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A hearing profile of children with HIV/AIDS on HAART that undergo hearing screening

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A HEARING PROFILE OF CHILDREN WITH HIV/AIDS on HAART THAT UNDERGO HEARING SCREENING

KURAISHA TRISHEL NAIDOO

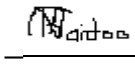
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A research report submitted to the Faculty of Health Sciences, University of Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Child Health-Neurodevelopment.

JANUARY 2017

DECLARATION

I, **Kuraisha Trishel Naidoo**, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Child Health-Neurodevelopment in the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Signature: 

Date: **16 January 2017**

ABSTRACT

Aim and objectives: *The aim of this study was to describe the hearing screening profile of children between 0-6 years living with HIV/AIDS currently on HAART at a virology clinic within a tertiary hospital in Gauteng using an audiological screening protocol. The objectives were to describe the demographic profile of children on HAART undergoing hearing screening, to determine the relationship between CD4 percent and the duration on HAART, to document and describe the occurrence of possible outer ear abnormalities, to document and describe the occurrence of possible middle ear pathologies and to document and describe the occurrence of possible inner ear pathologies.* ***Methodology:*** *This was a cross-sectional, prospective descriptive study; using purposive criterion sampling. It was conducted at a tertiary provincial hospital in Gauteng. A questionnaire and a hearing screening protocol was used to obtain data. Consent was obtained from the parent/caregiver of all participants. Ethical approval was obtained from the hospital and the University of Witwatersrand Medical Ethical Committee prior to the study.* ***Results:*** *There was the presence of possible ear pathologies detected by the hearing screening. The possible outer ear abnormalities existed in 26% of ears, possible middle ear pathologies existed in 29% of ears and possible inner ear pathologies existed in 1% of ears. However as the frequency increased the number of refers obtained in DPOAE screening also increased, which could be indicative of early cochlear pathology (inner ear pathology) in the high frequencies.* ***Conclusions:*** *Audiological screening in infants and children living with HIV/AIDS may be essential, as there may be a wide range of possible hearing deficits. If undiagnosed or not identified and managed early these deficits may result in language and cognitive delays.*

Keywords: Hearing profile, HIV, Audiology screening, HAART

DEDICATION

I would like to dedicate this research in the loving memory of my three grandmothers, Ama, Aya and Aunty Joe.

Your precious time, sacrifice, dedication, perseverance, and continued encouragement over the years have played a crucial part in my education. The emphasis placed on the importance of education throughout my life leaves me profoundly grateful.

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I would like to thank my research supervisor Ms. Dhanashree Pillay of the Speech Therapy and Audiology Department at the University of Witwatersrand who has provided supervision during this project. Prof. Jacklin, the course coordinator, who always had an open door and assisted whenever there was any query regarding the research.

My absolute appreciation and thanks also goes to my cousin, Dr. Pragashnie Govender, who assisted me during every step of this thesis. The countless hours, weekends, late nights, encouragement, and emotional support during my most difficult times of this thesis has made me succeed in competing it. Her expertise in the field provided me with the insight and information that was required to complete my research. I am eternally grateful for her priceless academic assistance which was provided with such enthusiasm and passion. Without her absolute dedication, participation and input this research would not be the same.

Finally, I must express my very profound gratitude to my parents, Dhana and Vasantha Naidoo, who have always placed the greatest emphasis on education. They have been supportive and encouraging throughout my schooling and university career, ensuring that I always perform at my best. Thanks to my brother, Tishen Naidoo and my fiance' Lee Govender for providing me with unfailing support and continuous encouragement throughout my years of study and throughout the process of researching and writing this thesis. This accomplishment would not have been possible without them.

Thank you all,

Kuraisha Trishel Naidoo

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND AND CONTEXT

The acquired immune deficiency syndrome (AIDS) and the human immunodeficiency virus (HIV) is a global challenge. HIV/AIDS is a growing epidemic and is the third leading cause of death in the world (Munderi, Paula, Grosskurth, Droti, Ross. 2012). In developing countries like South Africa, HIV/AIDS is one of the greatest health challenges (Khoza-Shangase, 2010) as HIV/AIDS is a disease that effects the immune system and causes depletion of CD4+ T helper lymphocytes (Gottlieb & Engl, 1981 cited in Weiss 1993) therefore increasing the susceptibility to contract illnesses such as tuberculosis (TB), pneumonia and other life threatening diseases.

In South Africa (SA) there are 270 000 HIV-exposed infants born annually and approximately 20% of these infants die within the first thirteen weeks of life (Sherman, Lilian, Bhardwaj, Candy & Baron 2014). In 2012, 188 203 of HIV-exposed infants were tested for HIV using polymerase chain reaction (PCR) testing before or by two months of age (Sherman et al., 2014) and 4 557 of these were diagnosed as being HIV positive, hence these children become more susceptible to opportunistic infections (Khoza-Shangase, 2010). Highly active antiretroviral therapy (HAART) drugs are said to reduce opportunistic infections such as pneumonia, otitis media and acute diarrhoea (Weber, Neto, Miziara & Filho 2006; Fassinou, Elenga, Laguide, Kouakoussui, Timite, Blanche & Msellati 2004), as well as reducing the mortality rate

in children (Brady, Oleske, Williams, Elgie, Mofenson, Danker, Van Dyke & Paediatric AIDS Clinical Trials Group 219/219C Team 2011).

HIV/AIDS envelops the CD4+ cell, thus resulting in the depletion of the CD4+ cells (Weiss, 1993) which causes the immune system to be compromised, thus increasing the prevalence of illnesses. Although HIV/AIDS affects the CD4+ cell there are CD4- cells that can also be affected by the virus (Weiss, 1993) and these cells include neuronal cells from the central nervous system therefore HIV/AIDS may result in neuronal cell death and other central nervous system deficits (Laughton 2004) which may result in central hearing loss. One of the most common medical audiological effects within the paediatric population with HIV/AIDS is otitis media (Shaw, 2012), in addition to hearing loss due to ear infections or damage of the inner ear (Khoza-Shangase, 2010; Shaw, 2012). Hearing loss in children can have detrimental effects on the child's overall development, especially in speech and language development (Diefendorf, 2002; Northern & Downs, 2002). Hearing is a complex process of the ears detecting sounds and the brain's interpretation of these sounds (Gelfand, 2009; Northern & Downs, 2002) thus there are many structures and processes working together to form the auditory process. There is a dearth of information internationally and locally, pertaining to hearing loss in children that are on HAART medication. The antiretroviral guidelines in South Africa indicate that it is mandatory for all children under five years of age who are diagnosed with HIV/AIDS to receive the HAART medication (Department of Health, 2013). It is crucial to determine if there are audiological abnormalities in this population, as this is the age where significant language acquisition and development occurs (Singleton & Ryan, 2004).

1.2 PROBLEM STATEMENT

Hearing loss is not a visible disorder and can go unidentified in children under 18 months of age before speech and language delays may be detected (Diefendorf, 2002), thus it is crucial for the early identification of hearing loss in children. There is an increasing rate of infection and many children are infected with the virus in utero or during the birth process (Jeena, Pillay, Pillay & Coovadia 2002). However with the use of HAART, the life expectancy of individuals living with HIV/AIDS is extended (Mofenson, Brady, Danner, Dominguez, Hazra, Handelsman, Havens, Nesheim, Read, Serchuck & Van Dyke 2010), thus it is important to determine the quality of life of individuals in this population.

Research that focused on hearing loss in the HIV/AIDS population and conducted in the adult population revealed that the disease itself has effects on both the neurological and central nervous system, which can result in hearing difficulties (Harris, Peer & Fagan 2012; Khoza-Shangase 2010). Research on the effects of ARVs and HAART on hearing in the adult population also revealed a higher occurrence of hearing loss on a population of HIV patients who were on HAART (Khoza-Shangase, 2010). However this cannot be generalized to the paediatric population as the effects of medication on children are often different to adults due to their level of neural and audiological maturation (Giaquinto, Morelli, Fregonese, Rampon, Penazzato, de Rossa & D'Elia 2008; Bluestone & Doyle 1988). There is hence the need for further research on the effects of HAART on the paediatric population. The research that is currently available in children with HIV/AIDS also shows that there is a high prevalence of middle ear infections in this population. Due

to the high prevalence of HIV/AIDS in children in South Africa, diagnostic audiology testing on all these children will be difficult due to a lack of resources, and time constraints (Swanepoel, Delport, Swart 2004). Hearing screening will however be able to identify possible outer, middle and inner ear pathologies in this population to reduce the overuse of resources if diagnostic assessments were to be performed on all children with HIV/AIDS. Children who are identified with possible ear pathologies can then undergo diagnostic audiology testing. There is currently no hearing profile of children on HAART medication in South Africa.

