detect hearing loss earlier and more accurately than selective risk-screening (Grill et al., 2005). Swanepoel et al. (2005) have stated that UNHS is more widespread with the evidence of benefit, with hearing loss being identified before the age of 6 months. However, the momentum for implementing widespread newborn audiological screening programmes in the developing world has not persisted.

According to Asma et al. (2008), UNHS is one of the latest developments in the healthcare domain and the need for universal newborn hearing screening is a mandatory issue (Bolat et al., 2009). However, major obstructions surrounding the implementation of UNHS programmes have been reported (White, 2003). The current research project has addressed one of the many obstructions regarding newborn hearing screening, as it adheres to the suggestion made by the JCIH (2007) which states that the timing of neonatal OAE audiological screening, relative to post-birth discharge, is to be deliberated for the development of effective context specific newborn hearing screening programmes. The

researcher has thus strived to ascertain the impact that time frames for neonatal audiological screening may have on the dependability of these programmes in primary healthcare settings in South Africa. This is closely linked to the recommendation made by Lim and Daniel (2008) that screening protocols are to be established and analysed. Through the current study, the practicability and efficiency of an audiological screening programme within the MOU 3-day assessment clinic has been affirmatively proven.

The HPCSA (2007) position statement on hearing screening has referred to 3 hearing screening contexts: the well baby nursery, on discharge from the NICU, as well as Mother Child Health Clinics at the 6 week immunisation clinic. The current study has rendered results that suggest an additional screening platform not previously considered or recommended. While the HPCSA has made bold and positive recommendations and has proposed guidelines regarding EHDI, contextualising such recommendations remains crucial. Current findings have verified that the MOU 3-day assessment clinic could be one of the most appropriate test times and may present as a suitable platform to roll out neonatal audiological screening in South Africa. This platform would ensure wide coverage, while keeping the rate of false-positive test results at a minimum. This does have significant impact on resource-stricken environments where high false-positive rates have implications for both State personnel as well as for those who would need to return for repeated screening and test measures; a majority of whom come from low socio-economic backgrounds.

Current findings have also emphasised the importance of having personnel other than an audiologist conducting the hearing screening. This would ensure that, if UNHS had to be conducted before discharge, personnel such as nurses or midwives who are available 24 hours everyday could conduct the screening.

The outcomes of the current study add to the development of methodologies for the early identification of hearing impairment within the South African neonatal population. In addition to this, current findings could influence the design of neonatal audiological screening protocols going forward in general. The results of the current research project may contribute to benchmarks in healthcare. This is fundamental, as the untimely detection of congenital hearing loss is a major public health problem (Pastorino et al., 2005).

In terms of further research, Young and Andrews (2001) have highlighted the need for more in-depth investigations into the effects of demographic and cultural aspects in the successful realisation of UNHS programmes. Comparisons need to be made between screening at the MOU 3-day assessment clinic and at the 6 week immunisation clinic in order to determine which is more feasible, practical and which offers wider coverage.

An additional recommendation for further research includes researching the feasibility of having nursing staff or personnel other than hearing healthcare professionals carry out newborn hearing screening.

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Appendix A

Document of Participant Information and Informed Consent

Participant Information Leaflet

Study Title: Audiological screening of low-risk neonates at different times following birth through the use of otoacoustic emissions: A feasibility study.

Investigator: Shannon. L. Harbinson (Speech Therapist & Audiologist at Phola Park Community Health Centre/ Masters Student at The University of the Witwatersrand).

Institution: The University of the Witwatersrand.

Daytime and After Hours Contact Number: 082-430-4303.

This leaflet may contain words that you do not understand. Please ask me to explain any information that you do not clearly understand. Trained interpreters are available if needed. Please take a copy of this leaflet home to think about or to discuss with family and friends before making a decision.

