



The use of high frequency tympanometry (HFT) (1000Hz) in South Africa

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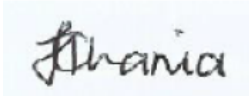
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Declaration

I, Heena Chania, declare that this research report, entitled ‘The use of high frequency tympanometry (HFT) (1000Hz) in South Africa’ is my own work and that any assistance obtained has been only in the form of professional guidance and supervision. No part of this research has previously been submitted to any other research institution of higher learning or university. The theoretical components of this report have been referenced accordingly. I claim complete responsibility for the conclusions drawn in this research study.



08/09/2014

Heena Chania

Date

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‘Never give up on what you really want to do.

The person with big dreams is more powerful than one with all the facts’

~ Albert Einstein ~

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Abstract

Otitis media (OM) is one of the most common causes of hearing loss (HL) in neonates and infants. The correct identification of OM is critical in the management thereof. Research has confirmed that high frequency tympanometry (HFT) should be a part of the newborn hearing screening (NHS) as it reliably and accurately identifies OM. Although it is imperative that HFT equipment is available to audiologists working with neonates and infants, there is a dearth of information regarding the use of HFT in South Africa. The purpose of this study was to determine the use of HFT by South African audiologists in clinical practice. In addition, the pass and refer rates between HFT and other screening tests used in the identification of possible middle ear pathology in neonates and infants were determined.

A non-experimental, descriptive, cross-sectional survey design was used to describe the use of HFT in clinical practice. A total of 113 questionnaires, completed by paediatric audiologists, were analysed. Results indicate that only 50% of audiologists had access to and included HFT in their test battery. These participants mainly worked in government hospitals ($n=25$) and private practice ($n=23$). The rest of the participants reported HFT to be unavailable, mainly due to lack of equipment, clinical protocols and training in conducting and interpreting HFT.

A correlation research design was used to determine the pass and refer rates of HFT and other screening tests used in the identification of possible middle ear pathology. Participants were neonates and infants from birth to six months of chronological age ($N_2=303$ ears) (mean gestational age=37 weeks; $SD=4.03$). For the four hearing screening tests the highest pass rates were obtained using low frequency tympanometry (LFT) (right ear = 84%; left ear = 86%). In the three hearing screening tests the highest pass rates were obtained using LFT (right ear = 99%; left ear = 93%). However, the agreement of LFT with other screening tests was poor in both the four and three hearing screening tests. The results confirm that HFT and otoscopy had the best agreement in both the four (0.7237 and 0.7983) and three hearing screening tests (0.5062 and 0.6264) in terms of pass and refer rates bilaterally.

The findings suggest the need for promoting improved training at undergraduate level and clinical practice within the area of paediatric audiology, specifically regarding the use of HFT in the identification of possible middle ear pathology in neonates and infants.

Keywords: high frequency tympanometry, otitis media, clinical practice, pass rate, refer rate

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LIST OF ABBREVIATIONS

AABR	Automated auditory brainstem response
AOM	Acute otitis media
BC ABR	Bone conduction auditory brainstem response
CA	Corrected age
CHL	Conductive hearing loss
COM	Chronic otitis media
dB	Decibel
ECV	Ear canal volume
EDHI	Early hearing detection and intervention
GA	Gestational age
LF	Low frequency
LFT	Low frequency tympanometry
HF	High Frequency
HFT	High frequency tympanometry
HI	Hearing impairment
HL	Hearing loss
JCIH	Joint Committee on Infant Hearing
MEE	Middle ear effusions
MFT	Multi frequency tympanometry
NP	No pressure
NICU	Neonatal intensive care unit
OAEs	Otoacoustic emissions
OM	Otitis media
OME	Otitis media with effusion
SNHL	Sensori-neural hearing loss
STAs	Speech therapists and audiologists
TM	Tympanic membrane
TPP	Tympanometric peak pressure
UNHS	Universal newborn hearing screening

Glossary

Admittance

This refers to the ease with which acoustic energy is transmitted in the outer and middle ear. Admittance is measured in mmho (Clark, Roeser & Mendrygal, 2007).

Conductive Hearing Loss

This type of HL is a result of problems in the external and middle ear that impacts the transmission of sound from the external auditory canal (EAC) to the inner ear; however there are no problems with the inner ear. Conductive hearing loss (CHL) presents with normal bone conduction results. It is also associated with presence of middle ear pathology which can be either treated medically or surgically (Vinson, 2001).

False Negative Results

When the test outcome is a negative in the presence of a disease, this results in a false negative (Steffens & Krishnan, 2003).

False Positive Results

When the test outcome is a positive in the absence of a disease, this results in a false positive (Steffens & Krishnan, 2003).

High Frequency Tympanometry

Tympanometry is the indirect measurement of the compliance and impedance of the tympanic membrane (TM) and middle ear system. High frequency tympanometry (HFT) utilises high frequency probe tones (such as 668 Hz, 800 Hz and 1000Hz). The use of HFT has shown

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to be sensitive in the identification of middle ear pathologies in neonates and infants, whose middle ear systems are mass-dominated (Kei et al., 2003).

Infant

This term is used to describe a baby from one to 12 months of age (Aehlert & Vroman, 2011).

Mass Susceptance

Mass susceptance is the admittance offered by mass elements in the middle ear system of the neonate or infant (Shahnaz, 2007).

Middle Ear Effusion

Middle ear effusion (MEE) is the buildup of fluid (effusion) in the middle ear (Gelfand, 2009). This causes the colour of the tympanic membrane (TM) to change and impairs the mobility of the TM, making it stiff, for instance (Al-Khatib, 2010).

Neonate

The term neonate is used to describe a baby from birth to one month of age (Aehlert & Vroman, 2011).

Pass Screening Test Result/Rate

This indicates a negative test. It implies that the individual does not present with a disease and therefore no further follow up is required (Meyer, 2000; Spivak, 2007).

Paediatric Population

The paediatric population is defined as those persons aged between birth and 18 years of age (European Medicines Agency, 2007).

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Peak Susceptance

Susceptance (B) is energy flow that is associated with reactance and the susceptance tympanograms; it is expected to notch first before the conductance tympanograms. The measured susceptance includes effects of the volume of the ear canal, the stiffness of the TM as well as mechanical stiffness of the middle ear system (Stach, 2003; Roberts, 2007; Moser, 2009).

Peak Compliance

The point of maximum mobility on a tympanogram that refers to the degree of mobility of the middle-ear system (Minnesota Department of Health [MDH], 2009).

Refer Screening Test Result/Rate

This indicates a positive test as it implies the individual does present with a disease, therefore further follow up is required (such as diagnostic testing) (Meyer, 2000; Spivak, 2007).

Screening Test

It is a simple test performed on a large number of people to identify those who have or are likely to develop a particular disease. No screening test can divide normal and abnormal individuals with complete accuracy as it is not intended to give a diagnosis (Screening test, n.d; Moore & De Costa, 2005; Gelfand, 2009).

Static Acoustic Immittance

This evaluates the ease of flow of acoustic energy through the middle ear system. In order to determine this measurement, immittance is established under the positive pressure (+200 daPa) artificially induced in the ear canal. Thereafter, determination is made with the TM in its

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most compliant position, which maximises conduction through the middle ear space (Bess & Humes, 2008).

True Negative Results

When the test outcome is a negative in the absence of a disease, this results in a true positive (Steffens & Krishnan, 2003).

True Positive Result

When the test outcome is a positive in the presence of a disease, this results in a true positive (Steffens & Krishnan, 2003).

Tympanometric Peak Pressure

Tympanometric peak pressure (TPP) is the representation of air pressure in daPa at which the peak of tympanograms occurs (Stach, 2003). Various factors result in the change of TPP, such as variation in ear canal pressure during tympanometry. This is associated with variation in the middle ear volume with movement of the eardrum (Gerber, 1996).

Tympanograms

Tympanograms are graphic representations of mobility of the TM as a function of mechanically varying the air pressure in a hermetically sealed ear canal (Clark et al., 2007

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Chapter One

Orientation

This chapter provides an orientation to the study and includes the background and rationale for conducting the study. An outline of each of the chapters is also included.

Background

Middle ear infections (such as otitis media [OM]) are the most common cause of hearing loss (HL) during early childhood years (Deiner, 2010). Due to this high prevalence rate and association with varying degrees of conductive hearing loss (CHL), tympanometry forms an important component of the screening test protocol to identify middle ear pathology in neonates and infants (Health Professionals Council of South Africa [HPCSA], 2007; Swanepoel et al., 2007). Tympanometry is a highly sensitive method used to screen for middle ear pathologies (Bluestone & Klein, 2007). However, the use of low frequency tympanometry (LFT) in neonates and infants often result in higher false positive rates. Therefore, it is recommended that high frequency tympanometry (HFT) forms part of the screening protocol to assist in clarifying false positive screening results (Kent, 2004; HPCSA, 2007; Swanepoel et al., 2007).

The anatomical and acoustical differences between that of a neonate or infant and an adult middle ear system implies that adult tympanometry protocols are not appropriate for the use in neonates and infants (Baldwin, Sutton, Gravel & Low, 2008). It has been found that HFT is the most reliable measure in the evaluation of the mass-dominated middle ear system of neonates and infants (Swanepoel et al., 2007).

Although HFT is readily available in a number of tympanometers today (Pettrak, 2002), the high cost of HFT equipment often precludes its use in primary care practice (Al-Khatib, 2010). It has been reported that the shortage of equipment in South Africa is one of the main

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obstacles for the successful implementation of newborn hearing screening (NHS) programmes (Theunissen & Swanepoel, 2008).

NHS protocols advocate for the use of otoacoustic emissions (OAEs) and/or automated auditory brainstem response (AABR) measures (Joint Committee on Infant Hearing [JCIH], 2007; HPCSA, 2007). Results obtained from these screening tests may be affected by middle ear pathologies resulting in the neonate or infant failing the hearing screening (Holte, Margolis & Cavanaugh, 1991; Purdy & Williams, 2000; JCIH, 2007). It is therefore important to include HFT when identifying middle ear pathologies in paediatrics (birth to six months of age). HFT has been shown to present with the most significant correlation with OAEs and otoscopy (Purdy & Williams, 2000; Kent, 2004; HPCSA, 2007; JCIH, 2007; Swanepoel et al., 2007; Garcia, De Azevedo & Testa et al., 2009).

Despite this, LFT is still used in neonates and infants between the ages of birth and six months. It has however been found that the use of a low frequency (LF) probe tone is unreliable in this population due to its poor sensitivity in identifying middle-ear pathologies (Swanepoel et al., 2007). This can be attributed to the fact that HFT is less straightforward to interpret than LFT (Baldwin, 2006).

As there are limited clinical guidelines available for the use and interpretation of HFT, audiologists should carefully interpret results in combination with other audiological results (American Speech-Language-Hearing Association [ASHA], 2004). Although many normative studies on HFT have been published, the use of these norms has proved clinically challenging for clinicians (Wilson, 2008). There is a need for standard clinical protocols and guidelines for interpretation of HFT to promote its extensive application in the clinical paediatric setting (Wilson, 2008).

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The rapid implementation of universal newborn hearing screening (UNHS) programmes has also exposed a need for a reliable screening test of middle ear functioning. This will allow for the timely identification of middle ear pathology and for differentiation between sensori-neural hearing loss (SNHL) and CHL (Van Rooyen, 2006). Correct identification of middle ear status in the neonatal and infancy period can direct timely and appropriate referrals to medical and audiological personnel. This in turn will lead to improved efficacy of NHS programmes (Swanepoel et al., 2007).

Even though the importance of HFT in neonates and infants has been confirmed, there is limited information available on the current clinical practice in South Africa. As a result this research study aimed to address the following research questions:

- How readily available is HFT in audiology departments or practices in South Africa?
- Do South African audiologists have HFT clinical protocols available to provide guidance in correctly and accurately identifying middle ear pathologies in neonates or infants?
- Are South African audiologists aware of the clinical applications of HFT and theoretical background of a neonate's or infant's middle ear system?
- What is the level of agreement between the pass and refer rates of hearing screening tests (HFT, LFT, otoscopy and DPOAE) used in the identification of possible middle ear pathology in neonates or infants?

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Chapter Outlines

This dissertation is comprised of six chapters, namely:

Chapter One

This chapter provides an introduction to the study as it describes the rationale for, and importance of conducting the study. An outline for every chapter is herewith is also provided.

Chapter Two

This chapter provides a broad overview of HL, NHS and OM. It also provides information on maturational changes, tympanometry and requirements for performing HFT. This chapter further focuses on the interpretation of HFT, validation of testing and hearing screening tests used in NHS.

Chapter Three

The methodology chapter illustrates the aims of the study and the research design utilised and describes the various research phases. It further includes the pilot study results, description of the main studies as well as the data collection procedures. Furthermore, it addresses the reliability, validity and ethical principles of the study.

Chapter Four

This chapter presents the results obtained from the two main studies, namely the survey questionnaires and hearing screening. The results are presented in relation to the aims of the study.

Chapter Five

This chapter highlights trends and differences in the data obtained from the survey questionnaire and hearing screening. This allows for conclusions to be drawn with regard to the use of HFT in neonates and infants.

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Chapter Six

This chapter provides a summary of the results obtained for the current study followed by a critical review, implications of the study and recommendations for future research.

Reference and Appendices

This section provides all the references used for the current study and appendices, which provides important information for understanding the data collection procedures.

Chapter Two

Literature Review

This chapter provides a broad overview of hearing loss. It provides information on otitis media, maturational changes of the infant's middle ear system, tympanometry and requirements for performing HFT. This chapter further focuses on the interpretation of HFT and validation of testing, high risk factors of hearing loss, and hearing screening tests used in newborn hearing screening.

Prevalence of Hearing Loss

'Hearing impairment (HI) in children across the world constitutes a particularly serious obstacle to their optimal development and education, including language acquisition' (World Health Organization [WHO], 2010, p.7). There is an increase in the prevalence of HL globally (Swanepoel, Delport & Swart, 2004; HPCSA, 2007). Preliminary reports in South Africa estimate that approximately 17 babies are born with hearing loss (HL) in South Africa every day (Copley & Friderichs, 2010). HL is the most commonly occurring birth abnormality, thus the early identification and diagnosis of neonates and infants with HL is vital (Swanepoel et al., 2007; Alexiades & Hoffman, 2008).

Otitis Media

One of the most common causes of HL in the paediatric population is middle-ear infection (Zand, Routree & Walton, 2003). Otitis media (OM) has been reported as the most frequently occurring middle ear infection in neonates and infants (Zand et al., 2003; National Institute of Deafness and Other Communication Disorders [NIDCD], 2010; Marschark & Hauser, 2012). OM is defined as the inflammation of the middle ear, which is mainly a result of Eustachian tube (ET) dysfunction (Stach, 2010a). There are three types of OM namely; acute

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otitis media (AOM), otitis media with effusion (OME), and chronic otitis media with effusion (COM) (Pichichero, 2013).

Literature indicates that OM affects 75% to 95% of the paediatric population (McCabe & Racanello, 2006). OM-related HI has a prevalence of 30.82 per 10 000 births. It has been reported that annually 21 000 people die due to complications of OM (e.g. acute mastoiditis and meningitis) (Dodson & Peng, 2009; Monasta et al., 2012). The prevalence of OM is the highest during the first two years of a child's life and declines with age (Stach, 2010a).

Maturational Changes of the Infant Middle Ear System

Anatomical changes.

There are many anatomical differences between the infant and adult middle ear system. Anatomically, the external auditory canal (EAC) in neonates and infants are narrower, shorter and straighter in orientation when compared to an adult (Cai, 2010). The EAC increases rapidly in diameter and length in early infancy (Keefe & Bulen, 1993). In infants, the wall of the EAC comprises of cartilage and soft tissue which makes the structure flexible and compliant (Anson & Donaldson, 1981). As the infant matures, the cartilage and canal wall becomes thicker and bone is formed. This results in more rigidity, stiffness and decreased compliance of the structures (Anson & Donaldson, 1981). In adulthood the inner two-thirds of the EAC is bony and the outer third is made of soft-tissue (Anson & Donaldson, 1981). These changes affect the impedance of the infant EAC; as canal volume increases, impedance decreases (Keefe, Bulen, Arehart & Burns, 1993).

In the middle ear structure, the tympanic cavity of a neonate and infant is smaller than that of an adult ear (Ikui, Sando, Haginomori & Sudo, 2000). The middle ear cavity will reach adult size by approximately six months of age (Baldwin, 2006; Keefe & Bulen, 1993). Within

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this time other middle ear structures such as the ossicular joints and the stapes footplate attachment to the oval window tightens. In addition, fusion of the tympanic ring results in the decrease in resistance (Anson & Donaldson, 1981). As maturation proceeds, bone erosion of the stapes occurs. This results in the reduction of bone density and thus an overall decrease in mass (Meyer, Jardine & Deverson, 1997).

At birth the tympanic membrane (TM) is located horizontally to the EAC. The TM gradually becomes vertical until it reaches the adult position (50° to 60°) at around three to four years of age (Eby & Nadol, 1986). According to Roush (2001, as cited in Cai, 2010) the TM is also thicker and more vascular if compared to the TM of an adult. Furthermore, according to Eavey (1993, as cited in Cai, 2010) the unabsorbed foetal tissue (e.g. mesenchyme), remaining amniotic fluid and cellular debris may be present within the tympanic cavity up to five months after birth. This together with a thicker TM possibly contributes mass to the middle ear system and decreased compliance. Therefore, as the infant matures there is an overall decrease in mass and resistance in the middle ear system (Cai, 2010). Within the first six to seven months of life, the middle ear system thus transforms from a mass-dominated to a stiffness-dominated system (Baldwin et al, 2008).

Acoustical differences.

As a result of maturational changes in the anatomy of the EAC and middle ear system, the acoustic response properties within these structures also changes considerably over the first two years after birth (Lantz, Petrak & Prigge, 2004). The middle ear is a mechano-acoustic system which consists of three components: stiffness, mass and resistance (Wiley & Stoppenbach, 2002).

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There are a number of elements within the EAC and middle ear space that dictates stiffness. These include ligaments, the TM and the air enclosed in the ear canal and middle ear space (Purdy & Williams, 2000). The stiffness elements exert effects at low frequencies and are related to the enclosed volume of air in the outer and middle ear (Popelka & Hunter, 2013).

The mass of the middle ear is affected by the pars flaccida of the TM, ossicles and the perilymph in the cochlea (Purdy & Williams, 2000). These components are responsible for controlling the transmission of the high frequency (HF) response of the middle ear (Cai, 2010).

Resistance is the cause of energy loss through dissipation of heat (Lantz et al., 2004). Resistance is independent of frequency and determines the dissipation of acoustic energy known as acoustic conductance (G_a) or acoustic resistance (R_a) in the impedance system (Popelka & Hunter, 2013). The form of the frequency response is controlled by the resistive elements such as the ossicular joints, the annular ligament around the footplate of the stapes, and cochlear fluids (Cai, 2010).

Stiffness, mass and resistance in combination interact and determine the impedance or opposition to the flow of energy of the middle ear system and allow successful sound transmission to the cochlea (Lantz et al., 2004; Wiley & Stoppenbach, 2002). These properties contribute to the total acoustic impedance or total acoustic admittance.

Acoustic impedance (Z_a in acoustic ohms) refers to the total opposition of flow to the middle ear system to the flow of acoustic energy (Popelka & Hunter, 2013). It constitutes of resistance (R) and reactance (X), which in turn has two components namely compliant reactance and mass reactance (Palmu, 2001). Acoustic admittance (Y_a in acoustic ohms) is the amount of acoustic energy that travels into the middle ear system (Popelka & Hunter, 2013). It constitutes of conductance (G) and susceptance (B), which has two components namely compliance and

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mass susceptance (Palmu, 2001). Acoustical impedance and acoustical admittance are reciprocal and is described as the following:

$$Z_a = \frac{1}{Y_a}$$

$$Y_a = \frac{1}{Z_a}$$

The total acoustic susceptance, determined through a vectorial sum of the stiffness and mass elements, is used to identify whether the middle ear system is mass- or stiffness-dominated (Popelka & Hunter, 2013). A stiffness-dominated middle ear system is present when the total acoustic susceptance (B_a) is positive between 0° and 90° phase, whilst a mass-dominated middle ear system is present when the total acoustic susceptance (B_a) is negative between 0° and 90° phase (Popelka & Hunter, 2013).

In the neonatal and infant middle ear system the mass and resistive elements are high and their middle ear system can thus be described as mass-dominated (Holte, Margolis & Cavanaugh, 1991; Shahnaz, Miranda & Polka, 2008). A mass-dominated middle ear system has an influence on the conductance of high frequencies into the cochlea (Cai, 2010). As the cochlea is found to be mature at the time of birth; the middle ear system in neonates and infants may be responsible for the loss of energy transfer into the cochlea during the conduction of sound (Abdala & Keefe, 2006).

Energy transmission into the neonate and infant middle ear is reported to be most efficient in the 1000 Hz- 4000 Hz range (Holt et al, 1991; Baldwin, 2006). Frequencies below 500 Hz resulted in the transmission of decreased power into the middle ear system of neonates and infants less than four months of age. This is a result of ear canal wall vibration and resonance (Baldwin, 2006). These differences between the neonate or infant and adult disappear by the age of six months (Baldwin, 2006).

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In addition, the shorter EAC length in neonates and infants results in a higher resonant frequency when compared to adults (Cai, 2010). As a result of the small ear canal diameter and compliant EAC wall in neonates and infants, there is decreased resonance gain (Saunders, Doant & Cohen, 1993). Thus, in neonates and infants the resonance of the EAC occurs at higher frequencies and exhibits a lower gain than that seen in the adult EAC (Saunders et al., 1993).

Research has confirmed these above findings. In a study conducted by Meyer et al. (1997) the resonant frequency of an infant was measured. Repeated measurements between the ages of two weeks and six and a half months were made. Results revealed that the resonant frequency remained below 550 Hz until the infant was three and half months old (Meyer et al., 1997). An average adult middle ear resonant frequency of 900 Hz (range 800 Hz to 1200 Hz) was measured by four months of age. This was supported by research conducted by Lantz et al. (2004) and Silman and Silverman (1991) who reported that between three to four months of age resonant frequency similar to those found in the adult ear were measured in neonates and infants. This supports the theory that the infant middle ear changes from a mass- to stiffness-dominated system (Silman & Silverman, 1991; Meyer et al., 1997; Baldwin, 2006). Otoscopy and tympanometry is used in medical and audiological practice to evaluate the middle ear system.

Identification of OM

The goal of screening for middle ear pathologies is to identify individuals who may have the disease but in whom it would otherwise go unidentified (Bluestone & Klein, 2007). Current clinical methods used for the identification of OM in neonates and infants include HFT tympanometry and otoscopic examination (Kent, 2004).

Otoscopy is the subjective examination that is performed to inspect the ear canal and the TM for malformations or any presence and absence of OM that may impede on the neonate or

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infant's hearing (Kent, 2004; Easterbrooks & Estes, 2007). Otosopic examination is also essential to determine if there is any obstruction in the ear canal that would preclude placement of a probe for acoustic immittance screening, thereby confounding the tympanometric results (Kent, 2004).

The examination of the EAC and middle ear are usually performed by otolaryngologists, general practitioners, nurses and audiologists using an otoscope. There are various types of otoscopes available namely a standard otoscope, a pneumatic otoscope, otomicroscope and a video-otoscope (Wilson, 2008). The sensitivity and specificity of some of the otologic instruments available are described in Table 2.1.

Table 2.1

Sensitivity and Specificity of Otologic Instruments

Instrument	Studies	Sensitivity (%)	Specificity (%)
Standard otoscope	KC et al. (2007)	78.7	22.2
Pneumatic otoscope	Lee & Yeo (2004)	38.5	97.2
	Shiao & Guo (2005)	77.3	90.5
	Harris et al. (2005)	100	84.5
	KC et al. (2007)	33.3	90.4
Otomicroscope	Lee & Yeo (2004)	100	61.5
Video otoscope	Shiao & Guo (2005)	100	97.8

Paediatricians and audiologists generally make use of a standard otoscope to identify the presence or absence of middle ear pathology. Audiologists in addition perform tympanometry to detect the presence of middle ear pathology (Kent, 2004; Wilson, 2008). A standard otoscope has been found to have the lowest sensitivity and specificity (Wilson, 2008). However, it is reported to be a useful screening tool (O'Malley & Haynes, 2010). Pneumatic otoscopes are most often used by otolaryngologists to improve diagnostic accuracy of OM (Alper, Bluestone, Casselbrant, Dohar & Mandel, 2004). These instruments however do not always improve

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diagnostic accuracy of OME in the paediatric population when compared to a standard otoscope (Al-Khatib, 2010).

When performing an otoscopic evaluation, a small ear speculum is utilised and the pinna is gently pulled downwards in order to straighten the horizontal ear canals of the neonate or infant to obtain a clear view of the ear canal and TM (Cavaliere & Sansoucie, 2013; Hockenberry, 2012).

The challenge of performing an otoscopic evaluation is the difficulty in visualizing the TM in neonates and infants. This is due to the small external meati which are often filled by vernix caseosa, debris and cerumen making it challenging to identify common landmarks of the middle ear system (Baldwin, 2006). Vernix is commonly present in the ear canals of neonates and usually disappears within 1 or 2 weeks after birth (Whitaker, 2001). It is reported that 70 % of infants of two to six months of age require cerumen removal in order to improve visualization of the outer and middle ear (Carlson & Carlson, 2003).

Otoscopically, a normal TM appears pale, grey and translucent with visual projections of the malleus, short lateral process and manubrium. Furthermore, a reflective cone of light is visible (Mangione, 2008). In the presence of the ear infection the TM can also be found to be bulging or retracted. It is therefore important that the examination of an eardrum should take the vascularity, mobility, integrity as well as position into consideration (Chiocca, 2011; White, Duncan & Baumle, 2013).

Tympanometry

Tympanometry is defined as “the dynamic measure of acoustic immittance in the external ear canal as a function of change in air pressure in the ear canal” (Fowler & Shanks, 2002, p.

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175). The tympanometer records compliance of the TM, which offers quantitative information on structural function and the presence of middle ear effusion (MEE) (Al-Khatib, 2010).

There are various types of tympanometry currently and routinely used in clinical practice, namely low frequency tympanometry (LFT) and multi-frequency tympanometry (MFT) (Harris, Hutchinson & Moravec, 2005). Several HF probe tones have also been studied such as 660Hz, 880 Hz and 1000 Hz. However, 1000Hz probe tone is currently the highest frequency available on commercial clinical tympanometers and is known as HFT (Wilson, 2008).

The use of LFT (226 Hz probe tone) has been validated for use in adults. This frequency probe tone is especially relevant as it is below the normal adult resonance of approximately 900 Hz, negating the effects of mass and resistance. The adult middle ear system is also stiffness-dominated below this frequency (Lantz et al., 2004).

HFT (1000Hz probe tone) is however advocated for the use in neonates and infants due to the greater mass contribution, higher resistance and lower compliance in the middle ear (Purdy & Williams, 2000; Alaerts, Luts & Wouters, 2007). This HF probe tone allows for the measurement of admittance where mass susceptance is significant (Purdy & Williams, 2000). The mass components are larger in HF probes. In HF probe tones (1000Hz) the involvement of every anatomical structure is changed and the acoustic admittance measured at the middle ear inlet becomes more predominated by the mass (Holte et al., 1991; Kei et al., 2003; Silva, Novaes, Lewis & Carvalho, 2007).

Tympanometry is used in clinical practice to determine the presence of middle ear pathology (Al-Khatib, 2010).

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Use of Tympanometry in Neonates and Infants.

Low frequency tympanometry. Although tympanometry is used to detect middle ear pathologies, there is still controversy regarding the use of LFT and HFT in the neonates and infants. Despite confirmation that the neonate and infant middle ear system is mass-dominated, LFT is still used in this population.

Research conducted by Baldwin (2006) to determine the sensitivity and specificity of LFT in neonates and infants below five months of age revealed poor sensitivity (0.02%) in correctly identifying the presence of MEE. This has been confirmed by other studies that found that LFT were reported to produce false positive and false negative results when performed on neonates or infants under seven months of age (Meyer et al., 1997; Purdy & Williams, 2002; Macedo de Resende et al., 2012). It is postulated that the physiological differences between the neonate or infant and adult middle ear transmission system may be a contributing factor to these false positive and false negative rates (Keefe & Levi, 1996; Petrak, 2002).

Meyer et al. (1997) suggests that LFT are valid in infants from four months of age when the middle ear system reaches an adult middle ear resonant frequency and has transformed from a mass-dominated to stiffness-dominated system. The use of LFT in older infants is supported by a number of research studies describing the sensitivity and specificity of LFT in infants older than 7 months of age (Table 2.2).

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Table 2.2

Sensitivity and Specificity of LFT in Infants over Seven Months of Age

Studies	Sensitivity (%)	Specificity (%)
Shiao & Guo (2005)	89.4	81.8
Lee & Yeo (2004)	87.5	0
Watters, Jones & Freeland (1996, as cited in Harris, Hutchinson & Monroe, 2005)	91	79
Palmu, Puhakka, Rahko & Takala (1999, as cited in Harris et al. 2005)	94	
Mills (1987) and Finitzo, Friel-Patti, Chinn & Brown (1992)	80-90	71-100
Harris et al. (2005)	80	100
KC, Guragain & Sinha (2007)	98.9	14.8

Longitudinal studies are however required to establish the variability in the age at which LFT becomes valid (Baldwin, 2006; Baldwin et al., 2008).

High frequency tympanometry. The use of HFT in the neonate and infant population has been studied extensively (Keefe & Levi, 1996; Rhodes, Margolis, Hirsch & Napp, 1999; Margolis, Bass-Ringdahl, Hanks, Holte & Zapala, 2003; Baldwin, 2006; Alaerts et al., 2007; Garcia et al., 2009; Kei & Mazlan, 2012). There is however still controversy regarding the age range for which HFT is most appropriate (Hoffman et al., 2013).

Both the JCIH (JCIH, 2007) and ASHA (ASHA, 2004) recommends the use of HFT for neonates and infants from birth to six months of age. The guidelines are based on research confirming the validity of HFT results in this age range (Keefe & Levi, 1996; Rhodes et al., 1999; Baldwin, 2006; Alaerts et al., 2007; Garcia et al., 2009; Kei & Mazlan, 2012). Two studies validated the use of HFT in neonates (Kei et al., 2003; Margolis et al., 2003). However, in these studies, the age effects were not evaluated (Alaerts et al., 2007). Baldwin (2006) found HFT to have a high sensitivity in detecting middle ear pathology in infants below the age of five months.

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A more varied age-dependent protocol is suggested by Alaerts et al. (2007) in which both HFT and LFT are used. In neonates and infants younger than three months of age it is suggested that only HFT is performed. For infants between three and nine months of age HFT should be performed; and in cases of failure, LFT must be carried out as confirmation of pathology (Alaerts et al., 2007). The suggestions were made because Alaerts et al. (2007) deemed HFT to be most reliable in neonates and infants up to the age of three months. This view was supported by Macedo de Resende et al. (2012). The limitation of the Alaerts et al. (2007) study was that the presence or absence of middle ear pathology was not confirmed with an otoscopic examination. Hence, results cannot be generalised to all neonates and infants (birth to 36 weeks) as different tympanometric results may be obtained in those with confirmed middle ear pathology (Baldwin, 2006). The clinical relevance of HFT up to the age of nine months was supported by Hoffman et al. (2013). The age of participants in the Hoffman et al. (2013) study did however not report any information on the age of participants (such as gestational age [GA] or corrected age [CA]) at the time of testing.

Baldwin et al. (2008) however recommended that HFT should only be used up to six months CA (Baldwin et al., 2008). His findings were supported in recent studies (Table 2.3).

Table 2.3

Sensitivity and Specificity of HFT in Infants Under Six Months of Age

Studies	Sensitivity (%)	Specificity (%)
Baldwin (2006)	99	89
Swanepoel et al. (2007)	57	95
Garcia et al. (2009)	11.1-95	41.7-60

HFT is therefore the frequency of choice in neonates and infants due to its high sensitivity in correctly detecting middle ear components in early infancy (Kent, 2004; HPCSA,

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2007; Swanepoel et al., 2007). Some studies however reported decreased sensitivity of HFT in this population (Swanepoel et al., 2007). Decreased sensitivity could be associated with the presence of MEE in a number of ears with present but decreased OAEs (Sutton, Gleadle & Rowe, 1996; Kei et al., 2003). This causes an overlap of true positive HFT results and false negative OAE results which results in decreased immittance sensitivity (Swanepoel et al., 2007).

The possible implications of not performing HFT with neonates and infants of the appropriate age are that it may lead to inaccurate identification of middle ear pathologies (Bosaghzadeh, 2011; ASHA, 2004). Untreated and recurrent middle-ear pathologies may result in a temporary HL. This may result in delayed speech and language development and poor academic performance (ASHA 2004; Bosaghzadeh, 2011; Marschark & Hauser, 2012).

Research findings have revealed that HFT is sensitive in accurately identifying middle ear pathologies in neonates and infants when compared to other types of tympanometry screening tests (Kent, 2004; HPCSA, 2007; Johnson & Seaton, 2012; Wilson, 2008, Stach, 2010b). Therefore HFT is recommended to be included as part of the paediatric test battery, both in the NHS programmes and for diagnostic clinical practice (HPCSA, 2007; ASHA, 1997). It is imperative though that clinicians performing HFT in neonates and infants have appropriate clinical skills in performing and interpreting HFT.

Requirements for Performing HFT

Knowledge and training is necessary in performing tympanometry. Personnel performing hearing screening usually include audiologists and speech therapists (Al-Khatib, 2010). Individual state regulations may allow additional people to perform screening (Kooper, 2008).

