Outcomes with OAE and AABR screening in the first 48 hours – implications for newborn hearing screening in South Africa

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M. Communication Pathology

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ABSTRACT

Title: Outcomes with OAE and AABR screening in the first 48 hours - implications for newborn hearing screening in South Africa

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Despite the global focus on newborn hearing screening, this practice has remained almost exclusively reserved for the developed world (Olusanya, Luxon, & Wirz, 2004; Swanepoel, Hugo, & Louw, 2006). In South Africa, a developing country, estimates indicate that fewer than 10 per cent of newborns have any prospect of being screened for hearing loss (Theunissen & Swanepoel, 2008; Meyer, Swanepoel, Le Roux, & Van der Linde, 2012). Early discharge of newborns (<24 hours after birth) is an important barrier to successful newborn hearing screening (NHS) in South African hospitals, more specifically in the public health care sector, as healthy infants are discharged between 6 and 24 hours after birth (Government Communication and Information System, 2011; Mowbray Maternity Hospital, 2011). The objective of this study was to evaluate the outcomes of NHS within the first 48 hours, using an automated auditory brainstem response (AABR) device without the need for costly disposables, compared to transient evoked otoacoustic emissions (TEOAE) screening.

This study used a quantitative approach employing a within-subject comparative quasi-experimental design to compare screening effectiveness of TEOAE and AABR techniques across different time intervals post birth (Shuttleworth, 2009; Hall, 1998; Leedy & Ormrod, 2001). NHS was performed on 150 healthy newborns (300 ears) with TEOAE and AABR techniques before discharge in a private hospital. A three-stage screening protocol was implemented consisting of an initial screen with

TEOAEs (GSI AUDIOscreener+) and AABR (Maico MB 11). Infants were screened at several points in time as early as possible after birth. Infants were only re-screened if either screening technique (TEOAE or AABR) initially yielded a refer outcome. The same audiologist (the researcher) performed all TEOAE and AABR screenings.

Over the three-stage screen, findings indicated that AABR had a significantly lower referral rate of 16.7% (24/144 subjects) compared to TEOAE (37.9%; 55/145 subjects). Screening referral rate per ear showed a progressive decrease with increasing age. For both TEOAE and AABR, referral rate of ears for infants screened after 24 hours was significantly lower than for those screened before 24 hours. For infants screened before 12 hours after birth, the AABR referral rate per ear (51.1%) was significantly lower than the TEOAE referral rate (68.9%). Lowest initial referral rates per ear (TEOAE 25.8%, AABR 3.2%) were obtained after 48 hours post birth (Average age: TEOAE 61 hours post birth, AABR 57 hours post birth).

In the light of the early hospital discharge typical in South Africa and other developing countries, screening with AABR technology is significantly more effective than screening with TEOAEs. AABR screening also has the advantage of identifying auditory neuropathy, and devices like the MB 11 that do not require disposables are particularly appropriate for developing countries with limited resources. Universal NHS protocols for contexts like South Africa may require AABR technology (without the burden of costs for disposables) in hospital-based settings for infants discharged after 24 hours. Otoacoustic emission (OAE) technology might be reserved for screening remaining infants once they are slightly older and attending routine health care visits such as immunisation clinics or midwife obstetric units.

Keywords:

Developing countries

Early intervention

Newborn hearing screening

Screening techniques

Age at screen

Hospital-based

Referral rate

Transient conditions

Public and private health care

Follow-up default

Discharge times

OPSOMMING

Titel: Outcomes with OAE and AABR screening in the first 48 hours - implications for newborn hearing screening in South Africa

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Ten spyte van die wêreldwye ingesteldheid op gehoorsifting by pasgebore babas, bly dit ‘n praktyk wat bykans uitsluitlik tot die ontwikkelde wêrelddele beperk is (Olusanya, Luxon, & Wirz, 2004; Swanepoel, Hugo, & Louw, 2006). In Suid-Afrika, wat ‘n ontwikkelende land is, dui skattings daarop dat minder as 10 persent van pasgebore babas enige vooruitsig het op gehoorsifting om moontlike gehoorverlies te identifiseer (Theunissen & Swanepoel, 2008; Meyer, Swanepoel, Le Roux, & Van der Linde, 2012). Vroeë ontslag van pasgeborenes (<24 ure na geboorte) is ‘n beduidende struikelblok in die weg van geslaagde projekte ten opsigte van gehoorsifting vir pasgeborenes (GSP) in Suid-Afrikaanse hospitale, meer spesifiek in die openbare gesondheidssorg sektor, aangesien gesonde babas tussen 6 en 24 ure na geboorte ontslaan word (Government Communication and Information System, 2011; Mowbray Maternity Hospital, 2011). Die hoofdoel van hierdie studie was ‘n evaluasie van die uitkomste van GSP binne die eerste 48 ure, met die gebruik van ‘n geoutomatiseerde breinstamrespons (OBSR) meter wat nie van duur weggooibare items gebruik maak nie, in vergelyking met sifting deur middel van transiënte ontlokte oto-akoestiese emissie (TOOAE) metings.

Hierdie studie het gebruik gemaak van ‘n kwantitatiewe benadering met ‘n intra-proefpersoon vergelykende kwasi-eksperimentele ontwerp, om die doeltreffendheid van TOOAE and OBSR tegnieke oor verskillende tydsintervalle post-geboorte te vergelyk (Shuttleworth, 2009; Hall, 1998; Leedy & Ormrod, 2001). GSP is, met beide

TOOAE en OBSR as tegniek, uitgevoer op 150 gesonde pasgebore babas (300 ore) voordat hulle uit ‘n private hospitaal se kraamafdeling ontslaan is. ‘n Siftingsprotokol in drie stadia is gebruik. Dit het bestaan uit ‘n aanvanklike sifting met TOOAEs (GSI AUDIOscreener+) en OBSR (Maico MB 11). Babas is op verskillende tye so vroeg as moontlik na geboorte getoets. ‘n Tweede siftingstoets is slegs uitgevoer as een van die twee siftingstegnieke (TOOAE of OBSR) in die aanvanklike sifting ‘n verwysingsuitslag gelewer het. Al die TOOAE en OBSR siftingstoetse is deur dieselfde oudioloog uitgevoer.

Bevindings oor die drie-stadium siftingsproses het getoon dat OBSR ‘n beduidend laer verwysingskoers van 16.7% (24/144 proefpersone) gehad het in vergelyking met TOOAE (37.9%; 55/145 proefpersone). Die verwysingskoers per oor het ‘n progressiewe afname getoon met toename in ouderdom. Vir beide TOOAE en OBSR was die verwysingskoers van ore van babas wat ná 24 ure getoets is, beduidend laer as vir dié wat binne 24 ure na geboorte getoets is. Vir babas wat voor 12 ure na geboorte getoets is, was die OBSR verwysingskoers per oor (51.1%) beduidend laer as die TOOAE verwysingskoers (68.9%). Die laagste aanvanklike verwysingskoers per oor (TOOAE 25.8%, OBSR 3.2%) is verkry na 48 ure post-geboorte (gemiddelde ouderdomme: TOOAE 61 ure post-geboorte, OBSR 57 ure post-geboorte).

In die lig van die vroeë ontslag uit die hospitaal wat tipies in Suid-Afrika en ander ontwikkelende lande voorkom, is sifting met OBSR tegnologie beduidend meer doeltreffend as sifting met TOOAEs. OBSR sifting het ook die voordeel dat dit ouditiewe neuropatie kan identifiseer en verder is toerusting soos die MB 11 wat nie weggooibare items vereis nie, besonder gepas vir lande met beperkte finansiële hulpbronne. Enige universele GSP protokol vir ‘n konteks soos Suid-Afrika vereis waarskynlik OBSR tegnologie (sonder die kostelas van weggooibare items) in hospitaal-gebaseerde omgewing vir babas wat na 24 ure ontslaan word. Oto-akoestiese emissie (OAE) tegnologie moet waarskynlik gereserveer word vir gehoorsifting by babas as hulle eers ‘n bietjie ouer is en roetine-besoeke bring aan gesondheidsorgfasiliteite soos inentingsklinieke of vroedvrou-obstetriese eenhede.

Sleutelwoorde:

Ontwikkelende lande

Vroeë intervensie

Gehoorsifting vir pasgeborenes

Siftingstegnieke

Ouderdom by gehoorsifting

Hospitaalgebaseerd

Verwysingskoers

Transiënte toestande

Openbare en private gesondheidssorg

Opvolgingsversuim

Ontslagtye

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"And we know that in all things God works for the good of those who love Him..."

Romans 8 vs 28a (NIV)

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ACRONYMS

The list below indicates the acronyms used throughout this study in alphabetical order:

AIDS	Acquired Immune Deficiency Syndrome
AABR	Automated Auditory Brainstem Response
EHDI	Early Hearing Detection and Intervention
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
JCIH	Joint Committee on Infant Hearing
MOU	Midwife Obstetric Units
NHI	National Health Insurance
NHS	Newborn Hearing Screening
NICU	Neonatal Intensive-Care Unit
OAE	Otoacoustic Emissions
SASHLA	South African Speech-Language-Hearing Association
TEOAE	Transient Evoked Otoacoustic Emissions
UNHS	Universal Newborn Hearing Screening
WHO	World Health Organization

1. INTRODUCTION

Hearing loss is the most common congenital abnormality in newborns and is more than twice as prevalent when compared to other conditions screened for at birth (Cao-Nguyen, Kos, & Guyot, 2007; Khairi et al., 2011; Kumar & Mohapatra, 2011; Olusanya, Luxon, & Wirz, 2004). According to a range of studies and surveys conducted in different countries, 0.5 to 5 in every thousand neonates and infants have congenital or early childhood onset hearing impairment (Olusanya, 2011a; World Health Organization [WHO], 2010). Since at least 90% of this population lives in developing countries, early detection and intervention for hearing impaired infants is an essential aspect of neonatal care (Olusanya, Emokpae, Renner, & Wirz, 2009; Swanepoel, Hugo, & Louw, 2006). South Africa is classified as a developing country (World Bank, 2015), where the majority of hospitals do not provide any newborn hearing screening (NHS) services (Theunissen & Swanepoel, 2008). More than 90% of all infants born in South Africa have no prospect of early detection and identification of hearing loss (Theunissen & Swanepoel, 2008). Research within South Africa is therefore essential to provide contextually appropriate NHS solutions which allow newborns within the public and private health care sector to be identified as early as possible before hospital discharge (Swanepoel, Ebrahim, Joseph, & Friedland, 2007).

1.1 Background

Congenital or early-onset infant hearing loss is considered to be a silent epidemic due to its high prevalence worldwide, especially in developing countries, where its invisible nature prevents detection by means of routine clinical examination (Joint Committee on Infant Hearing [JCIH], 2007; Swanepoel, 2009b, 2010; Swanepoel, Delport, & Swart, 2007; Swanepoel et al., 2006; Olusanya et al., 2004; Van der Spuy & Pottas, 2008). Hearing loss usually only becomes apparent once secondary symptoms such as delayed speech and language or behavioural problems appear (Diefendorf, 2002; JCIH, 2007; Kerschner, 2004; Swanepoel, 2009b). If a hearing loss is not detected at birth, it often goes undetected beyond 18 months of age,

especially in children who have no medical condition and/or other disabilities (JCIH, 2007). Undetected hearing loss can lead to delayed or impaired speech and language development, social and emotional problems, academic failure, and restricted vocational outcomes (Diefendorf, 2002; Erenberg, Lemons, Sia, Trunkel, & Ziring, 1999; Hayes & Northern, 1996; Jakubíková, Kabátová, Pavlovčinová, & Profant, 2009; JCIH, 2007; Khairi et al., 2011; Korres et al., 2006; Kumar & Mohapatra, 2011; WHO, 2010). Early detection of hearing loss in newborns is essential if early intervention is to be introduced (Jakubìková et al., 2009).

In both developed and developing countries, efforts have been focused on newborn hearing screening in order to obtain early diagnosis of hearing impairment and to provide intervention as soon as possible (Korres et al., 2006). Research evidence indicates that an infant with a hearing loss who is identified early and receives intervention within the first six months of life is likely to have linguistic, speech, and cognitive development comparable to normal hearing peers in contrast to persistent delays for those who are identified late (Moeller, 2000; Moeller et al., 2007; Yoshinaga-Itano, 2004). It is therefore essential that hearing impairment is recognized as early in life as possible, to allow the remediation process to take full advantage of the plasticity of the developing sensory systems in the brain (Bansal, Gupta, & Nagarkar, 2008). Early Hearing Detection and Intervention (EHDI) programmes aim to provide optimal and timely opportunities for children with hearing loss to develop linguistic, literacy, and communicative competence in keeping with their full potential (Health Professions Council of South Africa [HPCSA], 2007). The earlier detection occurs, the earlier intervention can begin, thereby increasing the likelihood of optimizing a child's potential in all developmental areas and allowing them equal opportunities in society alongside all other children (Diefendorf, 2002; WHO, 2010).

The significant impact of hearing on early childhood development has led to early detection and intervention for infants with hearing loss rapidly becoming the standard of care in developed countries, such as the United States of America (USA), United Kingdom (UK) and Canada, where close to 95% of all infants are screened before discharge from hospital (JCIH, 2007; Swanepoel, 2009b; Swanepoel, Delport, et al.,

2007; WHO, 2010). Unfortunately the momentum for implementing such widespread screening programmes has not spilt over to developing countries where two thirds of the world's children with hearing loss reside (Swanepoel, Delport, et al., 2007; Olusanya et al., 2004). Research outcomes provide evidence that when a screening programme is established the age of identification of hearing loss is reduced, the age of intervention initiation is lowered, and the outcomes of intervention are better (Yoshinaga-Itano, 2004).

Universal Newborn Hearing Screening (UNHS) is a method to detect hearing loss in newborns before hospital discharge, which ensures early identification and early access to services including amplification and family-centered communication intervention (Khairi et al., 2011; Swanepoel, Störbeck, & Friedland, 2009). Since target-based screening only identifies permanent hearing loss in 50% of cases, universal screening of all newborns and infants is recommended with objective electrophysiological techniques to ensure sensitivity and specificity (HPCSA, 2007; JCIH, 2007; South African Speech-Language-Hearing Association [SASLHA], 2011; Swanepoel, 2009b). The only valid screening techniques with acceptable sensitivity and specificity available to detect hearing impairment in infants are the measurement of otoacoustic emissions (OAE) and automated auditory brainstem responses (AABR) (HPCSA, 2007; JCIH, 2007; Swanepoel, 2009b).

According to the Joint Committee on Infant Hearing (2007), there are important differences between the two screening techniques. OAE measurements are obtained from the ear canal by using a sensitive microphone within a probe assembly that records cochlear responses to acoustic stimuli. Thus, OAEs reflect the status of the peripheral auditory system extending to the cochlear outer hair cells (HPCSA, 2007; JCIH, 2007; Keefe et al., 2000; Swanepoel, 2009b). In contrast, AABR measurements are obtained from surface electrodes that record neural activity generated in the cochlea, auditory nerve, and brainstem in response to acoustic stimuli delivered via an earphone. AABR measurements therefore reflect the status of the peripheral auditory system, the eighth nerve, and the brainstem auditory pathway (HPCSA, 2007; JCIH, 2007; Keefe et al., 2000; Swanepoel, 2009b).

Either or both AABR and OAE screening techniques have been used successfully for UNHS due to the short test time required to conduct the screening, the noninvasiveness of both screening methods and the fact that both are easily performed on neonates and infants (HPCSA, 2007; JCIH, 2007; Swanepoel, 2009b). Advances in hearing screening technology, primarily in AABR and OAEs, allow for all newborns to be screened before hospital discharge (Yoshinaga-Itano, Coulter, & Thomson, 2001). OAE and AABR screening techniques therefore provide equally effective early identification opportunities that are attainable and justifiable through hospital-based UNHS (HPCSA, 2007).

1.2 Hospital-based Newborn Hearing Screening

Despite the tremendous growth of NHS, it has remained a practice almost exclusively reserved for the developed world, making the benefits of early intervention an elusive luxury, out of reach for infants born in developing countries (Olusanya et al., 2004; Swanepoel et al., 2006). South African estimates indicate that fewer than 10% of newborns have any prospect of being screened for hearing loss, which translates to fifteen babies born with hearing loss every day who will be sent home without parents or professionals being aware of the infants' condition (Meyer, Swanepoel, Le Roux, & Van der Linde, 2012; Swanepoel, 2009b; Swanepoel et al., 2009; Theunissen & Swanepoel, 2008). The Joint Committee on Infant Hearing (2007) therefore recommends that a screen result be obtained before hospital discharge whenever possible to reduce the subsequent need for outpatient follow-up.

Both OAE and AABR devices may present with false-positive results for NHS before hospital discharge, due to patient and environment related factors (JCIH, 2007; Mehl & Thomson, 2002). Environmental factors such as excessive ambient noise in the test environment, or test skills and experience of the screening staff, may negatively affect screening outcomes for both OAE and AABR (Olusanya & Bamigboye, 2010). Patient factors such as the infant's state of consciousness and the increased incidence of transient outer and middle-ear conditions also negatively affect screening outcomes in the first hours post birth (Erenberg et al., 1999; Olusanya &

Bamigboye, 2010). The recommended time for NHS is therefore after 24 hours post birth (Erenberg et al., 1999; Olusanya & Bamigboye, 2010).

Screening with an OAE technique within the first 24 hours post birth reportedly results in referral rates as high as 20% (Erenberg et al., 1999; Korres et al., 2006; Lupoli, Garcia, Anastasio, & Fontana, 2013). Referral rates drop to as low as 3% when OAE screening is performed between 24 and 48 hours after birth (Erenberg et al., 1999; Korres et al., 2006; Lupoli et al., 2013). AABR is less affected 24 to 48 hours post birth than OAE by transient conditions in the external auditory canal (e.g. collapse of the ear canal and the presence of debris) and middle ear (e.g. presence of amniotic fluid and mesenchyme), making it more likely that newborns will be referred within this timeframe with OAE screening than with AABR screening (Akinpelu, Peleva, Funnell, & Daniel, 2014; Gabbard, Northern, & Yoshinaga-Itano, 1999). Referral rates of less than 4% are generally achievable when an infant is screened with OAE combined with AABR in a two-step screening system or with AABR alone before discharge (Mehl & Thomson, 1998; Olusanya & Bamigboye, 2010). However, this procedure is not being conducted in the vast majority of private and public hospitals in South Africa due to several challenges and limitations (Meyer et al., 2012; Theunissen & Swanepoel, 2008).

1.3 Problem Statement

Essentially, UNHS programmes need to be implemented while taking into consideration the context-specific challenges faced within each country. South Africa has a heterogeneous population with mixed sections of developed and developing contexts, which provides challenges in terms of the standard implementation of NHS (Swanepoel, 2006). The divergence in context is manifestly apparent in the health care sector of South Africa which is divided into public and private sectors (Swanepoel, 2009a; Swanepoel, Ebrahim, et al., 2007). These vary from the most basic primary health care, offered free of cost by the state, to highly specialised, hi-tech health services available in the both the public and private health care sector (South Africa Information, 2012). Unlike other social sectors in South Africa, health has a significant private sector component (National Treasury Department, Republic

of South Africa, 2015). Although the amount of expenditure in the public (51.3%) and private (48.7%) health care sectors is relatively similar, 81% (43 million) of the population in South Africa relies on the public health services and only about 18% (9.7 million) on health services paid for by medical schemes (National Treasury Department, Republic of South Africa, 2015; South Africa Information, 2012). The dual health care system is inequitable and not only are many services inaccessible to a large portion of South Africans, but institutions in the public sector have suffered poor management, underfunding, and deteriorating infrastructure (South Africa Information, 2012).

This very large disparity, together with the higher burden of diseases (such as human immunodeficiency virus [HIV], acquired immune deficiency syndrome [AIDS] and tuberculosis) among the uninsured population, has major significance for the public health care sector (National Treasury Department, Republic of South Africa, 2015). South Africa is suffering an epidemic of infectious diseases of which HIV/Aids is the most rampant (Swanepoel et al., 2006). In March 2014, 2.68 million people were on antiretroviral treatment in South Africa (National Treasury Department, Republic of South Africa, 2015). The overwhelming burden of infectious disease, especially HIV/Aids which has reached pandemic proportions, is another unique challenge affecting financial contributions to NHS services in South Africa (Swanepoel, 2006; Swanepoel et al., 2006). This situation leads to health priorities and funding that are aimed at saving lives above improving quality of life in chronic non-communicable conditions and neglect an invisible non-life-threatening condition such as hearing loss (Olusanya et al., 2004; Swanepoel, 2006; Swanepoel et al., 2006). The consequences are especially relevant in developing countries where a non-life-threatening yet debilitating condition, such as hearing impairment, becomes a severe threat to essential quality of life indicators unless intervention occurs early during infant development (Swanepoel, 2006; Swanepoel, Delport, & Swart, 2004).