Good day,

My name is Shannon Leigh Harbinson and I am a Master's student at the University of the Witwatersrand. I am required to conduct research in the field of Audiology and my proposed study is titled: *Audiological screening of low-risk neonates at different times following birth through the use of otoacoustic emissions: A feasibility study*. I would like to invite you to consider the participation of your baby in this study. This leaflet is designed to help you decide if you would like your baby to participate in this study. It explains the purpose, procedures, benefits/risks and rights of participants and their parents in the study. You should understand all that is involved before making a decision. If you decide to have your baby participate, I will ask you to sign this document to verify that you understand the study. You shouldn't agree to participation unless you are satisfied with the procedures involved. Irrespective of your decision, you will still have access to the hearing screening services offered at Phola Park Community Health Centre (PPCHC).

Newborn hearing screening refers to basic hearing tests that are conducted on newborns. This screening aims to detect if a baby has a hearing loss or not. These tests are quick and painless to perform so many babies can be tested.

The ear has 3 parts: outer ear (A), middle ear (B), inner ear (C). Otoacoustic emissions (OAEs) is a type of hearing test used in screening. OAEs measure (C)'s response to sound. (A) and (B) are also tested as sound travels from (A) to (B) to (C) to the brain. An OAE is performed by placing a small probe into the ear. The probe sends a sound into the ear and records the response of the ear to that sound. The baby does not have to respond in any way, the OAE machine gives a 'pass' or 'refer' result.

Procedures: Should you decide to have your baby participate in this study, I will ask you some questions to ensure that your baby qualifies for participation. Then, on the day of birth and/or 3 days after birth at the Midwife Obstetric Unit (M.O.U) 3-day assessment clinic:

1. I will examine your baby's eardrums by looking into both ears, with an ear torch.
2. I will test the functioning of your baby's outer, middle and inner ear, for both ears, using an OAE measure.

Time required is a maximum of 15 minutes on the day of birth and 3 days later. The results will be given to you in the form of 'pass' or 'refer' directly after each session, a 'pass' will mean a clean, clear ear canal with a visible eardrum and a 'pass' OAE result, for both ears. A 'refer' result means that follow-up testing is needed to confirm or exclude the presence of a hearing loss, should this be the case, the Audiology Department at PPCHC will provide counselling, in-depth tests and the necessary intervention for you and your baby. This will ensure early detection of hearing loss and early intervention for your baby. It is important to note that any factor that interferes with the sound going into the ear and the response back to the OAE machine, including fluid in the ear from the birth process, may cause an incorrect 'refer' result. Also, the OAE only measures up to the inner ear and does not test hearing from the inner ear to the brain, so a 'pass' result does not automatically mean that your baby can hear.

Tests conducted on your baby are not painful and do not pose any risk to your baby.

Participation is voluntary; you may refuse /withdraw your baby's participation from this study at any time without stating reason. Your decision to withdraw your baby's participation will be respected and won't result in your baby not receiving Audiology services at PPCHC. No expenses will be incurred, nor will you be paid for having your baby participate in this study. This clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC). The 24-hour number on which you may contact me is 082-430-4303. If you need any information on your rights or if you wish to lodge a complaint about this study, you may contact Prof. Cleaton-Jones, Chairperson of HREC, on (011)717-2301. HREC is an independent committee established to help protect the rights of research participants. Should you be interested in the results of this study, I would be willing to share the results with you.

Information obtained during this study will be kept confidential. A research number will be issued to your baby and used instead of his/her name/clinic file number. Information obtained during this study will be available to myself, my research supervisor, the Audiology Department at PPCHC and may be inspected by HREC. By signing this consent form, you give me permission to release the details of your baby's medical records to HREC. These records may only be used by HREC in order to complete their obligations regarding this study. If this study is published in any form, your baby's name will not be used.

Thank you for taking time to consider your baby's participation in this study.