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According to the HPCSA (2007) HFT is recommended to be included in NHS in order for effective implementation of early hearing detection and intervention (EHDI) programmes. The implementation for an effective EHDI programme also relies on an interdisciplinary team approach which include the following team members: audiologists, paediatricians and or general practitioners, otolaryngologists, speech therapists, nurses, community workers, other early intervention professionals and interpreters where needed. Therefore, it may be assumed that some of the above mentioned team members may perform tympanometry if efficient and comprehensive training is provided.

There is limited information with regard to who specifically performs tympanometry and provides training in South Africa. Qualified audiologists are trained professionals who generally are trained personnel in performing routine and specialised hearing evaluations (screening and diagnostic).

It is the audiologist's responsibility to ensure efficient training and supervision of support personnel (ASHA, 1997). Audiologists evaluate the middle ear status by performing tympanometry (Northern & Downs, 2002). Professionals or personnel other than audiologists who are involved in performing hearing screening, should have knowledge on the following after training: (i) the goal of hearing screening; (ii) familiarity with audiologic equipment and requirements for an appropriate test environment; (iii) how to instruct on screening procedures; (iv) the criteria for passing and failing the hearing screening; (v) how to report results; (vi) how to follow up with parents; and (vii) how to test neonates or infants (Kooper, 2008).

In addition, clinicians should also have essential clinical skills in the interpretation of HFT. HFT is being more implemented in NHS and has not been completely put into clinical

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practice due to difficulties in interpreting HF tympanograms (Alaerts et al., 2007). Hence, training is important especially due to the complexity of understating the fundamentals of HFT.

Interpretation of HFT and Validation of Testing

This section provides an overview on the various norms and classification systems available for the interpretation of HF tympanograms.

The quantification of tympanometric measurements is important as this allows for suitable guidelines to be developed in order to compare tympanometric measurements obtained in various clinical settings (Fowler & Shanks, 2002). For more precise characterization of tympanograms it is important to make use of both quantitative and qualitative data. This includes the height of the tympanograms; estimated middle ear air volume; description of the tympanograms shape close to the peak (tympanograms gradient and width); and tympanograms peak pressure (TPP) (Fowler & Shanks, 2002; Northern & Downs, 2002).

Several normative studies on HFT have been published in light of the widespread implementation of NHS programmes (Swanepoel et al., 2007). Normative guidelines have been suggested by Margolis et al. (2003) and Kei et al. (2003). These studies have created 5th to 95th percentile data for a number of test parameters which may be used as a pass or fail criteria for HFT (Kei et al., 2003; Margolis et al., 2003; Swanepoel et al., 2007).

Normative data described by Kei et al. (2003) were obtained from full term neonates who had no risk for HL, and with present transient otoacoustic emissions (TEOAEs) which were successfully measured in 87.9% of normal neonates. Kei et al. (2003) also classified HF tympanograms as described in Table 2.4.

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Table 2.4

Classification of tympanograms (Kei et al., 2003)

Configuration of Tympanograms	Classification
Peak tympanograms	Normal
Flat sloping tympanograms	Abnormal
Double peaked	Normal (according to Swanepoel et al. 2007)
Indeterminate	Other unclassified tympanograms

In addition, it is suggested using the 5th percentile for positive tail (+ 200 daPa) peak compensated static admittance as a pass or fail criteria given a value of 0.39 mmho. However, there is uncertainty with regard to transferring the norms from one age group to another and therefore may only serve as a guideline (Kei et al., 2003; Baldwin, 2006, Baldwin et al., 2008)

Margolis et al. (2003) obtained normative data from a group of full term infants who were screened with distortion product otoacoustic emissions (DPOAEs); a group of neonates from the neonatal intensive care unit (NICU); and well-babies. The 5th percentile for static admittance for NICU and full term infants was identical, allowing a single pass-fail criterion. Using that criterion, well-babies who passed a DPOAE screen presented with a 91% pass rate and presented with a higher static admittance than those who failed (Margolis et al., 2003). Therefore it was recommended that a single cut-off value for static admittance of 0.6 mmho is useful for neonates and infants from birth to one month chronological age (Margolis et al., 2003). However, the sensitivity of this criterion was found to be very low. The use of these data may result in tympanograms with small peaks being classified as abnormal (Baldwin et al., 2008). According to Baldwin (2006) these studies have not validated their findings on a group of neonates and infants with reliable evidence of middle ear pathologies.

Swanepoel et al. (2007) obtained normative data from a bigger sample of full term neonates (birth to one month of age) than Kei et al. (2003) and Margolis et al. (2003). The

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normative data obtained in this study demonstrate the important effects of age range and gender on tympanograms and the factors required to be taken into consideration when compiling norms (Swanepoel et al., 2007). This was not found to be taken into consideration in Kei et al. (2003) and Margolis et al. (2003) studies.

Mazlan et al. (2009) also aimed to establish normative data using the component compensation method from full term neonates and infants who had no risk for HL, passed TEOAEs and had single peaked HF tympanograms results. It was found that these normative values could only provide a starting point for the interpretation of HFT results (Mazlan et al., 2009).

Marchant et al. (1986) devised a classification system from neonates and infants below five months of age, where a baseline was drawn between pressures of +300 and -400 mmho and peak susceptance was measured above the baseline (Baldwin, 2006). It was recommended that a peak susceptance of ≤ 0 mmho (absence of a discernible peak) may indicate the presence of MEE (Baldwin et al., 2008). However, peaks at negatives pressures were not considered abnormal (Hoffman et al., 2013). Baldwin (2006) used an adaptation of Marchant's methodology to interpret admittance tympanometry instead of susceptance. A vertical line was drawn from the baseline to the peak either above or below the baseline (between between +200 and -400 daPa) and tympanograms were classified as described in Table 2.5.

Table 2.5

Classification of HF tympanograms (Baldwin, 2006)

Presence of Peak above or Below Baseline	Classifications
Tympanograms above baseline	Positive peak: Normal
Tympanograms below baseline or undulating in shape	Negative peak: Abnormal
Indeterminate	Tympanograms could not be classified as positive or negative peaks

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In addition, positive peaks were categorised as normal irrespective of its size, hence smaller peaks which fell under indeterminate tympanograms would be reclassified as normal. Therefore, this method was found to decrease the number of unclassifiable traces with the use of HFT (Baldwin; 2006). Baldwin et al. (2008) further describes two ways to classify tympanograms in Table 2.6.

Table 2.6

Classification Methods for Tympanograms

Method	Description
Classification of tympanograms by patterns	LF tympanograms have been effectively classified by pattern in adults with the use of the Jerger/Liden classification system. (Liden 1969; Jerger 1970). However, these systems have not been usefully applied to the neonatal and infant population as this method produces a high rate of false positive results and numerous unclassified tympanograms. This leads to the dismissal of HFT in this population (Marchant et al., 1986; Kei et al., 2003; Baldwin, 2006; Cai, 2010). The LF tympanograms are typically single-peaked and easier to interpret. More complex patterns are obtained when the probe tone is increased resulting in multi-peaked tympanograms (Lantz et al., 2004).
Classification of tympanograms by quantitative measure	Classifying HF tympanograms by a quantitative measure (peak susceptance or peak compliance) as described by numerous studies above (Marchant et al., 1986; Kei et al., 2003; Margolis et al., 2003; Baldwin, 2006; Swanepoel et al., 2007). This method has been usefully applied to neonates and infants under six months of age (Marchant et al., 1986; Sutton et al., 1996)

Numerous studies have also reported the use of the Vanhuyse model of tympanometric shapes to interpret tympanometric patterns (Alaerts et al., 2007). This model categorises the tympanograms based on the number of peaks or extrema on the B (susceptance) and G (conductance) tympanograms and predicts four tympanometric patterns at the 678 Hz probe tone (Cai, 2010; Bosaghzadeh, 2011). According to Alaerts et al. (2007) the Vanhuyse model has shown to be suitable for identifying 1000 Hz tympanograms as 99% of the neonates and infants

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tympanograms could be classified. However, the interpretation of tympanometric patterns is more complicated using the Vanhuyse model compared to the simple visual admittance classification methods. By simply looking at the B and G tympanograms pattern, middle ear pressure and the mobility of the TM are not taken into consideration and therefore the Vanhuyse model is less applicable to clinical hearing assessments (Alaerts et al., 2007).

The interpretation of HFT has been reported as challenging for clinicians. Factors contributing to the challenges experienced are the lack of normative data and difficulties interpreting HF tympanograms (Margolis et al., 2003; Baldwin, 2006; Baldwin et al., 2008; Cai, 2010; Marchant et al., 1986; Sutton et al., 1996). There is no universal agreement on the interpretation of HFT data (Kei & Mazlan, 2012). As a result there are limited clinical protocols available for HFT; hence careful interpretation of results is required in combination with other audiological results (ASHA, 2004; Kei & Mazlan, 2012).

Newborn Hearing Screening

High risk population and high risk factors of hearing loss.

The universal detection of infant HL requires universal screening of all infants (Task Force on Newborn and Infant Hearing, 1999). Screening involves two approaches, namely to identify neonates and infants who have significant sensori-neural hearing loss (SNHL), CHL and, neural HL at birth, and to identify neonates and infants who are at risk of delayed onset or progressive HL (Stach, 2010a). The challenge with any screening is to identify all individuals who are at risk and, with similar accuracy, those who are not at risk (Stach, 2010a).

The use of the high risk registry in isolation (e.g. family history of deafness) is only able to identify 50% of neonates and with congenital HL during NHS (Task Force on Newborn and Infant Hearing, 1999). Literature has found that neonates and infants presenting with mild to

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moderate HL are easily missed and may only be identified in the second year of life (Zamani, Daneshjou, Ameni & Takand, 2004). It has further been found that half of the neonatal population present with risk factors. It is therefore important that all neonates and infants obtain a hearing screening after birth or at least within the first three months of life. In several countries universal screening is not possible and therefore all those with high risk factors for HL should be screened (Zamani et al., 2004).

In South Africa there are financial and social constraints which impede the successful implementation of UNHS. These constraints need to be addressed in order to ensure that the goals of a UNHS programme are achieved (South African Speech-Language- Hearing Association [SASLHA], 2011). One alternative is to perform targeted neonatal hearing screening (TNHS) (SASHLA, 2011). TNHS is where high risk groups in the neonatal population are targeted (Kriek, 2006). This group includes neonates in intensive care units (ICUs) and other high care facilities. TNHS is more affordable than UNHS and hence it is more likely that the program will be successful in this country (SASLHA, 2011). There are a number of high risk factors and risk indicators associated with permanent congenital, delayed-onset, or progressive HL in childhood (JCIH, 2007). These include:

- Caregiver concerns with regard to speech, language and hearing developmental delay.
- Family history of permanent childhood HL.
- Neonatal intensive care (NICU) for more than 5 days.
- Extracorporeal membrane oxygenation (ECMO).
- Assisted ventilation.
- Ototoxic medication or loop diuretics.

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- Hyperbilirubinemia that requires transfusion: Premature infants and infants with low birth weight are at greater risk for high bilirubin levels.
- Known physical findings associated with a syndrome e.g. white forelock.
- In utero infections e.g. cytomegalovirus (CMV), herpes, rubella, syphilis, and toxoplasmosis.
- Craniofacial anomalies e.g. cleft palate
- Syndromes associated with HL or late-onset HL e.g. Waardenburg syndrome
- Neurodegenerative disorders e.g. Frederich ataxia
- Culture-positive postnatal infections associated with HL e.g. bacterial and viral meningitis.
- Head trauma e.g. basal skull or temporal bone fracture which requires hospitalization.
- Chemotherapy.

The most frequently occurring risk factors are ototoxic medications (>70%); severe birth asphyxia (>50%); mechanical ventilation less than 5 days (>25%); low birth weight (LBW) (>20%); parental/physician concerns (>15%); and ECMO (>10%) (Cone-Wesson, et al., 2000; Hall, 2007). The HPCSA Position Statement on EHDI (2007) states that infants who also present with a unilateral refer result on screening tests are at risk of a late-onset or progressive bilateral HL.

In South Africa, two additional contextual risk factors that may result in an acquired, late-onset or progressive HL have been included, namely maternal human immunodeficiency syndrome (HIV) and malaria (HPCSA, 2007). Infants born of HIV or acquired immunodeficiency syndrome (AIDS) infected mothers are at high risk of HL due to their very low birth weights and increased susceptibility in acquiring meningitis, viral encephalitis and

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CMV. In the case of malaria, the disease is prevalent in many areas of South Africa and the medication used in the treatment of malaria is ototoxic (HPCSA, 2007).

Hearing Screening Tests Used in Newborn Hearing Screening

Early detection of HL is essential for the provision of the correct support for hearing impaired neonates and infants to facilitate equal opportunities in society (WHO, 2010). EHDI services are essential for the identification of neonates or infants with a HL before one month of age; to obtain audiological diagnostic evaluations by three months of age, and to commence intervention, which includes hearing amplification and language intervention before six months of age (Morton & Nance, 2006; WHO 2010).

The most common cause of referral on NHS is CHL, the majority of which is secondary to OM (Boone, Bower, & Martin, 2005; Doyle, Burggraff, Fujikawa, & Macarthur, 1997). Hence the recommendation by HPCSA (2007) and ASHA (1997) for the inclusion of HFT in NHS protocol in order to assist in more accurate identification of OM in neonates and infants (HPCSA, 2007; Johnson & Seaton, 2012). Current procedures used to identify neonates and infants with HL stipulate that objective physiologic measures should be utilised, namely OAEs and AABR (HPCSA, 2007; JCIH, 2007). Both these measures are easy to perform, non-invasive and record the “physiologic activity underlying normal auditory functions” (JCIH, 2007, p. 903). However, there are distinct differences between these two measures.

OAEs are low intensity sounds produced within the inner ear (Coenraad, 2011). These sounds are responses of the cochlea that are recorded by a sensitive microphone which is securely fitted in the ear canal (Kemp, 2002; Coenraad, 2011). The cochlear responses are caused by the auditory stimulation which results in the motion of the sensory outer hair cells (Kemp, 2002). OAE measurements provide information on the condition of the peripheral

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auditory system, which includes the outer ear, middle ear and cochlea; it is frequently used to screen hearing in neonates and infants and can partially estimate hearing sensitivity within a limited range (Kemp, 2002, JCIH, 2007; Coenraad, 2011). OAE screening procedures alone are not capable of detecting mild HLs or isolated frequency region losses (JCIH, 2007). Therefore sensitivity and specificity of this screening test need to be considered for NHS as it may be affected by screening protocols, population being screened as well as other test variables (Coates & Gifkins, 2003).

There are four types of OAE measurements, namely; spontaneous otoacoustic emissions (SOAEs), TEOAEs, DPOAEs and sustained-frequency otoacoustic emissions (SFOAEs) (Campbell, 2012). All types of OAE present with a high degree of sensitivity to changes in the cochlea (Kemp, 2002). The estimated sensitivity for OAEs has shown to range from 80% to 98% (Coates & Gifkins, 2003).

DPOAEs and TEOAEs have both been used for NHS (Campbell, 2012). In clinical practice, TEOAEs have been used mainly for NHS. TEOAEs have been clinically used for a longer period and have shown better validation when associated with behavioral audiometric thresholds (Campbell, 2012). TEOAEs are stimulated by transient clicks or tone bursts which are of short and faster duration and therefore have limited frequency specificity (Campbell, 2012). TEOAEs are also more tolerant to noise and movement than DPOAEs (Cunningham, 2011). The presence of TEOAEs suggests that hearing sensitivity should be 30dB HL or better (Kemp, 2002; Campbell, 2012). DPOAEs have been used at a low stimulus level (e.g. 65/55 dB SPL) as a screening procedure. It allows for greater frequency specific information to be recorded as it allows higher frequencies than TEOAEs to be tested (Kemp, 2002; Campbell, 2012). DPOAEs can also obtain responses from individuals with mild to moderate HL for which

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TEOAEs are absent. It further presents with better reliability with audiometric thresholds (Kemp, 2002 & Campbell, 2012).

OAE screening performed on neonates and infants can be challenging as it may not be possible to obtain results in the LF range (< 1000Hz) (American Academy of Audiology [AAA], 2011). High ambient noise levels have been reported in hospital settings and have been found to affect the low frequencies (250Hz and 500Hz) (Olusanya, Wirz & Luxon, 2008a; Olusanya, Wirz & Luxon, 2008b). Noise levels have also been reported to affect 1000 Hz (Gorga et al, 2000). More reliable OAE results have shown to be obtained at 2000, 3000 and 4000 Hz (Gorga et al, 2000). However, there has been no appropriate pass or refer criteria for the HF range (>1000Hz) (AAA, 2011). Another limitation is the fact that OAEs are unable to detect any neural dysfunction such as eighth nerve or auditory brainstem disorders (JCIH, 2007; Coenraad, 2011).

In contrast, AABR measurements provide information on the peripheral auditory system, the eighth nerve and the brainstem auditory pathway (JCIH, 2007). It can therefore detect conditions such as auditory neuropathy in the paediatric population who are hard of hearing but present with normal OAEs (Coates & Gifkins, 2003).

It is important to note that both these physiologic screening test are not a true test of hearing sensitivity. The results of both these screening tests can be affected by outer or middle ear dysfunction (JCIH, 2007; Harlor & Bower, 2009). OAEs will be absent in the presence of ear canal debris, MEE, otosclerosis or ossicular discontinuity (Kemp, 2002). This results in the neonates or infants failing the hearing screening in the presence of normal cochlear and/or neural function (JCIH, 2007). OAEs are therefore very sensitive to middle ear conductive components.

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Hence, AABR is the preferred measure in NHS as it can be recorded in the first few hours of life when OAEs cannot be obtained (Kemp, 2002).

It is also important to correlate the results of other audiological screening tests with tympanometric results in order to better determine the hearing condition in neonates and infants (Carmo, de Oliveira Costa & Momensohn-Santos, 2013). HFT is also found to be in agreement with otoscopy and OAEs (Koivunen, Uhari, Laitakari, Alho & Luotonen, 2000; Swanepoel, Hugo & Louw, 2006; Garcia et al., 2009; Kilic et al., 2012; Camboim et al., 2012). HFT presents with a correlation with OAEs in both the evaluation of normal ears and ears with middle ear pathologies (Camboim et al., 2012). In comparison to LFT, this LF probe tone is found not to be in agreement with OAEs and otoscopy (Garica et al., 2009; Kilic et al., 2012). LFT presents with results more consistent with OAEs in the presence of a normal middle ear (Camboim et al., 2012).

However, immittance screening is reported to be less accurate in identifying the absence of a middle ear pathology resulting in an increased percentage of false-positive rates (Bluestone & Klein, 2007; Swanepoel et al., 2007). Significant efforts have been made to reduce the number of false positive results by producing comprehensive screening protocols. However, there is still no definitive data supporting the validity of immittance measurements for screening (Keefe, Zhao, Neely, Gorga & Vohr, 2003; Bluestone & Klein, 2007). This leads to over referral rates, increased expenses, reduced programme efficacy, and increased anxiety for parents (Thornton, Kimm, Kennedy & Cafarelli-Dees, 1993; Mencher & DeVoe, 2001; Bluestone & Klein, 2007).

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Despite this, it is commonly agreed among researchers that immittance screening is easy to perform, non-invasive and reliable (Bluestone & Klein, 2007). These factors would favor the use of immittance screening to identify middle ear pathologies (Bluestone & Klein, 2007). Normative values and objective pass or fail criteria are useful for both the neonatal or infant and adult population; however differences between the various criteria exist, as well as doubt with regard to feasibility of norms used with different age groups (Baldwin, 2006). Therefore no specific pass or fail criteria has yet been established and additional assessments are required to be performed in the neonatal and infant population to confirm middle ear pathology (Baldwin, 2006). Problems have also been highlighted with the use of these objective data (Baldwin et al., 2008; Wilson, 2008). Problems may include test parameters, non-standardized compensated versus uncompensated tympanograms as well as a lack of clarity on how development influences the need for age specific norms based on chronological age in weeks or months (Wilson, 2008).

Unfortunately the difficulties in establishing a “gold standard” to determine the presence of middle ear fluid in neonates and infants have been an unclear factor in developing tympanometry (Baldwin, 2006, p. 418). The use of tympanometry can be validated by determining a link between the results of other reference tests of auditory function (Baldwin, 2006). Therefore the current study aims to determine the use of HFT by South African audiologists in clinical practice as well as the pass and refer rates of HFT in comparison to other screening test used in the identification of possible middle ear pathology.

Chapter Three

Methodology

This chapter describes the aims of the study; research design utilised and elaborates on the research phases. The pilot study results, description of the main study, data collection and analysis procedures, as well as reliability and validity are explained.

Research Aims

Main aim 1. To describe the use of HFT in current paediatric audiological clinical practice in South Africa.

Sub-aims.

- To determine the availability of HFT equipment for screening and diagnostic paediatric audiological assessments.
- To determine the current clinical practice of HFT in paediatric audiological assessments.
- To determine audiologists' knowledge of the clinical application of HFT and theoretical background of the infant's middle ear system.

Main aim 2. To determine the pass and refer rates of screening tests (e.g. HFT, LFT, otoscopy and DPOAEs) used in the identification of possible middle ear pathology in neonates or infants.

Main aim 3. To determine the agreement of the pass and refer rates between HFT and other screening tests (LFT, otoscopy, DPOAEs) used in the identification of possible middle ear pathology in neonates or infants.

Research Design

A quantitative research approach was employed for the purpose of this study. A non-experimental, descriptive, cross-sectional survey design was used to describe the use of HFT in

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clinical practice in South Africa, whilst a correlation research design was used to determine the agreement of the pass and refer rates between HFT and other screening tests used in the identification of possible middle ear pathology in neonates or infants.

Non-experimental research involves the systematic collection of data and does not require control groups, randomization of subjects or statistical controls (Terry, 2012).

Descriptive research allows for the description of variables being studied as they exist naturally and is important in its own right as a source of essential knowledge (Gravetter & Foranzo, 2012). It is a useful approach to identify patterns and relationships in the data, and there is no manipulation of variables (Hauser, 2012).

A cross-sectional survey design is a procedure where the researcher administers a survey to a sample or the entire population of individuals to describe the attitudes, opinions, behaviours or characteristic of the population at a specific point in time (Creswell, 2012). It provides information in a short amount of time and for a large number of participants to be accessed (Terry, 2012; Cottrell & McKenzie, 2011). This method of collection also provides a description of the individual's responses to questions, information about a wide variety of different variables and is fairly easily administered (Gravetter & Foranzo, 2012). Although this type of method presents with disadvantages (e.g. limited in inferring causation and is unable to establish directionality), trends can be established (Salazar, Crosby & Diclemente, 2006).

A correlation research design is a procedure where the researcher "measures the degree of association (or relation) between two or more variables with the use of statistical procedure of correlational analysis" (Bauer & Brazer, 2012, p. 217). The limitation of this research design is its susceptibility to faulty interpretation as the researcher works with groups or variables that have been self-selected (selection bias) (Polit & Beck, 2009, p. 161). This limitation was

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addressed by determining the inter-rater reliability of the tympanometry results. In addition the researcher discussed the screening results with the research assistants prior to interpreting the results and providing feedback to parents or caregivers of the neonate and infant participants. It furthermore does not demonstrate causation among the measured groups or variables (Stangor, 2011). This has been acknowledged as a limitation of the current study. Despite this, this research design provided the researcher with opportunity to describe the pass and refer rate agreement between screening tests used in the identification of possible middle ear pathology in neonates or infants.

Research Phases

This research process comprised three phases, namely the developmental phase, pilot study phase and main study phase. These phases are described in Table 3.1.

Table 3.1

Research Phases

Research Phases	Objectives
Developmental phase	To develop measuring instruments to be used in the study. To identify and select appropriate audiological equipment to be used in the study.
Pilot study phase	To validate and finalise the measuring instruments, data collection procedures, site and equipment needs.
Main study phase	Phase 1 survey questionnaire: <ul style="list-style-type: none"> • Distribution of questionnaires. • Data analysis. Phase 2 hearing screening: <ul style="list-style-type: none"> • Selection of site and participants. • Application of all measuring instruments. • Data analysis.

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Pilot Studies

A pilot study is conducted prior to the main study and follows the design of the main study as closely as possible in order to ensure that the research is feasible (Taylor & Roberts, 2006; Offredy & Vickers, 2010). The pilot study improves the success, effectiveness of the research study and validity of the data collection tool (Liamputtong & Ezzy, 2007). Two pilot studies were conducted at the Dr. George Mukhari Academic Hospital, a tertiary hospital in Ga-Rankuwa.

Pilot study 1: Survey questionnaire.

Objectives. The objectives of this pilot study were:

- To determine the clarity of the questions.
- To determine the ease of completion.
- To determine that time required for completion of the questionnaire.
- To determine the ease of accessing, sending and receiving the survey questionnaires via the Survey Monkey website (Survey Monkey, n.d.).

Participants. Convenience sampling was used to select pilot study participants. Six participants that met the same inclusion criteria as for the main study were included in the pilot study. These participants were dually qualified as speech therapists and audiologists. All the participants were female and worked at government hospitals in the Gauteng Province. They all currently practiced as paediatric audiologists and had an average of four years' experience in this field. These participants were not included in the main study.

Procedures. All participants were informed of the nature of the study and written informed consent was obtained prior to inclusion in the study (Appendix A). The survey questionnaire was either distributed via Survey Monkey or as hard copies. Two participants

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completed the survey via the Survey Monkey website. On the e-mail cover letter, audiologists were informed that consent to participate in this study was assumed by completing and returning the survey questionnaire (Appendix B). Four audiologists completed hard copies of the survey questionnaires.

Results and recommendations. The objectives, results and recommendations from the first pilot study are presented in Table 3.2.

Table 3.2

Survey Questionnaire: Objectives, Measuring Instruments, Results and Modifications

Objectives	Measure	Results	Modifications
To determine the clarity of the questions	Survey questionnaire (Appendix C)	There were 12 questions that appeared to be similar and difficult to understand. Headings for each section required to be more clearly stated.	Similar questions were grouped together as well as stated more clearly for better understanding. More options were provided where necessary in order to obtain more specific and reliable responses. It was also made clear that HFT referred to the use of 1000Hz probe tone only.
To determine the ease and time taken in completing the questionnaire	Participants timed themselves and provided feedback to the researcher.	It took approximately 25 minutes to complete.	The anticipated time for completion was included in the information leaflet.
To determine the ease of sending questionnaires as well as receiving and accessing survey data via the Survey Monkey website.	The researcher performed a trial in using the Survey Monkey website. Feedback was obtained from participants who received the questionnaire via email.	A few spelling errors were noted. A number of ‘missing responses’ was also noted on the questionnaires. The researcher found the Survey Monkey website very user friendly with a good support service provided. It was easy to design the survey questionnaire as well as send and receive the questionnaires via the website. Participants reported they received the questionnaire easily through e-mail; there was no difficulty in accessing, completing and returning the questionnaire.	All spelling errors were corrected. Every question was made mandatory in order to decrease the number of missing responses. Therefore, more options were provided to the applicable and not applicable questions.

Pilot study 2: Hearing screening.

Objectives. The objectives of this pilot study were:

- To determine the ease of utilising the hearing screening form.
- To determine the estimated total time required for screening each participant and providing the caregiver with immediate feedback.
- To determine the ease of using the audiological screening equipment.
- To determine the feasibility of the site for data collection.

Participants. Convenience sampling was used to select participants. A total of nine participants who met the same participant selection criteria as for the main study were included in this pilot study. Pilot study participants were not included in the main study. These participants were either in- or out patients from Dr. George Mukhari Academic Hospital and were recruited from the paediatric outpatient department (POPD), paediatric wards and the Speech Therapy and Audiology Department. A demographic profile of the participants screened is presented in Table 3.3.

Table 3.3

Demographic Profile of Participants for Pilot Study 2

Demographic Information	Gender	Mean	Range	SD
Gender	7 Males 2 Females			
Birth weight (grams)		2605.56	1250-3990	912.17
Current age (in days)		46.38	28-112	44.55
Gestational age (in weeks)		38.25	32-40	2.65

Procedure. Permission was obtained from the Chief Executive Officer (CEO) prior to conducting the pilot study (Appendix D). Hearing screening was performed in the paediatric in-patient wards and two outpatient departments (OPDs) at the Dr. George Mukhari Academic

Hospital. Informed consent was obtained from all the parents and/or caregivers prior to the testing (Appendix E).

Results and recommendations.

The objectives, results and recommendations from the pilot study are presented in Table 3.4.

Table 3.4

Hearing Screening: Objectives, Measuring Instruments, Results and Modifications

Objectives	Measuring Instruments	Rationale	Results	Modifications
To determine the ease of utilizing the hearing screening checklist.	Hearing screening form (Appendix F)	A hearing screening form was required for documentation of case history, results obtained from the hearing screening and recommendations.	The hearing screening form was easy to complete. It was noted that more specific results were required to be recorded for otoscopic and DPOAE results. Minor grammatical and alignment errors were also evident on the form.	Modification to the hearing screening form was made based on the results of the pilot study. Numerous options were also provided for possible otoscopic results as well as various frequencies tested for DPOAEs. All grammar and alignment errors were also corrected.
To determine the ease of using the audiological screening equipment.	Various types of equipment was included: <ul style="list-style-type: none"> • Titan Suite (combination of a tympanometer, DPOAE & AABR). • GSI 39 Auto Tympanometer. • Madsen AccuScreen Handheld OAE screener. 	Important to determine the suitability of equipment for data collection such as the ease of use, availability and portability of equipment.	The Titan Suite was not found to be feasible for the purpose of this study. The reasons for this included: <ul style="list-style-type: none"> • High sensitivity to movement and noise. • Increased testing time. 	For the main study the following equipment were selected: <ul style="list-style-type: none"> • Standard otoscope. • Portable GSI 39 Auto Tympanometer. • Madsen AccuScreen handheld OAE Screener. It was also recommended to make use of the Maico MB11 to conduct AABR testing (due to time and cost effectiveness). However, the AABR measurement was excluded from the main study as this piece of equipment was not readily available for the time period required

Objectives	Measuring Instruments	Rationale	Results	Modifications
To determine the feasibility of the site for data collection.	Sites explored: <ul style="list-style-type: none"> • Dr George Mukhari Academic Hospital. • Rahima Moosa Mother and Child Hospital. • Children’s Homes. 	Access to potential research participants and suitability of sites such as noise levels and space had to be determined.	The most challenges to data collection were identified at the Dr George Mukhari Academic Hospital. The challenges included: <ul style="list-style-type: none"> • High noise levels. • Limited space. 	The most suitable sites for data collection were Rahima Moosa Mother and Child Hospital and two Children’s homes in Gauteng.
To determine the estimated total screening time	Timer	Important for planning for data collection.	Screening time with the Titan Suite ranged between 30 and 45 minutes and excluded caregiver feedback. High noise levels and equipment challenges contributed to the time required for screening. Other equipment used decreased the screening time	By implementing all recommendations, screening time per participant decreased resulting in the increase of the number of participants seen per day.

Main Study

This section provides a description of the participants, sample size, participant selection criteria as well as the measures and equipment used in both phases of the main study. This is followed by a description of the sites, various data collection procedures and ethical considerations.

Main study phase 1: Survey questionnaire.

Sampling strategy. A non-probability, convenience sampling strategy was used for this phase of the main study. Non-probability sampling allows the researcher to select available individuals that represent the characteristics the researcher seeks to study (Chatburn, 2011; Creswell, 2012). It is suitable to generalize findings to the population of South African audiologists (Creswell, 2012). It is also an easy, inexpensive and less time consuming technique (Jackson, 2012).

Sample size. The study included a total of 113 questionnaires. Contact details of potential participants were obtained from the two professional associations in South Africa, namely South African Association for Audiologists (SAAA) and South African Speech-Language Hearing Association (SASLHA) (SAAA, personal communication, February 2, 2013; SASLHA, personal communication, February 8, 2013). Questionnaires were distributed via Survey Monkey to the e-mail addresses obtained or as hard copies at the Provincial Forums attended by audiologists employed in the government sector. The total sample size has been described in Table 3.5.

Table 3.5

Description of the Total Sample Size of Survey Questionnaires ($N_1 = 113$)

Number of Questionnaires Distributed	Number				Number Included in Study	
	Method	Received	Incomplete	Complete		Did not meet inclusion criteria
Survey Monkey	1238	230	57	119	54	98
Hard copies	60	19*	4	15	0	15
Total	1298	249	61	134	54	113

* *Low return rate as many audiologists reported to have completed the survey online*

The response rate has been calculated as it provides guidance with regard to the representativeness of the sample respondents (Rubin & Babbie, 2013). The response rate was 19.1%, which according to Rubin and Babbie (2013) is poor. However, response rate guidelines have no statistical basis and there have been few agreements as to what represents an acceptable response rate (Rubin & Babbie, 2013). A “demonstrated lack of response bias” is much more important than a high response rate and therefore surveys with low response rates can have value (Maxfield & Babbie, 2009, p. 83; Rubin & Babbie, 2013).

It must be acknowledged that although questionnaires were sent to all audiologists registered with SAAA and SASLHA, not all of these individuals met the inclusion criteria. It is therefore assumed that only a small percentage of these audiologists are currently working in the field of paediatric audiology and therefore a relatively good response rate has been obtained.

Participant selection criteria. This section stipulates the inclusion and exclusion criteria used for professionals completing the survey questionnaire (Table 3.6).