Hence this study will focus on a hearing screening profile of children on HAART medication. The study will determine if there are outer, middle or inner ear pathologies that may be present.

1.3 AIMS AND OBJECTIVES

The aim of this study was to describe the hearing screening profile of children between 0-6 years currently on HAART at a virology clinic within a tertiary hospital in Gauteng using an audiological screening protocol.

Objectives

- To describe the demographic profile of children on HAART undergoing hearing screening
- To determine the relationship between CD4 percent and the duration on HAART

- To document and describe the occurrence of possible outer ear abnormalities.
- To document and describe the occurrence of possible middle ear pathologies.
- To document and describe the occurrence of possible inner ear pathologies.

1.4 SIGNIFICANCE OF THE STUDY

There is currently a dearth of information on the hearing profile of children that are on HAART medication. There is evidence that adults on HAART medication present with hearing loss, ranging in type and severity (Harris, Peer & Fagan 2012; Khoza-Shangase 2010). Research has shown that children living with HIV/AIDS are at a higher risk of otitis media, which results in a conductive hearing loss (Weber, Neto, Miziara & Filho 2006; Fassinou, Elenga, Laguide, Kouakoussui, Timite, Blanche & Msellati 2004; (Khoza-Shangase, 2010; Shaw, 2012). However we are uncertain if this is different to children on HAART medication. The aim of this study is thus to determine the hearing screening profile of children on HAART medication and thereby illustrating the possible need for hearing screening as a mandatory practice for all children on HAART medication.

Due to the high prevalence of HIV in South Africa (Khoza-Shangase, 2010; Shaw, 2012), there is a need to determine if this population is possibly more susceptible to a hearing loss. Hearing screening could result in the early identification of a hearing loss or the need for further intervention to reduce the effects of the hearing loss

(Shaw 2012; Swanepoel, Hugo & Louw 2006). If hearing loss is identified early it would allow for early intervention and less detrimental communication effects on the child (Northern & Downs, 2002).

1.5 OUTLINE OF THE CHAPTERS OF THIS STUDY

This study is presented in six chapters. Chapter 2 outlines the literature review, discussed from a broad aspect of hearing and HIV/AIDS, and then narrowed down to focus on the topic of this study. Chapter 3 discusses the methodology and includes the research design, study population, study site, data collection, data analysis, pilot study and ethical considerations that were implemented. Chapter 4 introduces the results of the study which include demographics, and the prevalence of possible ear pathologies that were detected from hearing screening. The last chapter of the research, Chapter 5, is a discussion that considers the findings of this research and this information will be related to the history of research in the field of audiology and hearing in children with HIV. Chapter 6 concludes the study with conclusions, recommendations and limitations of the study.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Hearing is complex and involves many processes working together by the utilisation of the peripheral and central parts of the auditory system (Rappaport & Provencal, 2002). The peripheral hearing system includes the outer ear, middle ear and the inner ear, whilst the central hearing system comprise of neural cells located in the brainstem and cerebral cortex (Gelfand, 2009). Deficits in any part of the hearing system may cause a hearing loss (Diefendorf, 2002). Hearing loss can be detrimental to the overall development of speech, language and cognition especially in the paediatric population, as children learn and develop communication through hearing (Diefendorf, 2002; Northern & Downs, 2002). Therefore, an undetected hearing loss can cause a delay in speech development as well as an overall developmental delay (Northern & Downs 2002; Smith, Bale & White 2005). Hearing loss can be caused by many factors including middle ear infections, infections of the central nervous system or deficits of the neural system (Northern & Downs, 2002; Shaw, 2012). Children living with HIV/AIDS are more susceptible to ear infections, resulting in a conductive hearing loss and if left untreated it can become a sensorineural hearing loss (Northern & Downs 2002; Shaw 2012; Matas, Iorio, Succi 2008). Previous research indicates that hearing loss is prevalent in individuals living with HIV/AIDS; however all the research that was reviewed indicated that there is a lack of information regarding hearing status in children on HAART. HIV/AIDS may also affect the central nervous system and auditory neural pathways (Shaw, 2012) resulting in deficits of the central nervous system and auditory neural pathways,

which may result in a hearing loss. HIV/AIDS can result in a hearing loss and the high rate of HIV/AIDS in children in South Africa (Khoza-Shangase, 2011) highlights the need to determine possible hearing loss in children living with HIV/AIDS. The early identification and management of hearing loss in this population could reduce the impact on communication, development and educational development. Hearing screening could result in the early identification of possible ear pathologies, which would then result in the referral for full diagnostic audiology testing when necessary.

2.2 HEARING AND HEARING LOSS

Hearing is known as the ability to perceive sounds and requires the use of complex systems. These include the entire auditory system including both peripheral and central auditory pathways.

2.2.1 Hearing (How do we hear) and the structures

The peripheral auditory system consists of the outer ear which includes the pinna of the ear, the ear canal and the tympanic membrane (Gelfand, 2009), the middle ear which includes the three ossicles, the malleus, incus and stapes and the Eustachian tube, which leads to the throat (Gelfand, 2009). The inner ear includes the semi-circular canals, the utricle, saccule and horizontal canal and the cochlear (Gelfand, 2009). Figure 2.1 illustrates the outer, middle and inner ear systems.

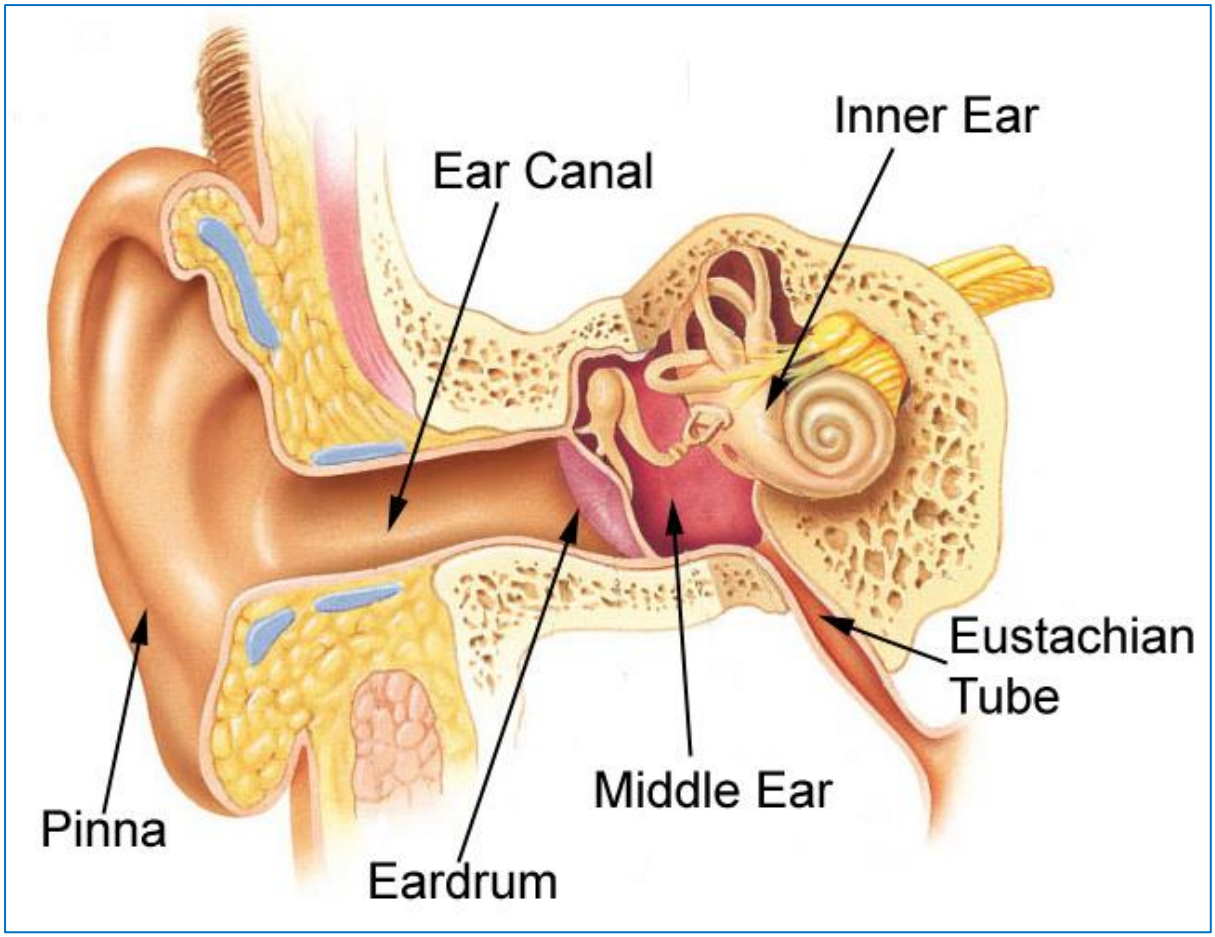


Figure 2.1 Peripheral Auditory System ("Parts of the Ear," 2016)

The central auditory system includes the cochlear nuclei, superior olivary nuclei, inferior colliculus, medial geniculate bodies, Heschl's gyrus and the association auditory cortex (Fitzgerald, Gruener, Mtui 2012). Refer to Figure 2.2. The cochlear nuclei are where the cochlear nerves terminate and are tonotopically arranged. The cochlear nuclei provide information regarding the intensity and pitch of sounds (Fitzgerald et al., 2012). The superior olivary nuclei interprets sounds from both ears and provides spatial information thus providing localization of sounds (Fitzgerald et al., 2012). The inferior colliculus integrates spatial, intensity and pitch information from the superior olivary complex, ventral cochlear nuclei and dorsal cochlear nuclei respectively (Fitzgerald et al., 2012). Heschl's gyrus is where the primary auditory

cortex is situated and is tonotopic in nature, the posterior part is responsible for high frequency sounds, whilst the anterior part is responsible for low frequency sounds (Fitzgerald et al., 2012).