Yours Sincerely,

Shannon Leigh Harbinson (Researcher)

Dr. Katijah Khoza-Shangase (Research Supervisor)

INFORMED CONSENT FOR PARENTS OF PARTICIPANTS

I hereby confirm that the researcher, *Shannon Leigh Harbinson*, has informed me about the nature, conduct, benefits and risks of the clinical study entitled: *Audiological screening of low-risk neonates at different times following birth through the use of otoacoustic emissions: A feasibility study.*

I have received, read and understand the above information (Participant Information Leaflet) regarding this research project. I am fully aware that the results of this study, including personal details regarding my newborn baby's screening results, will be anonymously processed into a research report. I may at any stage, without prejudice, withdraw my consent and my baby's participation from this study. I have been given sufficient opportunity to ask questions and I (of my own free will) declare myself prepared to have my baby participate in this research project. By signing this document, I consent to having my baby participate in this research project.

PARENT OF THE PARTICIPANT

PRINTED NAME	SIGNATURE	DATE AND TIME

RESEARCHER

I, *Shannon Leigh Harbinson*, hereby confirm that the above-signed (Parent of the participant) has been fully informed of the nature, conduct, benefits and risks of this study.

PRINTED NAME	SIGNATURE	DATE AND TIME

TRANSLATOR EXPLAINING INFORMED CONSENT_____(DESIGNATION)

PRINTED NAME	SIGNATURE	DATE AND TIME

WITNESS

PRINTED NAME	SIGNATURE	DATE AND TIME

Appendix B

Case History Checklist Form

PARTICIPANT CASE HISTORY FORM

For the study entitled: Audiological screening of low-risk neonates at different times following birth through the use of otoacoustic emissions: A feasibility study.

Research Number: PPCHC____

Participant's Date of Birth:_____
Participant's Time of Birth:_____
Participant's Age at Session 1 screen:_____
Participant's Age at Session 2 screen:_____

The following information is to be obtained from the participant's parent and/or from medical records:

Pregnancy

QUESTION	***YES***	***NO***	***NOTES***
Did the mother consume any alcohol/drugs whilst pregnant with the participant?			
Were there any complications during the pregnancy with the participant?			
Could the pregnancy with the participant be described as a healthy one?			
Current age of the participant's mother			

Birth

QUESTION	***ANSWER***	***NOTES***
Duration of labour prior to the participant's birth		
Any complications during the participant's birth?		
Did the participant cry immediately after birth?		
What was the participant's APGAR score?		
What was the participant's birth weight?		

Other

QUESTION	***YES***	***NO***	***NOTES***
Does the participant have a family history of hearing loss?			

Additional Information:_____

Appendix C

Data Collection Form

DATA COLLECTION FORM

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	

Appendix D

Certificate Of Ethical Clearance: Human Research Ethics Committee: University of The Witwatersrand

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mrs Shannon L Harbinson

CLEARANCE CERTIFICATE	**M090836**
PROJECT	Audiological Screening of Low-Risk Neonates at Different Times follwoing Birth through the Use of Otoacoustic Emissions: A Feasibility Study
INVESTIGATORS	Mrs Shannon L Harbinson.
DEPARTMENT	Speech Pathology & Audiology
DATE CONSIDERED	09.08.28
DECISION OF THE COMMITTEE*	Approved unconditionally

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

DATE 30.08.09 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr K Khoza-Shangase

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...

.....

Appendix E

Letter of Permission From Phola Park Community Health Centre

Good day,

My name is Shannon Leigh Harbinson and I am a Master's student at the University of the Witwatersrand. I am required to conduct research in the field of Audiology and my proposed study is titled: *Audiological screening of low-risk neonates at different times following birth through the use of otoacoustic emissions: A feasibility study.*

The aim of this study is to investigate whether otoacoustic emission (OAE) screening measures conducted in low-risk neonates on the day of birth, prior to discharge from the newborn nursery, is practical when compared to conducting these measures 3 days after birth as part of the Midwife Obstetric Unit (M.O.U) 3-day assessment clinic. The results of this study may contribute to the enhancement of methodologies for the identification of hearing loss in the neonatal population in South Africa.

The investigator will introduce the concept of OAEs and neonatal audiological screening as well as the process thereof to the mothers of potential participants at Phola Park Community Health Centre (PPCHC), M.O.U Section, during antenatal visits to the clinic. This will be achieved by providing an explanation of the screening procedure in layman's terms, trained interpreters will be utilised in the presence of language barriers. The mothers of potential participants will also be given participant information leaflets to read and keep.