Table 3.6

Survey Questionnaire: Participant Selection Criteria

Inclusion Criteria	Exclusion Criteria	Rationale
Qualified audiologists	Audiology mid-level workers or assistants, speech therapists, acousticians, audiometricians, paediatricians, ear-, nose- and throat (ENT) specialists and general practitioners.	Audiologists are professionals who perform acoustic immittance measurements in order to accurately identify a conductive component within the middle ear system (Wilson, 2008; Clark & Benson, 2008). Audiologists are also the most likely population to make use of HFT in their current clinical practice.
Required to be currently practicing and working with the paediatric population.	Audiologists not currently working with the paediatric population	For the purposes of this study, paediatrics is defined as children from birth to six years of age. Hearing screening of young children up to the age of six years should include tympanometry (Cherry & Rubinstein, 2012).

Participant description: Audiologists. The majority of the participants (70%; $n=79$) were dually qualified as Speech Therapists and Audiologists (STAs), whilst the rest of the participants (30%; $n=34$) were qualified as audiologists only. On average, participants were practicing in the field of audiology for 6.9 years (range: 3 months to 34 years; $SD=7.32$) and paediatric audiology for 6.2 years (range: 3 months to 33.3years; $SD=7.06$). Most participants (92%; $n=104$) worked with both paediatrics and adults, whilst the rest (8%; $n=9$) only worked with paediatrics. The most common population age range reported by participants was birth to geriatrics (76%; $n=86$) and 12 months to geriatrics (12%; $n=14$).

The majority of participants reside in Gauteng (59%; $n=67$), followed by Kwa-Zulu Natal (12%; $n=13$), the Western Cape (9%; $n=10$) and the rest of South Africa (20%; $n=23$). It is

evident that participants are representative of the provinces where the majority of the participants were found to be registered with the HPCSA (HPCSA, personal communication, May 2, 2013).

Measures. The measure was self-developed by examining current evidence-based practice and research (Appendix C). Questions were designed to probe main aim one and its related sub-aims. The questionnaires were developed to obtain context-specific information as no other measures exploring the South African context were available. The questionnaire included both open- and close ended questions. Open-ended questions allowed participants to generate responses within their experiences (Creswell, 2012). Close-ended questions provided a “greater uniformity” and are more easily processed than open ended questions (Babbie, 2010, p. 256). The questionnaire included a total of 30 questions, in five sections. Details regarding the content of the questionnaire are presented in Table 3.7.

Table 3.7

Description of Self-developed Questionnaire

Section	Type of Questions	Information Obtained	Rationale
Biographical information	Closed and open ended	Participant workplace (public vs. private) Qualification Current role Clinical experience	Clinical practice, training and work experience may affect a participant's confidence in performing and interpreting HFT to reliably detect middle ear pathologies (Burkey, Lippy, Schuring & Rizer, 1999; Lantz et al., 2004).
Equipment	Closed and open ended	The availability and inclusion of tympanometry in paediatric audiological test battery. Types of tympanometry tests used. The availability, inclusion and use of HFT equipment. Population and age-group for which HFT is used.	Acoustic immittance measures are one of the most important current clinical methods for evaluating the middle ear system in neonates and infants (Kent, 2004). HFT and LFT are routinely used in clinical practice (Harris et al., 2005). There is however a lot of controversy for which population age group LFT and HFT should be utilised (Alaerts et al., 2007; Baldwin, 2006; Baldwin et al., 2008; Garcia et al., 2009; Lantz et al., 2004; Mazlan et al., 2009; Wilson, 2008).
Current clinical practice	Closed and open ended	Availability of clinical protocols/guidelines. Interpretation and classification of HFT. Challenges faced. Practical aspects.	Paediatric audiologists must have the appropriate protocols for screening neonates and infants (Ditty, 2012). The interpretation and classification of HFT is controversial in the neonatal and infant population and has been found to be clinically challenging for clinicians (Baldwin, 2006; Baldwin et al., 2008; Cai, 2010).
Knowledge	Closed and open ended	Purpose and clinical application of immittance measures. Anatomical and acoustical differences. Maturational changes.	"Audiologists must have the appropriate knowledge and skill necessary for the use of current paediatric hearing evaluation methods and procedures" (Lewis, 2000, p. 173).

Main study phase 2: Hearing screening.

Sampling strategy. A non-probability, convenience sampling strategy was used for this phase of the main study. Permission was obtained from all sites to conduct the research (Appendices G– I). Written informed consent was obtained from parents or care givers prior to testing (Appendix E).

Description of sites. Hearing screening was performed at three sites (Table 3.8). These sites were specifically chosen as potential participants were readily available within the specific data collection time-frame.

Table 3.8

Description of Sites

Site	Description
Rahima Moosa Mother and Child Hospital	This is a secondary level hospital located in Coronationville (Johannesburg). More than 10 000 births occur annually at this hospital, therefore there are a very busy, neonatal, premature and Kangaroo Mother Care (KMC) unit. The neonatal unit admits approximately 2 000 babies each year. Hundred and thirty eight neonates and infants met the participant inclusion criteria and were include in the study. These participants were recruited from the medical wards, KMC unit, Audiology OPD and neonatal follow-up clinic.
Doors of Hope Children's Mission	This organisation has three baby homes; two situated in Glenvista and one in Berea. They provide a temporary Christian home for all babies and children who are abandoned, abused and orphaned. At this site it is the standard operating procedures that all newly admitted neonates and infants undergo hearing screening. Eleven neonates and infants at the Glenvista baby home met the participant inclusion criteria and were include in the study.
Mother Teresa	Mother Teresa is situated in Yeoville (Johannesburg) and provides care for abandoned children. Four neonates and infants at Mother Teresa that met the inclusion criteria were included in the study.

Participant selection criteria. The participant inclusion and exclusion criteria are presented in Table 3.9.

Table 3.9

Hearing Screening Participant Selection Criteria

Inclusion Criteria	Exclusion Criteria	Rationale
Neonates or infants from (birth to six months chronological age) with or without any high risk factors for HL.	Infants older than six months of age.	This age range is selected according to the age ranges stated in the literature for which HFT should be used for (Alaerts et al., 2007; Baldwin, 2006; Baldwin et al., 2008; Wilson, 2008). HFT is also useful in identifying middle ear pathologies in neonates and infants with risk factors for HL(e.g. prematurity) (Kilic et al.,2012; Do Carmo et al., 2012; Garcia et al.,2009; Hoffman et al., 2013).

Sample size. The hearing screening was performed on 153 paediatric participants and 303 ears (N_2). For three of the participants only unilateral testing could be conducted due to participants being restless during the screening. It is important to note that not all screening tests were performed on all participants due to challenges experienced with the equipment (Table 3.10)

Table 3.10

Number of Ears Screened (N₂=303)

Number of Hearing Screening Tests Performed	Hearing Screening Tests	Ear	Number of Ears
4	Otoscopy	Right	79
		Left	79
	226Hz probe tone	Right	79
		Left	79
	1000Hz probe tone	Right	79
		Left	79
	DPOAEs	Right	30
		Left	38
3	Otoscopy	Right	73
		Left	73
	226Hz probe tone	Right	72
		Left	73
	1000Hz probe tone	Right	72
		Left	73

Participant description. The majority of participants included were male ($n=79$; 52%). Birth history information (e.g. birth weight, GA and high risk factors) could only be obtained from 141 participants as caregivers were unable to provide the information. At the Mother Teresa children's home information of the participants birth weight and GA were not available. The least neonates or infants were screened at Mother Teresa children's home. This was due to the neonates or infants being very restless, hence reliable results could not be obtained and were excluded from the main study. The demographic profile of participants screened at each sites is presented in Table 3.11.

Table 3.11

Demographic Profile of Participants at each Site

Site	Participants <i>N</i>	Gender		Birth Weight (in grams)			GA(in weeks)			Chronological Age (in days)		
		M	F	Mean	Range	<i>SD</i>	Mean	Range	<i>SD</i>	Mean	Range	<i>SD</i>
Rahima Moosa Mother and Child Hospital	138	71	67	2634.88	860-5300	899.95	37.36	25-42	3.99	47.86	2-180	53.47
Mother Teresa Doors of Hope Children's Mission	4	3	1	-	-	-	-	-	-	142.5	120-180	28.72
Total	153	79	74	2635.49	860-5300	891.67	37.26	25-42	4.03	53.17	2 - 180	55.56

The majority of participants tested ($n=103$; 67%) presented with high risk factors for HL. The various risk factors found at each site is presented in Table 3.12. At Mother Teresa children's home no information was available as to whether the participants presented with any high risk factors for HL.

Table 3.12

High Risk Factors for HL Present in Participants at each Site (n = 103)

Site	High Risk Factors	N	%	
Rahima Moosa Mother and Child Hospital ($n=98$)	NICU	29	30	
	Neonatal jaundice	33	34	
	Prematurity	56	57	
	Meningitis	1	1	
	Birth asphyxia	2	2	
	Maternal HIV	15	15	
	Caregiver concerns	3	3	
	Cranio-facial anomalies	2	2	
	Mechanical ventilation	32	33	
	Ototoxic medication	4	4	
	Syphilis	1	1	
	Low birth weight	24	24	
	Hyperbilirubinemia	1	1	
	Doors of Hope Children's Mission ($n=5$)	Prematurity	4	80
		Maternal HIV	3	60
Ototoxic medication		3	60	
Low birth weight		1	20	

Measures and equipment. This section describes the hearing screening form, hearing screening test protocol and audiological equipment used.

Hearing screening form. The researcher developed a hearing screening form to record all relevant data as per the aim of this study (Appendix F). This form included four sections, namely the demographic information of the neonates and infants, high risk factors for HL, audiological screening test results and recommendations (Nicholas & Martin, 2012). More detail is provided in Table 3.13.

Table 3.13

Description of Hearing Screening Form

Sections	Information Obtained	Rationale
Demographic information	Gender Birth weight Current weight Gestational age`	Infants who are premature present with a number of risk factors that is usually associated with birth weight (Littleton & Engebretson, 2009). LBW (< 2500 g) and small gestational age (SGA) are factors linked to prematurity and places the neonate or infant at risk of HI (Littleton & Engebretson, 2009).
High risk factors	Provides information if whether or not the neonate and infant is at risk for HL.	The high risk factors included on the screening form assist the audiologists in identifying neonates and infants who may be at risk for various types of HL and auditory neuropathy (JCIH, 2007; HPCSA, 2007).
Audiological screening tests: <ul style="list-style-type: none"> • Otoscopy • DPOAEs • HFT and LFT 	Results obtained from these tests provide an indication if patients may be at risk of the following: <ul style="list-style-type: none"> • Middle ear pathologies. • CHL. • SNHL (cochlear involvement). • Auditory neuropathy. Reliability: Correlation of results.	These screening tests are found to be sensitive to middle ear pathologies resulting in neonates and infants failing the NHS. HFT has therefore also been recommended as a critical addition to NHS due to its reliable means of assessing a neonate’s or infant’s middle ear system (Nicholas & Martin, 2012; Baldwin, 2006). HFT has also shown to present the most significant correlation with OAEs and otoscopy (Garcia et al., 2009).
Recommendations	Parents/caregivers may require the following depending on the NHS results: <ul style="list-style-type: none"> • Rescreening. • Further diagnostic audiological evaluation. • Possible referrals to be made to other professionals (e.g. otolaryngologists, speech therapists). • Follow up appointments. 	Neonates and infants, who fail the NHS according to the hospital protocol, are required to be referred for a rescreening or for a further audiological diagnostic testing and/or referred to other professionals if required (Nicholas & Martin, 2012).

Hearing screening test protocol. Protocols establish a level of efficiency and offer clinical guidance in providing care and assist the clinician in evaluating data quickly (Clark & Benson, 2008). A protocol was specifically developed for the purposes of this study (Table 3.14).

Table 3.14

Hearing Screening Test Protocol

Screening Tests	Measuring Instruments/Equipment	Rationale	Testing Conditions	Frequencies Tested
Informed consent Case history	Informed consent form (Appendix E) Hearing screening form (Appendix F)	Case history is the essential starting point of any audiologic evaluation. It provides relevant information with regard to the nature of the auditory problem; reflects on the possible contributory factors of the hearing disorder and allows the audiologist to determine the clinical testing strategies (Stach, 2010a).	Caregiver or parent to be present to obtain case history.	N/A
Otoscopic examination	Otoscope Speculae Disinfectant	Otoscopic examination of the ear canal, TM and middle ear is the foundation for the identification and treatment of otologic diseases (Postic, 2000).	Calm or sleeping neonate or infant. Ensure correct positioning of neonate or infant.	N/A
Tympanometry testing	Portable GSI 39 Auto Tympanometer	Tympanometry is an objective measure that determines the mobility of the TM, air pressure of the middle ear and volume of the ear canal (Cherry & Rubinstein, 2012). Middle ear disorders which are frequently occurring in neonates and infants can be detected by simple analysis of the results obtained from tympanometry (Maico Diagnostics, 2010).	Calm or sleeping neonate or infant.	LFT (226 Hz) HFT (1000Hz)

Screening Tests	Measuring Instruments/Equipment	Rationale	Testing Conditions	Frequencies Tested
DPOAEs	Madsen AccuScreen handheld OAE Screener	OAEs offer an “efficient, non-invasive objective indicator” of appropriate cochlear functioning (Kemp, 2002, p. 223). It is also an important measure used for differential diagnosis, monitoring of treatment and assists in the selection of hearing aids and surgical options (Kemp, 2002). DPOAEs allow greater frequency specificity and permits higher frequencies to be recorder. It can also obtain responses for individuals with mild to moderate HL (Kemp, 2002; Campbell, 2012).	Quiet environment and sleeping neonate or infant.	The following frequencies were tested: <ul style="list-style-type: none"> • 1000 Hz • 2000 Hz • 3000Hz • 4000Hz • 5000Hz • 6000Hz
Parent and caregiver feedback	Graphic representation of the ear	It is important for every parent or caregiver to know what the hearing screening results mean and what the next step should be. It is also a good opportunity to assist parents or caregivers in understanding the importance of monitoring language development and hearing (White, 2008).		
Infection control	SASLHA guidelines (2011)	Frequent and thorough hand washing with an antiseptic agent as well as the use of disposable equipment is recommended to reduce the chance of spreading infections. Probe tips and speculae were disinfected with alcohol swabs and/or Milton before use.		

Testing parameters and norms.

Otoscopic examination. Otoscopy is a subjective examination that is performed to examine the ear canal and the TM for malformations, obstructions or any signs of infection that may impede on the neonate or infant's hearing (Easterbrooks & Estes, 2007). When performing an otoscopic examination, a small ear speculum is utilised and the pinnae is gently pulled downwards in order to straighten the horizontal ear canals of the neonate or infant to obtain a clear view of the ear canal and TM (Cavaliere & Sansoucie, 2013; Hockenberry, 2012).

Several options were stipulated on the hearing screening form (Appendix F).

Otoscopically, a normal TM appears pale, gray, and translucent with visual projections of the malleus, short lateral process and manubrium. Furthermore, a reflective triangular cone of light is visible as well as the pars flaccid and pars tensa (Mangione, 2008). The TM can also be found to be bulging or retracted; therefore the examination of an eardrum should take the vascularity, mobility, integrity as well as position into consideration (Chiocca, 2011). These aspects are essential for the identification of middle ear pathologies and ET dysfunction (White, Duncan & Baumle, 2013). However, it is important to note the presence of cerumen, vernix and other debris as these may partially or completely obstruct the visualization of the TM (Carlson & Carlson, 2003; Chiocca, 2011; Cavaliere & Sansoucie, 2013). Vernix is usually present in the ear canals of neonates and generally disappears by one or two weeks after birth (Whitaker, 2001). It is reported that 70 % of infants of two to six months of age require cerumen removal in order to improve the accuracy in identifying possible middle ear pathologies (Carlson & Carlson, 2003). The criteria and interpretation for otoscopic examination has been presented in Table 3.15.

Table 3.15

Criteria and Interpretation of Otoscope Examination

Otoscope Criteria	Interpretation of Results
Normal TM: Pale, gray, translucent, cone of light, visible projections of the malleus, short lateral process, manubrium, and visible pars flaccida and pars tensa.	Normal
Dull TM	Abnormal
Red TM	Abnormal
Bulging TM	Abnormal
Retracted TM	Abnormal
Infection	Abnormal
Vernix	Abnormal

The findings of the otoscopic examination were correlated with tympanometric results as presented in Table 3.16.

Tympanometry.

LFT (226Hz probe tone). A description, classification and norms utilised to analyse LF tympanograms are presented in Table 3.16.

Table 3.16

Norms and Analysis of LF Tympanograms (Liden, 1969; Jerger, 1970)

Classification: Types of Tympanograms	Description	Norms	Result	Possible Pathologies
A	Presents with a discernible peak, where there is a systematic increase in middle ear compliance due to the decrease in ear canal air pressure from +200 mmH ₂ O to atmospheric pressure 0 mmH ₂ O (Maico Diagnostics, 2010).	ECV: 0.26 to 0.96 (GSI, 2011) daPa: +50 to (-150) (Clark et al., 2007; Maico Diagnostics, 2010) c/z: 0.3 to 1.5 (Maico Diagnostics, 2010)	Normal	No middle ear pathology present (Harlor & Bower, 2009; Maico Diagnostics, 2010; GSI, 2011)
B	Presents with no clear peak over the air pressure range of +200 daPa to -400 daPa. Therefore the tympanograms presents as a flat line (GSI, 2011).	ECV: 0.26 to 0.96 (GSI, 2011) daPa: No pressure (NP) (Clark et al., 2007; Maico Diagnostics, 2010) c/z: NP (Maico diagnostics, 2010)	Abnormal	MEE Occluded cerumen Probe against canal Perforation Otosclerosis Cholesteatoma (Harlor & Bower, 2009; Maico Diagnostics, 2010; GSI, 2011)
C	Presents with a negative pressure peak and may appear as a “rounded maximum point”, instead of a “distinct peak” (Maico Diagnostics, 2010, p. 14).	ECV: 0.26 to 0.96 (GSI, 2011). daPa: exceeding the normal limits (> -150dapa). (Maico Diagnostics, 2010) c/z: 0.3 to 1.5 (Maico Diagnostics, 2010)	Abnormal	ET dysfunction Pre/Post OM Barometric pressure changes (Harlor & Bower, 2009; Maico Diagnostics, 2010; GSI, 2011)

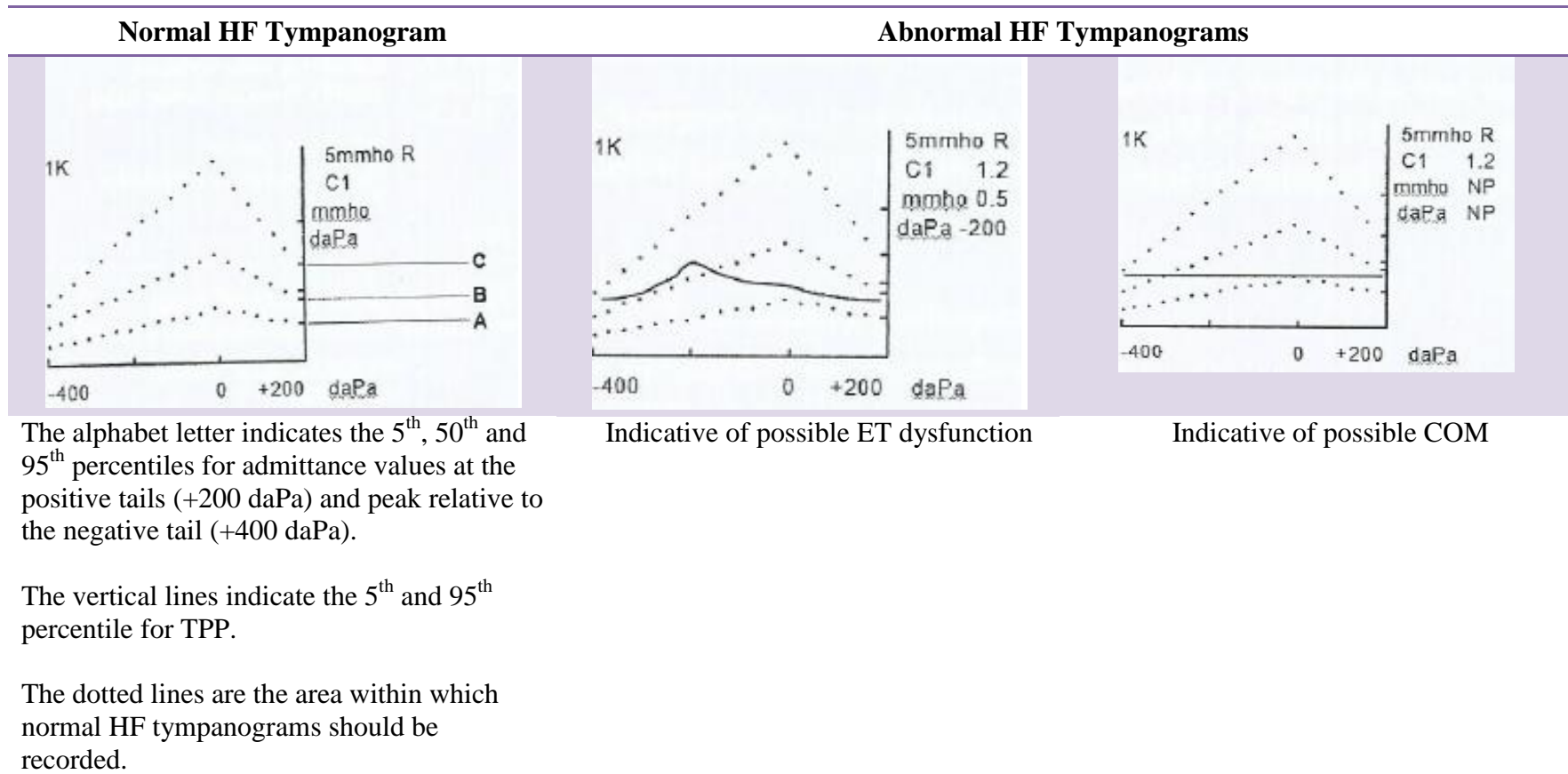
Classification: Types of Tympanograms	Description	Norms	Result	Possible Pathologies
Ad	Presents a high compliant middle ear system (Maico Diagnostics, 2010).	ECV: 0.26 to 0.96 (GSI, 2011) daPa: -50 to (+150) (Maico Diagnostics, 2010) c/z: >1.5 (Maico Diagnostics, 2010)	Abnormal	Ossicular discontinuity (Harlor & Bower, 2009; Maico Diagnostics, 2010; GSI, 2011)
As	This is a “shallow” type of tympanogram. When air pressure in the ear canal is decreased the middle ear compliance simultaneously decreases to a minimum value (Maico Diagnostics, 2010, p. 13).	ECV: 0.26 to 0.96 GSI (2011) daPa: -50 to (+150) (Maico Diagnostics, 2010) c/z: < 0.3 (Maico Diagnostics, 2010)	Abnormal	Stiff middle ear system TM scarring Otosclerosis (Harlor & Bower, 2009; Maico Diagnostics, 2010; GSI, 2011)

HFT (1000Hz probe tone). There are numerous normative data or guidelines available for the interpretation of HFT (Marchant et al., 1986; Sutton et al., 1996; Margolis et al., 2003; Kei et al., 2003; Baldwin, 2006; Swanepoel et al., 2007; Mazlan et al.2009). However, there are limited clinical protocols available and no universal agreement for the interpretation of HFT (ASHA, 2004; Kei & Mazlan, 2012). Hence, for the purpose of this study HF tympanograms were classified and interpreted using percentile areas as described in Table 3.16. These were the guidelines provided in the equipment manual for GSI 39 Auto Tympanometer (GSI, 2011). The researcher was also trained by a well-trained representative of the equipment supplier on the use of this method of classification and interpretation of HF tympanograms.

The choice of method for HFT interpretation could affect the validity of results. Due to the subjective nature of the interpretation (Hoffman et al., 2013), tympanograms may be inaccurately classified. However, a number of clinical studies have indicated the effectiveness of a simple normal or abnormal classification of HF tympanograms for neonates and infants less than 6 months of age (Baldwin et al., 2008). This method of interpretation is also used in an international NHS protocol (Baldwin et al., 2008). With this method, a significantly improved intra-tester agreement was reported (Baldwin et al., 2008). In order to limit the subjective interpretation, the HFT result screen on the equipment has clear indicators (dotted lines) to delineate the percentile area. This assisted in more accurately classifying and interpreting the HF tympanograms.

Table 3.17

Classification of HF Tympanograms according to Percentile Areas (GSI, 2011). Reprinted with permission.



DPOAEs. The test parameters for DPOAE testing were as follows (GN Otometrics, 2014):

- Evaluation method: Noise weighted phase statistics.
- Stimulus: Primary tone pair, $f_2/f_1 = 1.24$.
- Test frequencies: f_2 range 1, 2,3,4,5 and 6 KHz
- Test level: L1/L2=59/50 dB SPL.
- Display: DPOAE level, test progress, noise level and DP-Gram
- Result display: Overall pass or refer result, DP-Gram with DPOAE and noise level. The pass and refer results were interpreted as normal and abnormal respectively for all screening test results.
- A pass result (unilaterally or bilaterally) was obtained if a minimum of four out of the six frequencies reached a pass.

Interpretation and correlation of hearing screening results. In summary all the results were interpreted as normal and abnormal in order to ensure uniformity, ease of interpretation and correlation of results with other hearing screening tests.

Audiological equipment. The following audiological equipment was used:

- Otoscope and speculae
- Portable GSI 39 v3 Auto Tympanometer (recently calibrated) (Appendix J)
- Madsen AccuScreen handheld OAE Screener (recently calibrated) (Appendix K)
- Probe tips
- Antiseptic agent
- Alcohol swabs and Milton

Data Collection

Ethical considerations. The researcher adopted the ethical principles as described in the Declaration of Helsinki (World Medical Association [WMA], 2008). The four major ethical principles, namely autonomy, beneficence, non-maleficence and justice guided this research study (Breen, Cordner, Thomson & Pleuckhahn, 2010). These four ethical pillars do not stand on their own but are interpreted and applied as explanations for clinical decisions using structures of reasoning and thinking developed by moral philosophers. The following ethical principles were adhered to in this study (Breen et al., 2010):

Human ethics review committee and permission. A study that requires the involvement of human participants and access to confidential information necessitates ethical clearance from a formally constituted human ethics review committee (Taylor & Roberts, 2006; Lewis, Sheringham, Kalim & Crayford, 2008). Ethical clearance was obtained from the University of the Witwatersrand's Human Research Ethics Committee before the research study was commenced (Appendix L).

Permission to conduct the research was obtained from all the sites. Informed consent was obtained from the CEO of Rahima Moosa Mother and Child Hospital (Appendix G) and the two children's homes (Appendix H & Appendix I).

Confidentiality. All information obtained during the course of this research study, including personal participant information and research data was kept strictly confidential. Participant numbers were allocated to all participants. The raw data will be locked in the research supervisor's office to ensure safe keeping of the raw data and destroyed after a period of five years.

Autonomy. Participation in this study was voluntary. Participants had the right to withdraw from this study at any time without any negative consequences. If they decided to take part in this study, they were informed about the nature and predictable benefits of the study. The participants were informed that consent to participate in the study was assumed if he/she completed and returned the survey questionnaire.

Beneficence. The researcher should act in the best interest of the participant (Breen et al., 2010). As this study involves human subjects the researcher ensured that respect, safety and wellbeing of the participants took precedence over all other interests.

Non-maleficence. Although no direct harm came to participants during the study, the researcher considered the time involved for each participant to participate in the study.

Justice. This incorporates notions of equal and fair distribution of resources based on the analysis of benefits and burdens of decision (Breen et al., 2010). Justice was assured by approaching the parents or caregivers of all potential participants at the hospital site. These individuals therefore had the opportunity to have their children's hearing screened. The inclusion of the two children's homes as data collection sites provided them with the opportunity to have all the neonates' and infants' hearing to be screened. The benefits and risks of the study were thus fairly distributed and that all participants were treated equally.

Research personnel. Three research assistants assisted with some aspects of data collection. All were female and dually qualified as speech therapists and audiologists. On average, they had 3.6 years of experience in the field of paediatric audiology.

Prior to data collection, the purpose and nature of the study was explained to the research assistants. They were provided with the hearing screening protocol (that included getting informed consent) and were given the opportunity to ask clarifying questions. Training was

provided prior to data collection on the following aspects: (i) obtaining informed consent; (ii) obtaining case history information from caregivers and, if available, hospital files; (iii) performing the otoscopic examination; (iv) providing feedback to the caregivers on results obtained, and (v) recording of results. The screening protocol was revised on the day of data collection in order to ensure the research assistants clearly understood what was required of them.

Research assistants were only required to record information obtained from caregivers and hospital files as well as what was visualized during the otoscopic examination. The researcher was present at all times to confirm otoscopy results, if requested. Interpretation of otoscopic findings, as normal or abnormal, was only made by the researcher. The tympanometry and DPOAE screening was only performed by the researcher as the researcher was the only one trained by the suppliers of the equipment on how to perform and interpret the screening test results. Screening results and recommendations for every participant was discussed as a team (researcher and research assistants) prior to providing the parents or caregivers with the feedback.

Data collection procedures. The procedures for data collection during all phases of the research are described below:

- Ethical clearance was obtained from the HREC of the University of Witwatersrand to conduct this study (Appendix L).
- All measuring instruments were developed and audiological equipment was hired (Appendix C & Appendix F) (Table 3.7 & Table 3.13).
- Permission was obtained from Dr. George Mukhari Academic Hospital to conduct the pilot study (Appendix D).

- Two pilot studies were conducted to finalize the measuring instruments and determine the equipment to be used in the study.
- During the main study phase the following procedures were followed:

Main study phase 1: Survey questionnaire.

- All potential participants were contacted via email with the use of the Survey Monkey website. This communication included a cover letter describing the study (Appendix B) and the survey questionnaire (Appendix C). It was assumed that participants had consented to participate in the study by completing and returning the survey questionnaire. Only participants who returned the completed questionnaire and met the inclusion criteria were included in the study.
- In addition, the researcher also distributed hard copies of the survey questionnaire to delegates at the Mpumalanga and Gauteng provincial forums.
- Once the survey questionnaires were returned the raw data were encoded according to the data definitions and checked for any capturing errors.

Main study phase 2: Hearing screening.

- Permission was obtained from all sites to conduct the study (Appendix G-I). At Rahima Moosa Mother and Child Hospital consent was obtained by the Chief Executive Officer (CEO) of the hospital (Mrs. S. Jordaan). At Mother Teresa permission was obtained from the House Mother, whilst the Baby Care Manager at Door of Hope Children's Mission gave permission. Audiological equipment used was recently calibrated (Appendix J & Appendix K).
- Written informed consent was obtained prior to the testing from parents or caregivers of participants recruited from hospitals (Appendix E). The House

Mother from Mother Teresa and the Baby Care Manager at Door of Hope Children's Mission as the appointed caregivers of the children in their centers provided written informed consent for inclusion in the study.

- An interpreter was available for caregivers who were not proficient in English.
- Three research assistants rotated and were trained by the researcher to assist with some aspects of data collection.
- Participants were allocated participant numbers and these numbers were recorded on the data collection forms.
- All hearing screening tests (where possible) were applied during this phase of the study. Research assistants obtained informed consent and case history, performed the otoscopic examination, provided feedback to parents or caregivers and documented results on the data collection forms. Tympanometry and DPOAE screening was only performed by the researcher.
- Only one participant was screened by the research team at a time thus eliminating the possibility of double entry of participants. Once hearing screening was completed the parents or caregivers were provided with immediate results and recommendations for further management (if required) explained.
- Data were captured on an excel spread sheet and reviewed for accuracy.

Reliability and Validity

Reliability. Reliability refers to the consistency or stability of a measuring instrument (Jackson, 2012). Inter-rater reliability was the strategy implemented to ensure reliability.

Inter-rater reliability. Inter-rater reliability is a “measure of consistency” that evaluates

the percentage of agreement of observation made by raters (Jackson, 2012, p. 70). Inter-rater reliability was determined by requesting a second person to review 25% of tympanometry tests results. The second rater was an audiologist (and part-time lecturer) with eight years clinical experience in the field of screening and diagnostic audiology. The second rater was provided with minimal information regarding the outcomes of the research study. No analysed results were provided to the rater in order to decrease the bias in the analysis of tympanometry results. The following formula provided a means to determine the percentage of agreement (Jackson, 2012):

$$\text{Inter-rater reliability} = \frac{\text{Number of Agreements}}{\text{Number of possible Agreements}} \times 100$$

The inter-rater reliability was 88%. According to Doron, Chan, Tamir, Lenhardt (2002) a good percentage agreement should be between the ranges of 90–98 %. Results that the researcher and rater disagreed on were reviewed and re-analysed using clinical guidelines and theoretical background in order to further increase the reliability of interpreting the results as accurately as possible. This resulted in both the researcher and rater reaching agreement.

Inter-tester reliability. This is the consistency of measurements when more than one individual who takes the measurement indicates agreement of the measurement taken by different examiners (Kaplan, 2006). Inter-tester reliability was not documented despite research assistants requesting confirmation of the otoscopic findings. This is acknowledged as a limitation of the study. However, the correlations of screening test results were discussed as a team prior to providing feedback to parents or caregivers. This was done to ensure that all results were interpreted accurately.

Validity. Validity is the ability of a study to measure what it claims (Davis & Bremmer, 2006). There are two types of validity measures that relate to this study, namely face- and content validity.