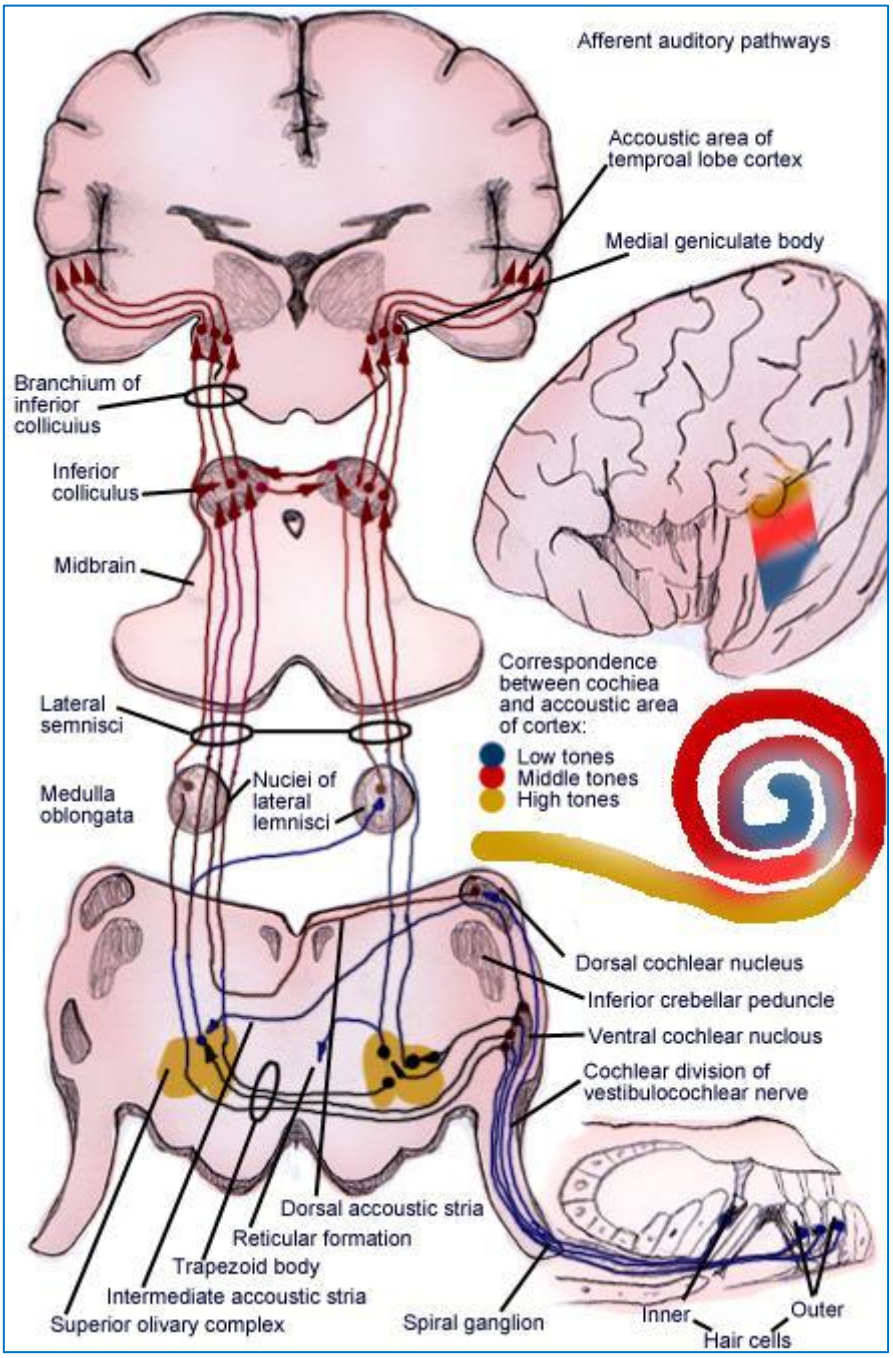


Figure 2.2 Central Auditory System (Tewfik, 2015)

A sound wave is directed into the ear canal by the pinna, it causes the tympanic membrane to vibrate, thus causing the ossicles to vibrate the stirrup which causes the oval window to vibrate and stimulate the cochlear (Gelfand, 2009), see Figure 2.1. The cochlear hair cells are the mechanoreceptors that detect the vibration of the incoming sound (Fitzgerald et al., 2012; Gelfand, 2009). The cochlear is a cone-like shape which is tonotopic in nature, thus there is specific regions that are stimulated to certain sound frequencies (Gelfand, 2009). The apical end of the cochlear is where low frequency sounds are detected, whilst the basal end is where high frequency sounds are detected (Gelfand, 2009). The cochlear is where the stimulus is converted from a mechanical stimulus into an electrical stimulus (Fitzgerald et al., 2012). From the cochlear the electrical stimulus synapse and moves into the auditory nerve, here it synapses with the cochlear nucleus and then with the superior olivary complex, where cross over occurs (Gelfand, 2009), see Figure 2.2. From the superior olivary complex the stimulus travels up the lateral lemniscus and to the inferior colliculus, there it synapses with the medial geniculate body where the signal then goes to the auditory cortex (Fitzgerald et al., 2012; Gelfand, 2009). The sound stimulus is decoded and further interpretation occurs in the primary and association auditory cortices (Fitzgerald et al., 2012). The hair cells in the cochlear are sensitive to toxins in the bloodstream and atrophy of these hair cells may occur with the use of certain medications; which results in permanent hearing loss.

2.2.2 Hearing Loss (what structures damage/affect hearing and conditions)

Hearing loss refers to a deterioration in hearing ability; and this deterioration could be due to abnormalities in the auditory system or on the auditory nerve or even the brain's ability to interpret sounds that are heard (Northern & Downs, 2002). There

are three different types of peripheral hearing loss, namely, conductive hearing loss, sensorineural hearing loss and mixed hearing loss (Gelfand, 2009; Northern & Downs, 2002). Hearing loss can be caused by many factors; including genetic factors and non-genetic factors (Smith et al. 2005; Morzaria, Westerberg, & Kozak 2004).

2.2.2.1 Causes of hearing loss in children

High risk factors for hearing loss in children include a family history of hearing loss, hyperbilirubinemia requiring a blood transfusion, congenital infections, craniofacial abnormalities, low birth weight (under 1500g), bacterial meningitis, poor Apgar scores (less than or equal to three at five minutes), ototoxic medication, prolonged mechanical ventilation (10 days or more) and syndromes associated with hearing loss (Diefendorf, 2002). Moreover genetic factors that are most commonly associated with hearing loss include Waardenburg Syndrome, Velocardiofacial Syndrome, Goldenhaar Syndrome, Branchio-otorenal Syndrome, Down Syndrome, Pendred Syndrome and Usher Syndrome (Morzaria et al., 2004; Smith et al., 2005). Non-genetic factors can be further classified into prenatal, perinatal and postnatal factors (Table 2.1).

HIV/AIDS may result in a hearing loss as it can affect the peripheral hearing as well as the central auditory system (Shaw, 2012).