Informed consent will be obtained from each mother prior to any screening being carried out. The prospective benefits of the screening will be presented to the mothers of potential participants at the time of obtaining this informed consent. The mothers will also be informed of their rights to refuse their newborn's participation in the study and to withdraw their consent at any time, without negative consequences.

The audiological screening will be carried out at PPCHC (M.O.U Section) on the day of birth, prior to discharge from the newborn nursery (when the audiologist is on duty), and at PPCHC (Rehabilitation Department) as part of the M.O.U 3-day assessment clinic. The procedure for data collection, per participant, will be as follows:

1. Bilateral otoscopic examination (The participant's eardrums will be examined by looking into both ears, with an ear torch).
2. Bilateral OAE measure (A small probe will be inserted into the baby's ear on both sides. The probe sends a sound into the ear and records the response of the baby's ear to that sound. No participation is required from the baby).

Mothers of participants will be provided with an explanation of the screening results immediately after each screening session and counseling will be offered where indicated. Counseling will be offered in aim of reducing maternal anxiety which may be associated with the neonatal screening process or may be due to the screening results obtained.

The head of the facility at PPCHC as well as the head of the M.O.U Section at this centre hereby grant permission for the researcher to approach the mothers of potential participants directly. The below-signed support this project and grant permission for this study to be conducted at PPCHC M.O.U Section and Rehabilitation Department.

Sr. R. Radebe
Head of Facility
Phola Park Community Health Centre
Dated: 22-7-2009

Sr. N. Khumalo
Head of M.O.U Section
Phola Park Community Health Centre
Dated: 22-07-2009