Face validity. The judgment that an instrument is assessing what it is supposed to, is mainly based on the coherent link between the questions and the objectives of the study. The establishment of this link is known as face validity (Kumar, 2005). Two audiologists were approached to determine the face validity of the survey questionnaire and hearing screening form. These audiologists had an average of eight years clinical experience in the field of paediatric audiology. The pilot study also assisted in establishing face validity as further changes were made to the measuring instruments thereafter.

Content validity. Content validity is the accuracy of procedures and equipment to measure what they claim to measure (Kumar, 2005).

Survey questionnaire and hearing screening form. It is equally important that the questions or items cover the full range of the issue being measured (Kumar, 2005). The items of instruments were assessed in order to determine if they adequately represent the content areas they are intended to measure (Kumar, 2005; Rubin, 2008). These validity measures were applicable to this study as it evaluated whether the questionnaire and hearing screening form are measuring what they are supposed to in order for the researcher to obtain appropriate data for this study. The content of the developed measuring instruments were mainly validated through the pilot study. The results obtained from the pilot study assisted in determining whether appropriate information was being retrieved for the purpose of the study.

Hearing screening tests. Calibration of equipment ensures accurate functioning of equipment, thus contributing to the validity of results (Valente, Fernandez & Monroe, 2011). All

the equipment utilised in the study was recently calibrated. It is also necessary for current and relevant calibration standards to be used for audiological equipment. This is to ensure that results obtained on different equipment, in different settings at different times can be accurately compared (Wood, 1995). Calibration standards were in accordance with those prescribed by the South African Bureau of Standards (SABS 0154-1; 0154-2), thereby ensuring that the results were accurate and valid.

As DPOAEs are affected by noise levels, noise levels were kept to the minimum by conducting the hearing screening in a sound proof room where available (hospital). At the children's homes screening was conducted in a quiet room and every attempt was made to minimize noise levels in the vicinity of the room where the hearing screening was conducted.

DPOAEs and tympanometry screening tests were repeated in order to ensure replicable results.

Data Analysis

The data were documented on all the relevant measuring instruments and encoded according to the data definitions. All the data were computerized for statistical analysis with the Statistical Analysis System (SAS) software. Results were analysed utilising a variety of statistical procedures, as listed in Table 3.18 and displayed in tables and figures in the results section of this report.

Table 3.18

Description of Statistical Methods

Statistical Procedures	Statistical Methods
Descriptive statistics: <ul style="list-style-type: none"> • Measures of central tendency e.g. mean • Measures of variability e.g. range and standard deviation (<i>SD</i>) • Frequency distributions 	Descriptive statistics are techniques that assist in describing a set of data (Gravetter & Foranzo, 2012). The goal of descriptive statistics is to organise and summarise information (Gravetter & Foranzo, 2012). Mean, range and <i>SD</i> was used to analyse the survey questionnaires in order to describe the use of HFT in current paediatric audiological clinical practice in South Africa. Descriptive statistics further allowed the researcher to look at frequency patterns through the use of contingency tables. Contingency tables are joint frequency distribution of two or more variables. When two variables are involved it is known as a two way contingency table (Powers & Xie, 2008). Two way contingency tables were used to determine the pass and refer rates of the screening tests.
Measures of agreement: <ul style="list-style-type: none"> • Cohen's kappa 	Cohen's kappa is a measurement of agreement that attempts to correct chance (Gravetter & Forzano, 2012). It provides values similar to a correlation coefficient. The values of kappa range from 0 – 1.00 with higher indicating better agreement (Kelly, 2009). Cohen's kappa was used to determine the agreement of the pass and refer rates of the various hearing screening tests.

Chapter Four

Results

This chapter presents the results in relation to the aims of the study. This chapter will first describe the results of the first phase of the main study (survey questionnaire) and then the last phase of the main study (hearing screening).

Main Study Phase 1: Survey Questionnaire

Main aim 1: Use of HFT in current clinical practice.

The aim of this survey was to describe the use of HFT in current paediatric audiological clinical practice in South Africa. The findings are presented according to the following sub-aims:

- The availability of HFT equipment in audiology departments for screening or diagnostic paediatric audiological assessments.
- The current clinical practice of HFT in paediatric audiological assessments.
- Audiologists' knowledge of the clinical application of HFT and theoretical background of the infant's middle ear system.

Availability of tympanometry equipment in paediatric audiology departments or practices. The total sample included 113 (N_1) participants. Ninety four percent of the participants ($n=106$) indicated that they have access to a tympanometer in their practice or department. Of these participants, only fifty percent ($n=53$) had access to a HFT. Only six percent of participants ($n=7$) did not have access to a tympanometer. They indicated that this was due to a lack of equipment (as a result of budgetary constraints) and broken equipment.

Participants were also required to indicate their workplace and were allowed to select more than one option. Participants (94%; $n=106$) who reported to have access to tympanometry

were found mainly to be working in the public health sector such as government hospitals (49%; $n=52$) and primary health care clinics (6%; $n=6$). Forty percent of participants ($n=38$) worked in private practices and 11% in private hospitals ($n=12$). The rest of the participants worked in the educational setting (6%; $n=6$) and universities or non-profit organizations (8%; $n=9$).

More specifically participants who have HFT (50%; $n=53$) are found to be mainly working in government hospitals (47%; $n=25$) and private practice (43%; $n=23$).

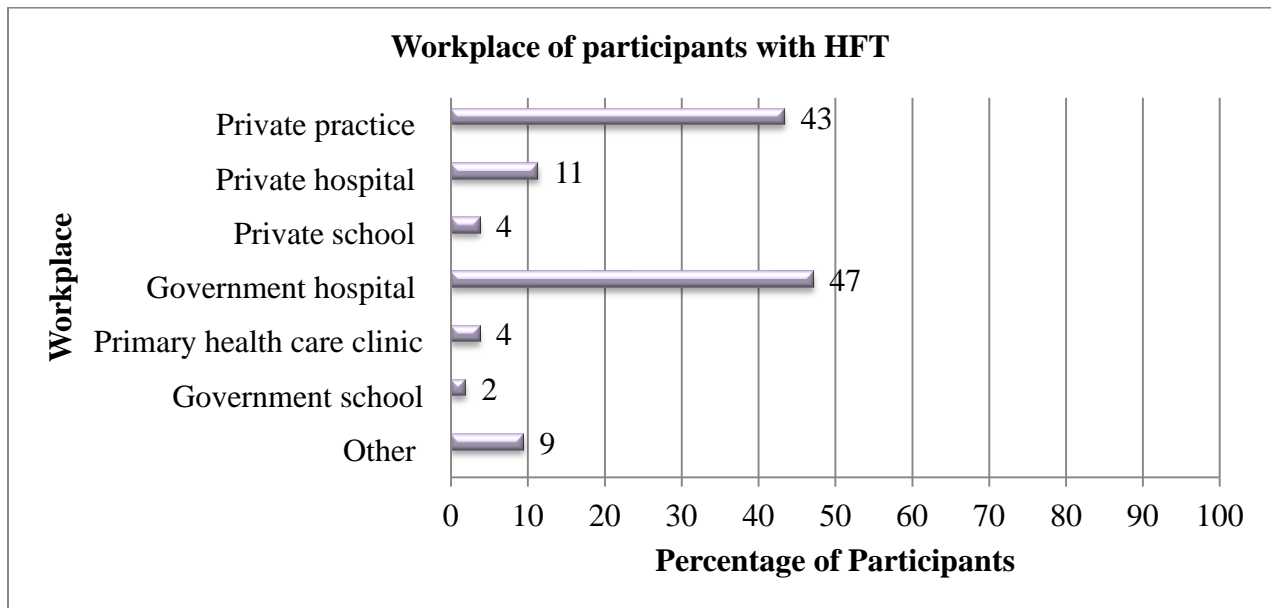


Figure 4.1. Workplace of participants with HFT.

Participants who do not use HFT (53%, $n=60$) include those that have access to a tympanometer but have no HFT available (88%; $n=53$) and those that have no access to a tympanometer resulting in no HFT being available in their clinical setting (12%; $n=7$). These participants (53%, $n=60$) were found mainly to working in the public health sector such as government hospitals (52%; $n=31$) and primary health care clinics (12%; $n=7$). Twenty percent of participants ($n=17$) worked in private practices and 10% in private hospitals ($n=6$). The rest of the participants worked in the educational setting (5%; $n=3$) and universities or non-profit organizations (7%; $n=4$).

Current clinical practice of HFT in paediatric audiological assessment.

Inclusion of HFT in paediatric audiological assessments. The majority of participants (98%, $n=104$) who have access to tympanometry reportedly included tympanometry in their basic paediatric test battery. Two of these participants (2%; $n=2$) did not include tympanometry in their basic paediatric test battery due to time constraints.

Participants (98%; $n=104$) were requested to indicate which type of tympanometry test was conducted for the paediatric population in their clinical practice. Participants could choose more than one option. LFT (78%; $n=81$), was found to be used by most of the participants followed by HFT (51%; $n=53$). MFT (13%; $n=13$) and 667Hz probe tone (5%; $n=6$) was the type of tympanometry least used by participants. Eight percent of participants ($n=9$) were unsure as to which type of tympanometry was used in their clinical practice, as they were unaware of what the settings were on their tympanometer.

Many participants also reported using a combination of two or more tympanometry tests in their clinical practice (Table 4.1).

Table 4.1

Tympanometry Tests Used in Combination

Type of Tympanometry Tests	<i>n</i>	%
LFT and HFT	45	85
MFT and HFT	4	8
MFT and 667Hz	1	2
LFT and 667Hz	3	6

LFT and HFT are found to be used in combination by a majority of the participants ($n=45$). These participants ($n=45$) are found to be mainly working in government hospitals ($n=21$; 47%) and private practice ($n=21$; 47 %) and a smaller percentage in private hospitals

($n=6$; 13%), universities ($n=5$; 11%), private schools ($n=2$; 4%) and government schools ($n=2$; 4%).

The use of HFT for neonates and infants with definitive middle ear pathologies was then explored. Fifty percent of all participants ($n=53$) completed this section on how often HFT is included within their paediatric test battery. Of these participants 68% ($n=36$) reported to always include HFT. Whilst 28% ($n=15$) reported to sometimes include HFT and majority of these participants (80%; $n=12$) did not provide any reasons as to why HFT is not always included. Some participants (20%; $n=3$) stipulated reasons such as a lack of training in conducting and interpretation of HFT; a lack of clinical protocols; believing that HFT is not clinically relevant; or that it is case dependent. Only 4% of participants with HFT ($n=2$) reported never including HFT, even though it is available in their clinical setting.

The remainder of the participants (53%; $n=60$) reported that HFT is never included in their paediatric test battery for neonates and infants with definitive middle ear pathologies. These participants provided various reasons as to why HFT is not being included (Figure 4.2). The most common reason is the lack of HF probe tone, followed by a lack of training in conducting and interpretation of HFT, as well as a lack of clinical protocols and budgetary constraints.

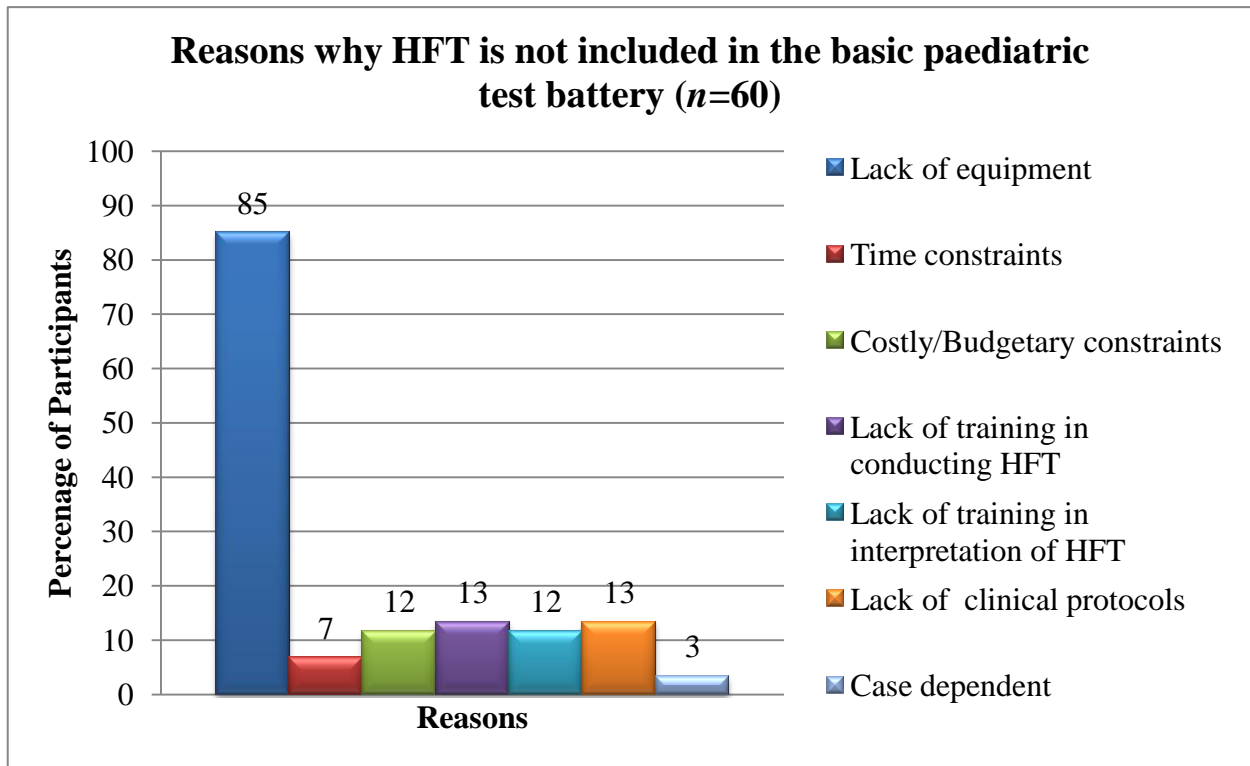


Figure 4.2. Reasons why HFT is not included in basic paediatric test battery.

The question on the age range for which HFT was used was answered by 50% of the participants (n=53). Participants were provided with ten options and were only allowed to select one. It was found that HFT is used in four main age ranges, namely: 0 to 6 months; 0 to 9 months; up to 1 year and up to 6 years of age (Figure 4.3).

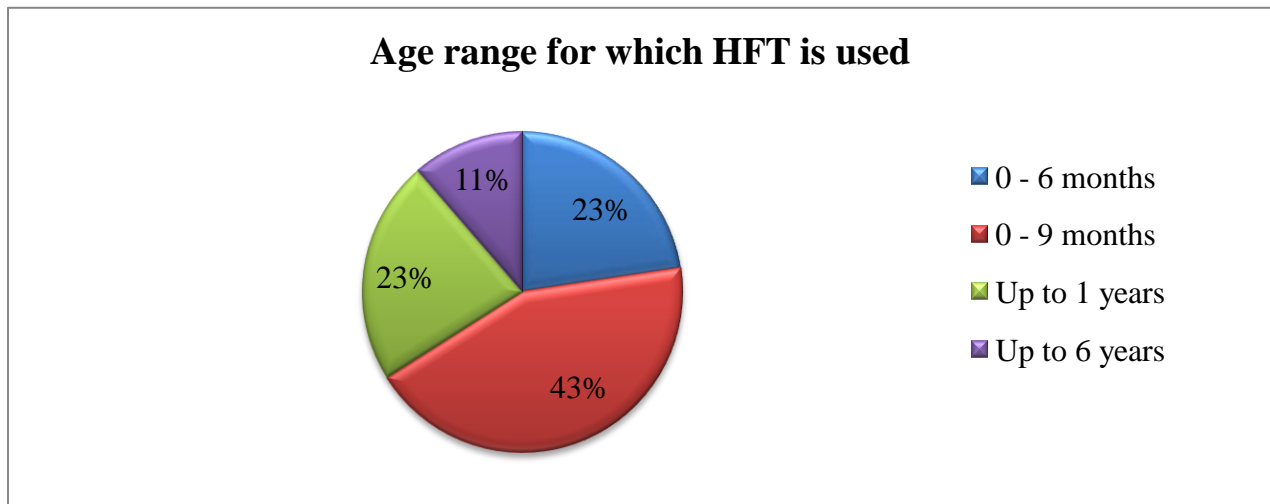


Figure 4.3. Age range HFT was used.

Most participants (43%; $n=23$) reported using HFT mainly for infants ranging from birth to nine months of age. A smaller percentage of participants (23%; $n=12$) utilised HFT for birth to six months (which is the recommended age range) of age.

The availability of departmental clinical protocols for HFT. Participants (50%; $n=53$) performing HFT had to indicate whether clinical protocols were available in their department or practice. Of these participants, the majority (70%, $n=37$) reported to have clinical protocols, whilst 30% ($n=16$) indicated that no clinical protocols were available.

Participants with no clinical protocols available for performing HFT ($n=16$). These participants provided reasons as to why clinical protocols are not available. Reasons included: '*lack of knowledge on application and interpretation of HFT*'; '*in the process of developing a protocol*'; '*every audiologist uses their own norms*'; '*caseloads are not comprised of many neonates and infants to develop a protocol*'; '*lack of protocols available and normative data that is available is not clear enough for practical application of HFT*'. Many participants also reported that they were '*unsure*' as to why clinical protocols were not available.

These participants ($n=16$; 30%) also indicated which norms and classification system are used for the interpretation of HFT. Some participants (31%; $n=5$), reportedly use the norms stipulated in the equipment manuals, but the majority (44%; $n=7$) were unsure as to which norms they used for the interpretation of HFT. The majority of the participants (69%; $n=11$) were also unsure as to which classification system they used for the interpretation of HFT. Only thirty-one percent of participants ($n=5$) reported using classifications systems such as quantitative measures (peak susceptance or peak compliance). Participants were also requested to provide a reference or elaborate on the norms and classification systems used. Participants reported making use of

the equipment manuals, relevant international research articles and books related to tympanometric testing. Not all participants provided references.

Participants with clinical protocols available performing HFT (n=37). These participants indicated the type of clinical protocols used (Figure 4.4). Participants were provided with four options and were allowed to choose more than one option.

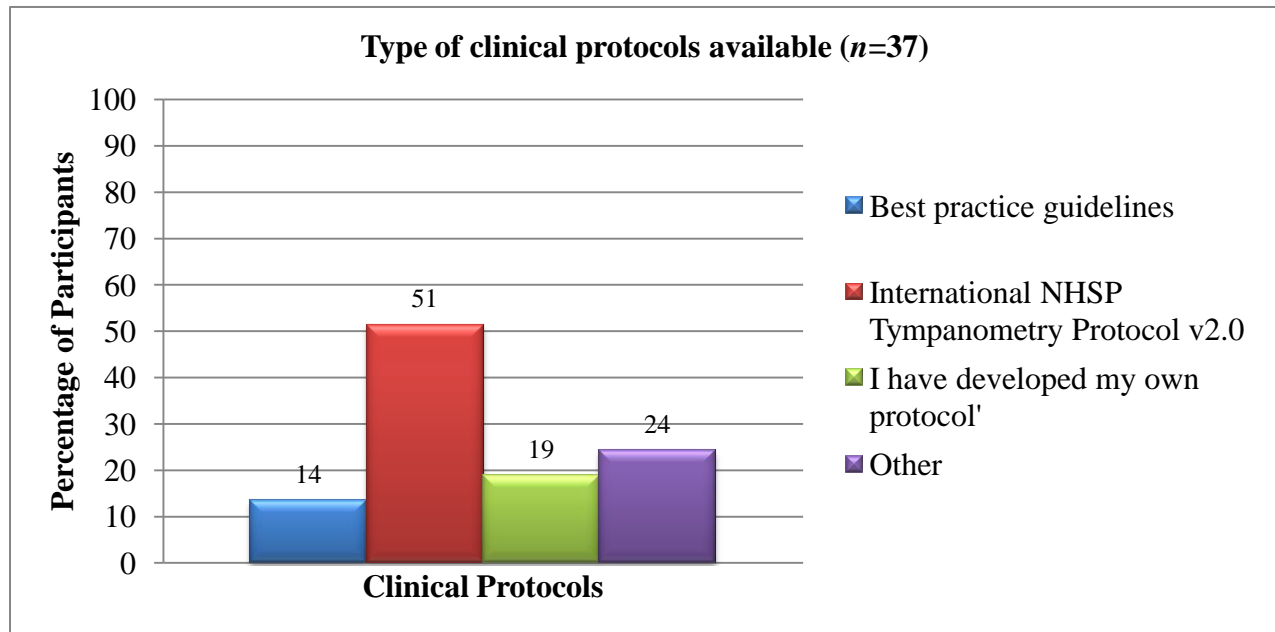


Figure 4.4. Current clinical protocols used.

The majority of the participants reported using the international Newborn Hearing Screening Program (NHSP) Tympanometry Protocol v2.0 (51%; $n=19$) (Baldwin et al., 2008) and self-developed protocols (19%; $n=7$). Twenty-four percent of participants ($n=9$) reported to also use other resources such as hospital protocols; a combination of various other protocols (participants did not provide more information on these protocols); university-developed instructional manuals; and hearing-aid company protocols.

Participants also indicated norms used for the interpretation of HFT (Figure 4.5). Participants were provided with 11 options and were able to select more than one option.

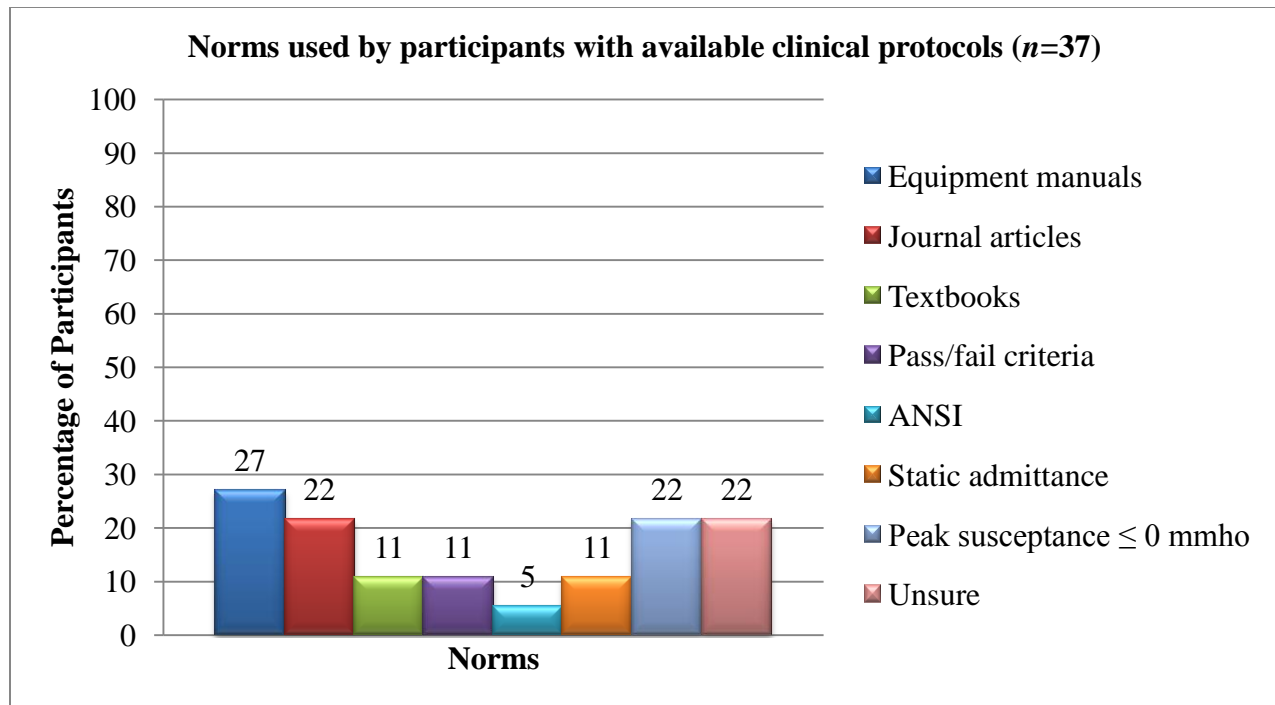


Figure 4.5. Norms used by participants (with available clinical protocols).

The majority of participants indicated that they use norms stipulated in the equipment manuals (27%; $n=10$) for interpretation. A large number also reportedly used journal articles (22%; $n=8$), peak susceptance [≤ 0 mmho] (22%; $n=8$) for interpretation and many were also unsure (22%; $n=8$) as to which norms were used for the interpretation of HFT. Some participants elaborated on the pass or refer criteria used (e.g. flat trace being indicative of abnormal results, a discernible peak being indicative of normal results or a peak compliance of at least 0.6mmho which is also indicative of a normal middle ear functioning).

Participants also indicated classification systems used for the interpretation of HFT (Figure 4.6).

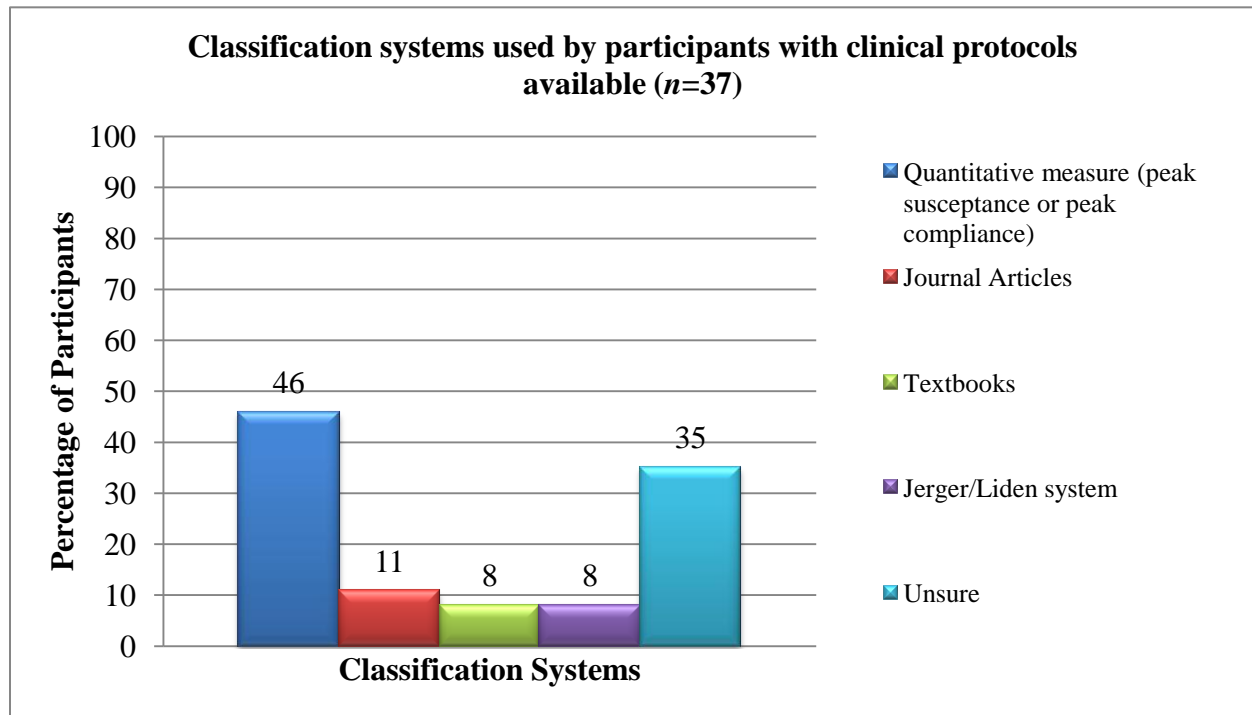


Figure 4.6. Classification systems used by participants (with available clinical protocols).

The majority of the participants (46%; $n=17$) make use of classification systems such as quantitative measures (peak susceptance or peak compliance), whilst many participants (35%; $n=13$) are unsure as to which classification system is used for the interpretation of HFT. Other classifications systems used by participants are reported to be described in journal articles (11%; $n=4$) and textbooks (8%; $n=3$).

Audiologists' knowledge of the clinical application of HFT and theoretical background of the infant's middle ear system. This section was answered by all participants ($N_I=113$). Participants were allowed to select more than one option for all questions.

Purpose of Tympanometry. Participants were required to state what the purpose of tympanometry is and the following options were provided with four options (Figure 4.7).

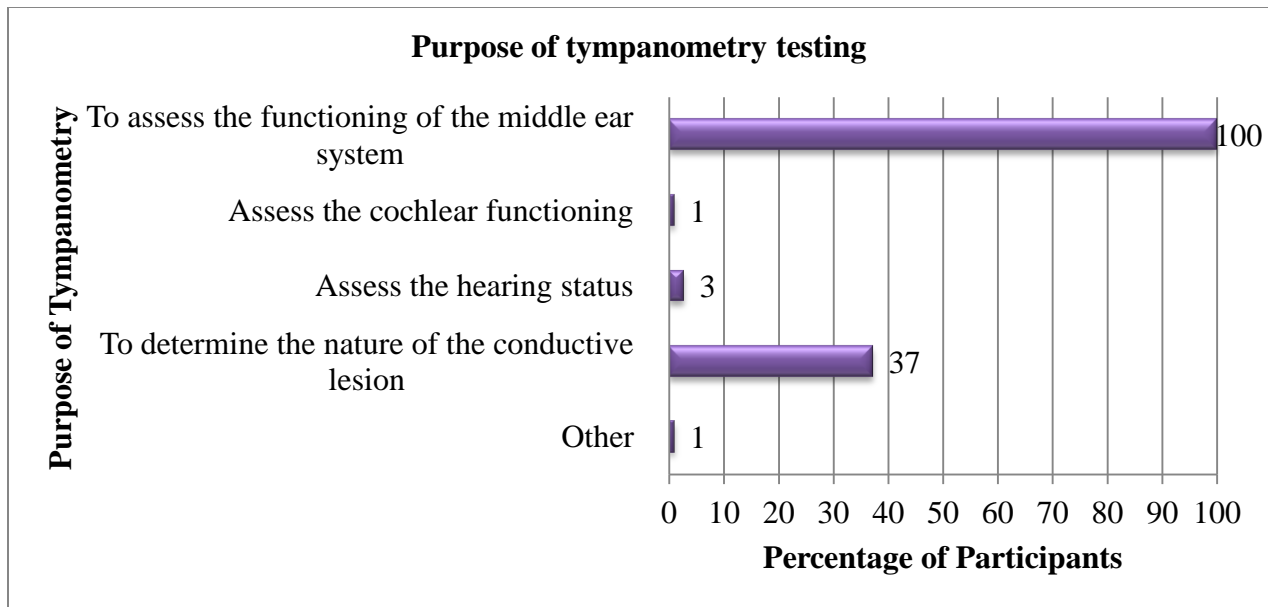


Figure 4.7. The purpose of tympanometry described by participants ($N_I=113$).

All of the participants ($N_I=113$) have stated that the purpose of tympanometry is to assess the functioning of the middle ear system. In addition, some of these participants ($n=42$; 37%) have indicated that the purpose of tympanometry is also to determine the nature of the conductive lesion. Both these responses are an appropriate description as to what the purpose of tympanometry is.

Clinical application of HFT. Participants were required to provide information with regard to the clinical application of HFT in their clinical setting. Participants provided more than one clinical application (Table 4.2).

Table 4.2

Clinical Application of HFT in the Clinical Setting

Clinical Applications	%	n
Unsure	22	25
To obtain reliable and accurate results of middle ear pressure and compliance of infants with middle ear pathologies.	18	20
Used for the paediatric population only.	9	10
To assess and determine the middle ear status or functioning in high risk populations.	15	17
To effectively assess the middle ear status or functioning and to identify MEE in infants birth to six months of age.	15	17
Valuable for hearing screening as it assists in identification, prevention and management of emerging hearing loss in infants.	5	6
Cross check principle for all audiological results.	5	6
To make appropriate recommendations, referrals and management.	4	4
Minimal clinical application in the setting.	3	3
Diagnostic completeness.	3	3
Assists with differential diagnosis.	2	2
Other	3	3

Knowledge of the infant middle ear system. Participants were required to describe the infant middle ear system and participants were provided with seven options (Figure 4.8).

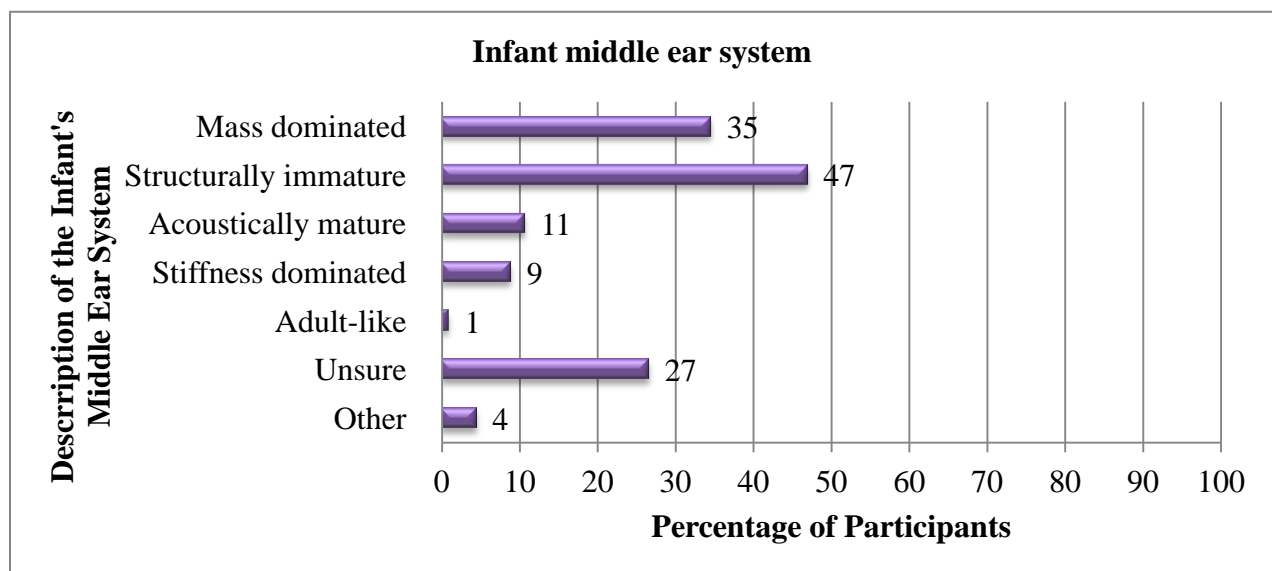


Figure 4.8. Description of an infant's middle ear system.