Table 2.1 Prenatal, perinatal and post-natal factors that can cause hearing loss

Prenatal Factors (Morzaria et al., 2004; Smith et al., 2005)	**Perinatal Factors** (Morzaria et al., 2004)	**Post-Natal Factors** (Morzaria et al., 2004; Shaw, 2012)
Rubella	Billirubinemia	Meningitis
Cytomegalovirus	Asphyxia	Trauma
Toxoplamosis	Prematurity	Extracorporeal membrane oxygenation
Herpes Simplex Viruses	A stay in the intensive care unit	Measles
Alcohol & Drug use by the mother	Exposure to drugs	HIV/AIDS
		Chemotherapy
		TB
		Other ototoxic medications

2.2.2.2 Types of hearing loss

A sensorineural loss refers to an abnormality in the inner ear, or the auditory nerve (Gelfand, 2009; Northern & Downs, 2002). This loss is generally caused by ototoxic medication, ageing, exposure to loud noise, prematurity, congenital disorders or genetics (Northern & Downs, 2002). It is a permanent loss and most often cannot be corrected with surgery, however cochlear implants provide some surgical intervention for sensorineural hearing losses. A sensorineural hearing loss may occur in 20%-50% of HIV infected adults (Khoza-Shangase, 2010).

A conductive hearing loss refers to a disorder of the outer or middle ear; this includes structural abnormalities, perforation to the tympanic membrane, disorders to the ossicles or otitis media (Northern & Downs, 2002). This loss is generally temporary and can be treated with medication or surgery.

A mixed hearing loss is a combination of a conductive and a sensorineural hearing loss; therefore there is dysfunction in the outer or middle ear as well as in the inner ear (Gelfand, 2009; Northern & Downs, 2002). A mixed hearing loss can be caused by trauma or chronic untreated otitis media. In children living with HIV/AIDS previous research has shown a high prevalence of otitis media, indicating the site of pathology as the middle ear (Shapiro & Novelli 1998; Weber et al. 2006; Jensen, Homøe, Andersson & Koch 2011).

2.2.2.3 Hearing Testing

There are many ways to determine and measure hearing acuity and hearing loss. These include in-depth and conclusive testing, as well as quick hearing screening measures that are used to either determine whether hearing is within normal limits or whether further diagnostic hearing tests are necessary (Northern & Downs, 2002).

2.2.2.3.1 Diagnostic Testing

Diagnostic hearing testing refers to complete and thorough investigations to determine hearing ability. This includes a battery of hearing tests, which have slight variations according to each institution. The types of hearing tests included in the test battery vary according to the target population. Some of the considerations when choosing the hearing tests within the test battery are age and physical and cognitive

abilities (Northern & Downs, 2002). One of the recommended hearing test battery for children includes otoscopic examination, acoustic immitance (tympanometry and acoustic reflex thresholds), behavioural audiometry, pure tone threshold audiometry, auditory brainstem response (ABR) and otoacoustic emmissions (OAE) (Gelfand, 2009; Northern & Downs, 2002).

Otoscopic examination should be the first test and is conducted to determine the status of the outer ear, using an otoscope, which is a light with a specule (Northern & Downs, 2002). Otoscopic examinations are geared towards determining abnormality in the external auditory canal, such as foreign bodies, impacted wax, discharge or tympanic membrane perforations.

Tympanometry is a test to determine the mobility of the tympanic membrane and the status of the middle ear transmission (Anderson et al., 2016). Tympanometry measures the integrity of the middle ear and remains the most appropriate measure of middle ear functioning (McClure, 2010). Tympanometry is measured by placing a probe in the ear canal, introducing pressure into the ear and produces a tympanogram (Anderson et al., 2016). A tympanogram is a graph drawn based on ear canal volume, static compliance and middle. This graph is then interpreted and classified into different types, such as Type A, Type B, Type C, Type As or Type Ad (Gelfand, 2009; Northern & Downs, 2002). The type of tympanogram can be used to suggest conditions that require medical attention, such as Eustachian Tube dysfunction or fluid within the middle ear (Anderson et al., 2016). Acoustic reflex threshold testing also involves placing a probe into the ear canal and presenting a

frequency specific tone into the ear, which can be used to determine the type and severity of the hearing loss (Northern & Downs, 2002).

Behavioural observation audiometry is generally done in children between birth and six months of age (Northern & Downs, 2002). It includes the use of noise makers, warble tones or speech stimuli and looks for any behavioural response from the infant, including: eye-blinks, startles, quieting, head-turning and localizing to the sound (Northern & Downs, 2002).

Pure tone audiometry involves testing all speech frequencies individually, compromising of 250HZ, 500Hz, 1kHz, 2kHz, 4kHz and 8kHz, using a pure tone or warble tone (Northern & Downs, 2002). Pure tone audiometry in children can be done by using visual reinforcement audiometry for young children and play condition audiometry in older children (Northern & Downs, 2002). Visual reinforcement requires the child to have normal visual acuity and uses positive reinforcement to condition the child to look at a visual stimulus every time a tone is presented (Northern & Downs, 2002). Play conditioned audiometry is when a child is given a toy (e.g. a block) and is required to throw the toy into a box whenever the tone is heard (Northern & Downs, 2002). Pure tone audiometry is dependent on the state of the child and requires the child to be attentive and able to understand the instructions of the test, thus it is difficult to administer on special populations.

ABR and OAEs are both objective measures and do not rely on the child's response, however it requires the child to be in a quiet and calm state (Northern & Downs, 2002). As both ABR and OAEs do not require a response from the child, it a good

cross-check principle, to verify the pure tone audiometry (Northern & Downs, 2002). ABR and OAEs can only be conducted once it has been established that the middle ear is functioning optimally and that there is no dysfunction of the Eustachian Tube (Gelfand, 2009), thus it should be conducted after tympanometry to ensure validity of the results. ABR can be measured using a click stimuli or frequency specific tone bursts (Gelfand, 2009). Thus it can be used to estimate audiological thresholds throughout the speech frequency range. OAEs measure the outer hair cell functioning in the cochlear, which are very sensitive to ototoxicity and play a major role in the proper functioning of the cochlear. There are two types of OAEs, transient evoked otoacoustic emissions (TEOAEs) and distortion product otoacoustic emissions (DPOAEs). TEOAEs can detect a moderate to profound hearing loss (Kemp, 1978 cited in McClure, 2010) and can be elicited by a click or tone burst stimulus (McClure, 2010). Whilst DPOAEs are elicited by simultaneously presenting two different pure tone stimuli at two different intensities (Anderson et al., 2016; McClure, 2010). DPOAE testing is very sensitive and can detect a hearing loss even before it is seen in pure tone audiometry, which is the gold standard for audiology testing (Ranjan & Bhat, 2008).

2.2.2.3.2 Hearing Screening

Hearing screening is a quick measure of hearing, which should be simple and aims to test a large population (American Academy of Audiology Task Force on Pediatric Amplification, 2011). Hearing screening indicates that hearing is within normal limits or can identify the need for further audiological testing. There are a few and varying types of hearing screening protocols which is dependent on the age, physical and cognitive ability of the target population. Hearing screening protocols vary; ranging from pure tone screening to distortion product otoacoustic emissions (DPOAEs),

transient evoked otoacoustic emissions (TEOAEs) and screening tympanometry. However the most sensitive screening protocol includes more than one objective measure (McClure, 2010). One of the hearing screening protocols that was considered in this study recommends the use of tympanometry and OAEs (Anderson et al., 2016), as described in Figure 2.3.