Appendix F

Raw Screening Data Per Participant

DATA COLLECTION FORM

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A1	31/8/2009 (17:10)									P		P		P		P		BORN NSH (M)
PPCHC A2	3/9/2009 (8:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A3	31/8/2009 (22:00)									P		P		P		p		BORN NSH (M)
PPCHC A4	1/9/2009 (2:00)	R/P			R	R/P			R									BORN PPCHC(M)
PPCHCA5	1/9/2009 (02:30)		R	R/P			R	R/P		P		P		P		P		BORN PPCHC(M)
PPCHC A6	30/8/2009 (06:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A7	3/9/2009 (17:45)									P		P		P		P		BORN PPCHC (F)
PPCHC A8	27/8/2009 (01:10)									P		P		P		P		BORN JD (F)
PPCHC A9	30/8/2009 (16:45)									P		P		P		P		BORN JD (F)
PPCHC A10	30/8/2009 (20:45)									P		P		P		P		BORN NSH (F)
PPCHC A11	5/9/2009 (08:17)									P		P		P		P		BORN PPCHC (F)
PPCHC A12	15/9/2009 (23:40)									P		P		P		P		BORN PPCHC (F)
PPCHC A13	7/9/2009 (19:35)									P		P		P		P		BORN PPCHC (F)
PPCHC A14	3/9/2009 (9:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A15	1/9/2009 (12:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (M)
PPCHC A16	1/9/2009 (12:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A17	20/9/2009 (09:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A18	16/9/2009 (21:55)									P		P		P		P		BORN NSH (M)
PPCHC A19	30/8/2009 (14:40)									P		P		P		P		BORN PPCHC (F)
PPCHC A20	4/9/2009 (23:15)									P		P		P		P		BORN PPCHC (M)
PPCHC A21	1/9/2009 (08:10)	P		R/P		P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A22	13/9/2009 (19:40)									P		P		P		P		BORN PPCHC (M)
PPCHC A23	28/8/2009 (19:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A24	29/8/2009 (18:40)									P		P		P		P		BORN NSH (F)
PPCHC A25	17/9/2009 (24:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A26	29/8/2009 (23:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A27	1/9/2009 (11:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A28	1/9/2009 (14:30)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A29	2/9/2009 (15:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A30	2/9/2009 (13:00)	P		P		P		P		P		P		P		P		BORN PPCHC (F)
PPCHC A31	1/9/2009 (16:20)									P		P		P		P		BORN PPCHC (F)
PPCHC A32	30/8/2009 (19:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A33	2/9/2009 (10:10)		R	R/P			R	R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A34	5/9/2009 (17:35)									P		P		P		p		BORN PPCHC (M)
PPCHC A35	27/9/2009 (03:00)									P		P		P		P		BORN PPCHC(M)
PPCHC A36	27/9/2009 (19:00)									P		P		P		P		BORN PPCHC(M)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A37	29/8/2009 (11:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A38	29/8/2009 (22:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A39	2/9/2009 (18:10)									P		P		P		P		BORN PPCHC (M)
PPCHC A40	29/8/2009 (19:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A41	30/8/2009 (16:45)									P		P		P		P		BORN PPCHC (M)
PPCHC A42	31/8/2009 (16:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A43	29/8/2009 (09:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A44	29/8/2009 (09:00)									P		P		P		R/P		BORN PPCHC (M)
PPCHC A45	28/8/2009 (11:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A46	28/8/2009 (19:05)									P		P		P		P		BORN PPCHC (M)
PPCHC A47	29/8/2009 (08:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A48	28/8/2009 (22:20)									P		P		P		P		BORN PPCHC (M)
PPCHC A49	4/9/2009 (5:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (M)
PPCHC A50	4/9/2009 (4:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A51	4/9/2009 (7:00)		R		R		R		R		R	P			R	P		BORN PPCHC (M)
PPCHC A52	4/9/2009 (2:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A53	31/8/2009 (16:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A54	1/9/2009 (16:20)									P		P		P		P		BORN PPCHC (M)
PPCHC A55	1/9/2009 (2:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A56	6/9/2009 (14:45)									P		P		P		P		BORN PPCHC (F)
PPCHC A57	1/9/2009 (6:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A58	1/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A59	12/9/2009 (13:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A60	1/9/2009 (4:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A61	1/9/2009 (15:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A62	1/9/2009 (02:00)	P		P		P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A63	31/8/2009 (22:10)									P		P		P		P		BORN PPCHC (M)
PPCHC A64	4/9/2010 (13:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A65	8/9/2009 (4:30)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A66	7/9/2009 (5:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A67	2/9/2009 (2:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A68	11/9/2009 (18:20)									P		P		P		P		BORN PPCHC (F)
PPCHC A69	4/9/2009 (11:40)	P		P		P			R	P		P		P		P		BORN PPCHC (M)
PPCHC A70	7/9/2009 (6:30)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A71	3/9/2009 (09:23)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A72	12/9/2009 (15:45)									P		P		P		p		BORN PPCHC (M)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A73	4/9/2009 (17:45)									P		P		P		P		BORN PPCHC (M)
PPCHC A74	3/9/2009 (22:25)									P		P		P		P		BORN PPCHC (M)
PPCHC A75	2/9/2009 (22:23)									P		P		P		P		BORN PPCHC (M)
PPCHC A76	5/9/2009 (01:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A77	29/8/2009 (05:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A78	1/9/2009 (16:40)									P		P		P		P		BORN PPCHC (M)
PPCHC A79	2/9/2009 (21:25)									P		P		P		P		BORN PPCHC (M)
PPCHC A80	2/9/2009 (19:15)									P		P		P		P		BORN PPCHC (M)
PPCHC A81	3/9/2009 (18:40)									P		P		P		P		BORN PPCHC (M)
PPCHC A82	7/9/2009 (19:20)									P		P		P		P		BORN PPCHC (M)