Benefits of early identification and subsequent intervention are not as accessible for infants in developing countries as in developed countries, due to factors such as early hospital discharge (Swanepoel et al., 2006). Developed countries like the UK report distribution of typical discharge times for newborns as: 16% within 24 hours

post birth, 35% the following day post birth; 21% after two days post birth and 28% three days post birth (Elattar, Selamat, Robson, & Loughney, 2008). In the USA, healthy infants are typically discharged from the hospital between 24 and 48 hours after birth (Southeast Georgia Health System, 2011). In comparison, healthy infants in South Africa are discharged from a public hospital or clinics between 6 and 24 hours after birth (Government Communication and Information System [GCIS], 2011; Mowbray Maternity Hospital, 2011). Postnatal care is provided by family members or at primary health care clinics (Ngunyulu & Mulaudzi, 2009), even though the World Health Organization (2014) recommends that newborns born in health facilities should not be sent home in the crucial first 24 hours of life. Early discharge of newborns from hospitals in South Africa is therefore an important challenge to successful implementation of hospital-based NHS.

In developing countries an additional challenge to hospital-based NHS is the cost associated with screening, as AABR equipment is typically more costly than OAE equipment (Kerschner, 2004). This applies particularly to the costs related to disposables involved in screening each infant (Kerschner, 2004). In South Africa the vast majority (81%) of private hospitals conducting screening reportedly use OAE screening in the healthy newborn ward compared to only 1% employing AABR, due to the additional costs associated with this type of screening (Meyer et al., 2012). AABR screening is therefore uncommon in both the public and private health care sector of South Africa (Meyer et al., 2012; Theunissen & Swanepoel, 2008). This is due to the significantly increased costs compared to the cost of OAE screening, even though the AABR's higher specificity reduces the costs of further diagnostic testing as well as false-positive results (Boshuizen et al., 2001).

The costs associated with NHS and false-positive results, as reported in developed countries, are generally regarded to be beyond the capacity of many developing countries (Olusanya et al, 2004). False-positive results may lead to parental anxiety and worry as well as monetary costs resulting from parents' lost time from work, transportation to health care facilitates, unnecessary tests, and probably more consequential costs and follow-up defaults - a matter of special concern in

developing countries like South Africa (Bess & Gravel, 2006; Fitzpatrick, Graham, Durieux-Smith, Angus, & Coyle, 2007).

Follow-up defaults are a major challenge for UNHS programmes worldwide especially in the early stages of NHS (Olusanya, Wirz, & Luxon, 2008a). Beliefs, customs, knowledge and attitudes regarding infant hearing loss are significant contributors towards South Africa's follow-up default, where concerns have been raised of cultural-based ignorance and resistance towards childhood disabilities (Olusanya et al., 2004; Swanepoel & Almec, 2008). Cultural beliefs and perceptions regarding disabilities may result in inaction towards early detection and intervention, as an estimated 80% of South Africans typically consult medical practitioners alongside traditional healers (South Africa Information, 2012; Swanepoel, 2006). A South African study demonstrated, however, that although superstitious cultural beliefs regarding causes of hearing loss were prevalent together with a low maternal awareness regarding infant hearing loss, there was also a readiness for the implementation of EHDI programmes (Swanepoel & Almec, 2008).

Unfortunately there is limited information regarding the status of EHDI programmes as well as the prevalence and etiology of infant hearing loss for South Africa (Swanepoel, 2006; Swanepoel et al., 2009). Data reporting NHS outcomes, the mean age of diagnosis, and particulars regarding intervention, is virtually non-existent due to largely unsystematic, sub-optimal, and variable protocols for EHDI programmes (Meyer et al., 2012; Olusanya et al., 2004; Van der Spuy & Pottas, 2008). Consequently the majority of infants with hearing loss in the South African public and private health care sector are not being identified early (Meyer et al., 2012). Research results are therefore necessary to initiate large-scale NHS programmes (Swanepoel, 2006). Successful NHS programmes rely on data management systems to ensure the process of screening through to diagnosis and intervention is efficient with adequate quality control (Meyer et al., 2012). Although the support services are an essential part of a complete EHDI programme, the need for early intervention services for infants with hearing loss will only truly be realised once NHS programmes are identifying these infants (Van der Spuy & Pottas, 2008).

1.4 Rationale

NHS programmes within the South African context face numerous challenges which are typical of developing countries (Friderichs, Swanepoel, & Hall, 2012; Olusanya et al., 2004; Swanepoel & Störbeck, 2008; Swanepoel et al., 2009; Swanepoel et al., 2010; Theunissen & Swanepoel, 2008; WHO, 2010). Regardless of these challenges, the necessity of developing and implementing NHS programmes in developing contexts remains an important objective (Swanepoel et al, 2006). Targeted screening of at-risk infants has been considered as an option for developing countries like South Africa (McPherson, 2012; Olusanya et al., 2004). A recent study showed, however, that risk factors for permanent childhood hearing loss were only present in 51.1% of cases (Le Roux, Swanepoel, Louw, Vinck, & Tshifularo, 2015). No other type of screening programme has demonstrated the same efficacy as UNHS to reduce the age of hearing loss identification or produced such positive outcomes (Yoshinaga-Itano, 2004).

Early hearing detection through UNHS has assumed unprecedented prominence as a measure of best practice in child health care (HPCSA, 2007; Olusanya, 2005). However, there is currently no consistent or systematic approach to UNHS within the private or public health care in South Africa (Swanepoel et al., 2006; Friderichs et al., 2012; Meyer et al., 2012; Theunissen & Swanepoel, 2008). Studies in South Africa have reported some form of NHS in 27% of public hospitals and 53% of private hospitals (Meyer et al., 2012; Theunissen & Swanepoel, 2008). Recent studies have identified immunisation clinics or midwife obstetric units as an alternative platform for NHS in South Africa compared to the traditional hospital-based platform (Friderichs et al., 2012; Olusanya & Okolo, 2006; Swanepoel et al., 2006). Although community-based NHS may be well suited for delivering these services (Friderichs et al., 2012), the majority (70%) of South African children are still born in hospitals within the public or private health care sector (Statistics South Africa, 2002). Hospital-based UNHS programmes in South Africa therefore need research-based evidence to address barriers such as lack of appropriate equipment, early discharge times, and high referral rates (Friderichs et al., 2012; Meyer et al., 2012; Swanepoel, 2009a; Swanepoel, Delport, et al., 2007; Swanepoel, Ebrahim, et al., 2007; Theunissen &

Swanepoel, 2008). Addressing these barriers will help to determine whether hospital-based UNHS can be an effective platform for a developing country like South Africa.

Hospital-based UNHS programmes in developed countries may need to be tailored to meet South Africa's NHS needs. Firstly, NHS needs to account for early hospital discharge times (<24 hours post birth) specifically in the public health care sector, which serves approximately 80% of the population (GCIS, 2011; Mowbray Maternity Hospital, 2011). Secondly, an objective electrophysiological technique is needed that meets the Joint Committee on Infant Hearing (2007) benchmarks and quality indicators before hospital discharge (<24 hours post birth). Lower referral rates are expected with AABR first stage screening (before 24 hours post birth) in comparison with an OAE screener, which will allow for a lowered follow-up rate, more time efficiency, and earlier intervention (Olusanya et al., 2009). Lastly, a screening technique is needed that will not only screen healthy infants but screen neonatal intensive-care unit (NICU) babies, detect auditory neuropathy, and be less affected by transient conditions in the middle and outer ear (JCIH, 2007; Kamal, 2013; Van den Berg, Deiman, & van Straaten, 2010). This poses a problem in terms of screening with an OAE screener as high referral rates (false-positives) are expected (Akinpelu et al., 2014; Gabbard et al., 1999). AABR is more accurate than OAEs, which reduces parental anxiety as well as the number of false-positive results that require infants to undergo further audiologic testing (Fitzpatrick et al., 2007; Kerschner, 2004).

AABR screening is uncommon in hospital-based UNHS programmes in both the public and private health sector of South Africa due to the significantly increased costs compared to OAE screening (Meyer et al., 2012; Theunissen & Swanepoel, 2008). However, it is the increased disposable-related expense of AABR (e.g., disposable ear tips or muffs and electrodes) that raise the costs significantly (Boshuizen et al., 2001). A newer generation AABR device, the BERAphone® MB 11 (Maico), has provided an alternative AABR tool without the requirement for disposables. Its design eliminates the need for disposable ear tips and electrodes, allowing for AABR screening at significantly reduced costs per screen (Meier, Narabayashi, Probst, & Schmuziger, 2004). This type of technology may allow

screening of infants at early ages in a health care context where babies are typically discharged before 24 hours after birth, without the costs associated with traditional AABR equipment.

AABR screening technology that is less susceptible to transient middle ear influences post birth and that requires limited disposable-related costs may more readily be utilised for hospital-based NHS in developing contexts like the South African public health care system. The research question of this study is therefore: *What are the outcomes of AABR screening using a device without disposable-related costs compared to typical transient evoked otoacoustic emissions (TEOAE) screening within the first 48 hours post birth?*

2. METHODOLOGY

2.1 Research Objectives

Primary objective

The primary objective of this study was to evaluate newborn hearing screening outcomes within the first 48 hours post birth, using TEOAE and AABR screening technology, in order to determine the implications for newborn hearing screening in South Africa.

Secondary objectives

1. To describe TEOAE and AABR three-stage screening outcomes according to age at screen.

2. To compare TEOAE and AABR screening outcomes as a function of age post birth.

Results of secondary objectives 1 and 2 were compiled and described in the article titled *"Outcomes with OAE and AABR screening in the first 48 hours- implications for newborn hearing screening in developing countries"* (Chapter 3), which was submitted to the *International Journal of Pediatric Otorhinolaryngology* (February 2015) and is currently in review.

2.2 Research Design

This study employed a within-subject comparative quasi-experimental research design comparing the screening effectiveness of TEOAE and AABR screening techniques across different time intervals post birth (Hall, 1998; Leedy & Ormrod, 2001; Shuttleworth, 2009). A within-subject design is a study in which the same group of subjects (newborns at one particular hospital) was screened by more than one screening method (TEOAE and AABR) over a period of 48 hours post birth (Hall, 1998; Shuttleworth, 2009). The within-subject design allowed individual differences to be separated from the error term (Kim, 2010) as the same subjects were screened

under multiple conditions, and each newborn therefore served as his or her own control. This design allowed the researcher to obtain a substantial amount of information by collecting multiple results from each newborn, which increased the statistical power to detect differences between the two screening techniques used (Hall, 1998; Kim, 2010; Shuttleworth, 2009).

This study, which involved representative samples and fairly structured data collection procedures, was quantitative in nature to allow for conclusive research findings (Kraska, 2010; Struwig & Stead, 2001). The type of data that was used allowed the researcher to establish relationships between the newborns' age of screen and their specific screening measure. Comparative research provided an effective method to collect, analyze, and describe the results of the two screening methods in order to compare the findings (Struwig & Stead, 2001). Comparative research using statistical methods assisted with the evaluation of the effectiveness of the two screening techniques as a function of age within 48 hours post birth (Struwig & Stead, 2001).

2.3 Ethical Considerations

In accordance with the guidelines provided by Mouton (2001) and Orb, Eisenhauer, and Wynaden (2001) the difficulties inherent in scientific research were alleviated by awareness and use of well-established ethical principles. These principles were adhered to throughout the research process and are discussed below.

2.3.1 Informed Consent

Informed consent is a foundational ethical principle which has been referred to as a negotiation of trust. The current study addressed the various components of this aspect (Hegde, 2003). Firstly, the parents of the infants (participants) needed to fully comprehend the research procedure. This was achieved by providing the parent/s with a letter (Appendix A) and a NHS brochure (Appendix B) informing them about the study. Mothers were often still under sedation from surgery when returning to the ward, and requesting informed consent had to be delayed until mothers were fully

alert. Nurses were able to assist with the explanation of the procedures to the mothers as well as to provide translations where necessary. These procedures increased parental awareness regarding infant hearing loss and the need for early intervention, which facilitated informed consent (Swanepoel, Ebrahim, et al., 2007).

Secondly, the research participants needed to be told the nature of the study to be conducted and be given the choice whether to participate or not (Leedy & Ormrod, 2001). The recognition of participants' rights, including the right to be informed about the study, the right to decide freely whether to participate in a study, and the right to withdraw from the research at any point in time without penalty, is considered to be a sign of respect. In this study the principle of respect was honoured by informing parents about the research through a letter (Appendix A) and a NHS brochure (Appendix B), as well as allowing each participant to choose whether to participate through acquiring written informed consent (Appendix C). Written consent was regarded as an indication that a participant had read and understood the informed consent form. The informed consent form (Appendix C) explained to the participant that the hearing screening was completely voluntary and that confidentiality would be ensured. The request for written consent also meant that participants could exercise their rights as autonomous persons to voluntarily agree or refuse to participate in this study at any given point in time.

Lastly, approval was obtained from the ethics committee of the University of Pretoria (Appendix D), hospital management (Appendix E) and the research committee of the Life Healthcare College of Learning (Appendix F).

2.3.2 Beneficence and Non-malfeasance

A second ethical principle to be observed in research involving people is beneficence and non-malfeasance —doing good to others and preventing harm. This principle was upheld by using non-invasive screening devices to screen the subjects' hearing (Leedy & Ormrod, 2001). Parents were informed about the screening techniques by including images of the screening equipment in the brochure (Appendix B) as well as providing the screening procedures both verbally and in writing (Appendix A & B) to

ensure their infants' well-being. Parents were informed about the preparation involved for both screening techniques (Leedy & Ormrod, 2001). The participants were informed (either verbally or visually) regarding what the AABR screening technique entailed. The procedure was clarified by informing them about the conduction gel, how it would be applied, and how the application of the gel may cause slight discomfort for their infants due to the gel being slightly cooler than body temperature. The participants were informed (either verbally or visually) regarding what the TEOAE screening technique entailed. The procedure was clarified by informing them about the probe, and how and where it would be placed in their infant's ear. If infants became restless for any reason, screening would be abandoned. Parents were also invited to be present while screening was being conducted. If a parent wanted to be present during the screening, but was unavailable when the screening needed to take place, the screening was postponed. There were no incentives or rewards (financial or other) offered for participation in this study.

2.3.3 Justice

The principle of justice refers to equal share and fairness. One of the crucial and distinctive features of this principle is avoiding exploitation and abuse of participants. The researcher's understanding and application of justice in this study was demonstrated by recognizing the vulnerability of the subjects and their parents. In order to ensure that the parents, especially the mothers, were informed correctly regarding the study, the informed consent form (Appendix C) was available and explained if necessary. The justice principle was also honoured through allowing mothers time to bond with their newborn after giving birth, which usually caused a time delay in attaining informed consent. Screening was therefore often conducted at the mother's discretion. To ensure fairness all newborns in the targeted hospital were given the opportunity to be screened irrespective of their race; place of origin; their families' religion, beliefs, language or culture; place of residence; or geographical location.

2.3.4 Quality of Screening

Researchers should at all times strive to conduct scientific research of a high quality. In the current research project, calibrated machinery for screening the hearing of newborn infants was used as well as standard screening parameters. NHS was conducted according to the parameters and specifications provided by the Joint Committee on Infant Hearing (2007) and the Health Professions Council of South Africa (2007) for hospital-based NHS. Quality was ensured by documenting results and limitations of the research findings as well as the methodological constraints. All NHS was performed by the researcher, a qualified audiologist, which also ensured consistency in quality.

2.3.5 Rejection of any Form of Plagiarism

To avoid plagiarism any source that was used to contribute to this study was acknowledged.

2.3.6 Confidentiality

The principle of confidentiality refers to the information gathered from subjects. This principle was upheld by ensuring that no identifying information of participants or subjects was included in the data analysis and reporting. The results from each subject were recorded by assigning a code to each participant to ensure that the names of the participants were not used. In this way the researcher respected the participants' right to privacy (Leedy & Ormrod, 2001). All data collected was used solely for the purpose of this study. This was clearly explained in both the informed consent form (Appendix C) and the letter to the parents (Appendix A).

2.4 Study Population

2.4.1 Population

The current study focused on newborns born at a hospital where proxy consent had been given. During the seven month research period, hearing screening with TEOAE and AABR was performed on one hundred and fifty healthy newborns (300 ears) before hospital discharge. All newborns screened were registered on the birth register in the hospital.

The population characteristics are described in Table 1 below:

Table 1. Population characteristics

Gender	75 (50%) Male
	75 (50%) Female
Median gestational age (in weeks)	39 (Range ≤37 to ≥41 weeks)
Mean birth weight (in grams)	3208.03 (Range ≤2600g to ≥3800g; SD 395.78)
Type of birth	74.2% Caesarean section (C-section)
	25.8% Normal vaginal delivery (NVD)

2.4.2 Criteria for Selection of Participants

All newborns participating in the study had no documented medical difficulties or risk indicators for hearing loss (Table 2).

Table 2. Risk indicators for hearing loss in infants younger than 28 days

	RISK INDICATORS IN SOUTH AFRICA * (Birth through 28 days of age)
A	An illness or condition requiring admission of 48 hours or greater to a NICU.
B	Stigmata or other findings associated with a syndrome known to include a sensorineural and or conductive hearing loss.
C	Family history of permanent childhood sensorineural hearing loss.
D	Craniofacial anomalies, including those with morphological abnormalities of the pinna and ear canal.
E	In-utero infection such as cytomegalovirus, herpes, toxoplasmosis, rubella, human immunodeficiency virus (HIV), or malaria.

* *Compiled from the JCIH Year 2000 Position Statement and HPCSA Year 2007 Position Statement*

2.4.3 Sampling Method

The participants were chosen for the study based on a non-probability quota sampling method (Leedy & Ormrod, 2001; Struwig & Stead, 2001). Infants not meeting the selection criteria were excluded from the study.

2.4.4 Research Setting

The research was aimed at providing a solution for hospital-based NHS (in the public or private health care sector) where infants are discharged early from hospital. This is most common in the public health care sector of South Africa (GCIS, 2011; Mowbray Maternity Hospital, 2011). The current study was conducted in a private hospital as this allowed the researcher the time necessary (due to longer hospital stays) to determine screening outcomes over a three-stage screening process

before hospital discharge. This process of data collection would not have been possible in a public hospital. Relevant resources and studies reveal evidence based barriers including early discharge of infants from hospital, expected high referral rates, and follow-up default (Meyer et al., 2012; Olusanya, Wirz, & Luxon, 2008b; Swanepoel et al., 2006; Theunissen & Swanepoel, 2008).

2.5 Material and Apparatus

The material and apparatus utilised to achieve the objectives of this study are discussed below.

2.5.1 Material

The birth register in the nursery was used to determine which infants were available for screening (i.e. in the nursery and not in NICU). A data collection form (Appendix G) was completed for each infant screened. For ethical purposes and in keeping with hospital policy, a copy of informed consent as well as the results obtained at each screening stage was noted in each infant's hospital file.

2.5.2 Apparatus

The screening techniques provided a pass or refer result without the need for a subjective data analysis. TEOAE screening was conducted using the GSI AUDIOscreener+™. The probe of this handheld device was placed in the external ear canal of the newborn with a rubber tip. The size of the rubber tip used was determined by the size of the infants' ear canal. The device used in-ear calibration before screening commenced. The click stimulus intensity was set at 84 dB peak equivalent SPL at a rate of 64 Hz for a maximum time of 240 seconds (band pass filter of 1000 to 4000 Hz). An automated pass criterion of two bands was utilised based on TEOAE signal to noise ratio (max. noise 60 dB and max. signal 70 dB) and TEOAE reproducibility within 128 to 2048 frames. The TEOAE frequency band low cut-offs were 3500, 2500, and 1500. The high cut-offs were 4500, 3500, and 2500. A

reproducibility value of 60 to 80% was required for the band response to be considered a pass.