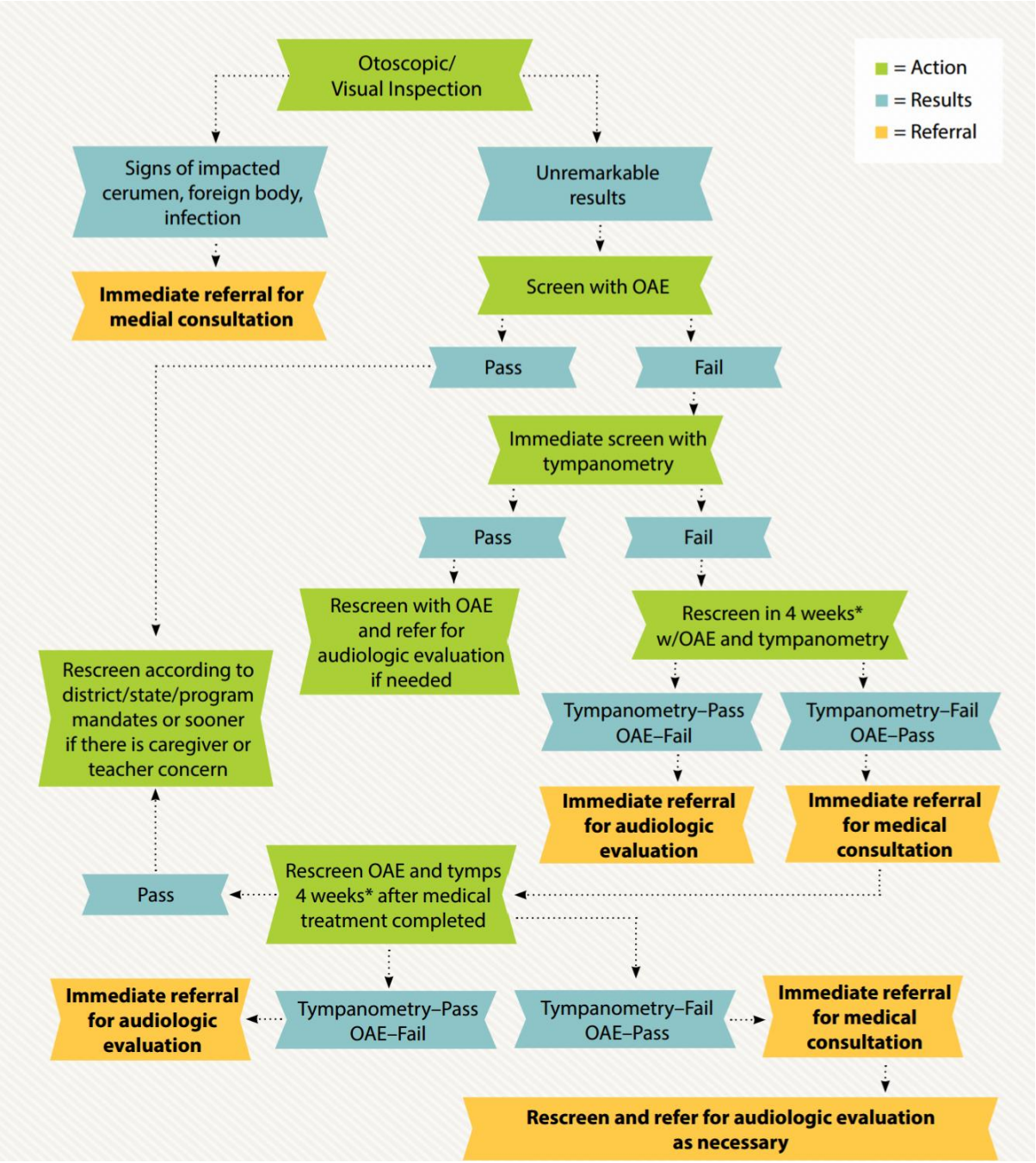


Figure 2.3 Tympanometry and OAE screening ("Tympanometry and OAE Screening," 2015)

This protocol was selected as it can be done in infants and young children and it does not require any response from the child; thus it can be performed on neonates, infants and difficult to test populations and can be done whilst they are asleep. It is therefore also more accurate than behavioural tests especially in paediatrics and is more time efficient.

2.2.2.4 Early identification of hearing loss

It is crucial for the early identification of hearing loss in children to reduce the effects of hearing loss. Thus hearing screening should be conducted in the paediatric population especially in the high risk population. Hearing screening involves quick tests to accurately identify individuals with a possible hearing loss (McClure, 2010). Hearing screening in children is crucial as hearing loss can go undetected until approximately 18 months of age, before speech and language delays are observed (Diefendorf, 2002). Hearing screening for HIV-infected children is particularly important as there is research evidence to indicate that HIV is associated with damage to the peripheral and central auditory system (Shaw, 2012). There has been South African research conducted with adults receiving HAART medication to determine the ototoxic effects on this population (Khoza-Shangase, 2010); however there is no published South African studies within the paediatric population. Hearing screening is also important to determine the effects of HAART medication on the paediatric population, as a younger age is associated with increased susceptibility to ototoxicity (Peleva, 2012).

2.2.2.5 HIV and Hearing Loss in Children

HIV/AIDS is common in children, where the disease is transmitted from mother-to-child either in utero or during the birth process (Giaquinto et al. 2008; Nielsen, McSherry, Petru, Frederick, Wara, Bryson, Martin, Hutto, Ammann, Grubman, Oleske & Scott 1997). There are an estimated 270 000 HIV-exposed infants born in South Africa annually (National Department of health, 2011 & Statistics South Africa, 2012 cited in Sherman et al. 2014). The HIV virus is the most progressive in the paediatric population, during the first few years of life (Giaquinto et al., 2008; Nielsen et al., 1997). However there are many children who are not able to access ARV therapy, particularly in resource limited countries (WHO, 2006). This could be due to limited ways to diagnose HIV in children under 18 months of age, a limited number of drug formulations for children, a lack of effective follow up and lack of knowledge and expertise in managing ARV therapy use in the paediatric population (Giaquinto et al., 2008). In the paediatric population the CD4 cell count and HIV RNA are not accurate measures of HIV progression, especially in infants under one year of age (Dunn, 2003 cited in Giaquinto et al. 2008; Smith et al. 2005). However the CD4 percentage is a more accurate measure of disease progression in this population (AIDS, 2006 cited in Giaquinto et al. 2008).

There is currently no cure for HIV/AIDS (Katlama, Deeks, Autran, Martinez-Picado, Van Luzen, Rouzioux, Miller, Vella, Schmitz, Ahlers, Richman & Sekaly 2013) and the on-going management and treatment of these patients is imperative (Khoza-Shangase, 2010). It is essential to identify newly infected individuals as counselling and psychosocial support should be conducted in great detail, to ensure that the

patient understands the side effects and implications of the disease (Munderi et al., 2012).

The auditory system of paediatrics is different to adults due to immaturity and structural differences (Bluestone & Doyle, 1988). The Eustachian tube in children is more horizontal than in adults and is at a 10 degree angle to the horizontal plane, compared to adults where the Eustachian tube is at a 45 degree angle to the horizontal plane (Bluestone & Doyle, 1988). The anatomical differences combined with the poor ventilator functioning of the Eustachian tube in children, particularly children under six years of age, results in a higher rate of otitis media in this population (Bluestone & Doyle, 1988). Otitis media may result in a mild to moderate conductive hearing loss, as it causes a fluid build-up in the middle ear system, which is normally an air filled cavity (Northern & Downs, 2002). There are different degrees of hearing loss ranging from mild hearing loss to profound hearing loss (Gelfand, 2009; Northern & Downs, 2002). Hearing loss is classified ranging from mild to profound, using normative data, as depicted in Table 2.2.

Table 2.2 Degrees of Hearing Loss in paediatrics (Northern & Downs, 2002)

Intensity (dB)	Degree of Hearing Loss
-10dB to 15dB	Normal hearing
16dB to 30dB	Mild hearing loss
31dB to 50dB	Moderate hearing loss
51dB to 70 dB	Severe hearing loss
71dB to 120dB	Profound hearing loss

2.2.2.5.1 HIV/AIDS in Hearing Loss (CD4 counts viral load)

HIV-infected individuals are more susceptible to opportunistic infections, such as tuberculosis (TB) (Harris et al., 2012; Jeena et al., 2002). The most common otologic findings in HIV/AIDS infected individuals are otitis externa, otitis media, sensorineural hearing loss, conductive hearing loss, cholesteotoma, recurrent otitis media with effusion, mastoiditis and perforated tympanic membranes (Matas, Leite, Cristina & Magliaro 2006). Of all the otological findings, a conductive hearing loss, mastoiditis, perforated tympanic membranes and otitis media with effusion is the result of untreated otitis externa and otitis media, thus it is crucial for the early identification and management of these ear infections as otitis media is present in 80% of children below 3 years of age (Northern & Downs, 2002) (Al-Mazrou, Shibl, Kandeil, Pirçon & Marano 2014; Takahashi 2012). Otitis media, recurrent otitis media and complications arising from otitis media is more common in HIV-infected paediatrics resulting in the prevalence of 32% of otorrhea (Karpakis, Rabie, Howard, Janse Van Rensberg & Cotton 2007; Shapiro & Novelli 1998) in this population. In addition to otitis media, HIV-infected children are more susceptible to central auditory pathologies (Heinze cited in Shaw 2012). Sensorineural hearing loss in HIV-infected individuals may be caused by ototoxic medication, either to treat opportunistic infections or to treat the HIV/AIDS. As the hearing loss is ototoxic the outer hair cells of the cochlear would be affected. DPOAEs are effective in determining early ototoxic hearing loss, even before it is evident in pure tone audiometric testing (Ranjan & Bhat, 2008). In a study conducted to determine the integrity of the auditory system in HIV-infected adults, 50% of the subjects had abnormal DPOAEs, indicative of hearing loss (Ranjan & Bhat, 2008). Of that 16,6% had absent DPOAE, with normal hearing sensitivity in pure tone audiometry (Ranjan & Bhat, 2008). Due

to all the otologic effects of HIV it is imperative for the early identification of hearing and ear pathologies. A good measure for early identification of a possible hearing loss is hearing screening assessments.

2.2.2.5.2 HAART

The use of ARV therapy has resulted in an increase in the lifespan of individuals who are HIV-infected (Giaquinto et al., 2008; Munderi et al., 2012). However highly active antiretroviral therapy (HAART) is recommended for the initial treatment of HIV-infected infants and children, as it restores the immune system and allows for the recovery from the manifestations of HIV (Giaquinto et al., 2008). HAART services includes access to medication, screening and monitoring of patients and their side effects, as depicted in figure 2.3 (Munderi et al., 2012).