PPCHC A83	13/9/2009 (13:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A84	12/9/2009 (07:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A85	7/9/2009 (11:00)		R		R		R	R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A86	7/9/2009 (9:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A87	7/9/2010 (14:40)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A88	7/9/2009 (14:40)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (M)
PPCHC A89	8/9/2009 (3:25)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A90	8/9/2009 (07:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A91	8/9/2009 (07:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A92	8/9/2009 (01:57)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A93	13/9/2009 (08:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A94	4/9/2009 (15:30)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A95	29/8/2009 (23:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A96	12/9/2009 (09:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A97	3/9/2009 (01:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A98	7/9/2009 (16:10)									P		P		P		P		BORN PPCHC (M)
PPCHC A99	4/9/2009 (16:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A100	7/9/2009 (03:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A101	3/9/2009 (01:40)									P		P		P		P		BORN PPCHC (M)
PPCHC A102	31/8/2009 (21:20)									P		P		P		P		BORN PPCHC (F)
PPCHC A103	2/9/2009 (00:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A104	12/9/2009 (06:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A105	3/9/2009 (22:05)									P		P		P		P		BORN PPCHC (M)
PPCHC A106	14/9/2009 (18:45)									P		P		P		P		BORN PPCHC (M)
PPCHC A107	5/9/2009 (00:45)									P		P		P		P		BORN PPCHC (F)
PPCHC A108	26/9/2009 (10:05)									P		P		P		P		BORN JD (M)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A109	4/9/2009 (00:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A110	6/9/2009 (10:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A111	8/9/2009 (04:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A112	8/9/2009 (03:30)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (M)
PPCHC A113	6/9/2009 (12:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A114	7/9/2009 (05:20)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A115	9/9/2009 (17:30)									P		P		P		p		BORN PPCHC (F)
PPCHC A116	7/9/2009 (06:20)	P		P		P		P		P		P		P		P		BORN PPCHC (F)
PPCHC A117	6/9/2009 (15:15)									P		P		P		P		BORN PPCHC (M)
PPCHC A118	7/9/2009 (04:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A119	7/9/2009 (03:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A120	6/9/2009 (19:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A121	5/9/2009 (21:50)									P		P		P		P		BORN PPCHC (M)
PPCHC A122	6/9/2009 (11:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A123	7/9/2009 (04:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A124	11/9/2009 (03:45)	R/P			R	R/P			R	P		P		P		P		BORN PPCHC (F)
PPCHC A125	11/9/2009 (05:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A126	11/9/2009 (11:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A127	7/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A128	8/9/2009 (16:45)									P		P		P		P		BORN PPCHC (M)
PPCHC A129	8/9/2009 (01:25)									P		P		P		P		BORN NSH (M)
PPCHC A130	4/9/2009 (19:00)									P		P		P		P		BORN NSH (F)
PPCHC A131	5/9/2009 (02:25)									P		P		P		P		BORN PPCHC (M)
PPCHC A132	13/9/2009 (06:35)									P		P		P		P		BORN PPCHC (M)
PPCHC A133	8/9/2009 (15:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A134	11/9/2009 (11:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A135	11/9/2009 (11:50)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A136	14/9/2009 (02:00)	R/P		P		R/P		P		P		P		P		P		BORN PPCHC (F)
PPCHC A137	14/9/2009 (02:15)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A138	14/9/2009 (05:20)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A139	14/9/2009 (07:10)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A140	14/9/2009 (02:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A141	14/9/2009 (03:10)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (M)
PPCHC A142	14/9/2009 (03:05)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A143	8/9/2009 (18:50)									P		P		P		P		BORN PPCHC (M)
PPCHC A144	12/9/2009 (20:00)									P		P		P		P		BORN PPCHC (M)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A145	19/9/2009 (03:40)									P		P		P		P		BORN PPCHC (F)
PPCHC A146	19/9/2009 (08:00)									P		R/P		P		R/P		BORN PPCHC (M)
PPCHC A147	20/9/2009 (13:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A148	19/2009(10:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A149	19/9/2009 (12:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A150	8/9/2009 (00:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A151	8/9/2009 (22:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A152	9/9/2009 (16:15)									P		P		P		P		BORN PPCHC (M)
PPCHC A153	10/9/2009 (09:10)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A154	11/9/2009 (19:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A155	10/9/2009 (20:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A156	10/9/2009 (23:45)									P		P		P		P		BORN PPCHC (F)
PPCHC A157	11/9/2009 (13:14)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A158	7/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A159	10/9/2009 (16:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A160	11/9/2009 (18:20)									P		P		P		P		BORN PPCHC (M)
PPCHC A161	8/9/2009 (19:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A162	14/9/2009 (16:55)									P		P		P		P		BORN PPCHC (M)
PPCHC A163	9/9/2009 (01:05)									P		P		P		P		BORN PPCHC (M)
PPCHC A164	10/9/2009 (07:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A165	4/9/2009 (17:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A166	14/9/2009 (11:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A167	14/9/2009 (10:20)	R/P			R	R/P			R	P		P		P		P		BORN PPCHC (M)