The BERAphone® MB 11 AABR device (Figure 1) consists of a handheld headphone unit that integrates the preamplifier and a set of three fixed touch-electrodes, which was connected to an ACER laptop computer (Meier et al., 2004). Electrode gel was applied at the three electrode sites (vertex, ground, and mastoid) on the infant's head. Electrode placement was as follows: non-inverting electrode was placed on the vertex; inverting electrode on the mastoid ipsilateral to the stimulus; and ground electrode was positioned just above the ear ipsilateral to the stimulus. The vertex electrode was adjusted to the individual size of the baby's head. Electrode gel was placed on the integrated electrodes before the earphone was placed surrounding the baby's ear with the resting electrodes on the prepared sites. The CE-Chirp stimulus™ was presented at 93 CE-chirps® per second at 35 dB nHL. Results were reported as either a pass or refer. The result was a pass if the presence of a non-random signal was detected with a confidence level >99.9% within 120 seconds. The result was a refer if pass criterion was not reached (Meier et al., 2004; Melagrana, Casale, Calevo, & Tarantino, 2007). The cut-off frequencies of the band pass filter were 163 Hz and 1930 Hz (Maico Diagnostic GmbH, 2003).

Figure 1. BERAphone® MB 11 screening an infant

2.6 Data Collection

2.6.1 Pilot Study

A pilot study with the TEOAE and AABR screening techniques was conducted on sixty healthy newborns before the formal data collection phase commenced. The pilot study allowed the researcher to refine screening techniques, test procedures, and data collection methods before commencing the study (Leedy & Ormrod, 2001).

The following changes were made in accordance with the results from the pilot study:

a) *Screening techniques:* The AABR gave a high artefact level during calibration for each screen which hindered the commencement of screening. The artefact level was addressed by sending the equipment in for calibration with the manufacturer in order for software to be updated. Once the software had been updated and the AABR was returned, artefact levels were much lower, which allowed for screening to commence.

b) *Test procedures:* On alternating the screening techniques, it was noted that the gel applied for the AABR screening technique tended to cause a change in the state of consciousness in the infants. This was a result of the gel being slightly cooler than body temperature. The gel was also difficult to remove before conducting the TEOAE. TEOAE was therefore used to screen first where possible.

c) *Data collection methods:* The original data collection form had space provided to write the participant's details. This deemed not practical as it was much quicker and more reliable to stick the patient's sticker, provided by the hospital, onto the form. The data collection form (Appendix G) was therefore redesigned to suit the needs of the study better.

2.6.2 NHS Protocol

All parents of infants were provided with an information brochure (Appendix B) prior to screening. Screening was conducted either in a room within the maternity ward or in the nursery, depending on the space available. After informed consent was obtained from a parent, each newborn underwent screening with the TEOAE and AABR. Infants were screened at several points in time as early as possible after birth. Infant age was calculated as the number of hours from birth to testing (Doyle, Fujikawa, Rogers, & Newman, 1998). Infants were only re-screened if either of the screening techniques (TEOAE or AABR) initially yielded a refer outcome. All TEOAE and AABR screening was performed by the same audiologist (the researcher). The audiologist was experienced in NHS.

A three-stage screening protocol (Figure 2) with the TEOAE and AABR was implemented. A refer outcome in the first stage indicated that further screening was required before discharge, to rule out any uncertainty regarding the hearing status of the infant. Refer criterion for subjects was a unilateral or bilateral refer for either screening device.

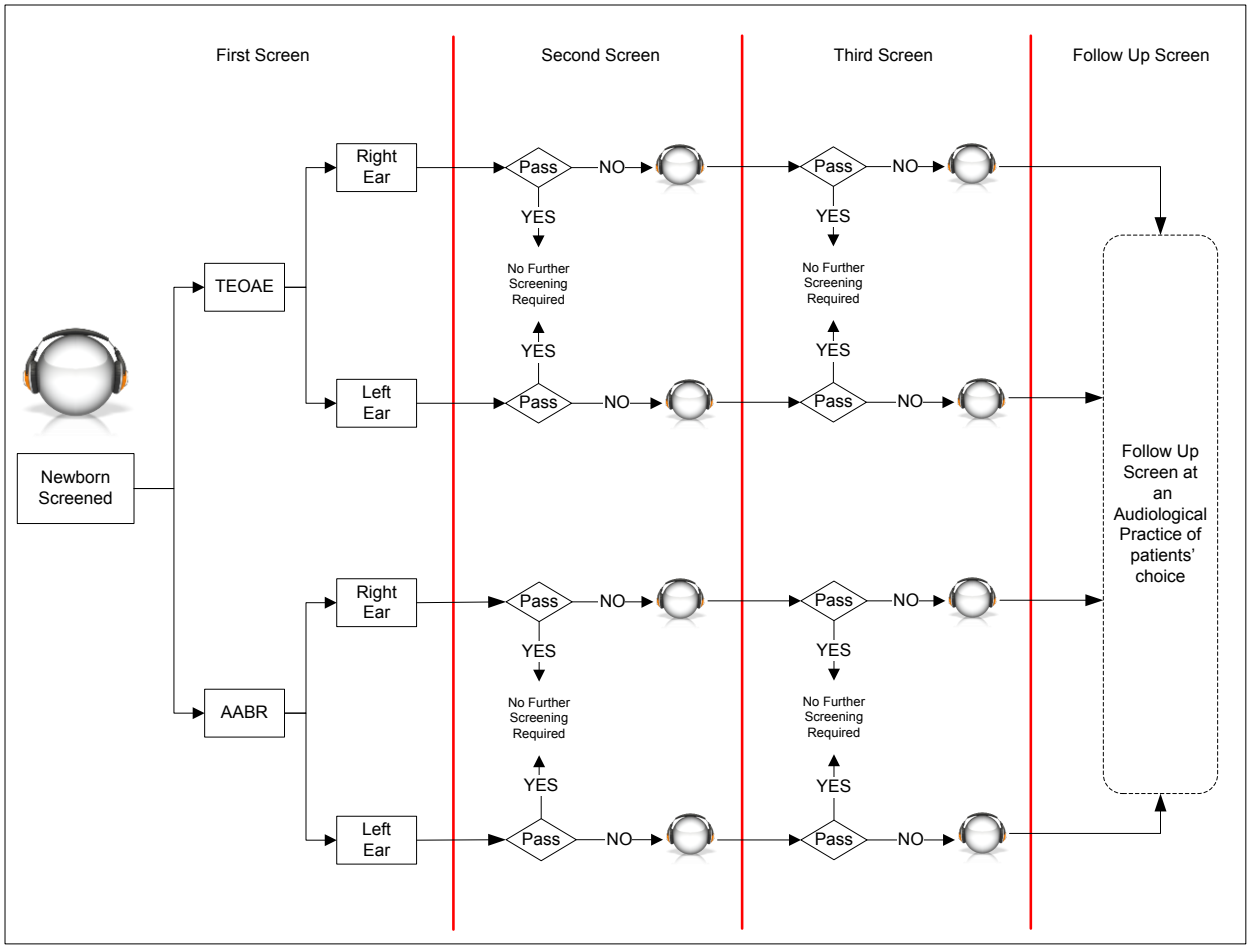

Figure 2. Three-stage screening protocol employed during data collection

A second-stage screen with the equipment (TEOAE or AABR) was only conducted on ears that yielded a refer result during the initial screen. The third-stage screen was also conducted in the same manner. If a newborn did not pass the third-stage screen, an opportunity was provided for an appointment for a re-screen at the hospital between 2 days and 6 weeks after birth. A screen was not repeated within a stage unless the environment was too noisy or incorrect placement/insertion was evident. "Too noisy" was defined by the noise parameters set on either the TEOAE or AABR, and a placement/insert problem was identified when the calibration of either screening technique was unsuccessful. The first ear to be screened was randomly selected, depending on which ear was most accessible (i.e. facing upwards away from the cot) before the infant was turned over to screen the opposite ear. TEOAE screening was conducted first 83.1% of time, while AABR was conducted first 16.9% of the time. This was due to equipment-related factors

established during the pilot study. Test time was recorded for each screening test, excluding the time required to set up, start up, and shut down each screening device and to prepare the infant. The ear specific time segments were measured with a stopwatch for the TEOAE and read from the MB 11 software for the AABR screening.

2.6.3 Data Collection Procedures

NHS was conducted between 7:00am and 9:00am and between 05:40pm and 07:15pm (Monday to Friday); and between 9:00am and 12:00pm (Saturday and Sunday). This study was not an established UNHS programme but rather a NHS programme implemented for the purposes of the research project. The study was implemented within the hospital-based research setting according to the data collection procedures described in Figure 3.

Infection control was of paramount importance due to the population involved and was also required by the hospital-based research setting (Kemp & Bankaitis, 2000). Infection control and screening materials were always set up for screening procedures and included hospital-grade disinfectant spray and wipes as well as gloves. The researcher's hands were washed before leaving a room in the ward and on entering and exiting the nursery. Contaminated items were disposed of correctly. Screening equipment was also disinfected on arrival and exit. Due to hospital infection control protocol, equipment was not allowed to be transported between rooms in the maternity ward for NHS because of the risk of cross infection.

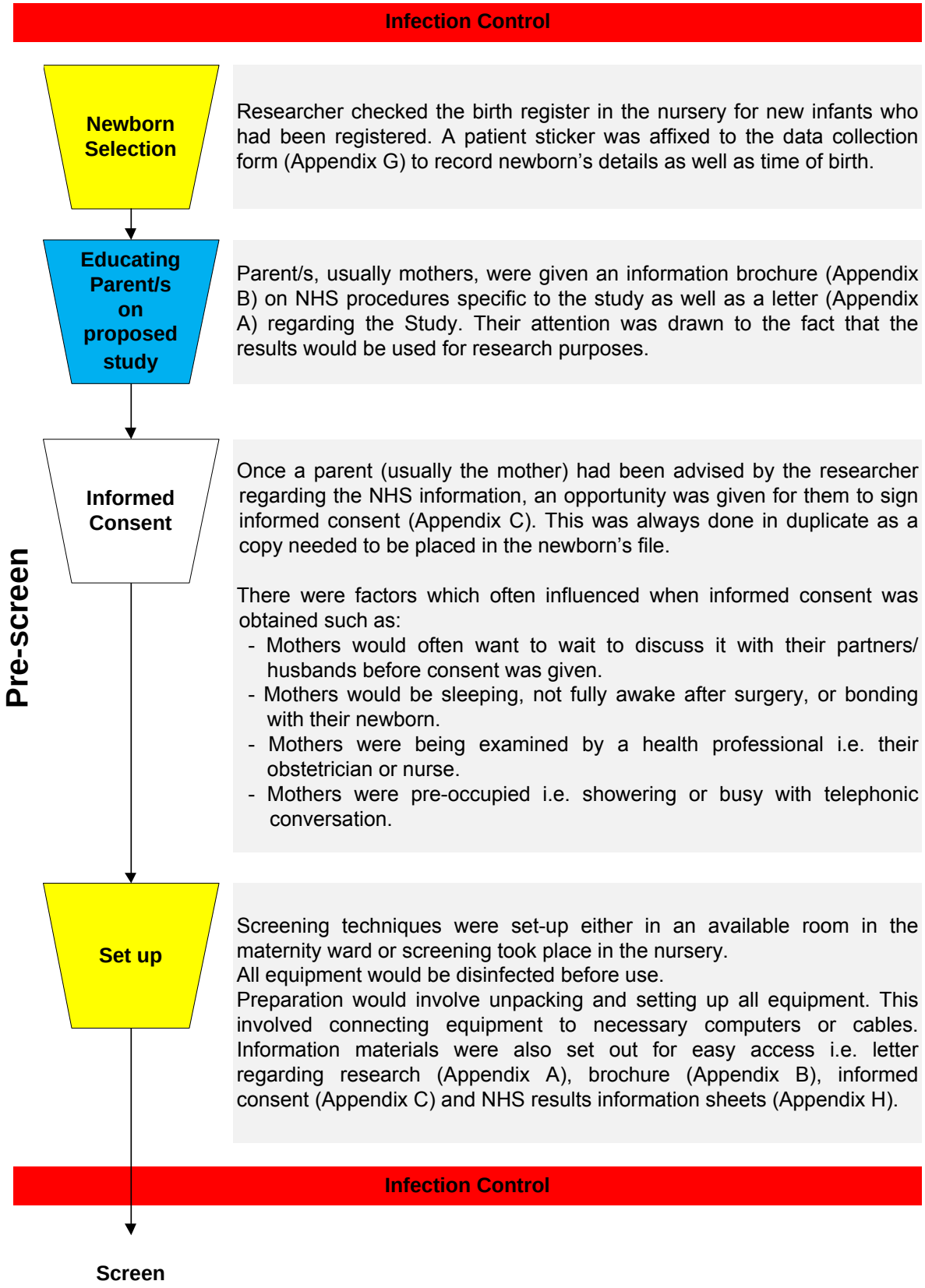

Figure 3a. Pre-screen data collection procedures

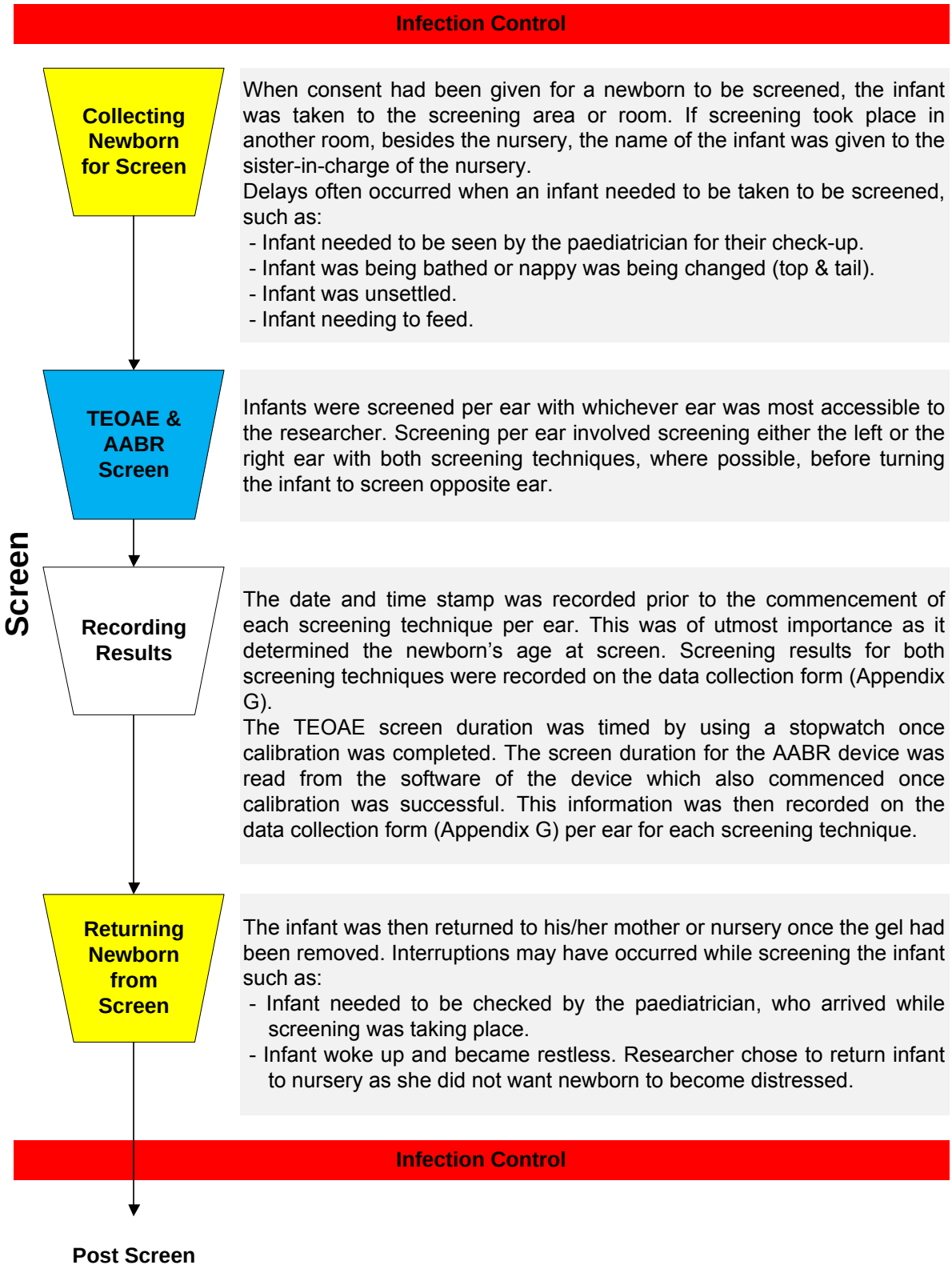

Figure 3b. Screen data collection procedures

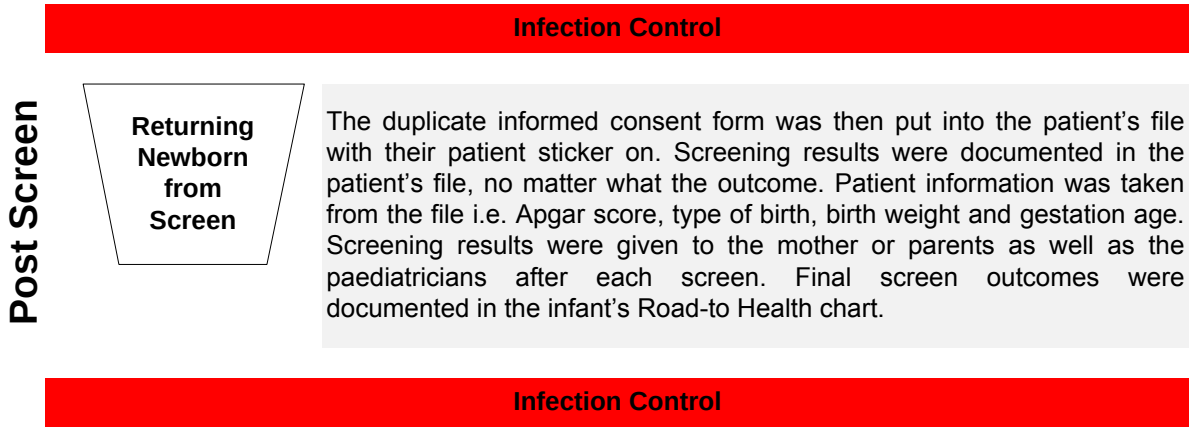

Figure 3c. Post screen data collection procedures

2.7 Data Processing and Analysis Procedures

The data in the current study was quantitative in nature which involved exploring possible correlations between NHS outcomes and an infant's age within the first 48 hours, while also comparing screening techniques (Leedy & Ormrod, 2001). Quantitative data analysis procedures were applied in various steps (Trochim, 2006).

2.7.1 Data Preparation

All data was recorded by logging the findings on the correct forms (Appendix G) and filing them appropriately. Once data had been collected and gathered it was checked for data accuracy. All data recorded was subsequently captured on an MS Excel database. Data was captured using a double-entry method which was transformed into variables that were usable in the analyses.

2.7.2 Data Analysis

Statistical Package for the Social Sciences (SPSS version 21) was used for the statistical analysis. Descriptive statistics provided the frequency distribution and measures of central tendency. Chi-square test was used to investigate

correspondence between test outcomes. Analysis of differences in outcomes across ages was performed by grouping three age categories and conducting the Wilcoxon signed rank test and Mann-Whitney test. The significance level for all statistical tests was set at the 5% level.

2.7.2.1 Descriptive and comparative statistics

Descriptive statistics were used to describe the data obtained for this study but mainly to describe the TEOAE and AABR screening outcomes according to age at screen. This allowed the data to be presented in a manageable form and allowed for representations of the data to be made.

Comparative statistics allowed conclusions to be drawn from the data obtained for both objectives 1 & 2. In order to compare the AABR and TEOAE screening outcomes, the pass and referral rates were calculated for the entire sample (300 ears) for each time interval (Doyle et al., 1998). These outcomes were also used to compare the efficiency of the TEOAE and AABR screening techniques within 48 hours post birth.