The majority of the participants (81%; $n=92$) were able to appropriately describe the infant middle ear system. However, it is noted that many participants (27%; $n=30$) responded that they were unsure as to what the infant middle ear system should be like. Other responses obtained described the infant middle ear system to be '*dependent on the infant's age*'; to have '*differences in compliance when compared to adults*'; '*immature structure and function of the ET*', and '*very prone to infection*'.

Acoustical differences between an infant and adult middle ear system. Participants were required to state the acoustical differences between an infant and adult middle ear system and were provided with six options (Figure 4.9).

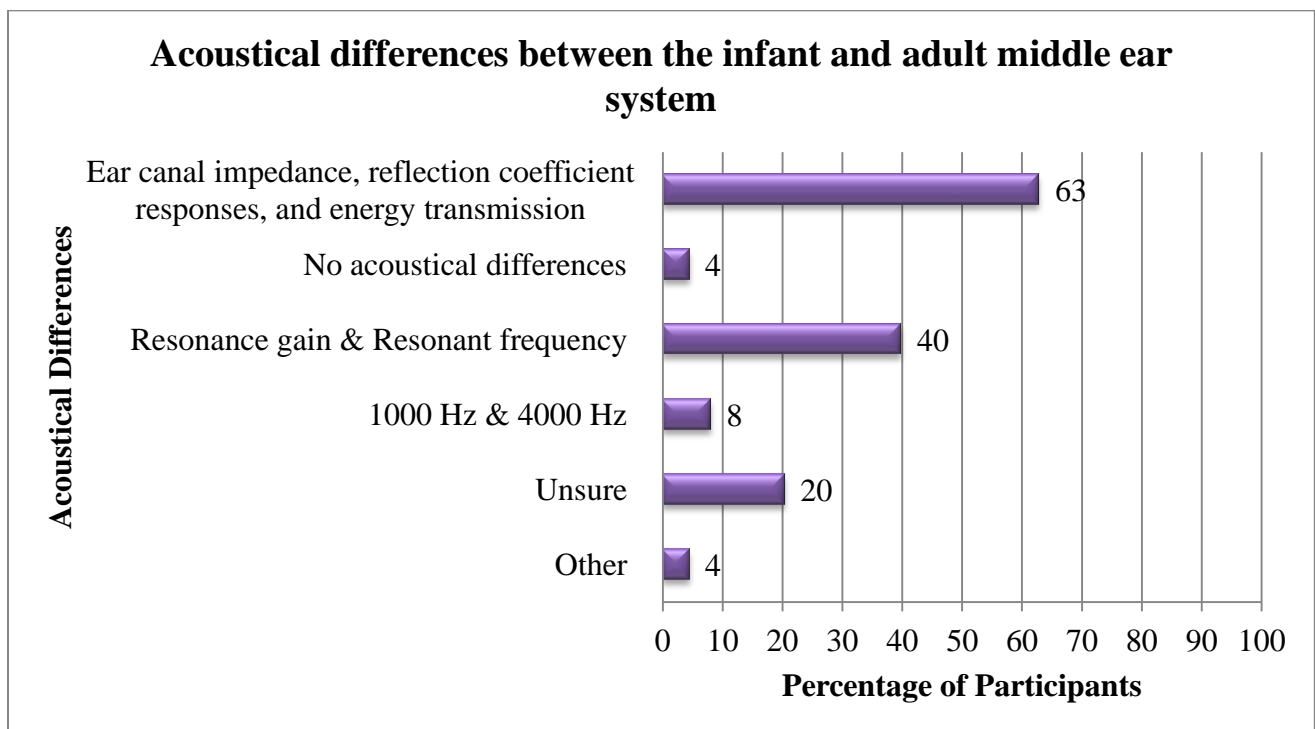


Figure 4.9. Description of the acoustical differences between an infant and adult middle ear system.

The majority of the participants (63%; $n=71$) have described the main differences between an infant and adult middle ear system to be ear canal impedance, reflection coefficient

responses and energy transmission, followed by (40%; $n=45$) resonance gain and resonance frequency. Many participants (20%; $n=23$) were also found to be unsure as to what the acoustical differences are. Some participants (4%; $n=5$) stipulated other acoustical differences (See Table 4.3).

Maturational changes. Participants were required to state whether maturational changes that occur in the infant's middle ear system affect the acoustical properties of the ear. Participants were also requested to provide an explanation for their response. However, this was not provided by all participants. Most of the participants (86%, $n=97$) reported that maturational changes do occur in the infant middle ear system and have an effect on the acoustical properties of the infant's ear. Some of these of participants (34%; $n=32$) provided explanations, which have been described in Table 4.3.

Table 4.3

Reasons Provided by Participants as to Why Maturational Changes Affect the Acoustical Properties of the Infant's Ear

Reasons	%	N
Development of the infant's middle ear system takes place as the infant grows resulting in structural changes.	33	11
Acoustical changes, such as changes in eardrum compliance, energy transmission and sound pressure level, occur.	15	5
Mass-dominated system moving to stiffness-dominated system	12	4
Changes to the natural resonance of the infant middle ear system occurs	12	4
Age dependent	12	4
Unsure	12	4

A small percentage of participants (14 %, $n=16$) also reported that maturational changes that occur to the infant's middle ear system, do not have an effect on the acoustical properties of the infant's ear. Some of these participants (44%; $n=7$) provided reasons for their response, such as '*immaturity of the inner ear affect acoustics*'; and '*the development of the ET makes the infant*

less susceptible to MEE but has no effect on acoustical properties of the ear' and the majority of the participants were *'unsure'*, hence could not provide any reason for their response.

Main Study Phase 2: Hearing Screening

This section describes the results obtained for the second and third aim of the last main study phase. The aims determine the pass and refer rates of the screening tests, and the agreement of these rates in the identification of possible middle ear pathology in neonates and infants.

The results are divided into two sub-sections, namely the four hearing screening tests and three hearing screening tests. This was due to equipment malfunction of the OAE screener which resulted in two different sample sizes for each section (Table 4.4). The number of right and left ears on which the statistical analysis was performed is presented in Table 4.4.

Table 4.4

Description of Sample Size

Total Number of Participants	Number of Hearing Screening Tests Performed	Types of Hearing Screening Tests Performed
80	4	Otoscopic examination LFT (226Hz probe tone) HFT (1000Hz probe tone) DOAEs
73	3	Otoscopic examination LFT (226Hz probe tone) HFT (1000Hz probe tone)

Table 4.5

Number of Ears Screened (N₂ = 303)

Number of Hearing Screening Tests Performed	Hearing Screening Tests	Ear	Number of Participants
4	HFT (1000Hz probe tone)	Right	79
		Left	79
	LFT (226Hz probe tone)	Right	79
		Left	79
	Otoscopy	Right	79
		Left	79
	DPOAEs	Right	30
		Left	38
3	HFT (1000Hz probe tone)	Right	72
		Left	73
	LFT (226Hz probe tone)	Right	72
		Left	73
	Otoscopy	Right	73
		Left	73

Note:

- Pass rate: A negative result indicating that no possible middle ear pathology has been identified.
- Refer rate: A positive result indicating that possible middle ear pathology has been identified.

Main aim 2: Pass and refer rates of screening tests.

This section describes the results of the second main aim of the main study. The table below describes the pass and refer rates of the various screening tests for the four hearing screening sample size.

Table 4.6

Pass and Refer Rates of Hearing Screening Tests (HFT, LFT, Otoscopy and DPOAEs)

Four Hearing Screening Tests				
HFT				
Ear	Right (n=79)		Left (n=79)	
	<i>N</i>	%	<i>n</i>	%
Pass	43	54	41	52
Refer	36	46	38	48
LFT				
Ear	Right (n=79)		Left (n=79)	
	<i>N</i>	%	<i>n</i>	%
Pass	67	84	68	86
Refer	13	16	11	14
Otoscopy				
Ear	Right (n=79)		Left (n=79)	
	<i>N</i>	%	<i>n</i>	%
Pass	36	46	35	44
Refer	43	54	44	56
DPOAEs				
Ear	Right (n=30)		Left (n=38)	
	<i>N</i>	%	<i>n</i>	%
Pass	8	27	14	37
Refer	22	28	24	63

LFT obtained the highest pass rates bilaterally when compared to the other screening tests. The pass rates were 84% ($n=67$) in the right ear and 86% ($n=68$) in the left ear. The pass rates for HFT were significantly lower than LFT. Pass rates for HFT in the right ear was 54% ($n=43$) and 52% ($n=41$) in the left ear. It was also found that the pass and refer rates obtained for HFT and otoscopy were relatively similar. The lowest pass rates were obtained for DPOAEs. This pass rate was lower when compared to HFT and LFT.

The table below describes the pass and refer rates of the various screening tests for the three hearing screening sample size

Table 4.7

Pass and Refer Rates of Hearing Screening Tests (HFT, LFT and Otoscopy)

Three Hearing Screening Test				
HFT				
Ear	Right (n=72)		Left (n=73)	
	<i>N</i>	%	<i>n</i>	%
Pass	62	86	61	84
Refer	10	14	12	16
LFT				
Ear	Right (n=72)		Left (n=73)	
	<i>N</i>	%	<i>n</i>	%
Pass	71	99	68	93
Refer	1	1	5	7
Otoscopy				
Ear	Right (n=72)		Left (n=73)	
	<i>N</i>	%	<i>n</i>	%
Pass	55	76	51	70
Refer	17	24	22	30

Similarly to the four hearing screening sample size, the highest pass rates were obtained with LFT bilaterally (right 99%, $n = 71$; left 93%, $n = 68$) when compared to the other screening tests. Lower pass rates were obtained for both the HFT and otoscopy. Furthermore, the pass and refer rates for HFT and otoscopy were not as similar as in the four hearing screening sample.

Main aim 3: Agreement of the pass and refer rates between HFT and other screening tests.

This section describes the results of the third main aim of the main study. The measure of agreement used for the purpose of this section is Cohen's kappa and the interpretive values used are illustrated in Table 4.8 (Fleiss, 1981).

Table 4.8

Values used for Interpretation of the Cohen's Kappa (Fleiss, 1981)

Values	Interpretation
< 0.40	Poor agreement
0.40 - 0.59	Fair agreement
0.60 - 0.74	Good agreement
> 0.75	Excellent agreement

The table below describes the agreement of the pass and refer rates among the various hearing screening tests.

Table 4.9

Agreement of the Pass and Refer Rates for all Hearing Screening Tests

Four Hearing Screening Tests		
Screening Tests	Right Ear	Left Ear
HFT and LFT	0.1656	0.1931
HFT and Otoscopy	0.7237*	0.7983*
HFT and DPOAEs	0.2697	0.2893
LFT and Otoscopy	0.1335	0.1812
LFT and DPOAEs	0.1667	0.1284
Three Hearing Screening Tests		
HFT and LFT	0.1606	0.1534
HFT and Otoscopy	0.5062	0.6264*
LFT and Otoscopy	0.0872	0.1534

*Good or excellent agreement

It is evident from the findings that the highest level of agreement was obtained between HFT and otoscopy. In the four hearing screening sample size an excellent agreement (0.7983) was found in the left ear, whilst a good agreement (0.7237) was found in the right ear. Similarly, a good agreement (0.6264) between HFT and otoscopy was found in the left ear of the three hearing screening sample size, whilst a fair agreement (0.5062) was found in the right ear. A poor agreement was found between HFT and LFT as well as the LFT and otoscopy in both the

four and three hearing screening tests. The agreement between DPOAEs and the other screening tests in the four hearing screening sample size was also poor.

This chapter highlighted the results of the research and were organised, analysed and described as it relates to the aims of the research study.

Chapter Five

Discussion

This chapter relates and compares the results presented in chapter four to relevant literature in order to highlight trends and difference in the results obtained. The discussion will allow for conclusions to be drawn with regard to the use of HFT in neonates and infants. This chapter will address the first phase of the main study (survey questionnaire), followed by the last phase of the main study (hearing screening).

Main Study Phase 1: Survey Questionnaire

Main aim 1: Use of HFT in current clinical practice.

Availability of tympanometry equipment in paediatric audiology departments or practices. The majority of the participants have access to tympanometry whilst only a small percentage of these participants reported to have access to HFT. These participants were found to mainly be employed within the public health sector. Furthermore, majority of the participants who reported to not use HFT was also mainly found to be employed within the public health sector.

South Africa consists of both the public and private health care sector (South African Rights Commission, 2009). The inequitable distribution of resources between the public and private health care sector is the greatest challenge that the South African health system is facing as a result of financial instability (South African Rights Commission, 2009). This appears to be evident in the current study as the reason for majority of the participants not using HFT was mainly ascribed to budgetary constraints. These budgetary constraints contributed to the limited availability of HFT in clinical settings. Al-Khatib (2010) confirms that the HFT is limited due to the high cost of the tympanometry equipment. This may negatively impact the availability of

services within the health care sector which in turn may result in delayed identification of middle ear pathologies in the paediatric population.

The majority of the South African population relies on services provided by the public health sector rather than on private health care sector. However, expenditure in the private health sector is found to outweigh that in the public health sector resulting in an over-serviced private health sector and under-serviced public health sector (Department of Health [DoH], n. d.; South African Rights Commission, 2009). This may support the findings of the current study as majority of the participants with no access to HFT were mainly found to be in government hospitals and primary health care clinics, resulting in an under-serviced public health sector. It has been reported for the unequal distribution and poor maintenance of equipment to be a major issue in service delivery since 1997 (DoH, 1997).

It has been noted that participants who reported to have access to HFT were found to be mainly working in the public health sector. According to challenges faced by the South African health system, it was expected for HFT to be more available within the private health sector but rather there appears to be a relatively equal distribution of HFT equipment among the private and public health sector for participants who have access to HFT. This distribution of equipment in South Africa cannot be generalized due to the small sample size of the current study.

Due to the above mentioned long standing challenges and financial instability in the South African health systems, audiologists working within both the private and public health care sector are recommended to continually be proactive by motivating for the importance of using HFT in their clinical setting. This is of utmost importance in light of the fact that OM is the most common cause of HL and frequently occurring middle ear pathology in neonates and infants (Zand et al., 2003; NIDCD, 2010; Marschark & Hauser, 2012). A multidisciplinary team

approach is essential to attain the goal of EHDI (Garcia et al., 2009; Swanepoel, 2006).

Collaboration in clinical practice allows for better quality of care for patients and for professionals to share knowledge and skills (Buttaro, Trybulski & Sandeberg-Cook, 2013).

Therefore audiologists should encourage collaborative work with other professionals (e.g. paediatricians and otolaryngologists) to ensure equipment availability for accurate identification or diagnosis of OM in the neonatal and infant population.

Current clinical practice of HFT in paediatric audiological assessment.

Inclusion of HFT in a paediatric audiological assessment. CHL is the most common reason for neonates and infants failing NHS, hence the inclusion of immittance screening in NHS is recommended (ASHA, 1997; HPCSA, 2007; Doyle et al., 1997).

The results of the current study confirm the inclusion of tympanometry as clinical practice by participants. In the current study LFT was the most often used type of tympanometry closely followed by HFT. It is postulated that this is due to the simplicity in performing LFT, in addition to the fact that results are easier to interpret when compared to results recorded using HFT (Lantz et al., 2004; Baldwin, 2006). The lack of equipment and the lack of training in conducting and interpreting HFT may be attributed as to why HFT is not being included in the participants' clinical setting. Calibration issues and equipment limitations (especially older equipment) are also reported as reasons why clinicians use LFT rather than HFT (Fowler & Shanks, 2002). According to Al-Khatib (2010) knowledge and training is essential in operating tympanometry equipment. The above discussion highlights the need for this as it may result in more audiologists performing HFT as well as increase in confidence in interpreting and conducting HFT on neonates and infants.

Many participants reportedly use a combination of two or more tympanometry tests in their clinical practice. LFT and HFT is found to be used in combination by the majority of the participants ($n=45$). This practice concurs with the recommendation made by Harris et al. (2005) and Alaerts et al. (2007) that both the LFT and HFT should be included in clinical practice. This is due to the fact that both these audiological screening tests are found to be sensitive in identifying middle ear pathologies in neonates and infants. However, one needs to take into consideration that Harris et al. (2005) suggested the use of HFT in infants up to nine months of age, much older than the ages reported in the current study. Whereas, in Alaerts et al.'s. (2007) study an age dependent protocol (birth to nine months) is recommended in order to provide a guideline for the use of both HFT and LFT in clinical practice for neonates and infants. The age dependent protocol corresponds to the findings of the current study. This supports the participants' use of both HFT and LFT in clinical practice and further indicating that the inclusion of HFT may be beneficial in the older paediatric population.

Hence, the population age for which HFT was used by participants in the current study was also found to be relevant. Participants in this study mainly used HFT for infants ranging from birth to nine months of age. HFT has been found to be relevant in this age range by both Alaerts et al. (2007) and Hoffman et al. (2013). However, it has been noted that otoscopic examination was not performed in Alaerts et al.'s. (2007) study.

Otosopic examination is a significant subjective technique required in the identification of middle ear pathologies (Palmu, 2001). Despite its challenges when performed in the paediatric population, an otoscopic examination ensures no obstructions within the EAC that may affect tympanometric results (Bluestone & Klein, 2007). Abnormalities of the EAC are common in neonates younger than four days old and this is usually as a result of vernix occlusion

(Doyle et al, 1997). Hence, the findings obtained by Alaerts et al. (2007) may not be generalised for all neonates and infants from birth to nine months of age. This may result in obtaining different tympanometric results to those with confirmed middle-ear pathologies (Baldwin, 2006). Therefore, it is recommended for audiologists to use these findings as a guideline.

Numerous authors have also reported that HFT is most accurate for the detection of middle ear pathologies in infants six months and younger (Keefe & Levi, 1996; Rhodes et al., 1999; ASHA, 2004; Baldwin, 2006; JCIH, 2007; Baldwin et al., 2008; Kei & Mazlan, 2012). In the current study only a small percentage of participants were found to use HFT in infants up to six months of age. In addition, a minority of participants was also found to utilise HFT for participants up to one year of age and up to six years of age. The use of HFT in this older population may result in the inaccurate identification and decreased accuracy in the diagnosis of middle ear pathologies (Bosaghzadeh, 2011; ASHA, 2004). Misdiagnosis may in turn result in HL as well as delayed speech and language development. However, the use of HFT in the older population is supported by Harris et al. (2005). Hoffman et al. (2013) recommends that future research be conducted on older infants, as HFT could be suitable in the older paediatric population. Hence, it remains uncertain up to which age HFT should be used (Hoffman et al., 2013). From the above discussion there is variability in age for which HFT is used and therefore it has been recommended by Baldwin et al. (2008) for HFT to be used up to the corrected age of six months.

It is difficult to accurately compare and relate the age ranges for which HFT is applicable as not all research studies have clearly stipulated if they refer to GA, CA or chronological age. Furthermore, it has also been seen as a limitation of the current study for not including questions regarding to whether the participants refer to GA, CA or chronological age when stipulating the

age range for the use of HFT. Despite this, HFT has shown to be applicable in premature neonates and infants. Prematurity is a common risk factor for HL (Marlow, Hunt & Marlow, 2000; Rosenblum, 2014) and research studies such as Garcia et al. (2009), Kilic et al. (2012), Do Carmo et al. (2012) and Hoffman et al. (2013) found HFT to be useful in neonates and infants with risk factors for HL. However, the various risk factors present in participants were not always stipulated by researchers.

The availability of departmental clinical protocols for HFT. Clinical protocols should be available in the clinical setting, especially when working with neonates and infants. Clinical protocols offer a level of efficiency; clinical guidance and assist the professional in evaluating data quickly (Clark & Benson, 2008; Ditty, 2012).

Despite these recommendations, a small percentage of participants in the current study are performing HFT with no clinical protocols available in their clinical setting. The development and implementation of clinical protocols are strongly tied to quality assurance, continuity of care, professional development and patient satisfaction (Clark & Benson, 2008). However, clinical protocols or clear guidelines for HFT are limited and none have been universally acceptable (ASHA, 2004; Alaerts et al., 2007; Kei & Mazlan, 2012). Therefore clinicians are required to be cautious when interpreting HFT and advised that this should be interpreted in light of other audiological results (ASHA, 2004). Participants in the current study cited the lack of availability of protocols and unclear normative data as reasons for clinical protocols not being readily available in their clinical setting. It is postulated that the lack of clear guidelines for the interpretation of HFT explains why participants (both with and without clinical protocols) were unsure with regard to the norms and classification systems used for the interpretation of HFT.

The interpretation and classification of HFT is controversial and clinically challenging for professionals (Marchant et al., 1986; Sutton et al., 1996; Margolis et al., 2003; Baldwin, 2006; Baldwin et al., 2008; Cai, 2010). Participants in the current study used various systems to classify HFT results. The systems reported by participants included mostly quantitative measures such as peak susceptance and peak compliance. These quantitative measures have been reported by researchers to be applicable for infants below six months of age (Marchant et al., 1986; Sutton et al., 1996).

Participants in the current study most often made use of the international NHSP Tympanometry Protocol v2.0 to classify HF tympanograms (Baldwin et al., 2008). The international NHSP Tympanometry Protocol v2.0 proposes a simple classification method that results in either normal (positive peak) or abnormal (flat traces or negative peaks) tympanograms which is indicative of a middle ear pathology being respectively, either absent or present (Baldwin et al., 2008). This protocol is also based on clinical research that has illustrated the efficiency of a simple normal and abnormal classification of HF tympanograms for infants below six months of age (Baldwin et al., 2008).

Participants were also found to use peak susceptance of ≤ 0 mmho to interpret HFT. This method was devised by Marchant et al. (1986) and has been found to correlate with otoscopic examination of MEE and evidence of MEE at myringotomy (Marchant et al., 1986). However, according to Hoffman et al. (2013) this method did not consider tympanograms at negative pressure. These types of tympanograms are of importance as it indicates an abnormal middle ear system due to ET dysfunction (Harlor & Bower, 2009; Maico Diagnostics, 2010; GSI, 2011). Infants and neonates are more prone to middle ear pathologies due to the ETs being smaller and more horizontal than they are in adults. This makes it difficult for fluid to drain out of the ear

(NICD, 2010). Baldwin (2006) adapted Marchant's methodology, using admittance measurements rather than susceptance to interpret HF tympanograms. This adapted method allows fewer tympanograms to be unclassified (Baldwin, 2006). It would therefore be the preferred method for audiologists to use for the interpretation of HF tympanograms.

In addition, participants with clinical protocols used their own pass or refer criteria as normative data for the interpretation of HFT. Participants elaborated the pass or refer criteria to be described as normal (discernible peak) and abnormal (flat trace) tympanograms, similarly to that stipulated in the international NHSP Tympanometry Protocol V 2.0 (Baldwin et al., 2008). There is no established choice of a pass or refer criteria and further research is required within this field to obtain data to better interpret HFT using this method (Baldwin, 2006). Therefore even though pass and refer criterion have been provided by researchers, the use of this data has been reported to be problematic (Baldwin et al., 2008; Wilson; 2008).

Furthermore, participants with clinical protocols reported to also determine the compliance of the peak of at least 0.6 mmho as proposed by Margolis et al. (2003) to classify tympanograms as normal and abnormal. This protocol indicates a pass or fail criterion of 0.6 mmho for negative tail compensated static admittance. It has been shown to be useful for neonates from birth to one month of chronological age (Margolis et al., 2003). However, this criterion was shown to be problematic as it presented with a very low sensitivity and resulted in smaller peaked HF tympanograms to be interpreted as abnormal (Margolis et al., 2003; Baldwin et al., 2008). Margolis et al.(2003) has not validated their findings on a group of neonates and infants with reliable evidence of middle ear pathology and therefore this may produce different tympanometric results to those with definitive middle-ear pathologies (Baldwin, 2006). In

addition, according to Swanepoel et al. (2007) the study was performed on a small sample size, and the effect of age range and gender was not considered (Swanepoel et al., 2007).

In a South African study, Swanepoel et al. (2007) found significant higher static peak admittance for males which were attributed to the difference in middle ear and TM sizes for females and males. Statistically significant differences in peak admittance values were also obtained for younger and older neonates highlighting a general increase in admittance with increasing age. Hence, these differences indicate the consideration of gender and age when establishing interpretation methods for HFT (Swanepoel et al., 2007). Despite these considerations, Swanepoel et al. (2007) and Margolis et al. (2003) has also shown some similarities in findings and therefore it would be recommended for Margolis criteria (Margolis et al., 2003) to be used as a guideline.

Not many participants in the current study made use of the Jerger and Liden system despite this being viewed as good clinical practice. The Jerger and Liden system has been found to successfully classify LF tympanograms. It has however not successfully been applied with the infant population due to a number of tympanograms being unclassified (Baldwin, 2006; Cai, 2010).

According to Hoffman et al. (2013) normative data or trace classification system of choice remains unclear. It may be postulated that participants make use of norms and classification systems which they are most familiar with and that are easy to use, despite their limitations. It is also not always clearly stated in literature as to whether the norms or classification methods provided by researchers are based on the use of screening or diagnostic HFT equipment.

Even though participants have reported to have clinical protocols, there is currently no universal agreement on the interpretation of HFT data (Kei & Mazlan, 2012). Hence, careful interpretation HFT results are required in combination with other audiological results (ASHA, 2004). This further highlights the need for the development of standardized clinical protocols that is age and gender dependent. In addition, it has been reported from earlier studies that HFT was not fully put into clinical practice due to the difficulties in interpreting tympanograms and the controversial classification systems (Holte et al., 1991; Meyer & Jardine, 1997; Sutton et al., 1996). This was also evident in the current clinical practice in South Africa.

Audiologists' knowledge of the clinical application of HFT and theoretical background of the infant's middle ear system. All participants provided appropriate responses regarding the purpose of tympanometry. Although various clinical applications for HFT were also provided by participants in the current study, most were unsure. It is postulated that this is why only 50% of participants use HFT in their clinical setting despite the fact that the HPCSA (2007) and ASHA (1997) has recommended its use in NHS. The most commonly reported clinical application was found to be obtaining reliable and accurate results of middle ear pressure and compliance of the infants with middle ear pathologies. Some participants also stated more specifically that HFT is used to determine middle ear status or functioning in the high risk populations or infants' birth to six months of age. It was noted that not all participants indicated the age range for which HFT is used and this is of significance as clinicians require knowing that adult tympanometry protocols are not applicable to the neonatal and infant population due to anatomical and acoustical difference that exist (Baldwin et al., 2008). The use of adult tympanometry protocols may result in inaccurate results in this population (Hunter & Margolis, 1992; Keef & Levi, 1996). However, due to the anatomical and acoustical difference there are some controversial

suggestions noted in literature with regard to the choice of probe-tone frequency in relation to age (Alaerts et al., 2007). This may be the result of participants being unsure of the age range for which HFT is clinically applicable; hence the variability in age ranges reported by participants which have been discussed above.

The discussion above highlights the significance of having knowledge with regard to the anatomy and physiology of the neonatal and infant middle ear system as well as the acoustical differences when compared to an adult middle ear system. Most of the participants were able to appropriately describe the neonate or infant middle ear system. However, many participants also reported they were unsure and this is of concern as knowledge of the anatomical differences provides probable causal factors to test outcome discrepancies in the adult and neonatal or infant population (Cai, 2010). The neonate and infant EAC and middle ear are structurally immature and mass- rather than stiffness-dominated (Baldwin, 2006; Baldwin et al., 2008; André, Sanches & Caravallo, 2012). Further anatomic differences occur with developmental changes which influences the tympanograms (Lantz et al., 2004; Baldwin et al., 2008).

Participants were also able to appropriately identify the acoustical differences between a neonate or infant and adult middle ear system, although many were also unsure in this regard. It was noted that a smaller percentage reported that there were no acoustical differences. It has been described by numerous authors that acoustical differences occur as the result of developmental changes which are found only to disappear by six months of age (Baldwin, 2006; Alaerts et al., 2007; Baldwin et al., 2008; Cai, 2010). The majority of the participants described the main differences between a neonate or infant and adult middle ear system as ear canal impedance, reflection coefficient responses and energy transmission, followed by resonance gain and resonance frequency. These acoustical differences have been reported by both earlier and

recent authors (Keefe & Bulen, 1993; Alaerts et al., 2007). Not many participants referred to the frequency range for which energy transmission is most efficient as one of the acoustical differences between a neonate or infant and adult middle ear system. It has been reported that in neonates and infants between 1000 Hz to 4000 Hz energy transmission is best whilst between 220 Hz and 660 Hz is seen as the worst (Keefe & Bulen, 1993).

Most of the participants also reported that maturational changes that occur in the neonate or infant middle ear system do have an effect on the acoustical properties of the infant's ears. This is confirmed by numerous authors (Holte et al, 1991; Baldwin, 2006; Alaerts et al., 2007; Baldwin et al., 2008; Cai, 2010). It has also been reported for both mechanical and acoustical properties of the neonate or infants' middle ear system to be affected during the course of postnatal development (Cai, 2010). This is a result of the middle ear structures being important components of the conductive mechanism which undergo significant changes during postnatal development in the first four months of life (Holte et al, 1991; Hall, 2000; Cai, 2010).

A small percentage of participants reported that maturational changes that do occur to the infant's middle ear system, do not have an effect on the acoustical properties of the infant's ear. It is important for audiologists to have knowledge about maturational changes as this will assist the clinician in understanding the development of hearing sensitivity and adds more significant interpretation of audiologic measures in neonates and infants, including UNHS outcomes (Cai, 2010). The use of HFT (1000Hz probe tone) is more applicable for the use of neonate and infants due to their great mass contribution, lower middle ear compliance and higher resistance (Purdy & Williams, 2000; Alaerts et al., 2007). LFT is only successfully used to evaluate middle ear functioning in infants over six months old due to the acoustical and anatomical differences (Baldwin, 2006; Baldwin et al, 2008).

It is essential for audiologists working in the field of paediatric audiology to have appropriate knowledge and necessary skills in the identification of middle ear pathologies in neonates and infants (Lewis, 2000, p. 173). The above discussion indicates the need for more clinical and in-service training of hearing health professionals on the importance, performance and interpretation of HFT. The limited availability of clinical protocols for HFT in South Africa confirms that audiologists are performing HFT despite being unsure of current best-practice guidelines. This highlights the need for the development of universal evidence-based guidelines for the use of HFT in neonates and infants.

Main Study Phase 2: Hearing Screening

Main aim 2 and 3: Agreement between the pass and refer rates of screening tests.

HFT and LFT. A poor agreement was obtained between HFT and LFT. This may be attributed to HFT being highly sensitive in the identification of OM in neonates and infants. LFT is also unable to detect subtle changes in the middle ear system if compared to HFT (Harris et al., 2005; Cai, 2010). Therefore, normal LF tympanograms may be recorded in neonates and infants even in the presence of MEE (Hunter & Margolis, 1992; Keef & Levi, 1996). This may be evident in the current study as LFT presented with a high pass rate bilaterally in both sample sizes when compared to HFT.

However, this is also found to be in contrast to two studies (Do Carmo et al., 2012; Alaerts et al., 2007). In Do Carmo et al. (2012) study LFT was found to present with a lower percentage (57.55%) and HFT obtained a higher percentage (72.64%) of normal type A tympanograms in neonates and infants less than seven months of age. In Alaerts et al.'s. (2007) study LFT was also found to present with a low pass rate (35%) and HFT obtained a higher pass rate (91%) in neonates younger than three months of age. Furthermore, in infants between three

and nine months of age LFT presented with a lower pass rate (57%) compared to HFT (70%) (Alaerts et al., 2007). The population in both these studies also presented with risk factors for HL as that of the current study.

Literature has reported that LFT has a high rate of false negative and false positive results when performed on neonates or infants under seven months of age (Meyer et al., 1997; Purdy & Williams, 2002; Macedo de Resende et al., 2012; Hoffman et al., 2013). LF tympanogram shapes obtained in neonates and infants are different than those seen in older paediatric population and adults (Keefe & Levi, 1996; Meyer et al., 1997). This may be attributed to the anatomical and acoustical difference which exists between the infant and adult middle ear transmission system (Keefe & Levi, 1996; Petrak, 2002). Therefore, LFT has been accepted as the criterion standard to differentiate a CHL from a sensori-neural hearing loss in adults and the older paediatric population. LFT is also known to have a low sensitivity when used in neonates and infants younger than six months of age (Baldwin, 2006; Alaerts et al., 2007; Baldwin et al., 2008).

Although, according to Do Carmo et al (2012) HFT can also present with false negative and false positive results, although not as high as for LFT. This could be due to the increased complexity of the tympanograms as well as the increased occurrence of double peaked tympanograms in neonates and infants. As a result highlighting the need for better interpretation of HF tympanograms (Hoffman et al., 2013; Do Carmo et al., 2012). This has also been a prominent factor implicated by participants in main study phase one, further indicating the significant need for the development of standardised clinical protocols.