HAART is recommended for the initial treatment of HIV infected children and should continue for life, due to the high progression of HIV in this population (Munderi et al., 2012). It is also more likely to preserve immune function, delay disease progression and it will obtain the most viral suppression, which will prevent ART-resistant strains of HIV (Giaquinto et al., 2008). HAART suppresses the replication of HIV and thus restores the immune system and allows the patient to recover from manifestations of the disease (Giaquinto et al., 2008; Munderi et al., 2012). Figure 2.1 illustrates that HAART does not only consist of a specific medication regimen; it incorporates many aspects of treatment that allows for a holistic healthy lifestyles approach. It is important to include counselling as a major component to HAART, as there is concealable stigma associated with HIV (Pachankis, 2007). Concealable stigma

refers to the ability of one to withhold the disclosure of their disease, as the disease is not visible.

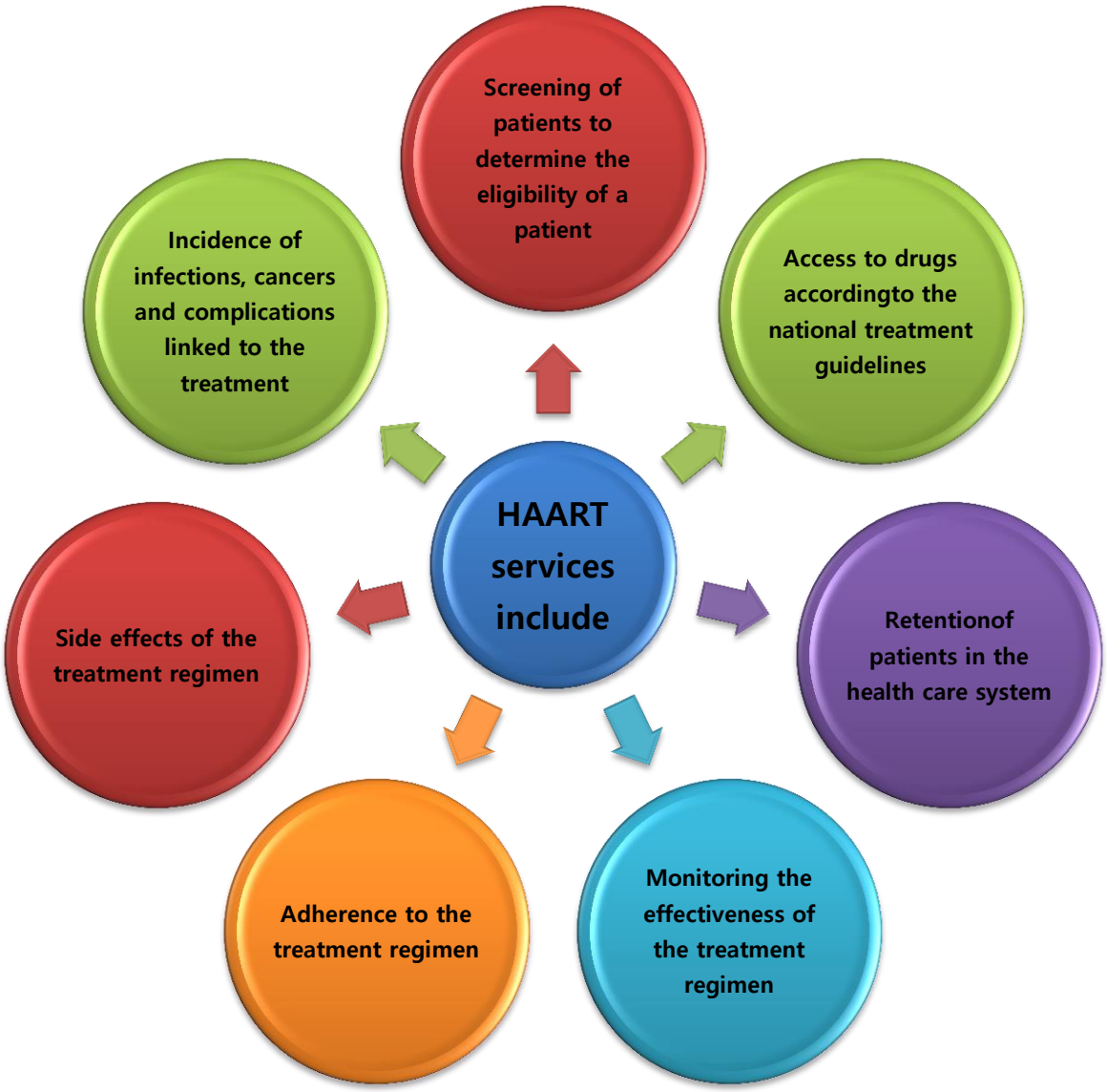


Figure 2.3 HAART services (Munderi et al., 2012)

HAART medication includes a combination of Lamivudine (3TC), Abacavir (ABC) and Efavirenz (EFV) or Lopinavir/ritonavir (LPV/r) (Department of Health, 2013). The doctor considers the weight and age of the patient when selecting between EFV or LVP/r as described in Table 2.3.

Table 2.3 Guidelines of HAART medication prescription (Department of Health, 2013)

Efavirenz (EFV)	Lopinavir/ritonavir (LPV/r)
3 years of age and older	Under 3 years of age
10kg weight or more	Less than 10kg weight

Children on HAART medication have higher CD4 counts when compared to children on ARTs, thus HAART is more effective in reducing the progression of HIV/AIDS (Weber et al., 2006). HAART provides an opportunity to restore the immune system (Giaquinto et al., 2008), therefore reducing the risks of infections, including otitis media (middle ear infection).

2.3 Hearing testing in HIV/AIDS

It is crucial to monitor the hearing status of HIV positive patients, as they are more susceptible to hearing loss from the virus itself, the treatment (ARVs) and they are at a higher risk of opportunistic infections that are treated with ototoxic medications (Harris et al., 2012; Khoza-Shangase, 2010).

2.3.1 Diagnostic Hearing Testing in HIV/AIDS

Khoza-Shangaze (2011),in South Africa monitored the auditory status in adults on HAART. This study consisted of 54 people in the experimental group and 16 people who were on HAART medication. The test battary included an otoscopy examination, tympanometry, conventional pure tone audiometry and DPOAEs. Results indicated that after three and six months of medication there was no significant change in pure tone audiometry both groups however there was a change at 6KHz and 8KHz when

using DPOAEs. Thus indicating a microcochlear pathology, highlighting the importance of the inclusion of DPOAE when testing HIV positive patients on HAART. The hearing loss that was seen could be attributed to HAART, as it was only seen in the experimental group, thus is unlikely to be due to HIV itself (Khoza-Shangase, 2010).

A descriptive study in Uganda was conducted to determine hearing impairment in 370 HIV postive children six months to five years of age (Ndoleriire, Turitwenka, Bakeera-Kitaaka & Nyabigambo 2013). Otoscopy, tympanometry and ABR (tone bursts at 500Hz and 4kHz) were conducted on all participants. The results revealed that 33% had hearing loss (Ndoleriire et al., 2013). Sensori-neural hearing loss was the most common (77%), followed by conductive hearing loss (36%) (Ndoleriire et al., 2013). This study showed that it is important to conduct holistic monitoring of the auditory system, as children on HAART have conductive hearing loss, which is generally treatable and not permanent (Northern & Downs, 2002); as well as sensorineural hearing loss, which is more permanent and requires audiological management such as amplification and rehabilitation (Northern & Downs, 2002).

A Mexican study was conducted to evaluate the audiologic and vestibular disorders in 23 children on HAART (Palacios, Montalvo, Fraire, Leon, Alvarez & Solorzana 2008). Pure tone audiometry, speech discrimination, ABR, electronystagmography and rotary chair testing were conducted. One of the limitations of the study is the small sample size, reducing the ability to generalise the findings of this study. The results showed that 13% had conductive hearing loss and 4,3% had sensorineural hearing loss (Palacios et al., 2008). The sample size was small, however the findings

from this study was similar to other studies, indicating that hearing loss in the HIV population are conductive and sensorineural, suggesting that there is a need for ongoing audiological montoring of thes patients (Ndoleriire et al., 2013; Palacios et al., 2008).