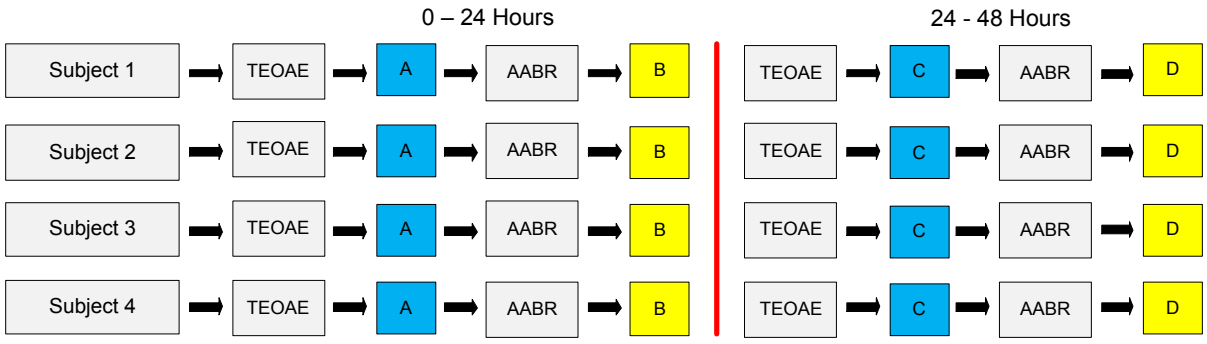

Figure 4: A figure showing how the TEOAE and AABR screening outcomes were used to process data within 48 hours post birth

Figure 4 illustrates how the TEOAE and AABR screening outcomes were firstly described according to the age at screen (Screening results: A vs B; and C vs D). Secondly, how the TEOAE and AABR data was compared as a function of age

(TEOAE: A vs C; AABR: B vs D) which also involved comparing the TEOAE and AABR before 24 hours and after 24 hours post birth.

2.7.2.2 Inferential statistics

By using inferential statistics, conclusions were reached that extended beyond the immediate data (Leedy & Ormrod, 2001; Silverman, 1998; Struwig & Stead, 2001). Thus, inferences were made from the descriptive and comparative statistics. A fundamental inferential statistics principle is that, as the number of subjects increase, statistical power increases, and the probability of beta error decreases (the probability of not finding an effect when one "truly" exists) (Hall, 1998). The main advantage that the within-subject design had over the between-subject design is that it required fewer participants (i.e. 150 newborns equaled 300 ears screened two or three times amounted to over 700 screen results), making the process much more streamlined and less resource heavy (Shuttleworth, 2009).

2.8 Reliability and Validity

The measurement instruments (i.e. the OAE and AABR screening devices) provided a basis on which the entire research depended, therefore their reliability and validity needed to be addressed (Leedy & Ormrod, 2001).

2.8.1 Reliability

Reliability is the stability or consistency with which the subjects are measured (Robson, 2002). In order to assure that the testing between measures was reliable, a pilot study on sixty newborns was conducted at Westville hospital by the researcher to ensure that the researcher was competent and confident to conduct the hearing screening on the newborns with both techniques.

According to Robson (2002) participant error may occur due to fluctuations in infant state of arousal and vernix in the ear canals, which in turn may affect reliability.

Using two screening methods could result in the participants being disrupted from sleep or becoming unsettled, which may influence results (Shuttleworth, 2009). Participant error was overcome by adding a rescreen to the NHS protocol as an attempt to avoid biasing the findings due to these fluctuations. The test-retest reliability also determined the extent to which the screening result was reliable after a period of time (Struwig & Stead, 2001).

The researcher ensured reliability by using the same informed consent form with each participant. This allowed for an overall consensus of understanding in terms of what was expected from each participant as well as what the objectives of the study were (Struwig & Stead, 2001). The reliability of this study was also addressed by conducting a pilot study. The pilot study allowed the researcher the opportunity to identify any possible issues that arose, which may have compromised the consistency and trustworthiness of the results obtained (Mouton, 2001; Leedy & Ormrod, 2001).

2.8.2 Validity

Validity refers to the accuracy of the results and the extent to which a research design is appropriately conducted (Struwig & Stead, 2001; Robson, 2002). Construct validity was determined firstly by comparing test results between the TEOAE and AABR screening techniques; and secondly by comparing the test results to other study findings and quality indicators (HPCSA, 2007; JCIH, 2007; South African Speech-Language-Hearing Association [SASHLA], 2011; WHO, 2010).

The internal validity of this study addressed the issue of whether the hearing screening of the newborns was influenced by extraneous variables (Robson, 2002). The extraneous variables which may have compromised the study were addressed in the following manner:

a) Maturation: When an infant's hearing is screened before 24 hours post birth, vernix in the ear canal may affect results. This possibility was addressed by having a second and third stage in the screening process.

b) Testing environment: Both screening methods are sensitive to noise. The noise effect was controlled by ensuring testing was only performed once calibration was successful.
c) Instrumentation: This variable was addressed by using standardized calibrated screening devices according to formalized test procedures (Robson, 2002).

With within-subjects designs, the conditions are always exactly equivalent with respect to individual difference variables since the participants are the same for each screening technique (Hall, 1998). The subjects act as their own control, which provides a way of reducing the amount of error arising from natural variance between individuals (Shuttleworth, 2009). Individual differences are subtracted from the error term, therefore within-subject designs often have substantially smaller error terms thereby increasing the validity of the study (Kim, 2010; Shuttleworth, 2009).

3. RESEARCH ARTICLE: OUTCOMES WITH OAE AND AABR SCREENING IN THE FIRST 48 HOURS - IMPLICATIONS FOR NEWBORN HEARING SCREENING IN DEVELOPING COUNTRIES

Authors: Michelle van Dyk, De Wet Swanepoel and James W. Hall III
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Note: This article was edited in accordance with the editorial specifications of the journal and may differ from the editorial style of the rest of this document.

3.1 Abstract

***Objective*:** Early discharge of newborns (<24 hours after birth) from birthing centres is an important barrier to successful newborn hearing screening (NHS) in developing countries. This study evaluated the outcome of NHS within the first 48 hours using both an automated auditory brainstem response (AABR) device without the need for costly disposables typically required, and transient evoked otoacoustic emissions (TEOAE).

Methods: NHS was performed on 150 healthy newborns (300 ears) with TEOAE and AABR techniques before discharge at a hospital. A three-stage screening protocol was implemented consisting of an initial screen with TEOAE (GSI AUDIOscreener+) and AABR (BERAphone® MB 11). Infants were screened at several time points as early as possible after birth. Infants were only re-screened if either screening technique (TEOAE or AABR) initially yielded a refer outcome. The same audiologist performed all TEOAE and AABR screenings.

Results: Over the three-stage screen AABR had a significantly lower referral rate of 16.7% (24/144 subjects) compared to TEOAE (37.9%; 55/145 subjects). Screening referral rate showed a progressive decrease with increasing age. For both TEOAE and AABR, referral rate per ear screened 24 hours post birth was significantly lower than for those screened before 24 hours. For infants screened before 12 hours post birth, the AABR referral rate per ear (51.1%) was significantly lower than the TEOAE referral rate (68.9%). Overall AABR referral rate per ear was similar for infants screened between 24 to 36 hours (20.2%) and 36 to 48 hours (18.9%) but significantly lower than for TEOAE (40.7% and 41.9%, respectively). Lowest initial referral rates per ear (TEOAE 25.8%, AABR 3.2%) were obtained after 48 hours post birth.

Conclusion: In light of the early post birth discharge typical in developing countries like South Africa, screening with AABR technology is significantly more effective than for TEOAEs. AABR screening with a device like the MB 11 is particularly appropriate because disposable costs are negligible. Universal newborn hearing screening (UNHS) protocols for contexts in developing countries like South Africa may require this type of AABR technology in hospital-based settings for infants discharged after 24 hours post birth. Otoacoustic emissions (OAE) technology might be reserved for screening remaining infants once they are slightly older and attending routine health care visits such as community-based immunisation clinics or midwife obstetric units.

3.2 Introduction

Prevalence of congenital and early-onset hearing impairment ranges from 0.5 to 5 per 1000 infants based on studies from various countries (Olusanya, 2011a; WHO, 2010). At least 90% of infants with hearing loss live in developing countries (Olusanya et al., 2009). Undetected hearing loss can lead to delayed or impaired speech and language development, social and emotional problems, academic failure, and restricted vocational outcomes (Erenberg et al., 1999; JCIH, 2007; Moeller, 2000; Yoshinaga-Itano, Sedey,Coulter, & Mehl, 1998). The earlier a hearing loss is detected, the earlier intervention can begin, which increases the likelihood of

optimizing a child's potential across developmental areas (Yoshinaga-Itano et al., 1998; WHO, 2010).

It is recommended that universal newborn hearing screening (UNHS) be performed within the first month of life, and that a screen result be obtained before hospital discharge whenever possible to reduce the subsequent need for outpatient follow-up (JCIH, 2007). All infants should have access to hearing screening during which a physiologic measure such as otoacoustic emissions (OAE) or automated auditory brainstem responses (AABR) is used (JCIH, 2007). Although both AABR and OAE are accepted as reliable measures for newborn hearing screening (NHS) they may present with false-positive results due to patient and environment related factors (Mehl & Thomson, 2002). AABR is less affected 24 to 48 hours post birth than OAE by transient conditions in the external auditory canal (e.g. collapse of the ear canal and the presence of debris) and middle ear (e.g. presence of amniotic fluid and mesenchyme), making it more likely that newborns will refer with OAE screening than with AABR screening (Akinpelu et al., 2014; Gabbard et al., 1999). Environmental factors such as excessive ambient noise in the test environment or test skills and experience of the screening staff may also negatively affect screening outcomes for both OAE and AABR (Olusanya & Bamigboye, 2010). False-positive results may lead to parental anxiety and worry as well as monetary costs resulting from parents' lost time from work, transportation to health care facilitates, unnecessary tests, and probably more consequential costs and follow-up defaults which is a matter of special concern in developing countries like South Africa (Bess & Gravel, 2006; Fitzpatrick et al., 2007).

The recommended time for NHS screening after birth is later than 24 hours to avoid the increased incidence of transient outer and middle-ear conditions affecting screening outcomes in the first hours post birth (Erenberg et al., 1999; Olusanya & Bamigboye, 2010). Screening with an OAE technique within the first 24 hours post birth reportedly results in referral rates as high as 20% (Erenberg et al., 1999; Korres et al., 2006; Lupoli et al., 2013). Referral rates drop to as low as 3% when screening is performed between 24 and 48 hours after birth (Erenberg et al., 1999; Korres et al., 2006; Lupoli et al., 2013). Referral rates of less than 4% are generally achievable

when an infant is screened with OAE combined with AABR in a two-step screening system or with AABR alone before discharge (Mehl & Thomson, 1998; Olusanya & Bamigboye, 2010).

The reported distribution of typical discharge times for newborns in the United Kingdom are 16% on the day of birth, 35% the following day; 21% after 2 days and 28% for 3 days after delivery (Elatter et al., 2008). In the US, healthy infants are typically discharged from the hospital between 24 and 48 hours after birth (Southeast Georgia Health System, 2011). In comparison healthy infants in South Africa are discharged from a state hospital or clinics between 6 and 24 hours after birth (GCIS, 2011; Mowbray Maternity Hospital, 2011). Postnatal care is provided by family members or at primary health care clinics (Ngunyulu & Mulaudzi, 2009), even though the World Health Organization (2014) recommends that newborns born in health facilities should not be sent home in the crucial first 24 hours of life.

Early discharge of newborns in South Africa is an important challenge to successful implementation of hospital-based NHS. An additional challenge is the cost associated with screening, particularly costs related to disposables involved in testing each infant. Typically AABR screening has been more expensive than OAE screening due to the higher costs of disposables (Boshuizen et al., 2001). In South Africa the vast majority (81%) of private hospitals conducting screening reportedly use OAE screening in the healthy newborn ward compared to only 1% employing AABR, due to the additional costs associated with this type of screening (Meyer et al., 2012). However, the AABR's higher specificity reduces the costs of further diagnostic testing, as well as the time parents have to invest in order to reach a diagnosis (Boshuizen et al., 2001). In South Africa, only 53% of private hospitals reported some form of NHS due to lack of appropriate equipment and time constraints (Meyer et al., 2012).

AABR screening is rare in the public health sector of South Africa due to the significantly increased costs compared to OAE screening. AABR screening is typically more costly than OAE screening (Kerschner, 2004). It is the increased disposable-related expense of AABR (e.g., disposable ear tips or muffs and

electrodes) that raise the costs significantly. A newer generation AABR device, the BERAphone® MB 11 (Maico), has provided an alternative AABR tool without the requirement for disposables. Its design eliminates the need for disposable ear tips and electrodes, allowing for AABR screening at significantly reduced costs per screen (Meier et al., 2004). This type of technology may allow screening of infants at early ages in a health care context where babies are typically discharged before 24 hours after birth, without the costs associated with traditional AABR equipment. Screening technology with limited disposable-related costs, and that is less susceptible to transient middle ear influences within the first 48 hours after birth, may more readily be utilised for hospital-based screening in typical developing world contexts like the South African public health care system. The aim of this study was therefore to evaluate the outcome of NHS within the first 48 hours using the MB 11 AABR device compared to TEOAE screening.

3.3 Methods

Newborn hearing screening was conducted in a hospital in South Africa. Institutional research and ethics committee approval was obtained from the University of Pretoria and the hospital involved before data collection commenced.

3.3.1 Subjects

Hearing screening with TEOAE and AABR was performed before hospital discharge for 150 healthy newborns (300 ears). Infants were screened at several points in time as early as possible after birth. Delays in obtaining informed consent due to hospital protocol, time of delivery, and other logistical factors resulted in some delays to screening. All newborns participating in the study had no documented medical difficulties and were in a well-baby nursery. There were 75 male (50%) and 75 female (50%) infants. The median gestational age was 39 weeks and the mean birth weight was 3208 grams (SD 396 grams). The majority of newborns were born via caesarean section (74.2%), which is representative of births in the private health care sector in South Africa.

A pilot study with TEOAE and AABR screening techniques was conducted on sixty healthy newborns before the formal data collection phase commenced. The pilot study allowed the audiologist to refine screening techniques, test procedures, and data collection before commencing the study.

3.3.2 Screening Protocol

All parents of infants to be screened were provided with an information brochure prior to screening. Screening was conducted either in a room within the maternity ward or in the nursery, depending on the space available. After informed consent was obtained from a parent, each newborn underwent screening with the TEOAE and AABR. Infants were screened at several points in time as early as possible after birth. Infants were only re-screened if either of the screening techniques (TEOAE or AABR) initially yielded a refer outcome. All TEOAE and AABR screening was performed by the same audiologist. The audiologist was experienced in NHS.

A three-stage screening protocol (Figure 2) with the TEOAE and AABR was implemented. A refer outcome in the first stage indicated that further screening was required before discharge, to rule out any uncertainty regarding the hearing status of the infant. Refer criterion for subjects was a unilateral or bilateral refer for either screening device.

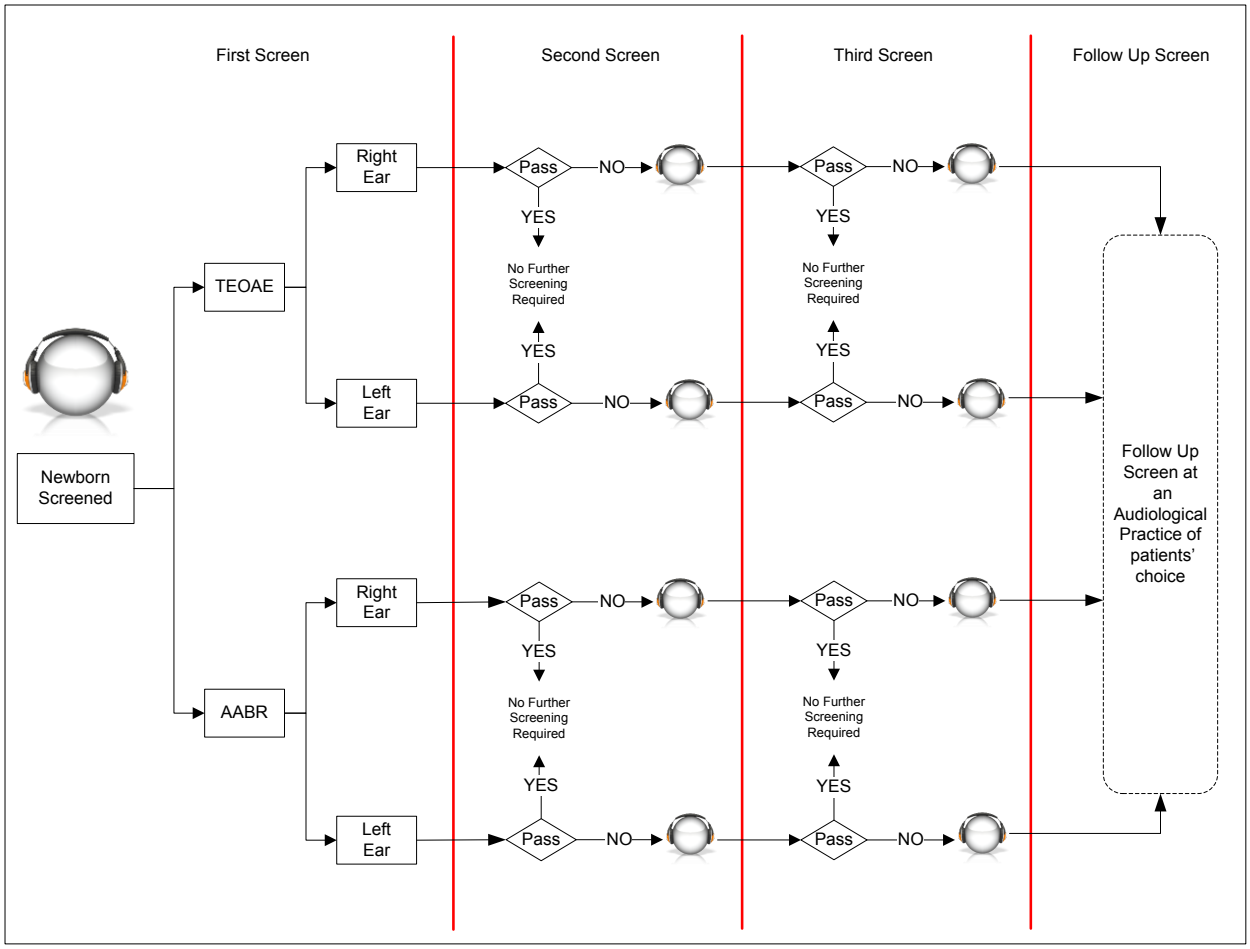


Figure 2. Three-stage screening protocol employed during data collection

A second-stage screen with the equipment (TEOAE or AABR) was only conducted on ears that yielded a refer result during the initial screen. The third-stage screen was also conducted in the same manner. If a newborn did not pass the third-stage screen, an opportunity was provided for an appointment for a re-screen at the hospital between 2 days and 6 weeks after birth. A screen was not repeated within a stage unless the environment was too noisy or incorrect placement/insertion was evident. "Too noisy" was defined by the noise parameters set on either the TEOAE or AABR, and a placement/insert problem was identified when the calibration of either screening technique was unsuccessful. The first ear to be screened was randomly selected, depending on which ear was most accessible (i.e. facing upwards away from the cot) before the infant was turned over to screen the opposite ear. TEOAE screening was conducted first 83.1% of time, while AABR was conducted first 16.9% of the time. This was due to equipment-related factors

established during the pilot study. The cold gel tended to wake babies if AABR screening was conducted first, and the gel was difficult to remove before conducting the TEOAE. The TEOAE was less invasive with regard to preparation of the newborn and, thus, had less effect on the newborn's state for the next screening method. Test time was recorded for each screening test, excluding the time required to set up, start up and shut down each screening device and to prepare the infant. The ear specific time segments were measured with a stopwatch for the TEOAE and read from the MB 11 software for the AABR screening.

3.3.3 Instrumentation

The screening techniques provided a pass or refer result without the need for a subjective data analysis. The BERAphone® MB 11 AABR device (Figure 1) consists of a handheld headphone unit that integrates the preamplifier and a set of three fixed touch-electrodes connected to a laptop computer (Meier et al., 2004). Electrode gel was applied at the three electrode sites (vertex, ground and mastoid) on the baby's head. Electrode placement was as follows: non-inverting electrode was placed on the vertex; inverting electrode on the mastoid ipsilateral to the stimulus; and ground electrode was positioned just above the ear ipsilateral to the stimulus. The vertex electrode could be adjusted to the individual size of the baby's head. Electrode gel was placed on the integrated electrodes before the earphone was placed surrounding the baby's ear with the resting electrodes on the prepared sites. The CE-Chirp stimulus™ was presented at 93 CE-chirps® per second at 35 dB nHL. Results were reported as either a pass or refer. The result was a pass if the presence of a non-random signal was detected with a confidence level >99.9% within 120 seconds. The result was a refer if pass criterion was not reached (Meier et al., 2004; Melagrana et al., 2007). The cut-off frequencies of the band pass filter were 163 Hz and 1930 Hz (Maico Diagnostic GmbH, 2003).

Figure 1. BERAphone® MB 11 screening an infant

Note: Permission was granted by Maico Diagnostic GmbH on the 10 August 2013 to use Figure 1 for publication purposes.