PPCHC A168	14/9/2009 (12:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A169	14/9/2009 (13:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A170	10/9/2009 (15:25)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A171	14/9/2009 (01:15)									P		P		P		P		BORN PPCHC (F)
PPCHC A172	14/9/2009 (01:05)									P		P		P		P		BORN PPCHC (F)
PPCHC A173	13/9/2009 (08:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A174	9/9/2009 (23:05)									P		P		P		P		BORN PPCHC (M)
PPCHC A175	12/9/2009 (10:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A176	13/9/2009 (20:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A177	12/9/2009 (10:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A178	13/9/2009 (11:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A179	14/9/2009 (00:17)									P		P		P		P		BORN PPCHC (M)
PPCHC A180	8/9/2009 (20:00)									P		P		P		P		BORN PPCHC (F)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A181	15/9/2009 (01:15)									P		P		P		p		BORN NSH (M)
PPCHC A182	15/9/2009 (22:15)									P		P		P		P		BORN NSH (F)
PPCHC A183	14/9/2009 (18:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A184	21/9/2009 (05:30)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A185	21/9/2009 (06:45)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A186	21/9/2009 (09:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A187	21/9/2009 (08:15)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A188	14/9/2009 (16:50)									P		P		P		P		BORN PPCHC (F)
PPCHC A189	16/9/2009 (04:15)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A190	17/9/2009 (09:40)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A191	14/9/2009 (18:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A192	18/9/2009 (07:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A193	13/9/2009 (10:25)									P		P		P		P		BORN PPCHC (M)
PPCHC A194	16/9/2009 (18:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A195	26/9/2009 (06:24)									P		P		P		P		BORN PPCHC (M)
PPCHC A196	21/9/2009 (12:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A197	21/9/2009 (09:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A198	17/9/2009 (00:55)									P		P		P		P		BORN PPCHC (F)
PPCHC A199	22/9/2009 (05:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A200	18/9/2009 (19:05)									P		P		P		P		BORN PPCHC (M)
PPCHC A201	22/9/2009 (08:50)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A202	22/9/2009 (04:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A203	21/9/2009 (03:50)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A204	17/9/2009 (19:25)									P		P		P		P		BORN PPCHC (M)
PPCHC A205	15/9/2009 (22:25)									P		P		P		P		BORN PPCHC (F)
PPCHC A206	16/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A207	16/9/2009 (23:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A208	17/9/2009 (16:15)									P		P		P		P		BORN PPCHC (F)
PPCHC A209	22/9/2009 (12:00)	R/P			R	R/P			R	P		P		P		P		BORN PPCHC (M)
PPCHC A210	21/9/2009 (18:45)									P		P		P		P		BORN PPCHC (F)
PPCHC A211	22/9/2009 (09:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A212	18/9/2009 (18:40)									P		P		P		P		BORN PPCHC (F)
PPCHC A213	22/9/2009 (10:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A214	17/9/2009 (17:45)									P		P		P		P		BORN PPCHC (M)
PPCHC A215	18/9/2009 (17:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A216	19/9/2009 (19:30)									P		P		P		P		BORN PPCHC (F)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A217	27/9/2009 (14:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A218	26/9/2009 (09:15)									P		P		P		P		BORN PPCHC (F)
PPCHC A219	19/9/2009 (12:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A220	20/9/2009 (08:15)									P		P		P		P		BORN PPCHC (F)
PPCHC A221	26/9/2009 (11:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A222	23/9/2009 (12:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A223	24/9/2009 (07:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A224	24/9/2009 (08:45)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A225	25/9/2009 (07:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A226	25/9/2009 (07:15)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A227	25/9/2009 (06:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A228	22/9/2009 (19:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A229	27/9/2009 (14:10)									P		P		P		P		BORN PPCHC (F)
PPCHC A230	22/9/2009 (23:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A231	23/9/2009 (12:00)		R		R		R		R									BORN PPCHC (F)
PPCHC A232	26/9/2009 (08:35)									P		P		P		P		BORN PPCHC (F)
PPCHC A233	23/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A234	21/9/2009 (22:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A235	22/9/2009 (19:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A236	25/9/2009 (09:00)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A237	22/9/2009 (22:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A238	26/9/2009 (21:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A239	27/9/2009 (21:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A240	26/9/2009 (16:50)									P		P		P		P		BORN PPCHC (M)
PPCHC A241	20/9/2009 (07:25)									P		P		P		P		BORN PPCHC (F)
PPCHC A242	27/9/2009 (11:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A243	27/9/2009 (15:40)									P		P		P		P		BORN PPCHC (F)
PPCHC A244	25/9/2009 (16:10)									P		P		P		P		BORN PPCHC (F)
PPCHC A245	24/9/2009 (18:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A246	21/9/2009 (22:45)									P		P		P		P		BORN PPCHC (M)
PPCHC A247	22/9/2009 (08:30)		R		R		R		R	P		P		P		P		BORN PPCHC (F)
PPCHC A248	22/9/2009 (00:30)									P		P		P		P		BORN PPCHC (M)
PPCHC A249	26/9/2009 (08:20)									P		P		P		P		BORN PPCHC (F)
PPCHC A250	12/9/2009 (09:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A251	23/9/2009 (03:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A252	16/9/2009 (21:10)									P		P		P		p		BORN PPCHC (M)