2.3.2 Hearing Screening in HIV/AIDS

There are no specific guidelines for hearing screening in HIV positive patients; however there are guidelines and protocols for adult patients receiving ototoxic treatment. It is important that the screening protocol is sensitive, specific and reliable (Konrad-Martin, Gordon, Reavis, Wilmington, Helt & Fausti 2005). Ultra-high frequencies (9kHz-14kHz) and DPOAEs are effective in identifying ototoxic hearing loss earlier than conventional pure tone audiometry (Konrad-Martin et al., 2005). The ASHA guidelines for ototoxic monitoring suggest that a baseline audiogram should be conducted, this should include case history, tympanometry, acoustic reflex threshold testing, pure tone audiometry including ultra-high frequencies (9kHz-14kHz) and where possible OAEs and/or ABR should also be conducted (Konrad-Martin et al. 2005). Thereafter follow-up questionnaires and pure tone audiometry should be routinely conducted; however if the patient is unreliable or too unwell to respond accurately and reliably, tympanometry and the same objective measure used in the baseline test battery should be used to monitor hearing status (Konrad-Martin et al. 2005).

Studies in the field of audiology in children living with HIV/AIDS highlight the need for hearing assessments in this population. Hearing testing in HIV positive patients is not always possible due to many hindering factors such as the lack of finances,

inadequate facilities. equipment availability and lack of audiological services in developing countries such as South Africa (Harris et al., 2012). Even though hearing testing cannot always be done in this population, we know that there are many detrimental effects of hearing loss in children. Some of the effects of hearing loss in children are delayed language acquisition and an overall delay in development and learning (Diefendorf, 2002; Northern & Downs, 2002). Due to the major implications of this in the lives of children, it is imperative to ensure that some form of hearing testing can be done in this population to ensure the early detection of hearing loss.

Hearing screening is a quick, cost effective measure of hearing and will indicate whether hearing is within normal limits or the need for a complete hearing test. Thus hearing screening will be a way to measure hearing ability in a large group of children, using an objective measure. Hearing screening will be able to identify hearing loss early, thus enabling the child to receive early intervention of hearing loss or outer or middle ear pathologies. The early intervention of hearing loss can reduce the impact of hearing loss on language and development in children.

2.4 SUMMARY

This chapter discussed research in the field of hearing loss and HIV/AIDS. The chapter highlighted studies on hearing and hearing loss, including the types and classifications of hearing loss. HIV/AIDS was discussed in the context of the burden of the disease symptoms and the effects of HIV/AIDS.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

The aim of this study was to describe the hearing screening profile of children between 0-6 years currently on HAART. In this chapter, the study design and methods that were employed in order to answer this aim is described. This includes a description of the study site, and the sample as well as the data collection methods and analysis. The chapter closes with ethical considerations that were observed in this study.

3.2 RESEARCH DESIGN

This study followed an observational (descriptive) cross sectional quantitative study design, in which data was collected from a sample in one specific point in time (Mann, 2003). In quantitative studies the researcher has a large degree of control when collecting the data and considers variables that can be analysed statistically (Botma, Greef, Mulaudzi, & Wright, 2010; Creswell, 2009). Descriptive study designs are non-experimental and describes a variable of interest (Botma et al., 2010) and they are commonly used when there is little information regarding the specific topic of interest (Botma et al., 2010). In this study, the researcher focused on the pathologies of the ear in a group of HIV positive children who are currently on HAART medication.

3.3 STUDY SITE

The study was located at a tertiary hospital located in Johannesburg in the Gauteng Province of South Africa. The sample was recruited from the out-patient Paediatric Virology Clinic where HIV and AIDS infected children are treated and monitored. Audiologists within this hospital provide services to children from catchment areas that feed into this tertiary hospital. Audiological screening of children occurs weekly (Tuesdays and Thursdays). All children under the age of 7 are given preference to assessment due to the importance of early identification. This study location was thus suited to meet the aim of this study. Relevant gatekeeper permission was granted from the hospital, prior to the commencement of the study *(Annexure 2).*

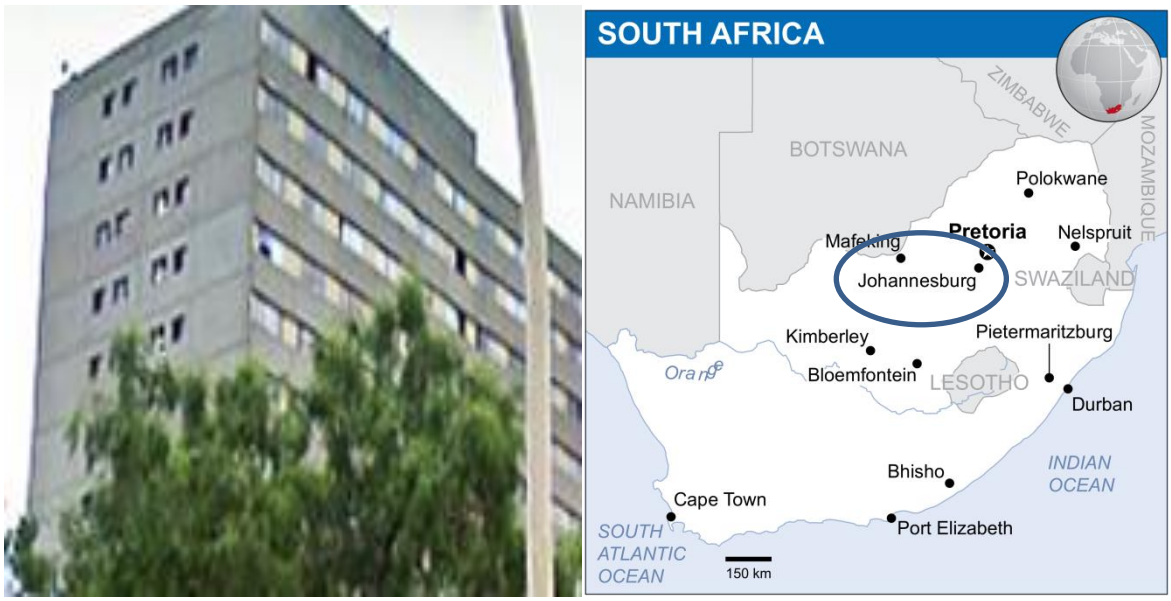


Figure 3.1 Study Site, a tertiary hospital located in Johannesburg, South Africa

3.4 STUDY POPULATION AND SAMPLE

3.4.1 Target Population

The target population comprised all children attending the virology clinic at a tertiary state hospital in a three month period. All children at the virology clinic were diagnosed with HIV/AIDS and attend the clinic for HAART medication. This includes approximately 50 children per week. The target population size was therefore N=600.

3.4.2 Sample

3.4.2.1 Sampling Strategy

Purposive criterion sampling was employed to select participants that met the inclusion criteria for the study (Coyne, 1997; Palys, 2008). Criterion sampling is a specific type of purposive sampling and refers to selecting an individual once a list of criteria has been met (Palys, 2008). All participants that met all inclusion criteria over a three-month period were included. Single stage sampling occurs when the researcher has access and the ability to sample the population directly (Creswell, 2009). In this study, all children that attended the virology clinic at a tertiary state hospital were screened by the audiologist. Children of parents who consented to participation in the study and those who met all the inclusion criteria in this time frame formed the sample for this study.

3.4.2.2 Recruitment of Participants

Participants were recruited from the waiting room at the virology clinic. The researcher approached caregivers in the waiting room to determine whether they would like their child to undergo hearing screening whilst they were waiting for their

doctor's consultation. Once they agreed to hearing screening, the child and caregiver were taken to a separate consultation room for hearing screening. Once in the consultation room, the researcher ensured that the child met all the inclusion criteria and confirmed the absence of all the exclusion criteria. Thereafter the information letter was given to the caregiver and the researcher answered any questions raised

.

3.4.2.3 Selection of Participants

The following selection criteria were used for the sample in this study.

3.4.2.3.1 Inclusion Criteria

The following inclusion criteria were observed in this study. These included children who were:

- medically diagnosed with HIV/AIDS
- currently receiving HAART medication
- attending the virology clinic at the sampled tertiary hospital in Gauteng
- between the chronological age of 0-6 years, as they are automatically given HAART once they are diagnosed with hearing loss (Department of Health, 2013).

The inclusion criteria for the sample in this study was based on evidence from the literature that has shown a higher prevalence of audiological deficits in young HIV positive children (Matas et al., 2006). In terms of audiological development, children over the age of 6 years are considered adult in terms of the ear anatomy. This study therefore considered children under the age of six (Northern & Downs, 2002).

3.4.2.3.2 Exclusion Criteria

The following exclusion criteria were observed in this study. The study excluded children with:

- co-morbidities that have known audiological implications, for example, Down syndrome, Usher Syndrome and Treacher Collins Syndrome(Northern & Downs, 2002; D. C. D. Swanepoel et al., 2004)
- history of bacterial meningitis as the disease itself can have a negative impact on hearing and the status of the auditory system (D. C. D. Swanepoel et al., 2004).
- history of ototoxic meds for example, kanamycin or cisplatin (Konrad-Martin et al. 2005; Biro, Nosezek, Prekopp, Nagyivanyi, Geczi, Gaudi & Bodrogi 2006).