TEOAE screening was conducted using the GSI AUDIOscreener+™. The probe of this handheld device was placed in the external ear canal of the newborn with a rubber tip. The device used in-ear calibration before screening commenced. The click stimulus intensity was set at 84 dB peak equivalent SPL at a rate of 64 Hz for a maximum time of 240 seconds (band pass filter of 1000 to 4000 Hz). An automated pass criterion of two bands was utilised based on TEOAE signal to noise ratio (max. noise 60 dB and max. signal 70 dB) and TEOAE reproducibility within 128 to 2048 frames. The TEOAE frequency band low cut-offs were 3500, 2500, and 1500. The high cut-offs were 4500, 3500 and 2500. A reproducibility value of 60 to 80% was required for the band response to be considered a *pass*.

3.3.4 Data Management and Analysis

All data was recorded and subsequently captured on an MS Excel database. SPSS version 21 was used for the statistical analysis. Descriptive statistics provided the frequency distribution and measures of central tendency. Chi-square test was used to investigate correspondence between test outcomes. Analysis of differences in outcomes across ages was performed by grouping three age categories and

conducting the Wilcoxon signed rank test and Mann-Whitney test. The significance level for all statistical tests was set at the 5% level.

3.4 Results

Initial TEOAE and AABR screening was completed on 150 healthy newborns (300 ears) at various ages post birth.

3.4.1 Screening Outcomes

As summarized in Table 3, most ears were successfully screened. A small number of ears were not screened due to the infants' state, noise levels, and/or probe fit issues. Only one ear (1/300; 0.3%) could not be screened with either the TEOAE or AABR throughout the three-stage screen, and 92.7% of ears (278/300) were screened with both TEOAE and AABR techniques initially. 41.3% of subjects passed bilaterally with both TEOAE and AABR at the initial screen. Over the three-stage screen TEOAE had a significantly higher referral rate of 37.9% (55/145 subjects) than AABR (16.7%; 24/144 subjects). Overall AABR had a significantly ($p<0.001$; Chi-Square) lower initial referral rate per ear compared to the TEOAE. Right ears had a significantly ($p<0.05$; Chi-Square) lower referral rate for both screening techniques compared to left ears. Rescreen referral rates were also higher per ear for TEOAE (49.5%) compared to AABR (36.1%) screening. The TEOAE presented with a higher false-positive (i.e. an ear referred initially but passed on the second or third screen) rate (39/103; 37.9%) than the AABR (3/61; 4.9%).

Table 3. Outcomes of three-stage newborn hearing screening with TEOAE and AABR

	TEOAE		AABR	
	N (ears)	%	N (ears)	%
FIRST SCREEN				
Refer rate right	56/146	38.4	27/145	18.6
Refer rate left	66/143	46.2	39/145	26.9
Refer rate combined	122/289	42.2	66/290	22.8
Unable to screen	11/300	3.7	10/300	3.3
SECOND SCREEN				
Refer rate right	21/43	48.8	14/25	56.0
Refer rate left	24/46	52.2	10/29	34.5
Refer rate combined	45/89	50.6	24/54	44.4
Unable to screen	3/92	3.3		
THIRD SCREEN				
Refer rate right	3/7	42.9	1/5	20.0
Refer rate left	3/7	42.9	–	–
Refer rate combined	6/14	42.9	1/7	14.3
Unable to screen			1/8	12.5
OVERALL SCREEN				
Refer rate right	31/146	21.2	12/145	8.3
Refer rate left	39/143	27.3	18/145	12.4
Refer rate combined	70/289	24.2	30/290	10.3
Unable to screen	11/300	3.7	10/300	3.3

Mean screen duration for a pass result was 31 seconds (SD 26) for TEOAE and 53 seconds (SD 40) for the AABR. The mean duration for a refer result was 109 seconds (SD 18) with TEOAE and always 180 seconds for AABR due to the test protocol. If the pass criterion was not reached after 180 seconds of test time, the result “refer” was displayed in the lower right corner. There was no significant difference ($p>0.05$; Wilcoxon) in time between the left and right ears when both

passed or both referred with a TEOAE. Half the TEOAE pass results (48.5%) were obtained within the first 20 seconds of screening and half the AABR pass results (50.0%) were obtained between 11 and 40 seconds.

3.4.2 Age Effect on Screening Outcome

Screening referral rate per ear showed a progressive decrease with increasing age (Figure 5). The AABR referral rate per ear was significantly lower ($p<0.001$; Chi-Square) than the TEOAE referral rate when an infant was screened before 12 hours after birth (Table 4). Overall TEOAE referral rate per ear was similar for infants screened between 24 and 36 hours (40.7%) and between 36 and 48 hours (41.9%). Overall AABR referral rate per ear for infants screened between 24 and 36 hours (20.2%) and between 36 and 48 hours (18.9%) was also similar but significantly lower than for the TEOAE. Lowest initial referral rates per ear and per subject (TEOAE 35.3%, AABR 5.6%) were obtained after 48 hours post birth (Average age for TEOAE, 61 hours post birth; average age for AABR, 57 hours post birth). As indicated in Figure 5, the referral rate for ears screened after 24 hours was significantly ($p<0.001$; Chi-square) less than those screened before 24 hours for both AABR and TEOAE. The majority of infants were screened between 24 and 48 hours (TEOAE 47.8%, AABR 47.2%). The percentage of infants screened before 24 hours post birth was 41.5% with TEOAE and 42.1% with AABR. Few of the infants were screened 48 hours post birth for both screening techniques (TEOAE 10.7%; AABR 10.7%).

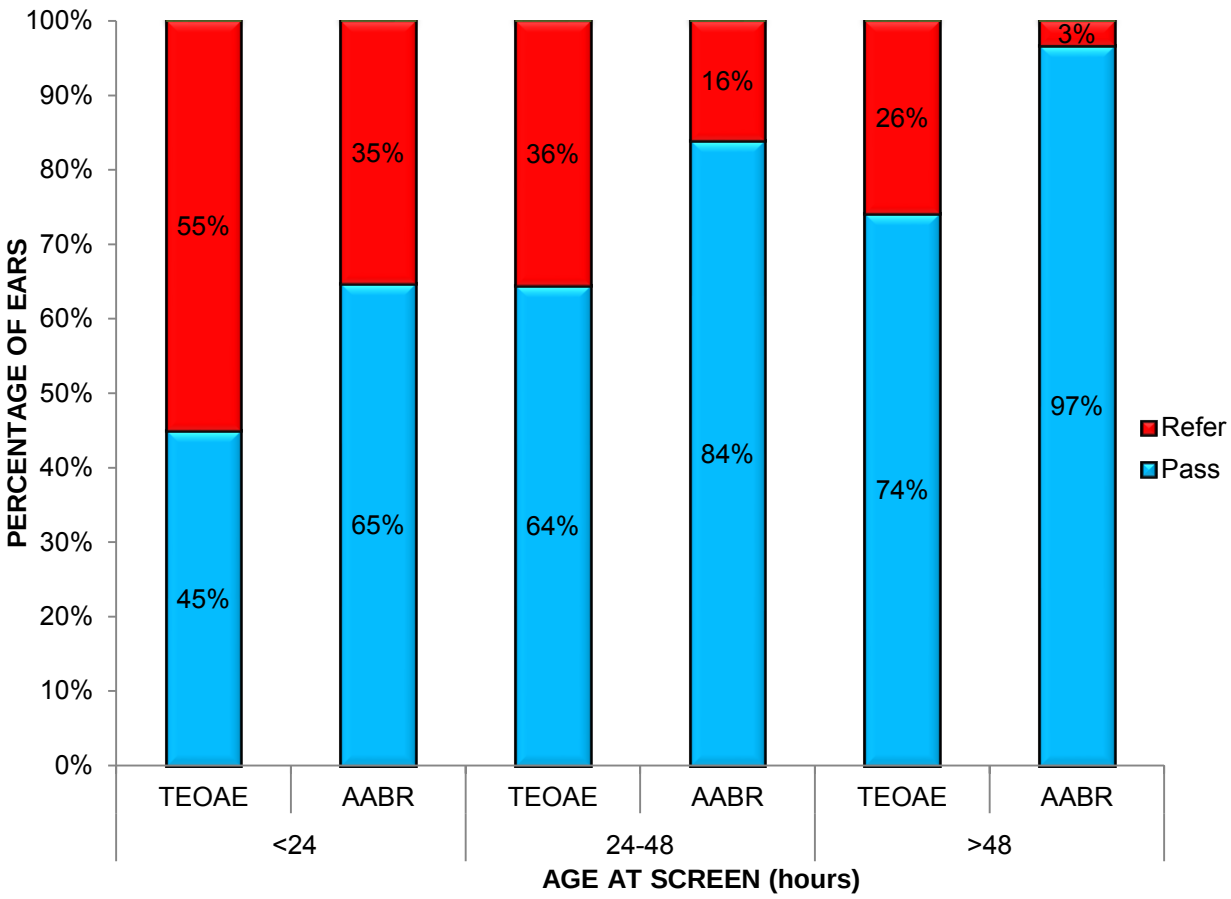


Figure 5. Initial screening outcomes according to age at screen (TEOAE n=289 ears; AABR n=290 ears)

The mean age for a pass result with the TEOAE during the first screen was 32 hours (SD 15) and 25 hours (SD 14) for a refer result. The mean age for an AABR pass result was 31 hours (SD 15) and 22 hours (SD 13) for a refer result. Mean age at screen was significantly greater for those with a pass result compared to those with a refer result with either the AABR or TEOAE ($p<0.05$; Mann-Whitney test).

Table 4. AABR and TEOAE screening outcomes in the first 48 hours post birth

	FIRST SCREEN		SECOND SCREEN		THIRD SCREEN	
	N (ears)	%	N (ears)	%	N (ears)	%
<12 hours						
TEOAE refer rate right	16/23	69.6				
TEOAE refer rate left	15/22	68.2				
TEOAE refer rate combined	31/45	68.9				
AABR refer rate right	10/24	41.7				
AABR refer rate left	14/23	60.9				
AABR refer rate combined	24/47	51.1				
12-24 hours						
TEOAE refer rate right	17/39	43.6	2/5	40.0		
TEOAE refer rate left	18/36	50.0	1/4	25.0		
TEOAE refer rate combined	35/75	46.7	3/9	33.3		
AABR refer rate right	8/40	20.0	1/4	25.0		
AABR refer rate left	11/35	31.4	4/5	80.0		
AABR refer rate combined	19/75	25.3	5/9	55.6		
24-36 hours						
TEOAE refer rate right	13/42	31.0	8/12	66.7		
TEOAE refer rate left	16/42	38.1	6/11	54.5		
TEOAE refer rate combined	29/84	34.5	14/23	60.9		
AABR refer rate right	4/38	10.5	5/8	62.5		
AABR refer rate left	6/40	15.0	4/8	50.0		
AABR refer rate combined	10/78	12.8	9/16	56.3		
36-48 hours						
TEOAE refer rate right	9/28	32.1	4/8	50.0	2/5	40.0
TEOAE refer rate left	11/26	42.3	7/14	50.0	1/3	33.3
TEOAE refer rate combined	20/54	37.0	11/22	50.0	3/8	37.5
AABR refer rate right	5/30	16.7	2/5	40.0		
AABR refer rate left	7/29	24.1				
AABR refer rate combined	12/59	20.3	2/11	18.2		
<48 hours						
TEOAE refer rate right	3/15	20.0	7/18	38.9	1/2	50.0
TEOAE refer rate left	5/16	31.3	10/17	58.8	2/3	66.7
TEOAE refer rate combined	8/31	25.8	17/35	48.6	3/5	60.0
AABR refer rate right			3/8	37.5		
AABR refer rate left	1/18	5.6	2/10	20.0	1/2	50.0
AABR refer rate combined	1/31	3.2	5/18	27.8	1/3	33.3

3.5 Discussion

Scheduling timing of newborn hearing screening beyond 48 hours, or even 24 hours, post birth to avoid excessive referral rates is a challenge in developing countries like South Africa where healthy newborns are typically discharged from 6 hours after birth (Western Cape Government, 2014). Even though AABR is typically less affected by transient conductive auditory dysfunction than OAE screening, it has not been widely adopted in existing newborn screening programmes in South Africa (Meier et al., 2004; Theunissen & Swanepoel, 2008). This has primarily been attributed to the increased costs related to screening due to the disposables typically required for AABR screening as opposed to OAE (Boshuizen et al, 2001). Although the AABR technique may involve a slightly higher initial equipment cost than OAE technique, a newer generation AABR (the MB 11 by BERAphone®) reduces screening costs and newborn preparation time because disposable electrodes and ear couplers are not required (Benito-Orejas, Ramírez, Morais, Almaraz, & Fernández-Calvo, 2008; Cebulla, Hofmann, & Shehata-Dieler, 2014; Konukseven et al., 2010).

Consistent with the findings of previous studies (Benito-Orejas et al., 2008; Vos, Lagasse, & Levêque, 2014), we found that referral rate decreased progressively with increasing age for OAE and AABR. Screening with AABR reduced referral rates significantly compared to TEOAE regardless of age at screen. AABR also had a lower rescreen referral rate than TEOAE. Overall subject referral (after initial and rescreen) using TEOAE was more than twice that of AABR. Referral rate for ears screened with either AABR or TEOAE after 24 hours was significantly less than those screened before 24 hours. Although AABR referral rate per ear improved with increasing age, slightly more than half of the infants yielded a refer outcome within 12 hours post birth and approximately one-quarter of the infants referred when screened between 12 and 24 hours after birth.

Transient conductive auditory dysfunction negatively influences screening results in newborns, leading to a significantly increased probability of a refer result (Lupoli, 2013). In public hospitals in South Africa infants may be discharged within 24 hours post birth when OAE referral rate is highest (Bansal et al., 2008; Benito-Orejas et al.,

2008). The constraint of birthing facility discharge typically from 6 hours after birth for healthy babies and their mothers may necessitate the introduction of an initial or second-stage screening with AABR to minimize the referral rates prior to diagnostic evaluation (Olusanya & Bamigboye, 2010; Vos et al., 2014). In this study newborns initially screened with AABR at 48 hours or later had the optimal subject referral rate of 5.6% when compared to the recommended benchmark of less than 4% (JCIH, 2007). Excessive referral rates place an additional burden on NHS programme resources (i.e., screening costs) and negatively influence successful tracking and follow-up of referred infants (Olusanya, 2011b).

The risk of high OAE referral rates before 48 hours post birth, as demonstrated in this study, make it difficult to overlook initial AABR screening even in a resource-constrained environment like South Africa (Olusanya & Bamigboye, 2010). However, OAE screening techniques are typically the most widely used for initial or two-stage NHS programmes worldwide, including in South Africa. The apparent explanation is a perception that OAE screening is easier and quicker to perform with less expense related to consumables than the AABR (Akinpelu et al., 2014; Meyer et al., 2012; Olusanya & Bamigboye, 2010; Pisacane et al., 2013; Smolkin et al., 2012). Reported overall OAE referral rates for subjects from NHS programmes in developing countries vary considerably from those for our study (37.9%) with referral rates of 33.2% reported for Nigeria, 30% in Brazil, and 10.5% in Turkey (Konukseven et al., 2010; Lupoli et al., 2013; Olusanya et al., 2009). The overall AABR screen referral rate per subject in this study (16.7%) was higher than AABR MB 11 screening programmes reported from other countries such as India (9.1%), Germany (3.8%) and Turkey (2%) (Augustine et al., 2014; Cebulla et al., 2014; Konukseven et al., 2010). A number of factors contribute to the higher referral rate in our study apart from the fact that this study was not an evaluation of an existing NHS programme. The test environment in this study was neither a separate dedicated room nor a sound treated room, and screening was often conducted in the nursery (Konukseven et al., 2010; Lupoli et al., 2013). Another contributing factor could be the high caesarean delivery rate compared to subjects in previously reported studies where the caesarean delivery rate was less than 15% (Gibbons et al., 2010; Smolkin et al., 2012). Most importantly however the higher average referral rate for both TEOAE

and AABR is largely due to the large number of ears screened within 24 hours post birth. Other studies typically screened primarily before hospital discharge but at least 48 hours post birth (Augustine et al., 2014; Cebulla et al., 2014; Konukseven et al., 2010; Olusanya et al., 2009).

Initial screening with AABR significantly reduces the number of infants that require follow-up retesting outside of hospital discharge even for those younger than 48 hours post birth. In developing countries like South Africa where most newborns are discharged before 24 hours after birth, OAE screening is not ideal (Benito-Orejas et al., 2008; Olusanya et al., 2008b; Scheepers, Swanepoel, & Le Roux, 2014). AABR is therefore recommended for NHS screening for these younger children. An added advantage of AABR is the possibility of detection of auditory neuropathy spectrum disorder typically missed by OAE screening (JCIH, 2007). Birthing facilities typically plagued with resource constraints related to disposable-related costs could benefit from an AABR device like the MB11 that does not require disposables. Ideally, however, newborns should be screened as late post birth as possible with best results evident after 48 hours post birth. If a hospital is unable to screen a newborn from 24 hours after birth before discharge, alternative screening contexts in developing countries like South Africa may need to be considered such as immunisation clinics and Midwife Obstetric Units (MOUs) in order to reduce high referral rates and the risk of excessive follow-up defaults (Friderichs et al., 2012; Olusanya et al., 2008a).

3.6 Conclusion

Initial screening with an AABR technology (MB 11 BERAphone®) is significantly more effective than TEOAE for newborns younger than 48 hours. Screening infants within 24 hours post birth with AABR results in reduced costs associated with high referral and false-positive rates. In view of the early discharge typical in South Africa and other developing countries, AABR screening using technology without disposable-related costs may be the most appropriate choice for sustainable and cost-effective programmes. However, even AABR may not be an entirely efficient option for birthing centres where infants are discharged within 24 hours after birth,

due to high referral rates which influence factors such as costs, logistics, infrastructural considerations, case definition, targeted referral rates, and follow-up default (Olusanya & Bamigboye, 2010). UNHS protocols for contexts like the South African public health care sector may require AABR technology (without the burden of disposable-related costs) in hospital-based settings, with OAE reserved for screening older infants at health care visits, such as community-based immunisation clinics or midwife obstetric units (Akinpelu et al., 2014; Friderichs et al., 2012; Olusanya et al., 2008b). Utilising different cost-effective technologies in various health care contexts relating to infant age, may be essential to ensure that such screening programmes in developing countries like South Africa are successful.

4. DISCUSSION AND CONCLUSION

4.1 Discussion of Results

Reports of studies in developing countries documenting hospital-based NHS outcomes within 48 hours post birth using AABR and OAE screening techniques are limited (Augustine et al., 2014; Meier et al., 2004; Meyer et al., 2012; Olusanya et al., 2009; Theunissen & Swanepoel, 2008). In South Africa the majority of infants are born in a hospital-based setting and are typically discharged from 6 hours after birth within the public health care sector (Statistics South Africa, 2002; Western Cape Government, 2014). Most UNHS programmes worldwide are hospital-based for reasons related to logistics and economies of scale (Olusanya et al., 2004). It is therefore important that hospital-based NHS research initiatives are conducted within the first 48 hours post birth in order to provide possible solutions for the South African context to avoid the greatest challenge to UNHS programmes, namely follow-up default (Augustine et al., 2014; Fitzpatrick et al., 2007; JCIH, 2007; Olusanya et al., 2009).

Most NHS platforms report follow-up default as the main contributor to delayed identification of and intervention for infants with hearing loss (Augustine et al., 2014; Fitzpatrick et al., 2007; JCIH, 2007; Olusanya & Bamigboye, 2010; Olusanya et al., 2009; Olusanya & Okolo, 2006; Scheepers et al., 2014). According to this study and previous reports, a major challenge of follow-up default for hospital-based UNHS programmes can be overcome by employing AABR screening as it reduces referral rates significantly compared to OAE screening regardless of age at screen (Benito-Orejas et al., 2008; Olusanya et al., 2008b; Vos et al., 2014). In this study the overall AABR subject referral rate was less than half that of the TEOAE screening technique which allowed for reduced referral and false-positive rates. Reduced referral rates is an important benchmark according to the HPCSA (2007) in the development of a reliable NHS programme (Guastini et al., 2010; Olusanya et al., 2009).