In contrast to the poor agreement obtained in the current study, Harris et al's (2005) study found a strong agreement between LFT and HFT in identifying the presence and absence of

middle ear pathologies. This may be as a result of the age of the population used in Harris et al.'s. (2005) study, as LFT is found to be valid in the older paediatric populations (Alaerts et al., 2007). Harris et al. (2005) revealed that even though the use of LFT was found to be a successful predictor of the presence or absence of fluid in the middle ear (with a sensitivity of 80% and a specificity of 100%), the LF probe tone still identified three out of 10 cases as normal while they were identified as abnormal by HFT results. In addition, it was found that the HF probe tones (667 Hz and 1000 Hz) presented with more consistent findings when compared to that of a LF probe tone (226 Hz). MFT tympanograms can show persistence of changes in the mass and stiffness balance of the middle ear which is not established by LFT (Harris et al., 2005). This indicates that LFT may also result in false negative and false positive results in the older paediatric population and not only in neonates and infants younger than six months of age.

It is also important to note that the method used to interpret tympanograms may also be a contributory factor for results of the current study to be in contrast to Harris et al.'s (2005) study. As the number of tympanograms classified as normal and abnormal may differ between the studies. The Jerger and Liden classification method was used by Harris et al. (2005) and the current study to interpret LF tympanograms. This method of interpretation has been effective in classifying the results by pattern in the older paediatric population and adults (Liden 1969; Jerger 1970; Baldwin et al., 2008). The LF tympanograms are typically single-peaked and easier to interpret (Baldwin et al., 2008).

The method of interpretation used for HF tympanograms in the current study is different to that used by Harris et al. (2005). The current study used the GSI equipment manual (GSI, 2011) to interpret HF tympanograms according to graphic representation and percentile areas based on the Margolis et al.'s. (2003) study, whereas Harris et al. (2005) made use of the

Vanhuyse model. The Vanhuyse model has shown to be effective in classifying HF tympanograms but it has been reported by Alaerts et al. (2007) to be more complex and less applicable to a clinical hearing assessment. Hence, the recommendation of a simple visual admittance classification method for the interpretation of HF tympanograms (Alaerts et al., 2007). This simple visual admittance classification method was found to have a high prevalence (91%) of single peaked HF tympanograms (infants younger than three months of age) in Alaerts et al's. (2007) study. These results were found to correspond with Kei et al's. (2003) and Margolis et al's. (2003) findings which revealed a prevalence of 92% and 91% single -peaked HF tympanograms respectively. These findings further indicated the efficiency of a simple visual admittance classification method for the interpretation of HF tympanograms, which was the method of choice used in the current study.

However, in Baldwin's (2006) study the number of single peaked tympanograms was shown to decrease with age. Limitations of these studies are that they have not validated their findings on neonates and infants with reliable evidence of confirmed middle ear pathologies (Baldwin, 2006). This was also a limitation of the current study, as the presence or absence of middle ear pathologies were not confirmed by an otolaryngologist and thus only the pass and refer rates of the various screening tests could be described. A combination of otolaryngological examination and tympanometry evaluation is sensitive to and important in the identification of OM especially in the neonatal and infant population (Garcia et al., 2009; Kilic et al., 2012).

In addition, Hoffman et al. (2013) states that the visual admittance classification methods are dependent on the examiners experience as well as the subjective judgment of a distinct peak. Therefore, this may also be a causative factor to the poor agreement obtained between the HFT

and LFT. However, the interpretation method used in the current study showed to be effective in classifying HF tympanograms accurately as a good inter rater reliability was obtained.

HFT and otoscopy. A fair to good agreement was obtained between HFT and otoscopy in the current study. This has been shown by numerous studies (Garcia et al., 2009; Kilic et al., 2012). In these studies, the age range of participants varied, yet HFT has shown to have the best correlation with otoscopic results. The participants in these studies also presented with similar risk factors for HL as participants in the current study. The age of participants in these studies ranged from birth to four months of age (Garcia et al., 2009) and two hours to nine days of age (Kilic et al., 2012). This confirms the validity of using HFT with neonates and infants birth to six months of age. It further highlights the importance of conducting both HFT and otoscopy to confirm the presence or absence of middle ear pathology.

In the current study, a standard otoscope was used to perform the otologic examination as part of the hearing screening protocol. However, studies have found it to have the least sensitivity and specificity when compared to other otologic instruments, such as pneumatic otoscope, otomicroscope and video-otoscope (Wilson, 2008).

Pneumatic otoscopy has found to be more accurate in the detection of MEE (Alper et al., 2004; Harris et al., 2005; Al-Khatib, 2010; Finitzo et al, 1992; Vaughn-Jones & Mills, 1992). Pneumatic otoscopy is mainly used by otolaryngologists in the diagnosis of OM, despite that it does not always improve diagnostic accuracy of middle ear pathologies in the paediatric population (Alper et al., 2004; Al-Khatib, 2010). Nevertheless, otoscopic examination with the use of a standard otoscope is the routine method used by audiologists and in general practice (Palmu, 2001).

The lack of a confirmed diagnosis of middle ear pathology by an otolaryngologist when there was a distinct possibility based on otoscopy and HFT results comprised the validity of the screening tests in the current study in identifying middle ear pathologies.

LFT and otoscopy. A poor agreement was found in the current study between pass and refer rates for LFT and otoscopy. The poor agreement between these screening tests was also found in other studies (Garcia et al., 2009; Kilic et al., 2012). In these studies LFT was performed on a population age where it is reported to be invalid due to its poor sensitivity (Baldwin, 2006; Baldwin et al., 2008; Wilson, 2008).

Overall when determining the agreement for HFT and LFT with otoscopy, it must be taken in consideration that an otoscopic examination is a subjective technique. An otoscopic examination is prone to observer bias and subjective to variability in technique (Palmu, 2001). This may be a contributory factor for not obtaining better agreements for HFT and LFT with otoscopy. Otoscopic examination results should be compared to tympanometry results (Palmu, 2001) as in the current study. Hence, validation of otoscopic skills is highly recommended for professionals working with the paediatric population. This however requires considerable time and resources (Palmu, 2001).

Furthermore, in the current study otoscopic examinations was performed by the researcher and the research assistants, who were all audiologists. However, inter-tester reliability was not established in order to determine the agreement in measurements taken by two different individuals. This would have increased the reliability of results obtained and this has been acknowledged as a limitation of the study.

HFT and DPOAEs. HFT was found to present with a poor agreement with DPOAEs in the four hearing screening sample size as DPOAEs obtained significantly low pass and refer

rates. This is contrary to findings of other studies (Koivunen et al., 2000; Swanepoel et al., 2006; Garcia et al., 2009; Camboim et al., 2012 & Kilic et al., 2012). In these studies HFT presented with significant agreement with OAEs. In Swanepoel et al's. (2006) study NHS was performed on neonates and infants from birth to 12 months of age and normal HF tympanograms were obtained in 87% (pass result) of the sample ears whilst DPOAEs presented with a high pass rate of 93%. HFT is reported to correlate with OAEs in both normal ears as well as ears with middle ear pathologies (Camboim et al., 2012). Therefore, HFT and DPOAEs was expected to present with relatively similar pass and refer rates and thus agreement in the current study.

Despite that HFT has been reported by numerous studies to be highly sensitive in the identification of middle ear pathologies, it has been found that HFT can present with decreased sensitivity and this can be attributed to the presence of MEE in a number of ears with present but decreased OAEs (Sutton et al., 1996; Kei et al., 2003; Swanepoel et al., 2007). This leads to an overlap of true positive HFT results and false negative OAE results, resulting in decreased immittance sensitivity.

LFT and DPOAEs. In the current study LFT and DPOAEs were found to have a poor agreement in the four hearing screening sample size as DPOAEs obtained significantly low pass and refer rates. This was also evident in a study conducted by Kilic et al. (2012). These results can be attributed to research confirming that LFT is invalid within the participant age range of the current study.

In addition, Do Carmo et al's. (2012) study found LFT to present with a predominance of normal results, regardless of the outcome of the OAE results. This indicated decreased sensitivity of LFT in the identification of middle ear pathologies in neonates and infants with risk factors for HL (Do Carmo et al., 2012). The current study may support these findings as a high

pass rates (normal results) were obtained by LFT bilaterally compared to other screening tests. However, LFT has found to present with results which are more consistent with OAEs in the presence of a normal middle ear functioning (Camboim et al., 2012). This does not appear to be evident in the current study as significant low pass rates were obtained for DPOAEs bilaterally.

Furthermore, there may be several other reasons as to why a poor agreement was obtained between HFT and DPOAEs, and LFT and DPOAEs which are explored below. However, it should be noted that when comparing the current study to research findings, majority of studies made use of TEOAEs in their test battery (Koivunen et al., 2000; Garcia et al., 2009; Camboim et al., 2012; Kilic et al., 2012) whilst in the current study DPOAEs were utilised. In clinical practice, TEOAEs have been used mainly for NHS and has shown correlation with behavioral audiometric thresholds (Campbell, 2012). TEOAEs are also more tolerant to noise and movement than DPOAEs (Cunningham, 2011).

Furthermore, the level of noise in the recording is a significant variable in the validity of OAE screening results. Therefore valid and reliable OAE results are dependent on the screening environment being very quiet and vibration free as possible (AAA, 2011). Thus this poor agreement may be attributed to the challenges experienced at various screening sites when using DPOAEs.

Table 5.1

Challenges Experienced at Various Testing Sites

Site	Description	Noise
Rahima Moosa Mother and Child Hospital	<p>Participants were screened in four different settings.</p> <ul style="list-style-type: none"> • Participants from the medical and caesar wards were screened in the nurses' duty rooms and emergency rooms. • Participants from the KMC wards were screened in any KMC room that was unoccupied. • Speech Therapy Department • Audiology Department 	<p>Medical wards:</p> <ul style="list-style-type: none"> • The room door could not be closed fully. • Nurses and doctors would enter the room on a regular basis to obtain medication and hospital records. • Noise of the refrigerator where medicines were stored for patients. • Doctors ward rounds. • Nurses meetings. • Baby monitors going on and off on a regular basis. • Other neonates and infants crying excessively in the ward. <p>KMC wards: The ward was located next to the NICU, where continuous noise of the baby monitors affected the testing.</p> <p>Speech Therapy Department: Noise from the children in the waiting area as well as therapist giving therapy in their rooms could be heard. Testing at times took place in the department due to the audiology department being occupied.</p> <p>Audiology Department: Noise of the generators and outside environmental noise of the cars affected the testing.</p>
Door of Hope of Children's Mission	<p>Testing was conducted in an isolation room, which was unoccupied at the time for testing.</p>	<p>The isolation room was located next to the dining room where meetings were held in the mornings and near the lounge area where neonates and infants were being fed by the volunteers.</p> <p>The crying of the neonates and infants as well as the meetings held increased the noise levels which made it difficult to perform DPOAEs.</p>
Mother Teresa	<p>A separate room for hearing screening was not available. Testing was conducted in a room where space was available to set up the equipment.</p>	<p>The day of testing volunteers arrived from various organizations to spend time and assist the housemothers with the neonates and infants. This caused a disturbance as volunteers would walk into the rooms whilst testing to fetch the neonates and infants.</p> <p>Volunteers singing with the neonates and infants in the opposite room could also be heard.</p>

Other common factors that may affect DPOAE screening are physiologic factors such as the sucking, movement, crying and the breathing noise of neonates and infants (AAA, 2011). All of which could lead to an increased number of false positive results (Palmu, 2001). In the current study, otoscopy and HFT were performed first and therefore by the time it came to performing DPOAEs neonates and infants would usually be awake or restless. All these challenges resulted in longer screening times. Despite this, the researcher tried to always obtain results from neonates and infants that were asleep or quiet.

The appropriate selection and placement of the probe tip to obtain an optimal acoustic seal can to some extent negate the influence of background noise (AAA, 2011). An optimal probe seal was ensured for every neonate and infant screened, however controlling background and other physiologic noise such as breathing and sucking noise was not always within the researcher's control.

These factors all contributed to the challenges experienced with performing DPOAEs in the current study. It has been confirmed that OAEs are difficult to obtain in settings with high ambient noise levels (Olusanya et al., 2008a; Olusanya et al., 2008b). This may result in difficulty completing OAE screening on neonates and infants in the LF range less than 1000 Hz (AAA, 2011; Gorga et al, 2000). Reliable results have shown to be obtained at 2000, 3000 and 4000 Hz (Gorga et al, 2000). For the current study, the default DPOAE protocol was used (GN Otometrics, 2014).

The clinical implications of the DPOAE screener malfunctioning during data collection needs to be considered. Equipment malfunction is one of the risks in NHS programmes as this result in invalid screening results (AAA, 2011). It is the responsibility of the audiologist to evaluate risk factors associated with the screening programmes and to develop procedures to

minimize or eliminate those factors (AAA, 2011). The researcher noted that the DPOAE was unable to calibrate the probe fit and provide reliable results. Hence, the use of the DPOAE screener was discontinued resulting in two sample sizes in the current study (Table 4.4). The equipment was sent in for repairs and no other DPOAE screener was readily available during the period of data collection. It is important for audiologists to undergo proper training in using the equipment, identifying factors that may impact on validity of the results, maintenance of equipment and repeating screening results to ensure reliability.

Despite these challenges OAEs are also very sensitive to the conductive components of hearing (Kemp, 2002). DPOAEs can be affected by outer or middle ear dysfunction as no results will be recorded if the neonate or infant presents with ear canal debris, MEE, and other pathologies such as otosclerosis or ossicular discontinuity (JCIH, 2007; Kemp, 2002). However, it has been reported that OAEs may not be affected by mild middle ear dysfunction (Picanco et al., 2012). Hence, OAEs is also not an adequate way to determine middle ear dysfunction and this may be due to numerous reasons such as poor probe fit, unfavorable testing conditions, as well as SNHL (Baldwin, 2006).

AABR is therefore recommended for NHS as it can be recorded in the first few hours of life, when OAEs cannot be obtained (Kemp, 2002). AABR is much more robust with less failure as result of mild middle ear pathologies. However, when infants present with severe OM, a refer result may be obtained (Taylor & Brooks, 2000; Hall, Smith & Popelka, 2004). AABR could not be utilised for the purpose of this study as equipment was not available to the researcher for the period required. Nevertheless, DPOAEs still presented to be a very useful screening test. The dependence on a “normal or close to normal functioning middle ear system” makes OAEs a functional measure for comparison to tympanometry results (Swanepoel et al., 2007, p.54). This

provides sensitivity and specificity estimates for HFT when air and BC ABR measurements are unavailable (Swanepoel et al., 2007).

Overall it must be taken in consideration that the poor agreements obtained among the screening tests can also be attributed to the common fact that neonates and infants are a difficult to test population. As well as any obstruction in the EAC (e.g. vernix caseosa, debris and cerumen) that may block the probe tip, thickened TM or crust on the TM as a sequelae of an OM episode may produce confounding tympanometric results (Palmu, 2001, Baldwin, 2006). This further highlights the importance of performing an otoscopic examination prior to tympanometry screening (Kent, 2004; Bluestone & Klein, 2007; Kooper, 2008).

MEE is a commonly identified among neonates and infants (Engel, Mahler, Anteunis, Marres & Zielhuis, 2001; Boone et al., 2005). A recent study has pointed out that OME may contribute up to 67% of the false positive newborn hearing screens (Boone et al., 2005). HFT has therefore been the frequency of choice due to its high sensitivity in correctly identifying middle ear components in early infancy (Baldwin, 2006). Hoffman et al. (2013) has reported the uncertainty up to which age HFT is used as well as the interpretation method of choice (Hoffman et al., 2013). The variability and uncertainty of this has been made evident by participants' responses in the survey questionnaires. Hoffman et al. (2013) has also reported for HFT to be superior to LFT in neonates and infants. This has also been shown to be evident in the current study as HFT was found to present with overall better Kappa values than LFT when compared to other audiological screening tests.

Comparing results of pass and refer rates and agreements among various screening tests for this current study with previous research studies is challenging as there are no findings that have evaluated these elements on HFT using the same test parameters, interpretation methods,

sample size, age range and participant population. Nevertheless, the above discussion has highlighted the following:

- LFT may also produce inaccurate results in the older paediatric population.
- Further research on the use of HFT in the older paediatric population is required.
- Need for standardized clinical protocols or guidelines for the interpretation of HFT.
- Importance of performing otoscopy prior to tympanometry and DPOAEs.
- Importance of suitable test environment to obtain reliable and accurate results.

Chapter Six

Conclusion

This chapter provides a summary of the results obtained for the current study, followed by a critical review and implications of the study and ends with recommendations for future research.

Overview of Results

Main study phase 1: Survey questionnaire.

Main aim 1: Use of HFT in current clinical practice.

Availability of tympanometry equipment in paediatric audiology departments or practices. Majority of the participants reported to have access to a tympanometer in their practice or department. However, of these participants only 50% had access to HFT.

Current clinical practice of HFT in paediatric audiological assessment.

Inclusion of HFT in paediatric audiological assessments. The majority of participants who have access to tympanometry reportedly included tympanometry in their basic paediatric test battery. Many participants used a combination of LFT and HFT. The majority of the participants using HFT reported to always include HFT in their paediatric test battery. Participants who reported to never include HFT in their paediatric test battery said this was mainly due to a lack of equipment. HFT was also found to mainly be used for infants ranging from birth to nine months of age.

The availability of departmental clinical protocols for HFT. Most of the participants using HFT reported to have clinical protocols. The majority of these participants reported to be using the international NHSP tympanometry protocol v2.0 (Baldwin et al., 2008) or self-developed protocols. Many participants were also found to be unsure as to which norms and

classification systems are used for the interpretation of HFT. The majority of the participants were also 'unsure' as to why no clinical protocols were available in their clinical setting as well as to which norms and classification systems are used for the interpretation of HFT.

Audiologists' knowledge of the clinical application of HFT and theoretical background of the infant's middle ear system. Most of the participants were able to appropriately indicate what the purpose of tympanometry is. The most commonly reported clinical application of HFT was stipulated to obtain reliable and accurate results of middle ear pressure and compliance of the infants with middle ear pathologies. The majority of the participants appropriately described the infant's middle ear system and acoustical differences. However, many participants were also unsure. Most of the participants also reported that maturational changes do have an effect on the acoustical properties of the infant's middle ear.

Main study phase 2: Hearing screening.

Main aim 2: Pass and refer rates of screening tests. The highest pass rates were obtained by LFT bilaterally when compared to the other screening tests in both the four and three hearing screening sample size. In the four hearing screening sample size the pass rates for HFT was significantly lower than LFT. However, the pass and refer rates of HFT and otoscopy are relatively similar. The lowest pass rates were obtained for DPOAEs and were significantly lower when compared to HFT and LFT. In the three hearing screening sample size lower pass rates were obtained for both the HFT and otoscopy. However, the pass and refer rates for HFT and otoscopy was not as similar to the four hearing screening sample size.

Main aim 3: Agreement of the pass and refer rates between HFT and other screening tests.

- A fair to good agreement was obtained between HFT and otoscopy.
- A poor agreement was obtained between HFT and LFT.

- A poor agreement was obtained between HFT and DPOAEs.
- A poor agreement was obtained between LFT and otoscopy.
- A poor agreement was obtained between LFT and DPOAEs.

Overall HFT and DPOAEs, and HFT and otoscopy were found to present with better Kappa results when compared to LFT and DPOAEs, and LFT and otoscopy.

Critical Evaluation of the Study

Strengths of the study.

- The validity of the survey questionnaire was established prior to data collection was found to have good face- and content validity.
- The use of the Survey Monkey website allowed for survey questionnaires to be distributed to large number of participants at a time. It also facilitated easy access to data.
- Good response rate was obtained from the survey questionnaires.
- Large sample size was obtained which was representative of the population age for which HFT should be used.
- Calibration of equipment was confirmed prior to testing.
- This was the first study that specifically focused on the use of HFT in South Africa.

Limitations of the study.

- Missing data was noted on survey questionnaires that were hand distributed. This resulted in incomplete questionnaires and decreased sample size as these questionnaires were excluded from the main study.

- Although a pilot study was done for the survey questionnaires, there is still a possibility to misinterpret questions. Participants were provided with the researcher's contact details on the cover letter for any queries.
- The following questions were not included in the survey questionnaire and this would have allowed for a more detailed analysis of the results:
 - Is the age of the participants for which HFT is used, GA, CA or chronological age?
 - Is the tympanometer (LFT and HFT) available in their clinical setting a screening or diagnostic tympanometer?
- Sensitivity and specificity of the hearing screening tests could not be established as a confirmed diagnosis of the presence or absence of middle ear pathologies were not made by an otolaryngologist.
- The OAE screener malfunctioned during the data collection period resulting in a decreased sample size of participants with DPOAE results.
- High noise levels were experienced at various sites which affected DPOAE screening. This is a significant variable in obtaining valid and reliable DPOAE results. However, DPOAE screening was repeated and every attempt was made to perform the screening in favorable conditions; to ensure reliable and valid results are obtained.
- A sound level meter was not used to determine the level of noise in the screening environment. This would have allowed the researcher to monitor the level of noise during DPOAE screening.

- Inter-tester reliability was not done for otoscopic examination; therefore the agreement in measurements taken by two different individuals could not be determined. This would have increased the reliability of results obtained.
- Duration of performing HFT was not recorded in order to determine the approximate time required as well as the effects of timing on reliability and validity.
- NHS also involves the use of an AABR (JCIH, 2007; HPCSA, 2007). This screening test could not be included in the study as equipment was not available. The inclusion of the AABR would have added an additional dimension as it can assist in distinguishing between possible SNHL and CHL.

Implications of the Study

- Undergraduate curricula should include more in-depth training on the importance and use of HFT as this will increase audiologists' confidence level in performing HFT.
- Continuing professional development activities should be offered on use of HFT in order to increase audiologists' knowledge in this field and improve their current clinical practice.
- Clinical protocols for audiological screening and assessments of neonates and infants should include HFT. These protocols should include information on the interpretation of HFT.
- Suppliers of audiological equipment should ensure that appropriate training is given to audiologists on the HFT equipment (screening or diagnostic) supplied as well as on the interpretation of normative data specific to the equipment.
- It is essential that audiologists (both in the private and public health care sector) have access to audiological equipment that is relevant for use in the paediatric population. Equipment should be well-maintained and timeously repaired. Funding must be made available in the public health care sector for the procurement and maintenance of equipment.

Recommendations for Future Research

Preliminary answers and many more questions were raised by this study that can be answered by conducting research in the following areas:

- To obtain clear and specific normative data for HFT that is age dependent within the age range of birth to six months.
- To investigate the follow up results of neonates and infants failing NHS measures including HFT.
- To determine the sensitivity and specificity of HFT on premature neonates and infants who refer NHS.
- The development, implementation and effectiveness of national, evidence-based guidelines for HFT.
- To determine the use of HFT in current clinical practice by ENTs.
- To determine the reliability and validity of a standard otoscope vs. a pneumatic otoscope in the diagnosis of middle ear pathologies in neonates and infants.
- To investigate the various middle ear acoustics of premature babies in comparison to full term neonates and infants and its effects on NHS measures.

Overall, this study concludes that there is room to improve South African audiologists' knowledge and theoretical background within this area, as well as the significance of performing HFT for the correct paediatric population age.

'I have walked that long road to freedom.

I have tried not to falter; I have made missteps along the way. But I have discovered the secret that after climbing a great hill, one only finds that there are many more hills to climb. I have taken a moment here to rest, to steal a view of the glorious vista that surrounds me, to look back on the distance I have come. But I can only rest for a moment, for with freedom come responsibilities and I dare not linger, for my long walk is not ended.'

~ Nelson Mandela ~

References

- Abdala, C., & Keefe, D.H. (2006). Effects of middle ear immaturity on distortion product otoacoustic emission suppression tuning in infant ears. *Journal of the Acoustical Society of America*, *120*, 3832-3832.
- Aehlert, B., & Vroman, R. (2011). *Paramedic practice today: Above and beyond*. Barlington, MA: Jones & Bartlett Learning.
- Alaerts, J., Luts, H., & Wouters, J. (2007). Evaluation of middle ear function in young children: Clinical guidelines for the use of 226- and 1000-Hz tympanometry. *Otology & Neuro-Otology*, *28*(6), 727-732. Retrieved from <https://lirias.kuleuven.be/bitstream/123456789/77510/1/alaerts+et+al>
- Alexiades, G., & Hoffman, R. A. (2008). Medical evaluation and management of hearing loss in children. In J. R. Madell & C. Flexer (Eds.), *Pediatric audiology: Diagnosis, technology, and management* (pp. 25-30). New York, NY: Thieme Medical Publishers.
- Alper, C., Bluestone, C., Casselbrant, M., Dohar, J., & Mandel, E. (2004). *Advanced therapy of otitis media*. Hamilton, Ontario: BC Decker.
- Al-Khatib, T. A. (2010). *Does pneumatic otoscopy improve the diagnostic accuracy of otitis media with effusion in clinical practice? A randomized single-blind control trial*. (Unpublished master's thesis). McGill University, Montreal.
- Alper, C., Bluestone, C., Casselbrant, M., Dohar, J., & Mandel, E. (2004). *Advanced therapy of otitis media*. Hamilton, Ontario: BC Decker.
- American Academy of Audiology. (2011). *Childhood hearing screening guidelines*. Retrieved from https://www.cdc.gov/.../hearingloss/.../aaa_childhood-hearing-guidelines_2011
- American Speech-Language-Hearing Association. (1997). *Guidelines for audiologic screening* [Guidelines]. Retrieved from <https://www.asha.org/policy>.
- American Speech-Language-Hearing Association. (2004). *Guidelines for the audiologic assessment of children from birth to 5 years of age*. Retrieved from <https://www.asha.org/policy/GL2004-00002>
- André, K. D., Sanches, S. G. G., & Carvallo, R. M. M. (2012). Middle ear resonance in infants: Age effects. *International Archives of Otorhinolaryngology*, *16*(3), 353-357. doi: 10.7162/S1809-97772012000300009
- Anson, B. J., & Donaldson, J. A. (1981). *Surgical anatomy of the temporal bone* (3rd ed.). Philadelphia, Pennsylvania: W. B. Saunders.
- Babbie, E. (2010). *The practice of social research*. Belmont, CA: Wadsworth Cengage Learning.
- Baldwin, M. (2006). Choice of probe tone and classification of trace patterns in tympanometry undertaken in early infancy. *International Journal of Audiology*, *45*(7), 417-427. doi: 10.1080/14992020600690951

- Baldwin, M., Sutton, S., Gravel, J., & Low, R. (2008). *Tympanometry in babies under 6 months: A recommended test protocol v. 2.0*. Antenatal and Newborn Screening Programmes. University of Manchester, Manchester.
- Bauer, S. C., & Brazer, S. D. (2012). *Using research to lead school improvements: Turning evidence into action*. Thousand Oaks, California: Sage Publications.
- Bess, F. H., & Humes, L. E. (2008). *Audiology: The fundamentals (4th ed.)*. Philadelphia, PA: Lippincott Williams & Wilkins.
- Bluestone, C., & Klein, J. (2007). *Otitis media in infants and children (4th ed.)*. Hamilton, Ontario: BC Decker.
- Boone, R. T., Bower, C. M., & Martin, P. F. (2005). Failed newborn hearing screens as presentation for otitis media with effusion in the newborn population. *International Journal of Pediatric Otorhinolaryngology*, 69(3), 393-397. Retrieved from <http://www.sciencedirect.com/science/article/pii/S0165587604003726>
- Bosaghzadeh, V. (2011). *Conventional and multi-frequency tympanometric norms for Caucasian and Chinese school-aged children*. (Unpublished master's thesis). University of British Columbia, Vancouver.
- Breen, K. J., Cordner, S. M., Thomson, C. J. H., & V. D. Pleuckhahn. (2010). *Good medical practice: Professionalism, ethics & law*. Port Melbourne, Australia: Cambridge University Press.
- Burkey, J. M., Lippy, W. H., Schuring, A. G., & Rizer, F. M. (1999). *Hearing better: Understanding your hearing and ear care options*. Parkland, Florida: Universal Publishers.
- Buttaro, T. M., Trybulski, J., & Sandberg-Cook, J. (2013). The changing landscape of collaborative practice. In T. M. Buttaro, J. Trybulski, P. P. Bailey & J. Sandberg-Cook (4th ed.), *Primary care: A collaborative practice* (pp. 1-4). St Louis, Missouri: Elsevier Mosby.
- Campbell, K. C. M. (2012, June 15). *Otoacoustic emissions*. Medscape Reference. Retrieved from <http://www.emedicine.medscape.com/article/835943-overview>
- Camboim, E. D., Correia, A. M. N., Vasconcelos, D., Torres, R., Scharlach, R. C., Azevedo, M. F. (2012). Comparative analysis of otoacoustic emissions with tympanometry in 0-6 month infants. *Rev CEFAC-Speech, Language, Hearing Sciences and Education Journal*, 14(3): 403-412.
- Cai, A. (2010). *Longitudinal investigation of middle ear function using multi-frequency, multi-component tympanometry from birth to 6 months of age*. (Unpublished master's thesis). University of British Columbia, Vancouver.
- Carlson, L. H., & Carlson, R. D. (2003). Clinical management: Diagnosis. In R. M. Rosenfeld & C. D. Bluestone (2nd ed.), *Evidence-based otitis media* (pp. 136 -146). Ontario, Canada: BC Decker.