Research No.	Birth Date & Time	Session One								Session Two								Notes
		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		Otoscopy (Left)		Otoscopy (Right)		OAE (Left)		OAE (Right)		
		P	R	P	R	P	R	P	R	P	R	P	R	P	R	P	R	
PPCHC A253	26/9/2009 (10:00)									P		P		P		P		BORN PPCHC (F)
PPCHC A254	25/9/2009 (08:00)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A255	25/9/2009 (08:10)		R	R/P			R	R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A256	24/9/2009 (01:15)									P		P		P		P		BORN PPCHC (M)
PPCHC A257	24/9/2009 (14:30)		R		R		R		R									BORN PPCHC (F)
PPCHC A258	25/9/2009 (05:00)	R/P		R/P		R/P		R/P		P		P		P		P		BORN PPCHC (F)
PPCHC A259	27/9/2009 (18:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A260	3/9/2009 (01:45)									P		P		P		P		BORN PPCHC (F)
PPCHC A261	17/9/2009 (16:05)									P		P		P		P		BORN PPCHC (F)
PPCHC A262	8/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)
PPCHC A263	9/9/2009 (23:10)									P		P		P		P		BORN PPCHC (F)
PPCHC A264	13/9/2009 (11:35)									P		P		P		P		BORN PPCHC (F)
PPCHC A265	6/9/2009 (16:15)									P		P		P			R	BORN PPCHC (M)
PPCHC A266	5/9/2009 (14:30)									P		P		P		P		BORN PPCHC (F)
PPCHC A267	24/9/2009 (22:20)									P		P		P		P		BORN PPCHC (F)
PPCHC A268	4/9/2009 (06:50)		R		R		R		R	P		P		P		P		BORN PPCHC (M)
PPCHC A 691	2/9/2009 (03:15)		R		R		R		R									BORN PPCHC (M)
PPCHC A269	13/9/2009 (15:05)									P		P		P		P		BORN PPCHC (F)
PPCHC A270	17/9/2009 (23:55)									P		P		P		P		BORN PPCHC (F)
PPCHC A271	27/9/2009 (17:00)									P		P		P		P		BORN PPCHC (M)