Significant variations exist in the efficiency of NHS programmes in South Africa, due to the screening techniques utilised (Meyer et al., 2012; Meyer & Swanepoel, 2011; Theunissen & Swanepoel, 2008). OAE screening techniques are typically the most widely used for initial or two-stage NHS programmes worldwide, and also in South Africa (Akinpelu et al., 2014; Meyer et al., 2012; Olusanya & Bamigboye, 2010). The apparent explanation is the perception that OAE screening is easier and quicker to perform with less expense related to consumables than AABR screening (Pisacane et al., 2013; Smolkin et al., 2012). The risk of high OAE referral rates before 48 hours post birth, as demonstrated in this study, makes it difficult to overlook initial stage AABR screening even in a resource-constrained environment like South Africa (Olusanya & Bamigboye, 2010). The introduction of an initial or second-stage screening with AABR would principally serve to minimize the referral rates prior to diagnostic evaluation (Olusanya & Bamigboye, 2010; Vos et al., 2014).

Excessive referral rates place an additional burden on NHS programme resources (i.e. screening costs) and negatively influence successful tracking and follow-up of referred infants (Yoshinaga-Itano, 2011). High referral rates usually result from transient conductive auditory dysfunction, which negatively influences screening results in newborns leading to a significantly increased probability of a refer result (Lupoli et al., 2013). Although the AABR and TEOAE referral rate improved with increasing age in this study, the referral rate for either screening technique was significantly higher before 24 hours post birth compared to after 24 hours post birth, in accordance with previous reports (Erenberg et al., 1999; Meier et al., 2004; Olusanya & Bamigboye, 2010). The research findings of this study were therefore in line with previous studies where higher referral rates due to transient conductive factors were expected when performing NHS on infants discharged within 24 hours post birth (Bansal et al., 2008; Benito-Orejas et al., 2008). AABR is however still the preferred screening technique in a setting of early hospital discharge (i.e. the South African public health care sector) as transient conductive auditory dysfunction is less likely to adversely affect the screening result, as the results in this study show (Konukseven et al., 2010; Mehl & Thompson, 1998).

This study has demonstrated that initial screening with AABR significantly reduces the number of infants that have to be retested outside of hospital discharge even for those younger than 48 hours post birth. The optimal referral rate of 5.6% per subject, when compared to the Joint Committee on Infant Hearing (2007) recommended benchmark of less than 4%, was only achieved with newborns 48 hours or older initially screened with the AABR screening technique. Overall a number of factors contributed to the high TEOAE and AABR referral rates and these must be considered when comparing the current findings to those of other studies (Augustine et al., 2014; Cebulla et al., 2014; Konukseven et al., 2010; Lupoli et al., 2013; Olusanya et al., 2009). Firstly, this study was not an evaluation of an existing NHS programme. Secondly, the test environment was neither a separate dedicated room nor a sound treated room, as screening was often conducted in the nursery (Konukseven et al., 2010; Lupoli et al., 2013). Thirdly, the high caesarean delivery rate may have caused a higher transient conductive component which negatively affected NHS outcomes (Smolkin et al., 2012). Lastly, the higher average referral rate, for both TEOAE and AABR, was largely due to the large number of ears screened within 24 hours post birth (TEOAE 41.5%; AABR 42%). Other studies typically screened primarily before hospital discharge i.e. 48 hours post birth (Augustine et al., 2014; Cebulla et al., 2014; Konukseven et al., 2010; Olusanya et al., 2009).

In a country like South Africa where most newborns are discharged before 24 hours after birth, OAE screening would not be ideal (Benito-Orejas et al., 2008; Olusanya et al., 2008b; Scheepers et al., 2014). AABR is therefore recommended for NHS screening for these younger children, especially as it has the added advantage of being able to detect auditory neuropathy (JCIH, 2007). Public hospitals typically plagued with resource constraints related to disposable-related costs could benefit from an AABR device like the MB11 that does not require disposables. Ideally, however, newborn infants should be screened as late post birth as possible with best results evident after 48 hours post birth. If a hospital is unable to screen a newborn infant from 24 hours after birth before hospital discharge, countries like South Africa may need to consider alternative screening platforms such as immunisation clinics

and Midwife Obstetric Units (MOUs) in order to reduce high follow-up rates (Friderichs et al., 2012; Olusanya, 2008).

4.2 Clinical Implications

Limited data exists on screening outcomes for NHS in South Africa with OAE and AABR screening techniques within the first 48 hours post birth. In developed countries UNHS has been established as a standard of newborn care; the issue for developing countries is not 'whether' but 'how' NHS should be delivered (Olusanya, 2012). Evidence-based guidelines are therefore necessary to address the NHS challenges for the South African context by determining the outcomes with OAE and AABR (without disposables) screening techniques within 48 hours post birth.

The two variables investigated in this study, screening techniques utilised, and the timing of NHS relative to hospital discharge, were recommended by the Health Professions Council of South Africa (2007) to be investigated before the development of NHS programmes or protocols take place. The objective is to improve hearing health care for all infants in a cost-effective and accountable manner in both the public and private health care of South Africa (Swanepoel et al., 2004). The current research findings endeavour to provide context-specific implications for the planning of NHS programmes and/or protocols in South Africa.

Context-specific implications for South Africa are multifaceted as the country has the diverse combination of developed and developing contexts (i.e. private and public health care sectors) (Swanepoel, 2006). NHS programmes and/or protocols therefore need to reflect this context. Hospital-based NHS as an initial stage screening platform would ideally cover 90% of the population in South Africa as the majority of births within this context are hospital-based (Public: 70%; Private 20%) (National Treasury Department, Republic of South Africa, 2015; Statistics South Africa, 2002). This study agrees with previous studies, however, that infants' age at screen before 24 hours post birth negatively affects the NHS outcome (Doyle et al., 1998; Erenberg et al., 1999; Lupoli et al., 2013). As mentioned previously, early hospital discharge before 24 hours post birth remains a challenge to NHS

implementation within the South African context. The findings of this study, in accordance with previous research, therefore proposes an integrated NHS model for NHS in South Africa (Figure 6) (Friderichs et al., 2012; Olusanya et al., 2008a).

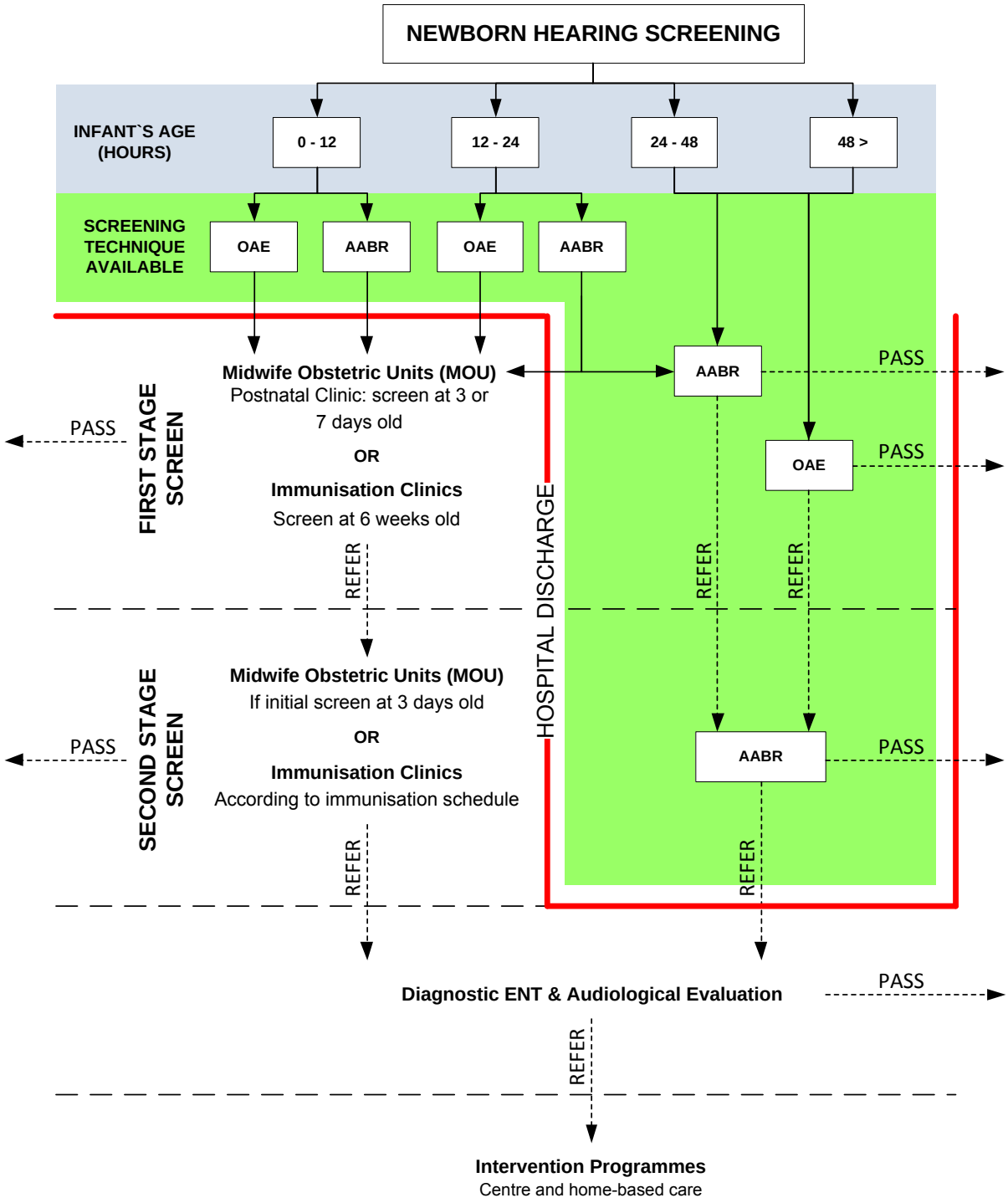
An integrated NHS model (Figure 6) for the public health care sector would involve combining recommended screening platforms such as hospitals, immunisation clinics, and midwife obstetric units (MOUs) to serve the population (Friderichs et al., 2012; Swanepoel et al., 2006). As this study shows, hospital-based screening as a platform in isolation is not practical or efficient for the public health care population due to the typical hospital discharge times of infants. Incorporating immunisation clinics and MOUs as screening platforms, automatically improves coverage rates (Friderichs et al., 2012; Swanepoel et al., 2006). Figure 6 summarizes the proposed timeline for the most effective NHS outcomes within the public health care sector based on the study findings, available screening technique, and infant age at screen. The private health care sector would follow a similar model except that immunisation clinics and MOUs would be replaced with individual initiatives by private audiologists (Scheepers et al., 2014). As seen in Figure 6, if an AABR screening technique (without the need for disposables) is available to screen an infant 12-24 hours post birth, hospital-based screening within the public or private health care sector may be an option. The current study showed high referral rates within this time frame, but if the initial screen formed part of a two-stage NHS protocol and/or the infant was screened as close to 24 hours post birth as possible, referral rates may be reduced (Lupoli et al., 2013). The choice between UNHS in a hospital or in a community based setting within the first 24 hours post birth would therefore largely be determined on case-by-case basis depending on available resources within each province (Olusanya, 2012). This decision would also be influenced by efficiency considerations such as overall yield, cost per baby screened, cost per infant detected, and follow-up effectiveness (Olusanya, 2012). The result of the integrated NHS platform would be the early detection and identification of infants with hearing loss within the South African context.

Consistent with the findings of previous studies, this study found that certain factors contributed to the implementation of NHS for the early identification of infants with

hearing loss. The following aspects should be considered when planning or conducting NHS programmes and/or protocols:

- Personnel: Both screening techniques require trained, dedicated personnel to administer the screening procedure (Friderichs et al., 2012; Kerschner, 2004).
- Location: Finding a suitable test environment for NHS could prolong the period of screening and reduce coverage if not properly managed (Olusanya & Okolo, 2006).
- Screen duration: Screening can be accomplished in a matter of minutes (Kerschner, 2004).

Improving the health and well-being of children through early identification and intervention remains the key priority within the context of an integrated NHS approach to supporting children and families (Swanepoel & Almec, 2008; WHO, 2010). The integrated NHS model (Figure 6), based on this study's findings, should provide the empirical evidence to garner support from government ministries of health, education and social development for EHDI services (Swanepoel et al., 2009). This integrated NHS platform would rely on a national database registry which currently does not exist in South Africa (Friderichs et al., 2012). The lack of a national database registry may, however, be addressed through the introduction of National Health Insurance (NHI), which aims to provide universal health coverage to all South African citizens (Matsoso & Fryatt, 2013; National Treasury Department, Republic of South Africa, 2015). Effective EHDI programmes implemented within NHI may contribute to the growing body of evidence which suggests long-term economic benefits to initial investments in such programmes (HPCSA, 2007).



* Compiled from an adapted version of the proposed community-based NHS model by Friderichs (2012) and the results of this study

Figure 6. Integrated NHS model: A proposed timeline for the most effective NHS according to infant's age at screen and the screening technique available

4.3 Critical Evaluation

A critical evaluation of the study within the conceptual framework of evaluating the strengths and limitations is necessary to determine the value of the research findings of the study. This critical evaluation could assist in identifying gaps that require further investigation by future research.

4.3.1 Strengths of Study

The strengths of this study are highlighted below.

- The within-subject design allowed for individual difference variables to be reduced, which increased the subject validity (Hall, 1998; Kim, 2010; Shuttleworth, 2009). It also allowed the research to be conducted per ear, which increased the sample size in terms of data analysis.
- The combined approach of utilising both TEOAE and AABR screening techniques before hospital discharge, provided the opportunity to differentiate between patient (e.g., transient conductive auditory dysfunction) and environmental factors (e.g., noise) with reasonably accurate sensitivity and specificity (Hall, Smith, & Popelka, 2004).
- By utilising the same audiologist as tester during the data collection phase, inter-tester bias was eliminated (Struwig & Stead, 2001).
- The research setting in a private hospital provided the opportunity for the rescreening of infants within a three-stage screen protocol before hospital discharge. This allowed for the progression of screening outcomes to be measured over time.
- Subjects were from the healthy infant nursery which reduced the possibility of additional factors such as hearing loss risk indicators influencing the screening outcomes (Table 2).
- Educating the stakeholders (i.e. parents, nurses, and paediatricians) involved in the research project regarding NHS and hearing loss through appropriate

brochures increased the awareness and buy-in for the purpose of this study (Scheepers et al., 2014; Swanepoel & Almec, 2008).

4.3.2 Limitations of Study

The limitations of this study are discussed below:

- The order of testing may have caused carryover effects where a confounding extraneous variable was created that varied with the independent variable i.e. where the first screening technique (TEOAE), adversely influenced the second technique (AABR) (Hall, 1998; Shuttleworth, 2009).
- In the private health care sector in South Africa the rate of birth by caesarean section is more than twice that of the public health care sector where vaginal deliveries are more common (Dhai, Gardner, Guidozzi, Howarth, & Vorster, 2011). A high caesarean section rate negatively affects the screening outcomes for both screening techniques (TEOAE and AABR) within the first 24 hours post birth, but more specifically the TEOAE screening technique (Smolkin et al., 2012). The results of this study may therefore not be a true reflection of NHS outcomes within the public health care sector but serves as a pilot study for such initiatives.
- The small sample size restricts the generalization of the research findings (Leedy & Ormrod, 2001).
- Screening outcomes may have been biased by the screening location as noise levels within the screening environment were not monitored while data collection was conducted (Olusanya & Bamigboye, 2010).

4.4 Future Research

This study provided important information on the implications of NHS in South Africa based on TEOAE and AABR screening outcomes in the first 48 hours post birth. While reported results have addressed various issues related to hospital-based NHS within the South African context, however, outstanding questions still remain. This

creates opportunities for future research on a number of aspects which include, but are not limited to, the following (Olusanya, 2008):

4.4.1 NHS Screening Context

- A pilot study which investigates the outcomes with OAE and AABR (MB 11) screening techniques in the first 48 hours post birth in a public hospital with a larger sample size may further assist in creating evidence to support a UNHS model in the public health care sector. These results (i.e. referral rates) may impact on the proposed model (Figure 6) in terms of the recommended age for NHS screening within the first 24 hours post birth in South Africa.
- A study investigating a UNHS programme using objective screening techniques (OAE and AABR) at the various NHS platforms (hospital, MOUs and immunisation clinics) may assist in establishing a national model for UNHS according to the Health Professions Council of South Africa (2007) and the Joint Committee on Infant Hearing (2007) benchmarks and quality indicators.

4.4.2 Costing

- A study similar to the study conducted in Nigeria (Olusanya et al., 2009), determining the costs and performance of hospital-based and community-based infant hearing screening models, may demonstrate clear links between test performance and cost-effectiveness. A study which aims to determine the cost-effectiveness of NHS programme implementation is needed to provide significant evidence for public and private health care protocols and policies. The results of the study would assist with NHS development while the initiative is still in the preliminary stages before considering provincial or nationwide implementation.
- Investigating the cost of UNHS, including the cost per infant screened, the material required, the personnel involved to run the programme, and the follow-up may be useful as even the most expensive budget for a UNHS programme appears profitable (Cao-Nguyen et al., 2007).

4.4.3 Screening Technique

Longitudinal pilot studies utilising the AABR (MB 11) screening technique for UNHS programmes in both the public and private health care sector would provide empirical evidence for engaging relevant government ministries (education, health, and social welfare) for appropriate provisions for EHDI within the context of overall early childhood development in current health and educational policies (Olusanya, 2008). These findings are necessary as UNHS is the only programme that can detect a significant number of infants with hearing impairment early enough for optimal intervention (Olusanya, 2011a).

4.5 Conclusion

The current study is the first to report on the implications of NHS in South Africa according to the screening outcomes with TEOAE and AABR screening techniques in the first 48 hours post birth. Reported results indicated that initial screening with the AABR (MB 11 BERAphone®) screening technique was significantly more effective than the TEOAE screening technique for newborns younger than 48 hours old. Screening infants from 24 hours post birth with the AABR screening technique in the public and private health care sector would reduce costs associated with high referral and false-positive rates. AABR screening without disposable-related costs, such as with the MB11, may be the most appropriate choice for sustainable and cost-effective programmes with regard to the early hospital discharge typical in South Africa and other developing countries (Swanepoel et al., 2006). The AABR screening technique, however, may not be an efficient option for hospital-based NHS where infants are discharged before 24 hours, due to high referral rates which influence factors such as costs, logistics, infrastructural considerations, case definition, targeted referral rates, and follow-up default (Olusanya & Bamigboye, 2010).

Poor NHS coverage, high referral rates, and follow-up default contribute to delayed identification and intervention of hearing loss in both the private and public health care sector in South Africa (Friderichs et al., 2012; Meyer et al., 2012; Scheepers et

al., 2014; Theunissen & Swanepoel, 2008). The findings of this study emphasise the need for an integrated NHS model in order to address these barriers to the implementation of NHS in South Africa. The AABR screening technique (without the burden of disposable-related costs) may provide a solution for UNHS programmes and/or protocols in a hospital-based setting, like the South African public health care sector. The OAE screening technique, on the other hand, should be reserved for screening older infants at health care visits, such as immunisation clinics or midwife obstetric units (Akinpelu et al., 2014; Friderichs et al., 2012; Olusanya, 2008). These trade-offs between the costs and efficiency of the OAE and AABR screening techniques require careful consideration for NHS programmes and/or protocols within the public and private health care sector (Swanepoel, Ebrahim, et al., 2007). Utilising different cost-effective technologies within an integrated NHS model across various platforms relating to infant age may be essential to ensure that NHS programmes in developing countries like South Africa are successful.

5. REFERENCES

Akinpelu, O. V., Peleva, E., Funnell, W. R. J., & Daniel, S. J. (2014). Otoacoustic emissions in newborn hearing screening: A systematic review of the effects of different protocols on test outcomes. *International Journal of Pediatric Otorhinolaryngology*, *78*(5), 711-717. doi:10.1016/j.ijporl.2014.01.021

Augustine, A. M., Jana, A. K., Kuruvilla, K. A., Danda, S., Lepcha, A., Ebenezer, J., & Balraj, A. (2014). Neonatal hearing screening - Experience from a tertiary care hospital in Southern India. *Indian Pediatrics*, 51(3), 179-183. doi: 10.1007/s13312-014-0380-5

Bansal, S., Gupta, A., & Nagarkar, A. (2008). Transient evoked otoacoustic emissions in hearing screening programs - Protocol for developing countries. *International Journal of Pediatric Otorhinolaryngology*, *72*(7), 1059-1063. doi:10.1016/j.ijporl.2008.03.014

Benito-Orejas, J. I., Ramirez, B., Morais, D., Almaraz, A., & Fernández-Calvo, J. L. (2008). Comparison of two-step transient evoked otoacoustic emissions (TEOAE) and automated auditory brainstem response (AABR) for universal newborn hearing screening programs. *International Journal of Pediatric Otorhinolaryngology*, *72*(8), 1193-1201. doi:10.1016/j.ijporl.2008.04.011

Bess, F., & Gravel, J. (2006). *Foundations of Pediatric Audiology*. San Diego, CA: Plural Publishing Inc.