- Carmo, M. P., De Oliveira Costa, N. T., & Momensohn-Santos, T. M. (2013). Tympanometry in Infants: A study of the sensitivity and specificity of 226-Hz and 1,000-Hz probe tones. *International Archives of Otorhinolaryngology*, 17(4), 395–402.
- Cavaliere, T. A., & Sansoucie, D. A. (2013). Assessment of the newborn and infant. In C. Kenne & J. W. Lott (5th ed.), *Comprehensive neonatal nursing care* (pp. 71-112). New York, NY: Springer Publishing Company.
- Chatburn, R. L. (2011). *Handbook for health care research* (2nd ed.). Ontario, Canada: Jones & Bartlett.
- Cherry, R., & Rubinstein, A. (2012). The audiological screening for the speech-language evaluation. In C. Stein-Rubin & R. Fabus (Eds.), *A guide to clinical assessment and professional report writing in speech-language pathology* (pp. 95-116). Clifton Park, NY: Delmar Cengage Learning.
- Chiocca, E. M. (2011). Assessment of the ear. In E. M. Chiocca (Eds.), *Advanced pediatric assessment* (pp. 278-301). Philadelphia, PA: Lippincott Williams & Wilkins.
- Clark, J. L., Roeser, R. J., & Mendrygal, M. (2007). Middle ear measures. In R. J. Roeser., M. Valente & H. Hosford-Dunn (2nd ed.), *Audiology: Diagnosis* (pp. 380-399). New York, NY: Thieme Medical Publishers.
- Clark, T. M., & Benso, D. (2008). Private practice issues. In H. Hosford-Dunn, R. J. Roeser & M. Valente (2nd ed.), *Audiology: Practice management* (pp. 128-149). New York, NY: Thieme Medical Publishers.
- Coates, H., & Gifkins, K. (2003). Diagnostic tests: Newborn hearing screening. *Australian Prescriber*, 26(4), 82-84. Retrieved from [http:// www.australianprescriber.com/magazine/26/4/issue/106.pdf](http://www.australianprescriber.com/magazine/26/4/issue/106.pdf)
- Coenraad, S. (2011). *Auditory maturation and congenital hearing loss in NICU infants*. (Unpublished doctoral thesis). Erasmus University Rotterdam, Netherlands.
- Cone-Wesson, B., Vohr, B. R., Sininger, Y. S., Widen, J. E., Folsom, R. C., Gorga, M. P., & Nortorn, S. J. (2000). Identification of neonatal hearing impairment: Infants with hearing impairment. *Ear and Hearing*, 21(5), 488-507.
- Copley, G. J., & Friderichs, N. B. (2010). An approach to hearing loss in children. *South African Family Practice*, 52(1), 34-39. Retrieved from <http://www.safpj.co.za/index.php/safpj/article/download/1381/1736>
- Cottrell, R. R., & McKenzie, J. F. (2011). *Health promotion and educational research methods: Using the five chapter thesis/dissertation model* (2nd ed.). Ontario, Canada: Jones & Bartlett Publishers.
- Creswell, J. W. (2012). *Educational research: Planning conducting and evaluating quantitative and qualitative research* (4th ed.). Boston, MA: Pearson Education.
- Cunningham, R. F. (2011, March 14). *Otoacoustic emissions: Beyond newborn hearing screening*. [Online article]. Retrieved from <http://www.audiologyonline.com/articles/otoacoustic-emissions-beyond-newborn-hearing-838>

- Davis, A., & Bremner, G. (2006). The experimental method in psychology. In G. Breakwell, S. Hammond, C. Fife-Schaw & J. Smith (3rd ed.), *Research methods in psychology* (pp. 64-87). London, England: Sage Publications.
- Deiner, P. L. (2010). *Inclusive early childhood: Development resources and practice* (5th ed.). Belmont, CA: Wadsworth Cengage Learning.
- Department of Health . (n. d.). *The charter of the public and private health sectors of the republic of South Africa*. Retrieved July 18, 2012, from <http://www.doh.gov.za/docs/misc/healthcharter.pdf>
- Department of Health. (1997). *White paper: Transformation of the health system in South Africa*. Retrieved May 7, 2012, from <http://www.info.gov.za/whitepapers/1997/health.htm>
- Ditty, K. M. (2012). *Audiologists connecting the families to the EDHI process*. National Centre for Hearing Assessment and Management. Retrieved from http://www.infantheating.org/ehdi-ebook/2012_ebook/Chapter9.pdf.
- Do Carmo, M. P., Almeida, M. G., & Lewis, D. R. (2012). 226 Hz and 1 kHz tympanometry in infants with risk indicators for hearing loss. *Revista da Sociedade Brasileira de Fonoaudiologia*, 17(1), 66-72.
- Dodson, K. M., & Peng, A. (2009). Complications of acute otitis media. In R. B. Mitchell & K. D. Pereira (Eds.), *Pediatric otolaryngology for the clinician* (pp. 231-236). New York, NY: Human Press.
- Doron, R., Chan, F., Tamir, P., & Lenhardt, C. (2002). *Science educators guide to laboratory*. Arlington, Virginia: NSTA Press.
- Doyle, K., Burggraaff, B., Fujikawa, S., & Macarthur, C. (1997). Neonatal hearing screening with otoscopy, auditory brain stem response, and otoacoustic emissions. *Otolaryngology-Head and Neck Surgery*, 116 (6), 597-603.
- Easterbrooks, S. R., & Estes, E. L. (2007). *Helping deaf and hard of hearing students to use spoken language: A guide for educators and families*. Thousand Oaks, California: Sage Publications.
- Eby, T.L., & Nadol, J.B. (1986). Postnatal growth of the human temporal bone implications for cochlear implants in children. *Annals of Otolaryngology, Rhinology and Laryngology*, 95(4), 356-364.
- Engel, J., Mahler, E., Anteunis, L., Marres, E., & Zielhuis, G. (2001). Why are NICU infants at risk for chronic otitis media with effusion? *International Journal of Pediatric Otorhinolaryngology*, 57(2), 137-144. Retrieved from <http://www.sciencedirect.com/science/article/pii/S0165587600004626>
- European Medicines Agency. (2007). *Committee for medical products for human use: Guidelines on conduct of pharmacovigilance for medicines used by the paediatric population*. Retrieved from http://www.ema.europa.eu/docs/en_GB/...guideline/.../WC500003764.pdf

- Finitzo, T., Friel-Patti, S., Chinn, K., & Brown, O. (1992). Tympanometry and otoscopy prior to myringotomy: Issues in diagnosis of otitis media. *International Journal of Pediatric Otorhinolaryngology*, 24(2), 101–110. Retrieved from <http://www.sciencedirect.com/science/article/pii/016558769290136D>
- Fleiss, J. L. (1981). *Statistical methods for rates and proportions*. (2nd ed.). New York, NY: John Wiley and Sons.
- Fowler, C. G., & Shanks, J. E. (2002). Tympanometry. In J. Katz (5th ed.), *Handbook of clinical audiology* (pp. 183-185). Baltimore, Maryland: Lippincott Williams & Wilkins.
- Garcia, M. V., De Azevedo, M. F., & Testa, J. R. (2009). Acoustic immittance measures in infants with 226 and 1000Hz probe: Correlation with otoacoustic emission and otoscopy examination. *Brazilian Journal Otorhinolaryngology*, 75(1), 80-90. Retrieved from www.scielo.br/pdf/rboto/v75n1/en_v75n1a13.pdf
- Gelfand, S. (2009). *Essentials of audiology* (3rd ed.). New York, NY: Thieme Medical Publishers.
- Gerber, S. E. (1996). *The handbook of pediatric audiology*. Washington, DC: Gallaudet University Press.
- GN Otometrics. (2014). *Madsen AccuScreen OAE and ABR screener user manual*. Denmark: GN Otometrics A/S.
- Gorga, M. P., Norton, S. J., Sininger, Y. S., Cone-Wesson, B., Folsom, R. C.M., Vohr, B. R., Widen, J. E., & Stephen, T. (2000). Identification of neonatal hearing impairment: Distortion product otoacoustic emissions during the perinatal period. *Ear and Hearing*, 21(5), 400-424. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/11059701>
- Gravetter, F. J., & Foranzo, L. B. (2012). *Research methods for the behavioral sciences* (4th ed.). Belmont, CA: Wadsworth Cengage Learning.
- GSI. (2011). *GSI Auto tymp user manual*. Smorum, Denmark: Grason - Stadler.
- Hall, J.W. (2000). Development of the ear and hearing. *Journal of Perinatology*, 20(8), 11-19.
- Hall, J. W. (2007). *New handbook of auditory evoked potentials*. Boston, MA: Allyn & Bacon.
- Hall, J. W., Smith, S. D., & Popelka, G. R. (2004). Newborn hearing screening with combined otoacoustic emissions and auditory brainstem responses. *Journal of American Academy of Audiology*, 15(6), 414-425. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/15341223>
- Harlor, A. D. B., & Bower, C. (2009). Hearing assessment in infants and children: Recommendations beyond neonatal screening. *Pediatrics*, 124(4), 1252 -1263. doi: 10.1542/peds.2009-1997
- Harris, P. K., Hutchinson, K. M., & Moravec, J. (2005). The use of tympanometry and pneumatic otoscopy for predicting middle ear disease. *American Journal of Audiology*, 14(1), 3-13. Retrieved from www.units.muohio.edu/spa/documents/tympanometry.pdf

- Hauser, J. (2012). *Nursing research: Reading, using and creative evidence (2nd ed.)*. Ontario, Canada: Jones & Bartlette Learning.
- Health Professionals Council of South Africa. (2007). *Year position statement: Early hearing detection and intervention programmes in South Africa*. Retrieved from http://www.hpcsa.co.za/downloads/speech_education/early_hearing_detection_statement.pdf
- Hockenberry, M. J. (2011). Communication and physical assessment of the child. In M. Hockenberry & D. Wilson (9th ed.), *Wong's essentials of pediatric nursing* (pp. 117-226). St. Louis, Missouri: Elsevier Mosby.
- Hoffmann, A., Deuster, D., Rosslau, K., Knief, A., Zehnhoff-Dinnesen, A., & Schmidt, C. M. (2013). Feasibility of 1000 Hz tympanometry in infants: Tympanometric trace classification and choice of probe tone in relation to age. *International Journal of Pediatric Otorhinolaryngology*, 77(7), 1198–1203. Retrieved from <http://www.xa.yimg.com/kq/groups/18817297/585911890/.../görkem+ertuğrul.pdf>
- Holte, L., Margolis, R. H., & Cavanaugh, R. M. (1991). Developmental changes in multifrequency tympanograms. *Audiology*, 30 (1), 1-24. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/2059166>
- Hunter, L. L., & Margolis, R. H. (1992). Multifrequency tympanometry: Current clinical application. *American Journal of Audiology*, 1, 33-43. doi:10.1044/1059-0889.0103.33
- Ikui, A., Sando, I., Haginomori, S., & Sudo, M. (2000). Postnatal development of the tympanic cavity: A computer-aided reconstruction and measurement study. *Acta oto-laryngologica*, 120(3), 375-379.
- Jackson, S. L. (2012). *Research methods and statistics: A critical thinking approach (4th ed.)*. Belmont, CA: Wadsworth Cengage Learning.
- Jerger, J. (1970). Clinical experience with impedance audiometry. *Archives of Otolaryngology*, 92(4), 311-324. Retrieved from <http://archotol.jamanetwork.com/article.aspx?articleid=603185>
- Joint Committee on Infant Hearing. (2007). Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics*, 120(4), 898-921. doi: 10.1542/peds.2007-2333
- Johnson, C. D., & Seaton, J. B. (2012). *Educational audiology handbook (2nd ed.)*. Clifton Park, NY: Delmar Cengage Learning.
- Kaplan, R. (2006). *Physical medicine and rehabilitation review (2nd ed.)*. USA: The McGraw-Hill companies.
- KC, S., Guragain, R., & Sinha, B. (2007). Accuracy of otoscopy, tympanic membrane mobility and tympanometry in the diagnosis of otitis media with effusion. *Journal of Institute of Medicine*, 29(1), 17-20. Retrieved from <http://www.nepjol.info/index.php/JIOM/article/view/640>

- Keefe, D. H., & Bulen, J. C. (1993). Ear canal impedance and reflection coefficient in human infants and adults. *Journal of the Acoustical Society of America*, *94*(5), 2617-2638. Retrieved from <http://scitation.aip.org/content/asa/journal/jasa/94/5/10.1121/1.407347>
- Keefe, D.H., Bulen, J.C., Arehart, K.H., Burns, E.M. (1993). Ear canal impedance and reflection coefficient in human infants and adults. *Journal of the Acoustic Society of America*, *94*(5), 2617-38.
- Keefe, D. H, & Levi, E. (1996). Maturation of the middle and external ears: Acoustic power-based responses and reflectance tympanometry. *Ear Hear*, *17*(5), 361-373. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/8909884>
- Keefe, D. H., Zhao, F., Neely, S. T., Gorga, M. P., & Vohr, B. R. (2003). Ear-canal acoustic admittance and reflectance effects in human neonates. I. Predictions of otoacoustic emission and auditory brainstem responses. *Journal of the Acoustical Society of America*, *113*(1), 389–406.
- Kei, J., & Mazlan, R. (2012). High-frequency (1000 Hz) tympanometry: Clinical applications. In J. Kei & F. Zhao (Eds.), *Assessing middle ear function in infants* (pp. 39-67). San Diego, CA: Plural Publishing.
- Kei, J., Allison-Levick, J., Dockray, J., Harrys, R., Kirkegard, C., & Wong, J. (2003). High-frequency (1000 Hz) tympanometry in normal neonates. *Journal of American Academy of Audiology*, *14*(1), 20-28. Retrieved from <http://espace.library.uq.edu.au/eserv/UQ:12767/HighFrequencyTympan.pdf>
- Kelly, D. (2009). *Methods for evaluating interactive information retrieval system with users*. Hanover, MA: Now Publishers.
- Kemp, D. T., (2002). Otoacoustic emissions, their origin in cochlear function and use. *British Medical Bulletin*, *63*(1), 223-241. doi: 10.1093/bmb/63.1.223
- Kent, R. D. (2004). *The MIT encyclopedia of communication disorders*. Hong Kong: Massachusetts Institute of Technology.
- Kilic, A., Baysal, E., Karatas, E., Baglam, T., Durucu, C., Deniz, M., . . . Mumbuc, S. (2012). The role of high frequency tympanometry in newborn hearing screening programs. *European Review for Medical and Pharmacological Sciences*, *16*(2), 220-223. Retrieved from www.europeanreview.org/wp/wp-content/uploads/1306.pdf
- Koivunen, P., Uhari, M., Laitakari, K., Alho, O. P., & Luotonen, J. (2000). Otoacoustic emissions and tympanometry in children with otitis media. *Ear Hear*, *21*(3), 212-217. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/10890729>
- Kooper, R. (2008). Screening, evaluation and management of hearing loss in the school-aged child. In J. R. Madell & C. Flexer (Eds.), *Paediatric audiology: Diagnosis, technology, and management* (pp. 106-111). New York, NY: Thieme Medical Publishers.
- Kriek, F. (2006). *A hearing screening program for infants from a neo-natal intensive care unit in a South African provincial hospital*. (Unpublished master's thesis). University of Pretoria, Pretoria.

- Kumar, R. (2005). *Research methodology: A step-by-step guide for beginners (2nd ed.)*. London, England: Sage Publications.
- Lantz, J., Petrak, M., & Prigge, L. (2004). Using the 1000-Hz probe tone to measure immittance in infants. *Hearing Journal*, 57(10), 34-42. Retrieved from http://www.audiomed.com/Audiomed.com/ResourcesReferenceMaterials_files/Using%201KHz%20Probe%20Tone%20Tympanometry%20in%20Infants.pdf
- Lee, Y., & Yeo, D. (2004). Clinical diagnostic accuracy of otitis media with effusion in children, and significance of myringotomy: Diagnostic or therapeutic? *Journal of Korean Medical Science*, 19(5), 739-743. doi:10.3346/jkms.2004.19.5.739
- Lewis, D. E. (2000). Hearing instrument selection and fitting. In M. Valente, H. Hosford-Dunn & R. J. Roeser (2nd ed.), *Audiology Treatment* (pp. 149-177). New York, NY: Thieme Medical Publishers.
- Lewis, G. H., Sheringham, J., Kalim., K., & Crayford, T. J. B. (2008). *Mastering public health: A postgraduate guide to examination and revalidation*. Boca Raton, FL: Taylor & Francis Group.
- Liamputtong, P., & Ezzy, D. (2007). *Qualitative Research Methods (2nd ed.)*. New York, NY: Oxford University Press.
- Liden, G. (1969). The scope and application of current audiometric tests. *Journal of Laryngology and Otolaryngology*, 83(6), 507-520. Retrieved from <http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=1146772>
- Littleton, L. Y., & Engebretson, J. C. (2009). *Maternity nursing care*. Clifton Park, NY: Cengage Learning.
- Macedo de Resende, L., Ferreira, J. S., Carvalho, S. A. S., Oliveira, I. S., & Bassi, I. B. (2012). Tympanometry with 226 and 1000 Hertz tone probes in infants. *Brazilian Journal of Otorhinolaryngology*, 78(1), 95-102. Retrieved from http://www.scielo.br/pdf/bjorl/v78n1/en_v78n1a15.pdf
- Maico Diagnostics. (2010). *Pediatrics guide to otoacoustic emissions (OAEs) and tympanometry*. Retrieved from www.maico-diagnostics.com/.../us.../OAEPedTympanometry_2010.pdf
- Mangione, S. (2008). *Physical diagnosis secrets: With student consult online access (2nd ed.)*. Philadelphia, PA: Mosby Elsevier.
- Marchant, C. D., McMillan, P. M., Shurin, P. A., Johnson, C. E., Turczyk, V. A., Feinstein, J. C., & Panek, D. M. (1986). Objective diagnosis of otitis media in early infancy by tympanometry and ipsilateral acoustic reflexes. *Journal of Pediatrics*, 109(4), 590-595. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/3761072>
- Margolis, R., Bass-Ringdahl, S., Hanks, W., Holte, L., & Zapala, D. (2003). Tympanometry in newborn infants -1kHz norms. *Journal of the American Academy of Audiology*, 14(7), 383-392.
- Marlow, E. S., Hunt, L. P., & Marlow, N. (2000) Sensorineural hearing loss and prematurity. *Archives of Disease in Childhood-Fetal and Neonatal*, 82(2), 141-144.

- Marschark, M., & Hauser, P. C. (2012). *How deaf children learn: What parents and teachers need to know?* New York, NY: Oxford University Press.
- Maxfield, M. G., Babbie, E. (2009). *Basics of research methods for criminal justice and criminology (2nd ed.)*. Belmont, CA: Wadsworth Cengage Learning.
- Mazlan, R., Kei, J., Hickson, L., Khan, A., Gavranich, J., & Linning, R. (2009). High frequency (1000Hz) tympanometry findings in newborns: Normative data using a compensated admittance approach. *The Australian and New Zealand Journal of Audiology*, 31(1), 15-24. Retrieved from <http://www.espace.library.uq.edu.au/view/UQ:195108>
- McCabe, P. C., & Racanello, A. M. (2006). Otitis media (ear infections): Information for parents and teachers. *NASP Communique*, 35. Retrieved from <http://www.nasponline.org/publications/cq/cq354otitismedia.aspx>
- Mencher, G. T., & DeVoe, S. J. (2001). Universal newborn screening: A dream realized or a nightmare in the making? *Scandinavian Audiology*, 30 (53), 15-21.
- Meyer, D. H. (2000). Early identification: Principle and practices. In J. G. Alpiner & P. A. McCarthy (3rd ed.), *Rehabilitative audiology: Children and adults*. (pp.83-105). Philadelphia, PA: Lippincott Williams & Wilkins.
- Meyer, M. E., & Swanepoel, D. (2011). Newborn hearing screening in the private health care sector - A national survey. *South African Medical Journal*, 101(9), 665-667. Retrieved from <http://www.ajol.info/index.php/samj/article/download/69783/57850>
- Meyer, S. E., Jardine, C. A., & Deverson, W. (1997). Developmental changes in tympanometry: A case study. *British Journal of Audiology*, 31(3), 189-195. doi:10.3109/03005364000000021
- Minnesota Department of Health. (2009). *Otoscopy and tympanometry screening*. Community & Family Health Division/ Maternal & Child Health Section /Child & Adolescent Health Unit. Retrieved from <http://www.health.state.mn.us/divs/fh/mch/hlth-vis/materials/tympmanual.pdf>.
- Mills, R.P. (1987). Persistent middle ear effusions in children with recurrent acute otitis media. *Clinical Otolaryngology*, 12(2), 97-101. doi: 10.1111/j.1365-2273.1987.tb00169.x
- Monasta, L., Ronfani, L., Marchetti, F., Montico, M., Brumatti, L. V., Bavcar, A., . . . Tamburlini, G. (2012). Burden of disease caused by otitis media: Systematic review and global estimates. *Pediatric Clinics of North America*, 60(4), 391-407. doi:10.1371/journal.pone.0036226
- Moore, M. C., & De Costa, C. M. (2005). *A women's concise guide to common medical tests*. Piscataway, NJ: Rutgers University Press.
- Morton, C. C., & Nance, W. E. (2006). Newborn hearing screening-A silent revolution. *The New England Journal of Medicine*, 354, 2151-2164. Retrieved from http://www.ncham.org/coordinator_orientation/section3/16_a_silent_revolution.pdf
- Moser, J. M. (2009). *Electronics and instrumentation for audiologists*. New York, NY: Taylor & Francis Group.

- National Institute of Deafness and Other Communication Disorders. (2010). *Ear infections in children*. Retrieved from <http://www.nidcd.nih.gov>
- Nicholas, N., & Martin, P. F. (2012). Automated hearing screening. In S. R. Atcherson & T. M. Stody (Eds.), *Auditory electrophysiology: A clinical guide*. New York, NY: Thieme Medical Publishers.
- Northern, J., & Downs, M. (2002). Acoustic immittance assessment. In J. Northern & M. Downs (5th ed.), *Hearing in children* (pp. 217 – 252). Philadelphia, Pennsylvania: Lippincott, Williams & Wilkins.
- Offredy, M., & Vickers, P. (2010). *Developing a healthcare research proposal: An interactive student guide*. Ames, Iowa: Wiley- Blackwell Publishing.
- 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 Organisation*, 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
- O' Malley, M. R., & Haynes, D. S. (2010). Clinical diagnosis. In A. J. Gulya, L. B. Minor & D. S. Poe (6th ed.), *Surgery of the ear* (pp. 171-189). Shelton, CT: People's Medical Publishing House.
- Palmu, A. (2001). *Tympanometry in diagnosis and follow up of otitis media in children less than two years of age*. (Academic dissertation). Tampere University, Finland.
- Petrak, M. R. (2002). *Tympanometry beyond 226Hz-What's different in babies*. Retrieved from <http://www.audiologyonline.com/articles/tympanometry-beyond-226-hz-what-1148>
- Picanco, C. M., De Oliveira, N. T., & Momensohn-Santos, T. M. (2013). Tympanometry in infants: A study of the sensitivity and specificity of 226-Hz and 1,000-Hz probe tones. *International Archives of Otorhinolaryngology*, 17(4), 395-402.
- Pichichero, M. E. (2013). Otitis media. *Pediatric Clinics of North America*, 60(2), 391-407. doi: 10.1016/j.pcl.2012.12.007
- Polit, D. F., & Beck, C. T. (20013). *Essentials of nursing research: Appraising evidence for nursing practice* (8th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.
- Popelka, G. R., & Hunter, L. L. (2013). Diagnostic measurements and imaging technologies for the middle ear. In S. Puria, R. R. Fay & A. N. Popper (Eds.), *The middle ear: Science, otosurgery and technology* (pp. 211-252). New York, NY: Springer Science and Business Media.

- Postic, W. P. (2000). Introduction to pediatric otology. In R. F. Wetmore, H. R. Muntz, T. J. McGill, G. B. Healy & R. P. Lusk (Eds.), *Pediatric otolaryngology: Principles and practice pathways* (pp. 219-233). New York, NY: Thieme Medical Publishers.
- Powers, D. A., & Xie, Y. (2008). *Statistical methods for categorical data analysis* (2nd ed.). Bingley, UK: Emerald Group Publishing Limited.
- Purdy, S. C., & Williams, M. J. (2000). High frequency tympanometric: A valid and reliable immittance test protocol for young infants? *New Zealand Audiological Society Bulletin*, 10(3), 9-24.
- Rhodes, M., Margolis, R., Hirsch, J., & Napp, A. (1999). Hearing screening in the newborn intensive care nursery: Comparison of methods. *Otolaryngology-Head and Neck Surgery*, 120(6), 799-808.
- Roberts, C. M. (2007). *The impact of rheumatoid arthritis on middle ear function*. (Unpublished doctoral thesis). University of Maryland.
- Rosenblum, L. B. (2014). *Risk factors for hearing loss*. Retrieved from <http://health.cvs.com/GetContent.aspx?token=f75979d3-9c7c-4b16-af56-3e122a3f19e3&chunkiid=103120>
- Rubin, A. (2008). *Practioners guide to using research for evidence*. Hoboken, New Jersey: John Wiley & Sons.
- Rubin, A., & Babbie, E. (2013). *Essential research methods for social work*. Belmont, CA: Brooks/Cole Cengage Learning.
- Salazar, L. F., Crosby, R. A., & Diclemente, R. J. (2006). In R. A. Crosby, R. J. Diclemente & L. F. Salazar (Eds.), *Research methods in health promotion* (pp. 75-106). San Francisco, CA: John Wiley & Sons.
- Saunders, J.C., Doant, D.E., & Cohen, Y.E. (1993). The contribution of middle ear sound conduction to auditory development. *Comparative Biochemistry & Physiology*, 106(1), 7-13.
- screening test. (n.d.). *Collins English Dictionary - Complete & Unabridged 10th Edition*. Retrieved April 26, 2014, from Dictionary.com website: [http://dictionary.reference.com/browse/screening test](http://dictionary.reference.com/browse/screening_test)
- Shahnaz, N. (2007). *Multi-frequency tympanometry and evidence-based practice*. Hearing and Hearing Disorders: Research and Diagnostics. University of British Columbia, Vancouver.
- Shahnaz, N., Miranda, T., & Polka, L. (2008). Multifrequency tympanometry in neonatal intensive care unit and well babies. *Journal of the American Academy of Audiology*, 19(5), 392-418.
- Shiao, A. S., & Guo, Y. C. (2005). A comparison assessment of videotelescopy for diagnosis of pediatric otitis media with effusion. *International Journal of Pediatric of Otorhinolaryngology*, 69(11), 1497-502. Retrieved from <http://www.sciencedirect.com/science/article/pii/S0165587605001825>

- Silman, S., & Silverman, C. A. (1991). *Auditory diagnosis: Principles and applications*. San Diego: Singular Publishing Group.
- Silva, K. A., Novaes, B. A., Lewis, D. R., & Carvalho, R. M. (2007). Tympanometry in neonates with normal otoacoustic emissions: measurements and interpretation. *Revista Brasileira de Otorrinolaringologia*, 73(5), 633-639.
- Spivak, L. G. (2007). In R. J. Roeser, M. Valente & H. Hosford-Dunn (2nd ed.), *Audiology: Diagnosis* (pp. 497- 514). New York, NY: Thieme Medical Publishers.
- South African Rights Commission. (2009). *Public Inquiry: Access to Health Care Services*. Retrieved from <http://www.info.gov.za/view/DownloadFileAction?id=99769>
- South African Speech- Language- Hearing Association. (2011). *Guidelines: Newborn hearing screening*. Retrieved from [http:// www.saslha.co.za/B_Ethics_Standards.asp](http://www.saslha.co.za/B_Ethics_Standards.asp)
- Stach, B. A. (2003). *Comprehensive dictionary of audiology*. Clifton Park, NY: Thomson Delmar Learning.
- Stach, B. A. (2010a). *Clinical audiology: An introduction*. Clifton Park, NY: Delmar Cengage Learning.
- Stach, B. A. (2010b). Audiologic evaluation of otologic/neurotologic disease. In A. J. Gulya, L. B. Minor & D. S. Poe (6th ed.), *Surgery of the ear* (pp. 189-222). Shelton, CT: People's Medical Publishing House.
- Stangor, C. (2011). *Research methods for the behavioral sciences*. Belmont, CA: Wadworths Cengage Learning.
- Steffens, D. C., & Krishnan, K. R. R. (2003). Laboratory testing and neuroimaging: Implications for psychiatric diagnosis and practice. In K. A. Phillips & M. B. First (Eds.), *Advancing DSM: Dilemmas in psychiatric diagnosis* (pp.85-104). Arlington, VA: American Psychiatric Association.
- Survey Monkey (n.d.). *The clinical utility and use of high frequency tympanometry in South Africa (HFT)*. [Survey Questionnaire]. Retrieved October 27, 2013 from <https://www.surveymonkey.com>
- Sutton, G. J., Gleadle, P., & Rowe, S. (1996). Tympanometry and otoacoustic emissions in a cohort of special care neonates. *British Journal of Audiology*, 30(1), 9-17. doi: 10.3109/03005369609077925
- Swanepoel, D. (2006). Audiology in South Africa. *International Journal of Audiology*, 45(5), 262-266. doi:10.1080/14992020500485650
- Swanepoel, D. W., Hugo, R., Louw, B. (2006). Infant hearing screening at immunization clinics in South Africa [Abstract]. *International Journal of Pediatric Otorhinolaryngology*, 70 (7), 1241–1249.

- Swanepoel, D., Delpont, S. D., & Swart, J. G. (2004). Universal NHS in South Africa: A first-world dream? *South African Medical Journal*, 94(8), 633-634. Retrieved from <http://www2.samj.org.za/index.php/samj/article/viewFile/2661/1890>
- Swanepoel, D. W., Werner, S., Hugo, R., Louw, B., Owen, R., & Swanepoel, A. (2007). High frequency immittance for neonates: A normative study. *Acta Oto-Laryngological*, 127(1), 49-56. Retrieved from [http://www.dspace.up.ac.za/bitstream/handle/.../Swanepoel_High\(2007\).pdf](http://www.dspace.up.ac.za/bitstream/handle/.../Swanepoel_High(2007).pdf)
- Task Force on Newborn and Infant Hearing. (1999). Newborn and infant hearing loss: Detection and intervention, *Pediatrics*, 103(2), 527-530. doi: 10.1542/peds.103.2.527
- Taylor, B., & Roberts, K. (2006). Ethics in nursing and health research. In B. J. Taylor, S. Kermonde & K. L. Roberts (3rd ed.), *Research in nursing and healthcare: Evidence for practice* (pp 98-103). Melbourne, Australia: Thomson.
- Taylor, C. L., & Brooks, R. P. (2000). Screening for hearing loss and middle-ear disorders in children using TEOAEs. *American Journal of Audiology*, 9(1), 50-55. doi:10.1044/1059-0889
- Terry, J. A. (2012). *Clinical research for the doctor of nursing practice*. Ontario, Canada: Jone & Bartlett Learning.
- Theunissen, M., & Swanepoel, D. (2008). Early hearing detection and intervention services in the public health sector in South Africa. *International Journal of Audiology*, 47(1), 23-29. doi: 10.1080/14992020802294032
- Thornton, A. R. D., Kimm, L., Kennedy, C. R., & Cafarelli- Dees, D. (1993). External- and middle-ear factors affecting evoked otoacoustic emissions in neonates. *British Journal of Audiology*, 27(5), 319-327.
- Valente, M., Fernandez, E., & Monroe, H. (2011). *Audiology answers for otolaryngologists*. New York, NY: Thieme Medical Publishers.
- Van Rooyen, S. (2006). *Immittance in infants 0-12 months: Measurements using a 1000 Hz probe tone*. (Unpublished undergraduate thesis). University of Pretoria, Pretoria.
- Vaughn-Jones, R., & Mills, R. P. (1992). The Welch Allyn audioscope and microtympanometer: Their accuracy and that of pneumatic otoscopy, tympanometry, and pure tone audiometry as predictors of otitis media with effusion. *Journal of Laryngology and Otology*, 106(7), 600-602. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/1527455>
- Vinson, B. P. (2001). *Essentials for speech-language pathologists*. San Diego, CA: Delmar Singular Publishing.
- Weatherby, L. A., & Bennett, M. J. (1980). The neonatal acoustic reflex. *Scandinavian Audiology*, 9(2), 103-110.
- Whitaker, K. (2001). *Comprehensive perinatal and pediatric respiratory* (3rd ed.). Albany, NY: Delmar Cengage Learning.

- White, K. R. (2008). Newborn hearing screening. In J. R. Madell & C. Flexoer (Eds.), *Pediatric audiology: Diagnosis, technology and management* (pp. 31 – 44). New York, NY: Thieme Medical Publishers.
- White, L., Duncan, G., & Baumle, W. (2013). *Medical surgical nursing: An integrative approach* (3rd ed.). Clifton Park, NY: Delmar Cengage Learning.
- Wiley, T.L., & Stoppenbach, D.T. (2002). Basic principles of acoustic immittance measures. In J. Katz (Ed.), *Handbook of Clinical Audiology* (4th Ed.), (pp159-174). Baltimore (MD): Lippincott, Williams & Wilkins.
- Wilson, T. E. (2008). *Efficacy of high-frequency tympanometry in infant's birth to six months of age: A pilot study*. (Unpublished doctoral thesis). Washington University School of Medicine Program in Audiology and Communication Science, Washington.
- Wood, S. (1995). Pure tone audiometry. In B, McCormick (Eds), *The medical practitioners guide to pediatric audiology* (pp 31-480). Melbourne, Australia: Cambridge University Press.
- World Health Organisation. (2010). *Newborn and infant hearing screening: Current issues and guiding principles for action*. Geneva: WHO Press, 1-38.
- World Medical Association. (2008). *Declaration of Helsinki*. Retrieved from <http://www.wma.net/en/30publications/10policies/b3/>
- Zamani, A., Daneshjou, K., Ameni, A., Takand, J. (2004). Estimating the incidence of neonatal hearing loss in high risk neonates. *Acta Medica Iranica*, 42(3), 176-180. Retrieved from http://journals.tums.ac.ir/upload_files/pdf/_/380.pdf
- Zand, J., Routree, R., & Walton, R.C. (2003). *Smart medicine for a healthier child: A practical A to Z reference to natural and conventional treatments for infants and children* (2nd ed.). New York, NY: Janet Zand.

Appendix A: Informed consent for survey questionnaire

SPEECH PATHOLOGY AND AUDIOLOGY
School of Human & Community Development
Faculty of Humanities
University of the Witwatersrand
 Private Bag 3, WITS, 2050
 Tel: (011) 717 4577 Fax: (011) 717 4572



Title of Study: The use and clinical utility of high frequency tympanometry (HFT) in South Africa.

Dear Audiologist,

My name is Heena Chania. I am an Audiology Masters student from the University of the Witwatersrand. As part of the requirements for my studies I am required to complete a research dissertation. The aim of this study is to determine the availability and use of HFT in South Africa.

Hearing is a critical element in the development of speech, language and cognition in young children. Otitis media (OM) is one of the most common causes of hearing loss in young infants. The correct diagnosis of OM is critical in managing this frequently occurring childhood disorder. One of the most important acoustic immittance measures used to reliably and accurately diagnose OM in young infants is high frequency tympanometry (HFT). The purpose of this study is to determine the availability and use HFT by South African audiologists. I therefore wish to further investigate (i) the availability of HFT equipment and clinical protocols in clinical practice; (ii) opinions regarding current clinical skills in classification and interpretation of HFT, and (iii) the awareness of the importance of making use of HFT within the paediatric population.

I hereby invite you to participate in this pilot /main study in order to assist the researcher in enhancing the validity of this research study. A quantitative, descriptive, cross-sectional survey design will be employed for the purposes of the study. This study requires approximately 300 audiologists or speech therapist and audiologists to participate, in order to make accurate generalisation and to obtain a precise representation of the population. The study requires you to complete a survey questionnaire and to return the questionnaire via email. Your participation will require a maximum of 20 minutes to complete the questionnaire. The survey questionnaire has been developed by the researcher and it consists of open and closed ended questions. The questions in the survey questionnaire are related to the availability and use of HFT in your clinical setting. This questionnaire has also been evaluated for its reliability and has been validated by qualified audiologists.

There are no known risks associated with your participation in this research. The information obtained from this study will be of relevance to audiologist working with the paediatric

population. The findings will provide evidence of clinical practice in South Africa that can be used to inform student training, the development of national guidelines and motivation for appropriate equipment across all health care sectors. This will lead to better assessment and management of young infants with OM and reduce the occurrence of hearing loss. Results of this study will be accessible to all professionals.

Your participation in this research study is voluntary. A refusal to participate will involve no consequence or loss of benefits to which you are entitled. You may withdraw from the study at any stage should you wish, without any negative consequences. No persons will be identifiable as only participant numbers will be used for the research report. Every effort will be made to guarantee confidentiality and all personal information will only be reviewed by the research team (researcher and academic supervisor). Personal information will be safely stored and no other parties will have access to this. This information will be destroyed after a period of five years.

Please complete the tear off slip at the bottom to provide written consent to participate in this pilot study. Should you require further information or if you would like feedback on the results, please feel free to contact me on 083 651 995 or email: hchania@gmail.com or my research supervisor Dr. Karin Joubert on 011 717 4561 or email: karin.joubert@wits.co.za or my research co-supervisor on 011 717 4581 or email: dhanashree.pillay@wits.co.za. Alternatively, you may contact the administrator of the Medical Ethics Committee at the University of the Witwatersrand, Anisa Keshav on 011 717 1234 or e-mail: Anisa.Keshav@wits.ac.za or the chairperson, Prof. Cleaton-Jones on 011 717 2301 for additional enquiries.

Your participation will be highly appreciated.