Boshuizen, H. C., Van der Lem, G. J., Kauffman-de Boer, M. A., Van Zanten, G. A., Oudesluys-Murphy, A. M., & Verkerk, P. H. (2001). Costs of different strategies for neonatal hearing screening: a modelling approach. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, *85*(3), F177-F181. doi:10.1136/fn.85.3.F177

Cao-Nguyen, M. H., Kos, M. I., & Guyot, J. P. (2007). Benefits and costs of universal hearing screening programme. *International Journal of Pediatric Otorhinolaryngology*, *71*(10), 1591-1595. doi:10.1016/j.ijporl.2007.07.008

Cebulla, M., Hofmann, S., & Shehata-Dieler, W. (2014). Sensitivity of ABR based newborn screening with the MB11 BERAphone®. *International Journal of Pediatric Otorhinolaryngology*, *78*(5), 756-761. doi:10.1016/j.ijporl.2014.02.003

Dhai, A., Gardner, J., Guidozzi, Y., Howarth, G., & Vorster, M. (2011). Vaginal deliveries: is there a need for documented consent? *SAMJ: South African Medical Journal*, *101*(1), 20-22. Retrieved from http://www.scielo.org.za/scielo.php?script=sci_pdf&pid=S0256-95742011000100012&lng=en&nrm=iso&tlng=en

Diefendorf, A. O. (2002). Detection and assessment of hearing loss in infants and children. *Handbook of Clinical Audiology* (5th ed.). New York: Lippincott Williams & Wilkins.

Doyle, K.J., Fujikawa, S., Rogers, P., & Newman, E. (1998). Comparison of newborn hearing screening by transient otoacoustic emissions and auditory brainstem response using ALGO-2®. *International Journal of Pediatric Otorhinolaryngology*, *43*, (3), 207-211. doi:10.1016/S0165-5876(98)00007-X

Elattar, A., Selamat, E. M., Robson, A. A., & Loughney, A. D. (2008). Factors influencing maternal length of stay after giving birth in a UK hospital and the impact of those factors on bed occupancy. *Journal of Obstetrics & Gynecology*, *28*(1), 73-76. doi:10.1080/01443610701814187

Erenberg, A., Lemons, J., Sia, C., Trunkel, D., & Ziring, P. (1999). Newborn and infant hearing loss: detection and intervention. American Academy of Pediatrics. Task Force on Newborn and Infant Hearing, 1998-1999. *Pediatrics*, *103*(2), 527-530. doi: 10.1542/peds.103.2.527

Fitzpatrick, E., Graham, I. D., Durieux-Smith, A., Angus, D., & Coyle, D. (2007). Parents' perspectives on the impact of the early diagnosis of childhood hearing loss: Perspectiva de los padres sobre el impacto del diagnóstico temprano en la hipoacusia de la infancia. *International Journal of Audiology*, *46*(2), 97-106. doi: 10.1080/14992020600977770

Friderichs, N. (2012). *Efficacy of a community-based infant hearing screening program in the Western Cape.* Unpublished post-graduate research project, University of Pretoria, Pretoria, Gauteng, South Africa.

Friderichs, N., Swanepoel, D., & Hall, J. W. (2012). Efficacy of a community-based infant hearing screening program utilizing existing clinic personnel in Western Cape, South Africa. *International Journal of Pediatric Otorhinolaryngology*, *76*(4), 552-559. doi:10.1016/j.ijporl.2012.01.015

Gabbard, S. A., Northern, J. L., & Yoshinaga-Itano, C. (1999). Hearing screening in newborns under 24 hours of age. In *Seminars in Hearing* (Vol. 20, No. 04, pp. 291-304). Copyright© 1999 by Thieme Medical Publishers, Inc.

Gibbons, L., Belizán, J. M., Lauer, J. A., Betrán, A. P., Merialdi, M., & Althabe, F. (2010). The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage. *World Health Report*, *30*, 1-31. Retrieved from http://www.who.int/healthsystems/topics/financing/healthreport/30C-sectioncosts.pdf

Government Communication and Information System. (2011). A National Government Department of the Republic of South Africa, as represented by the Chief Executive Officer of the GCIS. Retrieved July 30, 2011, from http://www.services.gov.za›Home›Services for residents

Guastini, L., Mora, R., Dellepiane, M., Santomauro, V., Mora, M., Rocca, A., & Salami, A. (2010). Evaluation of an automated auditory brainstem response in a multi-stage infant hearing screening. *European Archives of Oto-Rhino-Laryngology*, *267*(8), 1199-1205. doi: 10.1007/s00405-010-1209-z

Hall, J. W., Smith, S. D., & Popelka, G. R. (2004). Newborn hearing screening with combined otoacoustic emissions and auditory brainstem responses. *Journal of the American Academy of Audiology*, *15*(6), 414-425. doi: http://dx.doi.org/10.3766/jaaa.15.6.3

Hall, R. (1998). Psychology World. Retrieved June 15, 2011, from http://web.mst.edu/~psyworld/within_subjects.htm

Hayes, D & Northern, J. L. (1996). *Infants and Hearing.* San Diego: Singular Publishing Group, Inc.

Health Professions Council of South Africa. (2007). Professional board for speech, language and hearing profession: *Early hearing detection and intervention programmes in South Africa, position statement year 2007*, 1–42. Retrieved from http://www.hpcsa.co.za/downloads/speech_education/early_hearing_detection_statement.pdf

Hegde, M. N. (2003). *Clinical research in communicative disorders: Principles and strategies* (3rd ed.). Austin, TX: PRO-ED.

Jakubíková, J., Kabátová, Z., Pavlovčinová, G., & Profant, M. (2009). Newborn hearing screening and strategy for early detection of hearing loss in infants. *International Journal of Pediatric Otorhinolaryngology*, *73*(4), 607-612. doi:10.1016/j.ijporl.2008.12.006

Joint Committee on Infant Hearing. (2000). Year 2000 position statement: Principles and guidelines for early hearing detection and intervention programs. *American Journal of Audiology*, *9*:9-29. Retrieved from http://pediatrics.aappublications.org

Joint Committee on Infant Hearing. (2007). Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics, 120,* 899 -921. doi:10.1542/peds.2007-2333

Kamal, N. (2013). Newborn hearing screening: opportunities and challenges. *Egyptian Journal of Ear, Nose, Throat and Allied Sciences*, *14*(2), 55-58. doi:10.1016/j.ejenta.2013.01.002

Keefe, D. H., Folsom, R. C., Gorga, M. P., Vohr, B. R., Bulen, J. C., & Norton, S. J. (2000). Identification of neonatal hearing impairment: Ear-canal measurements of acoustic admittance and reflectance in neonates. *Ear and Hearing*, *21*(5), 443-461. Retrieved from http://0-ovidsp.tx.ovid.com

Kemp, R. J., & Bankaitis, A. E. (2000). *Infection Control. Audiology: Practice Management*, edited by H. Hosford-Dunn, RJ Roeser, and M. Valente, Thieme Med. Pub., Inc., New York, NY, 257-272.

Kerschner, J. E. (2004). Neonatal hearing screening: to do or not to do. *Pediatric Clinics of North America*, *51*(3), 725-736. doi:10.1016/j.pcl.2004.01.005

Khairi, M. D. M., Rafidah, K. N., Affizal, A., Normastura, A. R., Suzana, M., & Normani, Z. M. (2011). Anxiety of the mothers with referred baby during Universal Newborn Hearing Screening. *International Journal of Pediatric Otorhinolaryngology*, *75*(4), 513-517. doi:10.1016/j.ijporl.2011.01.009

Kim, J. (2010). Within-subjects design. In N. Salkind (Ed.), *Encyclopedia of research design*. (pp. 1639-1645). Thousand Oaks, CA: SAGE Publications, Inc. doi: http://0-dx.doi.org.innopac.up.ac.za/10.4135/9781412961288.n503

Konukseven, O., Genc, A., Muderris, T., Kayikci, M. K., Turkyilmaz, D., Ozturk, B., & Gunduz, B. (2010). Can Automated Auditory Brainstem Response be used as an Initial Stage Screening Test in Newborn Hearing Screening Programs? *International Advanced Otolaryngology*, *6*, 231-238. Retrieved from http://www.advancedotology.org/sayilar/78/buyuk/IAOMay2010p231-238%20(2).pdf

Korres, S.G., Balatsouras, D.G., Gkoritsa, E., Eliopoulos, P., Rallis, E., & Ferekidis, E. (2006). Success rate of newborn and follow-up screening of hearing using otoacoustic emissions. *International Journal of Pediatric Otorhinolaryngology, 70*, (6), 1039-1043. doi:10.1016/j.ijporl.2005.10.018

Kraska, M. (2010). Quantitative research. In N. Salkind (Ed.), *Encyclopedia of research design.* (pp. 1167-1172). Thousand Oaks, CA: SAGE Publications, Inc. doi: http://0-dx.doi.org.innopac.up.ac.za/10.4135/9781412961288.n352

Kumar, S., & Mohapatra, B. (2011). Status of newborn hearing screening program in India. *International Journal of Pediatric Otorhinolaryngology*, *75*(1), 20-26. doi:10.1016/j.ijporl.2010.09.025

Leedy, P. D., & Ormrod, J. E. (2001). *Practical research and design* (7th ed.). New Jersey: Prentice Hall

Le Roux, T., Swanepoel, D., Louw, A., Vinck, B., & Tshifularo, M. (2015). Profound childhood hearing loss in a South Africa cohort: Risk profile, diagnosis and age of intervention. *International Journal of Pediatric Otorhinolaryngology*, *79*(1), 8-14. doi: http://dx.doi.org/10.1016/j.ijporl.2014.09.033

Lupoli, L. D. M., Garcia, L., Anastasio, A. R. T., & Fontana, A. C. (2013). Time after birth in relation to failure rate in newborn hearing screening. *International Journal of Pediatric Otorhinolaryngology*, *77*(6), 932-935. doi: http://dx.doi.org/10.1016/j.ijporl.2013.03.010

Maico Diagnostic GmbH (2003). *Operation instruction MB21*. Berlin, Germany: MAICO Diagnostic GMBH. Retrieved February 23, 2014, from http://www.maico-diagnostic.com/products/abr/mb-11-beraphone/

Matsoso, M. P., & Fryatt, R. (2013). National Health Insurance: the first 18 months. *SAMJ: South African Medical Journal*, *103*(3), 154-155. Retrieved from http://www.scielo.org.za/scielo.php?script=sci_pdf&pid=S0256-95742013000300021&lng=en&nrm=iso&tlng=en

McPherson, B. (2012). Newborn hearing screening in developing countries: Needs & new directions. *The Indian Journal of Medical Research*, *135*(2), 152. Retrieved from http://icmr.nic.in/ijmr/2012/February/0201.pdf

Mehl, A.L., & Thomson, V. (1998). Newborn hearing screening: the great omission. *Pediatrics*, 101(1). e4-e4. Retrieved from http://pediatrics.aappublications.org/content/101/1/e4.full.pdf+html.

Mehl, A. L., & Thomson, V. (2002). The Colorado newborn hearing screening project, 1992–1999: on the threshold of effective population-based universal newborn hearing screening. *Pediatrics*, *109*(1), e7-e7. Retrieved from http://pediatrics.aappublications.org/content/109/1/e7.full.pdf+html.

Meier, S., Narabayashi, O., Probst, R., & Schmuziger, N. (2004). Comparison of currently available devices designed for newborn hearing screening using automated auditory brainstem and/or otoacoustic emission measurements. *International Journal of Pediatric Otorhinolaryngology*, *68*(7), 927-934. doi:10.1016/j.ijporl.2004.02.008

Melagrana, A., Casale, S., Calevo, M. G., & Tarantino, V. (2007). MB11 BERAphone and auditory brainstem response in newborns at audiologic risk: comparison of results. *International Journal of Pediatric Otorhinolaryngology*, *71*(8), 1175-1180. doi:10.1016/j.ijporl.2007.04.011

Meyer, M. E., & Swanepoel, D. W. (2011). Newborn hearing screening in the private health care sector: a national survey. *SAMJ: South African Medical Journal*, *101*(9), 665-667. Retrieved from http://www.scielo.org.za/pdf/samj/v101n9/v101n9a25.pdf

Meyer, M. E., Swanepoel, D.W., Le Roux, T., & Van der Linde, M. (2012). Early detection of infant hearing loss in the private health care sector of South Africa. *International Journal of Pediatric Otorhinolaryngology*, *76*(5), 698-703. doi:10.1016/j.ijporl.2012.02.023

Moeller, M. P. (2000). Early intervention and language development in children who are deaf and hard of hearing. *Pediatrics*, 106(3), e43-e43. Retrieved from http://www.pediatrics.org/cgi/content/full/106/3/e43

Moeller, M. P., Hoover, B., Putman, C., Arbataitis, K., Bohnenkamp, G., Peterson, B., ... & Stelmachowicz, P. (2007). Vocalizations of infants with hearing loss compared with infants with normal hearing: Part II–Transition to words. *Ear and hearing*, *28*(5), 628-642. doi: 10.1097/AUD.0b013e31812564c9

Mouton, J. (2001). *How to succeed in your master's and doctoral studies: A South African guide and resource book*. Pretoria: Van Schaik.

Mowbray Maternity Hospital. (2011). *Maternal Care*. Retrieved February 21, 2014, from http://mowbraymaternity.co.za/index.php/maternal-care.html

National Treasury Department, Republic of South Africa. (2015). *Intergovernmental Fiscal Reviews (IGFR) - 2015 - Provincial Budgets and Expenditure*. Retrieved January 30, 2015, from http://www.treasury.gov.za/publications/igfr/2015/prov/default.aspx

Ngunyulu, R. N., & Mulaudzi, F. M. (2009). Indigenous practices regarding postnatal care at Sikhunyani Village in the Limpopo Province of South Africa. *Africa Journal of Nursing and Midwifery*, *11*(1), 48-64. Retrieved from http://0-reference.sabinet.co.za

Olusanya, B. O. (2005). Can the world's infants with hearing loss wait? *International Journal of Pediatric Otorhinolaryngology*, *69*(6), 735-738. doi:10.1016/j.ijporl.2005.03.024

Olusanya, B. O. (2008). Priorities for early hearing detection and intervention in sub-Saharan Africa. *International Journal of Audiology*, *47*(S1), S3-S13. doi:10.1080/14992020802287143

Olusanya, B. O. (2011a). Highlights of the new WHO Report on Newborn and Infant Hearing Screening and implications for developing countries. *International Journal of Pediatric Otorhinolaryngology, 75*(6), 745-748. doi:10.1016/j.ijporl.2011.01.036

Olusanya, B. O. (2011b). Making targeted screening for infant hearing loss an effective option in less developed countries. *International Journal of Pediatric Otorhinolaryngology*, *75*(3), 316-321. doi:10.1016/j.ijporl.2010.12.002

Olusanya, B. O. (2012). Neonatal hearing screening and intervention in resource-limited settings: an overview. *Archives of Disease in Childhood*, *97*(7), 654-659. doi:10.1136/archdischild-2012-301786

Olusanya, B. O., & Bamigboye, B. A. (2010). Is discordance in TEOAE and AABR outcomes predictable in newborns? *International Journal of Pediatric Otorhinolaryngology*, *74*(11), 1303-1309. doi:10.1016/j.ijporl.2010.08.010

Olusanya, B. O., Emokpae, A., Renner, J. K., & Wirz, S. L. (2009). Costs and performance of early hearing detection programmes in Lagos, Nigeria. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *103*(2), 179-186. doi:10.1016/j.trstmh.2008.07.001

Olusanya, B.O., Luxon, L.M., & Wirz, S.L. (2004). Benefits and challenges of newborn hearing screening for developing countries. *International Journal of Pediatric Otorhinolaryngology*, *68*(3), 287-305. doi:10.1016/j.ijporl.2003.10.015

Olusanya, B. O., & Okolo, A. A. (2006). Early hearing detection at immunization clinics in developing countries. *International Journal of Pediatric Otorhinolaryngology*, *70*(8), 1495-1498. doi:10.1016/j.ijporl.2006.04.002

Olusanya, B. O., Wirz, S. L., & Luxon, L. M. (2008a). Community-based infant hearing screening for early detection of permanent hearing loss in Lagos, Nigeria: a cross-sectional study. *Bulletin of the World Health Organization*, *86*(12), 956-963.doi:10.2471/BLT.07.050005

Olusanya, B. O., Wirz, S. L., & Luxon, L. M. (2008b). Hospital-based universal newborn hearing screening for early detection of permanent congenital hearing loss in Lagos, Nigeria. *International Journal of Pediatric Otorhinolaryngology*, *72*(7), 991-1001. doi:10.1016/j.ijporl.2008.03.004

Orb, A., Eisenhauer, L., & Wynaden, D. (2001). Ethics in qualitative research. *Journal of nursing scholarship*, *33*(1), 93-96. doi: 10.1111/j.1547-5069.2001.00093.x

Pisacane, A., Auletta, G., Toscano, F., Errichiello, M., Barrier, F., Riccardi, P., ... & Marciano, E. (2013). Feasibility and effectiveness of a population-based newborn hearing screening in an economically deprived region of Italy. *International journal of pediatric otorhinolaryngology*, *77*(3), 329-333. doi:10.1016/j.ijporl.2012.09.019

Robson, C. (2002). *Real world research* (Vol. 2). Oxford: Blackwell publishers.

Scheepers, L. J., Swanepoel, D., & Le Roux, T. (2014). Why parents refuse newborn hearing screening and default on follow-up rescreening - A South African perspective. *International Journal of Pediatric Otorhinolaryngology*, *78*(4), 652-658. doi:10.1016/j.ijporl.2014.01.026

Shuttleworth, M. (2009). *Within Subject Design*. Retrieved June 16, 2011 from http://www.experiment-resources.com/within-subject-design.html

Silverman, F. H. (1998). *Research design and evaluation in speech-language pathology and audiology* (4th ed.). United States of America: Allyn & Bacon.

Smolkin, T., Mick, O., Dabbah, M., Blazer, S., Grakovsky, G., Gabay, N., ... & Makhoul, I. R. (2012). Birth by cesarean delivery and failure on first otoacoustic emissions hearing test. *Pediatrics*, *130*(1), e95-e100. doi: 10.1542/peds.2011-3179

South Africa Information. (2012). *Health care in South Africa*. Retrieved January, 10, 2015, from http://www.southafrica.info/about/health/health.htm#.VOCPcDr9lMs.

South African Speech-Language-Hearing Association. (2011). *Guidelines infection control: Guidelines for speech-language therapists and audiologists regarding infection control.* Retrieved January 04, 2015, from http://www.saslha. co.za

Southeast Georgia Health System. (2011). *Delivery and your hospital stay*. Retrieved July 29, 2011, from http://www.sghs.org/body.cfm?id=158

Statistics South Africa. (2002). *Measuring Rural Development: Baseline Statistics for the Integrated Sustainable Rural Development Strategy*, Statistics South Africa, Pretoria. Retrieved February 12, 2015 form http://www.statssa.gov.za/publications/ruraldevelopment/ruraldevelopment.pdf

Struwig, F.W. & Stead, G.B. (2001). *Planning, designing and reporting research.* Cape Town: Pearson Education South Africa.

Swanepoel, D. (2006). Audiology in South Africa: Audiología en Sudáfrica. *International Journal of Audiology*, *45*(5), 262-266. doi: 10.1080/14992020500485650

Swanepoel, D. (2009a). Early detection of infant hearing loss in South Africa. *SAMJ: South African Medical Journal*, *99*(3), 158-159.

Swanepoel, D. (2009b). Identifying infant hearing loss-never too early, but often too late: more about... ENT. *CME: Your SA Journal of CPD: ENT*, *27*(8), 368-368.

Swanepoel, D. (2010). The global challenge of infant hearing loss. Sound Foundation through Early Amplification. Judith Gravel Lecture. Chicago, USA, 8-10 November 2010.

Swanepoel, D., & Almec, N. (2008). Maternal views on infant hearing loss and early intervention in a South African community. *International Journal of Audiology*, *47*(S1), S44-S48. doi: 10.1080/14992020802252279

Swanepoel, D., Clark, J. L., Koekemoer, D., Hall III, J. W., Krumm, M., Ferrari, D. V., & Barajas, J. J. (2010). Telehealth in audiology: The need and potential to reach underserved communities. *International Journal of Audiology*, *49*(3), 195-202. doi: 10.3109/14992020903470783

Swanepoel, D., Delport, S. D., & Swart, J. G. (2004). Universal newborn hearing screening in South Africa-a First-World dream? editorial. *South African Medical Journal*, *94*(8), p-634.