Thank you for your time,

Kind Regards

Heena Chania

Informed Consent

‘The use and clinical utility of high frequency tympanometry in South Africa’

I, _____ (name of participant), the undersigned, agree to participate in this pilot study. I have been informed of the aims and benefits of the study as well as my rights as a participant.

_____ Date: _____

(Participant signature)

_____ Date: _____

(Researcher signature)

Appendix B: Cover letter for survey questionnaire

SPEECH PATHOLOGY AND AUDIOLOGY
School of Human & Community Development
Faculty of Humanities
University of the Witwatersrand
 Private Bag 3, WITS, 2050
 Tel: (011) 717 4577 Fax: (011) 717 4572



Title of Study: The use and clinical utility of high frequency tympanometry (HFT) in South Africa.

Dear Audiologist,

Good day, my name is Heena Chania. I am an Audiology Masters student from the University of the Witwatersrand. As part of the requirements for my studies I am required to complete a research dissertation. The aim of this study is to determine the availability and use of high frequency tympanometry in South Africa.

Hearing is a critical element in the development of speech, language and cognition in young children. Otitis media (OM) is one of the most common causes of hearing loss in young infants. The correct diagnosis of OM is critical in managing this frequently occurring childhood disorder. One of the most important acoustic immittance measures used to reliably and accurately diagnose OM in young infants is high frequency tympanometry (HFT). The purpose of this study is to determine the availability and use HFT by South African audiologists.

I therefore wish to further investigate (i) the availability of HFT equipment and clinical protocols in clinical practice; (ii) opinions regarding current clinical skills in classification and interpretation of HFT, and (iii) the awareness of the importance of making use of HFT within the paediatric population.

I hereby invite you to participate in this study in order to assist the researcher in enhancing the validity of this research study. A quantitative, descriptive, cross-sectional survey design will be employed for the purposes of the study. This study requires approximately 300 audiologists or speech therapists and audiologists to participate, in order to make accurate generalisation and to obtain a precise representation of the population. The study requires you to complete a survey questionnaire and to return it via email/post. The return of the completed survey questionnaire will imply that consent has been granted to participate in this study. Your participation will require a maximum of 25 minutes to complete the questionnaire. The survey questionnaire has been developed by the researcher and consists of open and closed ended questions. The questions in the survey questionnaire are related to the availability and use of HFT in your clinical setting. This questionnaire has also been evaluated for its reliability and has been validated by qualified audiologists.

There are no known risks associated with your participation in this research. The information obtained from this study will be of relevance to audiologists working with the paediatric

population. The findings will provide evidence of clinical practice in South Africa that can be used to inform student training, the development of national guidelines and motivation for appropriate equipment across all health care sectors. This will lead to better assessment and management of young infants with OM and reduce the occurrence of hearing loss. Results of this study will be accessible to all professionals.

Your participation in this research study is voluntary. A refusal to participate will involve no consequence or loss of benefits to which you are entitled. You may withdraw from the study at any stage should you wish, without any negative consequences. No persons will be identifiable as only participant numbers will be used for the research report. Every effort will be made to guarantee confidentiality and all personal information will only be reviewed by the research team (researcher and academic supervisor). Personal information will be safely stored and no other parties will have access to this. This information will be destroyed after a period of five years.

Should you require further information or if you would like feedback on the results, please feel free to contact me on 083 651 995 or email: hchania@gmail.com or my research supervisor Dr. Karin Joubert on 011 717 4561 or email: karin.joubert@wits.co.za or my research co-supervisor on 011 717 4581 or email: dhanashree.pillay@wits.co.za. Alternatively, you may contact the administrator of the Medical Ethics Committee at the University of the Witwatersrand, Anisa Keshav on 011 717 1234 or e-mail: Anisa.Keshav@wits.ac.za or the chairperson, Prof. Cleaton-Jones on 011 717 2301 for additional enquiries.

Your participation will be highly appreciated.

Thank you for your time,

Kind Regards

Heena Chania

Appendix C: Survey questionnaire

Participant Number : _____ (for office use only)		
QUESTIONNAIRE		
The clinical utility and use of high frequency tympanometry (HFT) (1000Hz) in South Africa		
Aim: The aim of this study is to investigate the use and clinical utility of HFT in both the public and private health sectors in South Africa.		
Informed consent: By completing and returning this questionnaire, it is implied that participants have read the information letter and understand the aims of this research study, and therefore consent to participating in the study.		
<i>Please answer the questions below by ticking the appropriate box/s and elaborate in the spaces provided where necessary.</i>		
Participant email address: _____		
Section 1: Biographical Information		
1.1. Qualification	√	For official use only
a. Audiologist		1
b. Speech Therapist and Audiologist		2
c. Other (please specify below)		3
		A
1.2. What is the highest qualification you have obtained?	√	For official use only
a. Undergraduate degree in Audiology		1
b. Undergraduate degree in Speech Therapy and Audiology		2
c. Masters degree in Audiology		3
d. Doctoral degree in Audiology		4
e. Other (please specify below)		5
		B
1.3. Are you currently practicing in the field of audiology?	√	For official use only
a. Yes		1
b. No		2
1.4. Which province do you work in?	√	For official use only
a. North West		1

b. Gauteng		2
c. Free state		3
d. Limpopo		4
e. Eastern Cape		5
f. Western Cape		6
g. Kwa-Zulu Natal		7
h. Northern Cape		8
i. Mpumalanga		9
1.5. Workplace (Please tick all appropriate boxes)		
	√	For official use only
a. Private Practice		1
b. Private Hospital		2
c. Government Hospital		3
d. Government/ Primary Health Clinics		4
e. Government Schools		5
f. Private Schools		6
g. Other (please specify below)		7
		C
1.6. Which population do you work with?		
	√	For official use only
a. Paediatrics only		1
b. Adults only		2
c. Both adults and paediatrics		3
1.7. Please specify the age-range of the population chosen in 1.6.		
		For official use only
		D
1.8. For how long have you been practicing in the field of audiology? (Please indicate in years and months)		
		For official use only
		E
1.8. How many years of clinical experience do you have in working in paediatric audiology? (Please indicate in years and months)		
		For official use only

		F
1.9. What percentage of your current caseload is comprised of infants or young children (0-6 years) with middle ear pathologies?	√	For official use only
a. 0 - 15%		1
b. 16 - 25 %		2
c. 26 - 50%		3
d. 51 - 75%		4
e. 76-100%		5
Section 2: Equipment		
This section only to be completed by audiologists and dually registered speech therapist and audiologists working with the paediatric population		
2.1. Do you have access to a tympanometer in your clinical setting?	√	For official use only
a. Yes		1
b. No		2
If 'no', please specify why you do not have a tympanometer?		G
2.2. Is tympanometry included in your basic paediatric audiological test battery?	√	For official use only
a. Yes		1
b. No		2
Please answer the applicable questions 2.3, 2.4 & 2.5 below, based on your selection for question 2.2 above		
2.3 If yes, which tympanometry tests do you use for the paediatric population in your clinical practice? (Please tick all appropriate boxes)	√	For official use only
a. Low frequency tympanometry (LFT) (226 Hz probe tone)		1
b. Multi-frequency tympanometry (MFT) (series of sweeps: 250 Hz – 2000 Hz)		2
c. 667 Hz probe tone		3
d. HFT (1000 Hz probe tone)		4
e. Unsure		5

2.4. Please indicate the age range for which the above chosen tympanometry (indicated in 2.3) is used for in your clinical practice?	226Hz (LFT)	667Hz	1000Hz (HFT)	250 Hz-2000Hz (MFT)	For official use only
a. 0 - 6 months					1
b. 0 -9 months					2
c. 6 months and up					3
d. Up to 1 years					4
e. Up to 6 years					5
f. 6 - 10 years					6
g. 11-15years					7
h. 15-20 years					8
i. +20 years					9
j. Other (please specify below)					10
					H

2.5. If 'no', please indicate the reason why tympanometry is not being included in your basic paediatric audiological test battery?(Please tick all appropriate boxes)	√	For official use only
a. Lack of equipment		1
b. Time constraints		2
c. Not clinically relevant		3
d. Costly/Budgetary constraints		4
e. Lack of training		5
f. Lack of clinical protocol or guidelines		6
g. Case dependent		7
h. Other (please specify below)		8
		I

2.6. How often is HFT included in your basic paediatric audiological test battery for infants or young children with definitive middle ear pathologies?	√	For official use only
a. Always		1
b. Sometimes		2
c. Never		3

Please answer either question 2.7 or 2.8 below, based on your selection for question 2.2 above

2.7. If you perform HFT, please specify what percentage of the time is HFT being utilised in such cases?	√	For official use only
a. 0-15%		1
b. 16-25%		2
c. 26-50%		3
d. 51- 75%		4
e. 76- 100%		5
2.8 If you do not perform HFT, please indicate the reason why HFT is not being included in your basic paediatric audiological test battery?(Please tick all appropriate boxes)	√	For official use only
a. Lack of equipment		1
b. Time constraints		2
c. Not clinically relevant		3
d. Costly/Budgetary constraints		4
e. Lack of training conducting HFT		5
f. Lack of training in interpretation of HFT		6
g. Lack of clinical protocols or guidelines		7
h. Case dependent		8
i. Other (please specify below)		9
		J
2.9. How would you rate your confidence level in interpreting HFT on a scale of 1 to 10 (1 being the least confident and 10 being the most confident)?	√	For official use only
a. 1		1
b. 2		2
c. 3		3
d. 4		4
e. 5		5
f. 6		6
g. 7		7
h. 8		8
i. 9		9
j. 10		10
Section 3: Current clinical practice		
3.1. Are there clinical protocols/guidelines available for HFT in your clinical setting?	√	For official use only
a. Yes		1
b. No		2
If 'no', please provide a reason		K

3.2. If 'yes', which clinical guideline/protocol for HFT is used in your clinical setting?	√	For official use only
a. Best practice guidelines (provide reference below)		1
b. New born hearing screening programme (NHSP) Tympanometry protocol v2.0		2
d. 'I have developed my own protocol'		4
c. Other (please specify and provide reference below)		3
Please elaborate and/or provide reference on your selection:		L
3.3. Do you experience challenges in interpreting HFT results?	√	For official use only
a. Yes		1
b. No		2
If 'yes', please indicate the challenges experienced?		M
3.4. Which norms do you use to interpret HFT? (Please tick all appropriate boxes)	√	For official use only
a. Equipment manual, please explain		1
b. Journal Article, please provide reference		2
c. Textbook, please provide reference		3
d. Pass/ Fail criteria (please explain the criteria)		4
e. ANSI		5
f. Component compensation method		6
g. Static admittance		7
h. Peak susceptance ≤ 0 mmho		8
i. Unsure		9
j. 'Not applicable as I do not perform HFT, therefore do not use any norms'		10
k. Other (please specify below)		11
Please elaborate and/or provide reference on your selection:		N
3.5. Which classification systems or models do you use to interpret HFT? (Please tick all appropriate boxes)	√	For official use only

a. Quantitative measures (peak susceptance or peak compliance)		1
b. Journal Article, please provide reference		2
c. Textbook, please provide reference		3
d. Beery et al., 1975 classification system		4
f. ANSI		6
g. Marchant et al. (1986) classification system		7
i. Jerger/ Liden system		8
j. Vanhuysse Model		9
k. Unsure		10
l. 'Not applicable as I do not perform HFT'		11
m. Other (please specify below)		12
Please elaborate and/or provide reference on your selection:		0
3.6. What other aspects do you take into consideration when performing HFT? (Please tick all appropriate boxes)	√	For official use only
a. Otoscopy		1
b. Movement of infant and crying		2
c. Conical tips		3
d. Obstructions free ear canal		4
e. Positioning of the infants or child's head		5
f. Positioning of the pinnae		6
g. Results to be repeated		7
h. Exact value of ear canal volume		8
i. 'Not applicable as I do not perform HFT'		9
j. Pressure changes		10
k. Other (please specify below)		11
		P
3.7. What precautions do you take against cross infections when performing HFT?	√	For official use only
a. Disinfection &/or sterilization of probe tips between uses		1
b. Use of protective vinyl/ latex gloves		2
c. Handwashing after each patient		3
d. Disinfection &/or sterilization of all surface areas in contact with bodily fluids		4
e. Use of wipes or paper towels		5
f. Use of appropriate disposable supplies where possible		6

g. 'Not applicable, as I do not perform HFT'		7
h. Other (please specify below)		8
		Q
Section 4: Knowledge		
4.1. What is the purpose of tympanometry? (Please tick all appropriate boxes)	√	For official use only
a. To assess the functioning of the middle ear system		1
b. Assess the cochlear functioning		2
c. Assess the hearing status		3
d. To determine the nature of the conductive lesion		4
f. Other (please specify below)		5
		R
4.2. In your opinion, what is the clinical application of HFT in your clinical setting?	√	For official use only
		S
4.3. The infant middle ear system is described as (Please tick all appropriate boxes):	√	For official use only
a. Mass-dominated		1
b. Structurally immature		2
c. Acoustically mature		3
d. Stiffness-dominated		4
e. Adult-like		5
h. Unsure		6
i. Other (please specify below)		7
		T
4.4. What are the acoustical differences between an infant and adult middle ear system? (Please tick all appropriate boxes)	√	For official use only
a. Ear canal impedance, reflection coefficient responses, and energy transmission.		1
b. No acoustical differences		2
c. Resonance gain & Resonant frequency		3
d. 1000 Hz & 4000 Hz		4
g. Unsure		5
h. Other (please specify below)		6
		U

4.5. Do maturational changes that occur to the infants' middle ear system affect the acoustical properties of the infant ear?	√	For official use only
a. Yes		1
b. No		2
Please motivate your answer :		V

Appendix D: Letter of permission from Dr. George Mukhari Hospital**DR GEORGE MUKHARI HOSPITAL**

Enquiries: Dr. P. Shembe
 Director: Clinical Services
 Tel no: 012 529 3687
 Fax no: 012 5600099

To : Ms. Heena Chania
 Department of Speech Therapy & Audiology
 University of Limpopo
 MEDUNSA
 0204

Date: 21 November 2012

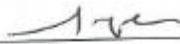
RE : PERMISSION TO CONDUCT RESEARCH.

The Dr. George Mukhari Hospital hereby grants you permission to conduct research on "The clinical utility, availability and use of high frequency tympanometry (HFT) in South Africa."

We note that you have already obtained ethical Clearance from the Human Research Ethics Committee.

- This permission is granted subject to the following conditions:
- That the Hospital incurs no cost in the course of your research.
 - That access to the staff and patients at the Dr George Mukhari Hospital will not interrupt the daily provision of services.
 - That prior to conducting the research you will liaise with the supervisors of the relevant sections to introduce yourself (with this letter) and to make arrangements with them in a manner that is convenient to the sections.

Yours sincerely


 DR. P. SHEMBE
 DIRECTOR: CLINICAL SERVICES

Appendix E: Informed consent for hearing screening

SPEECH PATHOLOGY AND AUDIOLOGY
School of Human & Community Development
Faculty of Humanities
University of the Witwatersrand
 Private Bag 3, WITS, 2050
 Tel: (011) 717 4577 Fax: (011) 717 4572



Title of Study: The clinical utility and use of high frequency tympanometry (HFT) in South Africa.

Dear Sir/Madam

My name is Heena Chania. I am an Audiology Masters student from the University of the Witwatersrand. As part of the requirements for my studies I am required to complete a research dissertation. The aim of this study is to determine the clinical utility, availability and use of HFT in South Africa.

Hearing is a critical element in the development of speech, language and cognition in young children. Otitis media (OM) is one of the most common causes of hearing loss in young infants. The correct diagnosis of OM is critical in managing this frequently occurring childhood disorder. One of the most important acoustic immittance measures used to reliably and accurately diagnose OM in young infants is HFT. The purpose of this study is to determine the availability and use of HFT by South African audiologists.

I therefore wish to further investigate (i) the clinical utility, (ii) the availability of HFT equipment and clinical protocols in clinical practice; (iii) opinions regarding current clinical skills in classification and the interpretation of HFT, and (iii) the awareness of the importance of making use of HFT within the paediatric population.

I hereby ask your permission for the patient to be a participant of this study. Should permission be granted to, the researcher will perform the following audiological tests on the patient namely; otoscopy, tympanometric testing and OAEs. The results obtained from these audiological testing will be provided to you on the day.

There are no known risks associated with the patient's participation in this research. The information obtained from this study will be of relevance to audiologist working with the paediatric population. The findings will provide evidence of clinical practice in South Africa that can be used to inform student training, the development of national guidelines and motivation for appropriate equipment across all health care sectors. This will lead to better assessment and management of young infants with OM and reduce the occurrence of hearing loss. Results of this study will be accessible to all professionals.

Yours and that of the patient's participation in this research study are voluntary. A refusal to participate will involve no consequence or loss of benefits to which you are entitled. You may

withdraw from the study at any stage should you wish, without any negative consequences. No persons will be identifiable, as only participant numbers; will be used for the research report. Every effort will be made to guarantee confidentiality; personal information will only be reviewed by the research team (researcher and academic supervisor). Personal information will be safely stored and no other parties will have access to it. This information will be destroyed after a mandatory period of five years.

Please complete the tear off slip at the bottom to provide written consent to participate in this pilot study. Should you require further information or if you would like feedback on the results, please feel free to contact me on 083 651 995 or email: hchania@gmail.com or my research supervisor Dr. Karin Joubert on 011 717 4561 or email: karin.joubert@wits.co.za or my research co-supervisor on 011 717 4581 or email: dhanashree.pillay@wits.co.za. Alternatively, you may contact the administrator of the Medical Ethics Committee at the University of the Witwatersrand, Anisa Keshav on 011 717 1234 or e-mail: Anisa.Keshav@wits.ac.za or the chairperson, Prof. Cleaton-Jones on 011 717 2301 for additional enquiries.

Your participation will be highly appreciated.

Thank you for your time,

Kind Regards

Heena Chania

Informed Consent

‘The use and clinical utility of high frequency tympanometry (HFT) in South Africa’

I, _____ (name of caregiver), the undersigned, provides permission for Heena Chania to conduct the audiological tests required for the purpose of this research on my child. I have been informed of the aims and benefits of the study. All my questions have been answered, and I know that I can withdraw from the study at any time without any negative consequences. I am also aware that confidentiality will be maintained throughout the study.

_____ Date: _____
 (Participant signature)

_____ Date: _____
 (Researcher signature)

Appendix F: Hearing screening form

HEARING SCREENING												
Patient Information												
Participant number: _____									Date: _____			
Date of Birth: _____			Hospital #: _____			Site/Ward #: _____		Diagnosis: _____				
Birth Weight: _____ kg			Current Weight: _____ kg			GA: _____		Gender: _____				
CA: _____												
Risk Factors												
NICU >48hrs				Caregiver concerns				Herpes			Head Trauma	
NNJ (photo/trans.)				Maternal malaria				Rubella				Other:
Premature				Cranio-facial anomalies				Syphillis				
Meningitis				Mechanical ventilation				Chemo				
Birth Asphyxia				Ototoxic medication				ECMO				
Head trauma				Syndromes associated with HL				LBW				
Taxoplasmosis				Neurogenerative disorders				CMV				
Maternal HIV				Hyperbilirubinemia								
Audiological Testing												
Otoscopy						DPOAE's						
R	Normal	Dull TM	Red TM	Bulging	Retracted	R		L		Comments		
	Infection	Vernix	Other:			PASS	Refer	PASS	Refer			
L	Normal	Dull TM	Red TM	Bulging	Retracted	1000Hz	1000Hz	1000Hz	1000Hz			
	Infection	Vernix	Other:			2000Hz	2000Hz	2000Hz	2000Hz			
Tympanometry						3000Hz	3000Hz	3000Hz	3000Hz			
226 Hz		R	L	Comments		4000Hz	4000Hz	4000Hz	4000Hz			
	EV:					5000Hz	5000Hz	5000Hz	5000Hz			
	dapa					6000Hz	6000Hz	6000Hz	6000Hz			
	c/z:					Recommendations						
	Type:					No additional risk: d/c from screening						
1000Hz	R		L		Comments	Diagnostic testing						
	Positive Peak:Normal		Positive Peak:Normal			Re-screen						
	Negative Peak: Abnormal		Negative Peak: Abnormal			Refer to ENT						
	Other:		Other:			Refer to Paeditrician						
						Other (please specify below)						

Appendix G: Letter of permission from Rahima Moosa Mother and Child Hospital

**health and
social development**
Department: Health and Social Development
GAUTENG PROVINCE



RAHIMA MOOSA MOTHER AND CHILD HOSPITAL
ENQUIRIES: MRS. S. JORDAAN
TEL: (011) 470 – 9030/4
FAX: (011) 477- 4117

School of Human and Community Development
Private Bag 3
WITS 2050
JOHANNESBURG
2001

Re: "The Clinical utility and use of high frequency tympanometry ((HFT)S.A"

Dear Me. Heena Chania,

Permission is granted for you to conduct the above survey as indicated in your request:

1. The Rahima Moosa hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study site.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.
5. NO file should leave the records department and/or the hospital premises.

Arrangement will be made with recordkeeping clerks so that you could occupy space in their department.

Kindly forward this office with the results of your research on completion of it.

I, HEENA CHANIA accept the terms and conditions set-in this document

sign *Heena* date 04/07/13

Yours sincerely,

CHIEF EXECUTIVE OFFICER
SJ/mdu. 2013-07.04

Appendix H: Informed consent from Doors of Hope Children's Mission

Title of Study: The clinical utility and use of high frequency tympanometry (HFT) in South Africa.

Dear Sir/Madam

Date: _____

Good day, my name is Heena Chania. I am an Audiology Masters student from the University of the Witwatersrand. As part of the requirements for my studies I am required to complete a research dissertation. The aim of this study is to determine the clinical utility, availability and use of high frequency tympanometry (HFT) in South Africa.

Hearing is a critical element in the development of speech, language and cognition in young children. Otitis media (OM) is one of the most common causes of hearing loss in young infants. The correct diagnosis of OM is critical in managing this frequently occurring childhood disorder. One of the most important acoustic immittance measures used to reliably and accurately diagnose OM in young infants is HFT. The purpose of this study is to determine the clinical utility, the availability and use of HFT by South African audiologists. I therefore wish to further investigate (i) The clinical utility of HFT; (ii) the availability of HFT equipment and clinical protocols in clinical practice; (iii) opinions regarding current clinical skills in classification and the interpretation of HFT, and (iii) the awareness of the importance of making use of HFT within the paediatric population.

I hereby ask permission to conduct this study at Door of Hope Children's Mission. I have chosen to conduct this study at your site as this research study requires a great sample of infants to be screened for hearing, which I will obtain at your home. Should permission be granted, the researcher will perform the following audiological screening tests on approximately 100 in or out paediatric patients (0 to 6 months of age) namely; otoscopy, tympanometric testing, and otoacoustic emissions (OAEs). These screening tests are a part of the paediatric hearing screening protocol. You will be provided with immediate results and be informed if further follow-ups are required. There are no known risks associated with the research. The participation in this research study is voluntary. A refusal of the caregiver or patient to participate will involve no consequence or loss of benefits to which the participant is entitled. The participant may withdraw from the study at any stage should they wish to, without any consequences.

No persons will be identifiable as only participant numbers; will be used for the research report. Every effort will be made to guarantee confidentiality; personal information will only be reviewed by the research team (researcher and academic supervisor). Personal information will be safely stored and no other parties will have access to this. This information will be destroyed after a mandatory period of five years.

The information obtained from this study will be of relevance to audiologist working with the paediatric population. The findings will provide evidence of clinical practice in South Africa that can be used to inform student training, the development of national guidelines and motivation for appropriate equipment across all health care sectors. This will lead to better assessment and management of young infants with OM and reduce the occurrence of hearing loss. Results of this

study will be accessible to all professionals.

Please complete the tear off slip at the bottom to provide written consent for the researcher to conduct this study at your site. Should you require further information or if you would like feedback on the results, please feel free to contact me on 083 651 995 or email:

hchania@gmail.com or my research supervisor Dr. Karin Joubert on 011 717 4561 or email:

karin.joubert@wits.co.za or my research co-supervisor on 011 717 4581 or email:

dhanashree.pillay@wits.co.za. Alternatively, you may contact the administrator of the Medical Ethics Committee at the University of the Witwatersrand, Anisa Keshav on 011 717 1234 or email: Anisa.Keshav@wits.ac.za or the chairperson, Prof. Cleaton-Jones on 011 717 2301 for additional enquiries.

Your approval will be highly appreciated.

Thank you for your time,

Kind Regards,

Heena Chania

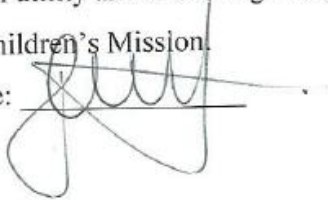
Junior Speech Therapist and Audiologist

(012) 521 5917/3371

Consent Form for Door of Hope Children's Mission

I, Nodene Crowder, have read the information letter and provide consent for Heena Chania to conduct her study, which is to determine the clinical utility and use of high frequency tympanometry in current clinical practice, at Door of Hope Children's Mission.

Designation: Baby Care Manager

Signature: 

Door of Hope
15 Barbara Ave.
Glenvista 2091
RSA

Appendix I: Informed consent from Mother Teresa's

SPEECH PATHOLOGY AND AUDIOLOGY
School of Human & Community Development
Faculty of Humanities

University of the Witwatersrand

Private Bag 3, WITS, 2050
 Tel: (011) 717 4577 Fax: (011) 717 4572

**Title of Study:**

The use and clinical utility of high frequency tympanometry (HFT) in South Africa.

Dear Sir/Madam

Date: _____

Good day, my name is Heena Chania. I am an Audiology Masters student from the University of the Witwatersrand. As part of the requirements for my studies I am required to complete a research dissertation. The aim of this study is to determine the clinical utility, availability and use of high frequency tympanometry (HFT) in South Africa.

Hearing is a critical element in the development of speech, language and cognition in young children. Otitis media (OM) is one of the most common causes of hearing loss in young infants. The correct diagnosis of OM is critical in managing this frequently occurring childhood disorder. One of the most important acoustic immittance measures used to reliably and accurately diagnose OM in young infants is HFT. The purpose of this study is to determine the clinical utility, the availability and use of HFT by South African audiologists.

I therefore wish to further investigate (i) The clinical utility of HFT; (ii) the availability of HFT equipment and clinical protocols in clinical practice; (iii) opinions regarding current clinical skills in classification and the interpretation of HFT, and (iii) the awareness of the importance of making use of HFT within the paediatric population.

I hereby ask permission to conduct this study at Mother Teresa. I have chosen to conduct this study at your site as this research study requires a great sample of infants to be screened for hearing, which I will obtain at your home. Should permission be granted, the researcher will perform the following audiological screening tests on approximately 100 in or out paediatric patients (0 to 6 months of age) namely; otoscopy, tympanometric testing, and otoacoustic emissions (OAE's). These screening tests are a part of the paediatric hearing screening protocol. You will be provided with immediate results and be informed if further follow-ups are required.

There are no known risks associated with the research. The participation in this research study is voluntary. A refusal of the caregiver or patient to participate will involve no consequence or loss of benefits to which the participant is entitled. The participant may withdraw from the study at any stage should they wish to, without any consequences.

No persons will be identifiable as only participant numbers; will be used for the research report.

Every effort will be made to guarantee confidentiality; personal information will only be reviewed by the research team (researcher and academic supervisor). Personal information will be safely stored and no other parties will have access to this. This information will be destroyed after a mandatory period of five years.

The information obtained from this study will be of relevance to audiologist working with the paediatric population. The findings will provide evidence of clinical practice in South Africa that can be used to inform student training, the development of national guidelines and motivation for appropriate equipment across all health care sectors. This will lead to better assessment and management of young infants with OM and reduce the occurrence of hearing loss. Results of this study will be accessible to all professionals.

Please complete the tear off slip at the bottom to provide written consent for the researcher to conduct this study at your site.

Should you require further information or if you would like feedback on the results, please feel free to contact me on 083 651 9995 or email: hchania@gmail.com or my research supervisor Dr. Karin Joubert on 011 717 4561 or email: karin.joubert@wits.co.za or my research co-supervisor on 011 717 4581 or email: dhanashree.pillay@wits.co.za. You may alternatively contact the administrator of the Medical Ethics Committee at the University of the Witwatersrand, Anisa Keshav on 011 717 1234 or e-mail: Anisa.Keshav@wits.ac.za or the chairperson, Prof. Cleaton-Jones on 011 717 2301 for additional enquiries.

Your approval will be highly appreciated.

Thank you for your time,

Kind Regards,

Heena Chania

Junior Speech Therapist and Audiologist

(012) 521 5917/3371

Consent Form for Mother Teresa

I, SR LAWRETTE M-C, have read the information letter and provide consent for Heena Chania to conduct her study, which is to determine the clinical utility and use of high frequency tympanometry in current clinical practice, at Mother Teresa.

Designation: sr incharge of children Signature: sr Lawrette

Appendix J: Calibration certificate for GSI Auto Tympt



Ear Institute, 1240 Webb Str. Queenswood Pretoria. Tel: (012) 333-3131 Fax: (012) 333-2298

H.A.S.S. Industrial (Pty) Ltd

Certificate of Calibration No. F GS3003539/13

This certificate is issued in accordance with the conditions for calibration of the instrument as described by the manufacturer or the South African Bureau of Standards (SANS 10154-1; 10154-2). It is a correct record of measurements made. Copyright protected. This certificate may not be reproduced, except with the prior written approval of H.A.S.S. Industrial (Pty) Ltd.


Calibrated for:	Heena Chania 37 & 39 Portion Road Zoutpansdrift Britz North West		
Calibration of:	GSI 39 V3		
Manufacturer:	GSI		
Serial Number:	GS3003539		
Calibration procedure:	Complete probe, reflex, pressure and audio calibration as described in the manufacturer's specification. Earphones (DD45: Right s/n 11012415077B; Left s/n 11012415077A).		
Traceability:	The calibration was performed using instruments traceable to national standards.		
Date of Calibration:	2013-06-04	Cal. Due Date:	2014-06-04
Results:	The instrument complies with the requirements for use as specified by the manufacturer.		
Remarks:	None.		
Calibrated by:	Heinrich Kruse		Signature

NOTE: The values in this certificate are correct at the time of calibration. Subsequently the accuracy will depend on such factors as the care exercised in the handling and use of the instrument and the frequency of use. Re-calibration should be performed annually to ensure that the instrument's accuracy remains within the desired limits.

Appendix K: Calibration Certificate for Madsen AccuScreener



P O Box 26318
 East Rand 1462
 Gauteng, South Africa
 Tel: 0861 amtronix (268766)
 Tel: 011 894 4632
 Fax: 011 894 4629
 info@amtronix.co.za
 www.amtronix.co.za
 Support: 0861 amtronix
 support@amtronix.co.za

Name and Address: Amtronix (Pty) Ltd P.O.Box 26318 East Rand Boksburg 1462		Calibration Certificate Number: 403982 41577		
Accuscreen				
Make:	Madsen / GN Otometrics			
Model:	Accuscreen TD			
Serial Number:	403982 - Loan Unit			
Calibration Site:	Audio room			
For Compliance With: SANS 10154 (Audiometer)				
Calibration Expiry Date:	31/01/2014	Function:	Mobile Unit	
Calibration Equipment:		Calibration Date		
Artificial Mastoid:	N/A			
Sound Level Meter:	Rion NL-32 # 00403215	Jan-13		
Sound Level Calibrator:	QC-20 #QOG020007	Jan-13		
1/3 Octave Filter:	Rion NX-21SA # 30800813	Jan-13		
Frequency Counter	Soar M4040 # 60802424	Jan-13		
Artificial Ear:	Bruel & Kjaer 4153 # 1251463	Jan-13		
Microphones:	17057/317173	Jan-13		
This certificate becomes invalid if either the audiometer or its earphones or inserts are: <ul style="list-style-type: none"> i. Subjected to any misuse or rough handling ii. Subjected to repairs, including replacement of an earphone or insert iii. Moved from site of calibration by road, rail or air, unless the procedures in SANS10154:2006 Annex A are followed. 				
Remarks: This Audiometer is hereby certified calibrated in accordance with ISO R389 and SANS 10154:2006. IEC 645-1,-2, including booth to SANS 10182. This audiometer complies to Type 3 and/or Type 4 specifications. This certificate is valid for 12 Months (365 Days)				
Customer Notes: All equipment in good operating order.				
Modalities calibrated are:	Hardware Test	Yes	Probe Test	Yes
	Y-Cable Test	No	ABR Test	No
	Loop Back Cable Test	No		
CALIBRATION OFFICER		Date & Time:		
 Shawn Hardy		30/01/2013 3:37:33 PM		

African Management Software
 NeuroCom Balance + Rehab
 Satellite Spirometers
 EasyOne Spirometers
 Tiltmus Vision
 ICS Medical
 Amplivox Med Acoustics
 Tremetrics Audiometers
 Madsen Audiometers
 Directors: S.C.Hardy
 S.J.Gaier

Appendix L: Ethical clearance certificate

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

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
 R14/49 Ms Heena Chania

CLEARANCE CERTIFICATE**M120814****PROJECT**

The Use of High Frequency Tympanometry (HFT)(1000Hz)
 in South Africa (Changed title 28/05/2014)

INVESTIGATORS

Ms Heena Chania

DEPARTMENT

Speech Pathology & Audiology
 Medical School

DATE CONSIDERED

31/08/2012

DECISION OF THE COMMITTEE*

Approved unconditionally

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

DATE 17/10/2012

CHAIRPERSON

(Professor P.E. Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr Karin Joubert

DECLARATION OF INVESTIGATOR(S)

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

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

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...