Swanepoel, D., Delport, S. D., & Swart, J. G. (2007). Equal opportunities for children with hearing loss by means of early identification. *South African Family Practice*, *49*(1), 3-3.

Swanepoel, D., Ebrahim, S., Joseph, A., & Friedland, P. L. (2007). Newborn hearing screening in a South African private health care hospital. *International Journal of Pediatric Otorhinolaryngology*, *71*(6), 881-887. doi:10.1016/j.ijporl.2007.02.009

Swanepoel, D., Hugo, R., & Louw, B. (2006). Infant hearing screening at immunization clinics in South Africa. *International Journal of Pediatric Otorhinolaryngology, 70*(7)*,* 1241-1249. doi:10.1016/j.ijporl.2006.01.002

Swanepoel, D., & Störbeck, C. (2008). EHDI Africa: Advocating for infants with hearing loss in Africa. *International Journal of Audiology*, *47*(S1), S1-S2. doi: 10.1080/14992020802300912

Swanepoel, D., Störbeck, C., & Friedland, P. (2009). Early hearing detection and intervention in South Africa. *International Journal of Pediatric Otorhinolaryngology*, *73*(6), 783-786. doi:10.1016/j.ijporl.2009.01.007

Theunissen, M., & Swanepoel, D. (2008). Early hearing detection and intervention services in the public health sector in South Africa. *International Journal of Audiology*, 47(S1), S23-S29. doi:10.1080/14992020802294032

Trochim, W. M. (2006). *The Research Methods Knowledge Base* (2nd ed.). Retrieved January 16, 2011, from http://www.socialresearchmethods.net/kb/

Van den Berg, E., Deiman, C., & van Straaten, H. L. M. (2010). MB11 BERAphone® hearing screening compared to ALGO™ portable in a Dutch NICU: A pilot study. *International Journal of Pediatric Otorhinolaryngology*, *74*(10), 1189-1192. doi:10.1016/j.ijporl.2010.07.020

Van der Spuy, T., & Pottas, L. (2008). Infant hearing loss in South Africa: Age of intervention and parental needs for support. *International Journal of Audiology*, *47*(S1), S30-S35. doi: 10.1080/14992020802286210

Vos, B., Lagasse, R., & Levêque, A. (2014). Main outcomes of a newborn hearing screening program in Belgium over six years. *International Journal of Pediatric Otorhinolaryngology*, *78*(9), 1496-1502. doi:10.1016/j.ijporl.2014.06.019

Western Cape Government. (2014). *Post-Natal (After birth) Health Care.* Retrieved June 28, 2014, from http://www.westerncape.gov.za/service/post-natal-after-birth-health-care

World Bank. (2015). *Country and Lending Groups*. Received January 28, 2015 from http://data.worldbank.org/about/country-and-lending-groups

World Health Organization. (2010). *Neonatal and infant hearing screening: current issues and guiding principles for action*. Outcome of a WHO informal consultation held at WHO head-quarters, Geneva, Switzerland, 9–10 November, 2009. Geneva: WHO Press, 1-40.

World Health Organization. (2014). *Postnatal Care*. Retrieved February 19, 2014, from http://www.who.int/maternal_child_adolescent/topics/newborn/postnatal_care/en/

Yoshinaga-Itano, C. (2004). Levels of evidence: universal newborn hearing screening (UNHS) and early hearing detection and intervention systems (EHDI). *Journal of Communication Disorders*, *37*(5), 451-465. doi:10.1016/j.jcomdis.2004.04.008

Yoshinaga-Itano, C. (2011). Achieving optimal outcomes from EHDI. *The ASHA Leader*, *16*(11), 14-17. Retrieved January 15, 2015 from http://www.asha.org/Publications/leader/2011/110920/Achieving-Optimal-Outcomes-From-EHDI.html

Yoshinaga-Itano, C., Coulter, D., & Thomson, V. (2001). Developmental outcomes of children with hearing loss born in Colorado hospitals with and without universal hearing screening programs. *Seminars in Neonatology*, 6(6), 521-529. doi:10.1053/siny.2001.0075

Yoshinaga-Itano, C., Sedey, A. L., Coulter, D. K., & Mehl, A. L. (1998). Language of early-and later-identified children with hearing loss. *Pediatrics*, *102*(5), 1161-1171. Retrieved from http://pediatrics.aappublications.org/content/102/5/1161.full.html

6. APPENDICES

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APPENDIX A

Letter to Parents regarding Informed Consent for their Child's Participation in the Newborn Hearing Screening Study

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Communication Pathology

Date:

Dear Parent,

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

Westville hospital has agreed to pilot a hospital-based infant hearing screening project whereby every child being born at Westville hospital hearing will be screened. This research is being conducted to decide the best method to screen the hearing of babies. If children cannot hear, their speech and language does not develop and this will impact on their ability to learn, and to attend school. It is therefore important to know as soon as possible whether they can hear or not. If they cannot hear, then they can be provided with assistance. The results will also help to decide on the nature of hearing screening programmes that must be set up at other hospitals in Durban and South Africa.

What are the screening tests?
The tests which will be used to screen your child's hearing is called an OAE and an AABR. Both tests give us information on your child's inner ear and hearing system respectively. Hearing of a number of other babies will also be screened.

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

What does screening with AABR involve?
This screening test involves gently wiping off any oils or creams from your child's forehead, above and below their ear. We will be putting a headphone (that looks like a phone) over your child's ear with a portion touching the forehead. The headphone produces a sound and has a microphone which will record the response of your child's hearing. The headphone is connected to the laptop which will tell us whether your child's ears are working as they should or whether we need to screen your child again. Your child may sleep, be awake or feed while this screening test is being done. Both ears (left and right) will be tested.

How long are the tests?
This test will not hurt or cause your child any discomfort. It is quick and will be completed in three minutes (provided your child is quiet).

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

What happens if my child passes the test?
If your child passes the test, it means that their inner ear and/or hearing system is working and that your child can hear. However, hearing loss may sometimes develop as your child grows. Therefore please read the information pamphlet provided very carefully - if you become aware of your child having difficulty hearing in the future, or your child does not begin to speak at the age of 1 to 2 years, or your child has frequent ear infections, please speak to your doctor. They will then refer your child to an audiologist for a hearing test or to an Ear-, Nose- and Throat specialist (ENT). You must try to do this as soon as you become concerned. It is important to find out whether there is a hearing loss as early as possible, so that assistance can be provided and to help your child's language development.

What happens if my child does not pass the test?
If you child does not pass the OAE/AABR test in both ears, you will also be informed. You will need to bring your child to *The Ear Institute* in 2 weeks time (or to an audiology practice of your choice) so that his/her hearing may be screened again. If your child fails the second OAE screening in both ears, he/she will be booked for an in-depth hearing evaluation at an Audiology practice of your choice to determine whether there is a hearing loss. If a hearing loss exists, then appropriate plans will then be made to manage your child's hearing loss and language development.

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

Confidentiality
A record of your child's hearing screening results will be stored in your child's hospital file and on a computer database. This information will only be made available to the audiologists who may be involved in testing your child's hearing and to the researcher. All information will be treated as confidential and your child's name will not be used since each participant will be assigned an identifying code which will be used for all data processing. Results may be

published in the final thesis report but no identifying information will be used at any time. Coded data will be stored for a minimum of 15 years according to University of Pretoria Regulations.

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

If you agree to have your child's hearing screened as part of this study, please sign the informed consent letter.

Sincerely,

Michelle van Dyk
M.Communication Pathology Student

Professor De Wet Swanepoel
Lecturer / Project Supervisor

Prof Bart Vinck
HEAD: Department of Communication Pathology

University of Pretoria
Pretoria, 0002
South Africa

Telephone : 00 27 12 420-2357
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APPENDIX B

Newborn Hearing Screening Brochure

Hearing can be tested at any age

The first few years of your baby's life are very important for developing communication skills.

Of course it is unlikely that your baby will have a hearing loss. However it is important for you to be sure that your baby has normal hearing.

Newborn hearing screening is conducted because your baby cannot tell you if he can't hear…

Hearing can change over time

Your baby may need a hearing test twice a year until age 3 if there was:

- Infection at birth (e.g. German measles, Toxoplasmosis, Cytomegalovirus)
- Infection after birth (e.g. Meningitis, Mumps)
- Very low birth weight (1500 grams or less)
- Jaundice requiring blood transfusion
- Differently shaped head or face (e.g. cleft lip or palate)
- Breathing difficulty at birth
- Head injury
- Medicine that can damage the ear
- Two or more days in the neonatal intensive care unit
- Family history of permanent or progressive hearing loss

References:

California Department of Health Care Services (2012)

Colorado Department of Public Health & Environment. (2012)

Newborn Hearing Screening

Why should my baby's hearing be screened?

One out of every 250 babies have a significant hearing loss at birth. Hearing loss in babies is easy to overlook because it is not visible and they cannot tell us if they are unable to hear.

50% of babies born with hearing loss are otherwise healthy and have no family history of hearing loss. To be sure we identify every baby with a hearing loss, once you have given consent, your baby's hearing will be screened before you go home.

A child who has a hearing loss which is detected and treated before 18 months of age can have normal speech-language development.

How do they screen my baby's ears?

Your baby's hearing will be screened in two ways within 24 hours after birth and between 24-48 after birth.

Otoacoustic Emissions Screening (OAE)

Tiny earphones will be placed in your baby's ears to pick up responses as sounds are played.

Automatic Auditory Brainstem Response Screening (AABR)

The headphone is simply placed onto your baby's head, after just some application of electrode gel.

What if my baby passes the first screening?

Passing the hearing screening indicates that your baby is able to hear in both ears at this time. Rarely will a baby with a hearing loss be missed. If you have any concerns in the future please contact your paediatrician.

What if my baby does not pass the first screening?

There are many reasons your baby may not pass the hearing screening. Perhaps your baby was too active; too wide awake; or due to middle ear fluid or debris in the ear canal from the birthing process (the most common reason); or a possible hearing loss.

It is recommended that your baby is re-screened in a month's time by an audiologist.

Hearing can be tested at any age

The first few years of your baby's life are very important for developing communication skills.

Of course it is unlikely that your baby will have a hearing loss. However it is important for you to be sure that your baby has normal hearing.

Newborn hearing screening is conducted because your baby cannot tell you if she can't hear…

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It is recommended that your baby is re-screened in a month's time by an audiologist.

APPENDIX C

Informed Consent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

INFORMED CONSENT

Newborn hearing screening outcomes post birth- a comparative study

We request your permission for your child to be screened at Westville hospital as part of hospital-based infant hearing screening project. The purpose of this is to identify, diagnose and treat newborns and infants with a hearing loss as early as possible. Please kindly note that the results of the screening will be used for a Master's degree at the University of Pretoria. Please also note that the information gathered will be stored at the hospital for archiving purposes for 15 years.

Please ask the health care professional any questions about the screening that you do not fully understand. Your child's participation is **entirely voluntary** and you are free to decline to participate at any point in time without any negative consequences to you.

Declaration by parent/legal guardian

By signing below, I *(name of parent/legal guardian)* ……..……. agree to allow my child (name of child) ……..……..to be screened for hearing.

I declare that:

- I have read or had read to me this information and consent form and that it is in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.

Signed at (*place*) .....…..…….. on (*date*) ……..…….

....

Signature of parent/legal guardian **Signature of witness**

APPENDIX D

Ethical clearance from the Research Ethics Committee of the Faculty Of Humanities at the University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Office of the Deputy Dean

4 October 2011

Dear Prof Swanepoel,

Project:	**Newborn hearing screening outcomes post birth - a comparative study**
Researcher:	**MM van Dyk**
Supervisor:	**Prof DCD Swanepoel**
Department:	**Communication Pathology**
Reference number:	**24121984**

I am pleased to be able to tell you that the above application was **approved** by the **Postgraduate Committee** on 13 September 2011 and by the **Research Ethics Committee** on 29 September 2011. Data collection may therefore commence.

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

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

We wish you success with the project.

Sincerely

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

APPENDIX E

Letter of Consent from Westville Hospital to Conduct Research Study

Life Group
HEALTH CARE

Life Westville Hospital
7 Spine Road, Westville 3630
PO Box 467, Westville 3630
Telephone: +27 31 251 6911
Telefax: +27 31 265 0952
www.westvillehospital.co.za

13 June 2011

Faculty of Communication Pathology
University of Pretoria
Pretoria

To Whom it May Concern

RE: MASTERS PROJECT ON NEWBORN SCREENING OUTCOMES – A COMPARATIVE STUDY – MASTERS STUDENT MICHELLE VAN DYK

This letter services to confirm that Michelle van Dyk has been given approval to carry out the above project in the Maternity Unit at Life Westville Hospital.

She is aware that written consent must be given by the mother of the babies involved in the research, and must comply with all professional, ethical and confidentiality requirements for a project of this nature.

I am willing to give any additional information as necessary.

Yours faithfully,

Jane van der Merwe
Hospital Manager

Life Healthcare Group (Proprietary) Limited
Reg. no. 2003/024367/07 Registered address Oxford Manor, 21 Chaplin Road, Illovo 2196, Private Bag X13, Northlands 2116
Directors: Prof GJ Gerwel (Chairman), CMD Flemming (Managing Director), RJ Hogarth (Financial Director),
MA Brey, Dr MP Ngatane, GC Solomon

APPENDIX F

Letter of Consent from the Research Committee of the Life Healthcare College of Learning to Conduct Research Study

Life Healthcare Head Office
Oxford Manor, 21 Chaplin Road, Illovo 2196
Private Bag X13, Northlands 2116, South Africa
Telephone: +27 11 219 9000
Telefax: +27 11 219 9001
www.lifehealthcare.co.za

15 February 2012

Attention: Michelle van Dyk

APPROVAL FOR RESEARCH STUDY

Our previous correspondence refers.

The Research Committee of the Life Healthcare College of Learning has granted permission for your study entitled:
'Newborn hearing screening outcomes post birth – a comparative study.'

We look forward to seeing the results of your research once it is completed.

Yours sincerely

Anne Roodt
Nursing Education Specialist

Life Healthcare Group (Proprietary) Limited
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APPENDIX G

Data Collection Form

<table>
<tr><td rowspan="5">1</td><td>DATE BABY BORN:</td><td colspan="3" rowspan="2">PATIENT STICKER:</td><td>TEST 1</td><td rowspan="2">TEOAE</td><td>START:
TEST TIME:</td><td>START:
TEST TIME:</td><td rowspan="2">COMMENTS:</td></tr>
<tr><td rowspan="2">TIME BABY BORN:</td><td>L:</td><td>R:</td></tr>
<tr><td rowspan="3">Date:</td><td rowspan="2">AABR</td><td>START:
TEST TIME:</td><td>START:
TEST TIME:</td></tr>
<tr><td>L:</td><td>R:</td><td rowspan="2">INFANT NOT SCREENED:
YES NO</td></tr>
<tr><td rowspan="2">PAEDIATRICIAN</td><td colspan="2">AGPAR</td><td colspan="2">SCORE</td><td rowspan="3">Date:</td><td rowspan="2">TEOAE</td><td>START:
TEST TIME:</td><td>START:
TEST TIME:</td></tr>
<tr><td>1 MIN /10</td><td colspan="2">5 MIN /10</td><td>L:</td><td>R:</td><td rowspan="2">REFUSE HEARING SCREENING
YES NO</td></tr>
<tr><td rowspan="5">2</td><td>DATE BABY BORN:</td><td colspan="3" rowspan="2">PATIENT STICKER:</td><td>TEST 1</td><td rowspan="2">TEOAE</td><td>START:
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</table>

APPENDIX H

Hearing Screening Results Information Sheets

YOUR BABY
PASSED
NEWBORN HEARING SCREENING

Baby's Name: _____
Date of Birth: _____
Hospital: _____
Date of Hearing Screening:_____

Right Ear: PASS Left Ear: PASS

CHECKING YOUR BABY'S HEARING IS IMPORTANT AND AS EASY AS 1, 2, 3!

1. Your baby passed the hearing screening, however it is important to be aware that there can be changes in hearing.
2. Speech and language start to develop right after birth, even though babies don't usually talk until they are about 12 months old. Identifying any loss of hearing is important because babies and children can be helped when a hearing loss is found.
3. If you think your baby is not hearing well in the future, contact your doctor/Paediatrician. The information on the reverse side will allow you to monitor your baby's speech and hearing development.

Your Baby's Hearing

If any of the following concerns apply to your baby (child) now or in the future please contact your baby's doctor:

- Either parent or close family member had a hearing loss as a child
- Your child has/had many ear infections
- Your child had/has a head injury
- You don't think your child is hearing well
- You don't think your child is talking well

Age	Developmental Stages
0-3 months	Startles or cries to loud sounds. Is soothed by familiar voices. Moves or wakes up when someone talks.
3-6 months	Coos, gurgles, and makes a variety of voice sounds. Looks towards loud voices or sounds. Enjoys rattles or other toys that make sounds.
6-12 months	Begins to imitate speech sounds ("baba", ma-ma"). Understands "no" or "bye-bye." Begins to turn head toward soft sounds. Looks at familiar objects when named.
12-18 months	Readily turns towards all sounds. Recognizes name and understands about 50 words. Uses 10 or more words. Follows simple directions ("find your ball").
18-24 months	Enjoys being read to. Points to body parts when asked. Starts to combine words like "more milk." Uses 20 or more words.

Adapted from Minnesota Department of Health: Newborn Hearing Screening.(2012)

NEWBORN HEARING SCREENING

FOLLOW-UP GUIDE FOR REFER RESULTS

Baby's Name: _____

Date of Birth: _____

Hospital: _____

Date of Last Hearing Screening:_____

Right ear: PASS ☐ REFER ☐

Left ear: PASS ☐ REFER ☐

An appointment for hearing re-screen was made:Yes ☐ No☐

Date and location:_____

A FOLLOW-UP ON YOUR BABY'S HEARING IS AS EASY AS 1, 2, 3!

1. Your baby did not pass the hearing screening. This does not mean your baby has a hearing loss, but it does mean your baby needs more testing to know for sure.
2. Hearing cannot be tested at home. Babies with hearing loss can still startle and seem to respond to sound.
3. Plan to have your baby's hearing re-screened as soon as possible.

REFER results & Your Baby's Hearing

Hearing Screening is Important

Speech and language start to develop right after birth, even though babies don't usually talk until they are about 12 months old. A child with a hearing loss may have difficulty with speech and spoken language. If a baby has a hearing loss it is usually not noticeable to parents or doctors. Screening and follow-up testing are the only ways to detect a hearing loss early. Discovering that your baby has a hearing loss allows you the opportunity to prevent speech and language delays.

If my baby has a REFER, does that mean he has a hearing loss?

A REFER result means that your baby did not pass the hearing screening. There are several reasons why a baby might have a REFER result. Sometimes there is fluid or debris in the baby's ear that can get in the way of testing - these babies can hear perfectly well. It is unlikely that your baby has a hearing loss but it is a possibility. Babies with a REFER hearing screening result need to see a hearing specialist (Audiologist) to determine if a hearing loss is present.

Can I check my baby's hearing at home?

Even though it may seem like your baby can hear at home - he jumps when there is a loud noise or turns when you clap your hands - it is still very important to have your baby's hearing checked again.

Adapted from Minnesota Department of Health: Newborn Hearing Screening.(2012)

YOUR BABY PASSED NEWBORN HEARING SCREENING

Baby's Name: _____

Date of Birth: _____

Hospital: _____

Date of Hearing Screening:_____

Right Ear: PASS Left Ear: PASS

CHECKING YOUR BABY'S HEARING IS IMPORTANT AND AS EASY AS 1, 2, 3!

1. Your baby passed the hearing screening, however it is important to be aware that there can be changes in hearing.
2. Speech and language start to develop right after birth, even though babies don't usually talk until they are about 12 months old. Identifying any loss of hearing is important because babies and children can be helped when a hearing loss is found.
3. If you think your baby is not hearing well in the future, contact your doctor/Paediatrician. The information on the reverse side will allow you to monitor your baby's speech and hearing development.

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NEWBORN HEARING SCREENING

FOLLOW-UP GUIDE FOR REFER RESULTS

Baby's Name: _____

Date of Birth: _____

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Date of Last Hearing Screening:_____

Right ear: PASS ☐ REFER ☐

Left ear: PASS ☐ REFER ☐

An appointment for hearing re-screen was made:Yes ☐ No☐

Date and location:_____

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