Confirmation of these criteria was obtained from the interview with the primary caregiver as well as from information gained from the child's medical records and laboratory records for verification of subjective reports provided by the primary caregiver.

3.4.2.4 Sample Size

Eighty children were screened within the three-month period. Eighty caregivers were interviewed at the time of the screening. Of these, the final sample was n=77, due to three children being excluded from the study. This was based on laboratory tests indicating a history of tuberculosis.

3.5 DATA COLLECTION

This study sought to describe the hearing screening profile of children between 0-6 years currently on HAART at a virology clinic within a tertiary hospital in Gauteng in order to document and describe the occurrence of possible outer, middle and inner ear pathologies. In order to achieve this aim, the methods, instrumentation and reporting is described in Figure 3.2.

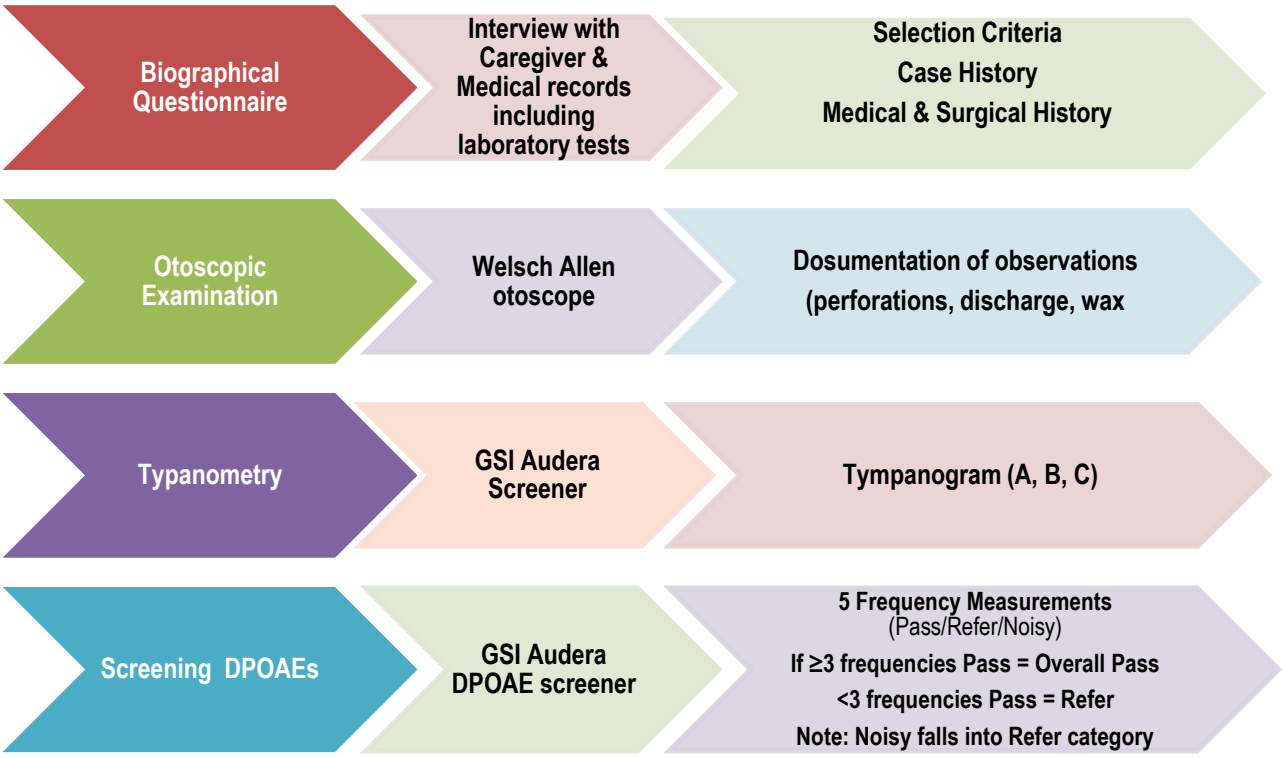


Figure 3.2 Data Collection Process

3.5.1 Data Collection Methods

3.5.1.1 Interview with Caregivers

A questionnaire *(Annexure 4; Section 1 and 2)* was used to capture information obtained from the interview with the primary caregiver and from evidence retrieved from medical documents. These included biographical and medical history.

Of the 80 caregivers originally interviewed, only one required the use of translation. A trained nursing sister assisted in the interview process to ensure correct and accurate documentation of the background and medical history. The researcher verbally asked each caregiver questions and recorded the response on the biographical questionnaire. All data was collected by the researcher; to ensure that a constant standard was maintained which reduced clinician variability during data collection.

3.5.1.2 Observation/Testing

Formal testing for the outer, middle and inner ear was conducted on each child. These were recorded in the questionnaire *(Annexure 4; Sections 3, 4 and 5).* Children under three years were allowed to sit on their caregivers lap during testing. Children, who were able to sit independently, were tested whilst they were in a seated position. Otoscopic and tympanometry were completed in the consultation room, whilst DPOAEs were conducted in an audiology screening booth. Details of these tests are provided in *Table 3.1.*

3.5.2 Pilot Study

A pilot study is a small scale or trial study in preparation for the actual research study (van Teijlingen & Hundley, 2001). The pilot study is used to (i) test the adequacy of the research instrument, (ii) establish if the sampling method is effective, (iii) identify logistical problems that may arise during data collection and (iv) assess the efficiency and effectiveness of the data analysis method; all of which may detect unforeseen difficulties (van Teijlingen & Hundley, 2001).

Table 3.1 Data Collection Instruments

Section	Objective	Procedure	Description of Testing and Observations Recorded
1	To describe the demographic profile of children undergoing audiological screening	Interview with Caregiver	Demographic information (e.g. age, gender)
2		Interview with Caregiver	Medical history questions were asked to determine whether the child had any medical condition or syndrome, history of meningitis, ear surgery or ototoxic medication. Medical records were accessed, by the researcher, to obtain the virology load and percentage of viral load.
3	To document and describe the occurrence of possible outer ear abnormalities	Otoscopic examination findings	The otoscopic examination entails looking at the outer ear, including the pinna, ear canal and tympanic membrane (Gelfand, 2009). This was conducted by the researcher, using a hand-held Welsch Allen otoscope.
4	To document and describe the occurrence of possible middle ear abnormalities	Tympanometry findings	Tympanometry is introducing air into the middle ear system, to determine the mobility of the ear drum, as well as to determine the Eustachian tube function and middle ear status (Gelfand, 2009). Tympanometry is conducted at 225Hz for all persons over 7 months of age (Gelfand, 2009). All infants under 7 months of age require high frequency tympanometry at 1kHz (Kei et al., 2003). Tympanometry is an objective measure, thus reducing inconsistencies among participants. Tympanometry was conducted using the GSI Audera Screener.
5	To document and describe the occurrence of possible inner ear abnormalities	DPOAE Findings	DPOAE screening was conducted using the GSI Audera DPOAE screener. DPOAE screening is also an objective measure, where a pass or refer result is obtained, maintaining consistency among participants. DPOAEs measure the outer hair cell functioning in the cochlear, this is used for early identification of hearing loss (Gelfand, 2009; Ranjan & Bhat, 2008).

A total of five participants (volunteers) were in the pilot study and all of them met the inclusion criteria of the study. The researcher approached all patients in the waiting room at the virology clinic on a specific day. The questionnaire and hearing screening procedures were piloted and any issues that arose were rectified prior to the commencement of the main study.

All of the participants of the pilot study had no difficulty in understanding the information sheet and in the completion of the consent form. Questions were addressed where clarification was needed. The pilot revealed missing biographical information such as gender, race, type and duration of treatment. This information was added and the format of the questionnaire was changed into a more user friendly format (for ease of documentation) by the inclusion of tick and multiple options *(Annexure 4)*.

Section 3, namely, virology information, had a typographical error that was corrected following the pilot study. The pilot study had % viral load, rather than % CD4. Section 5 of the questionnaire was also changed and more columns were added, to make the form more user-friendly. The pilot study also showed that it was quicker for the researcher to ask the parents or caregivers the questions and complete the data collection form, rather than waiting for them to complete the data collection form. This also assisted in probing towards accuracy of information obtained. All information that was required for the hearing screening in the study was accessed with ease during the virology clinic; therefore the research procedure did not have to be modified after the pilot study.

3.6 Validity and Reliability

3.6.1 Validity and reliability of the test procedures used

Screening procedures need to be quick, reliable and sensitive in order to be effective. This study used objective test procedures such as tympanometry and DPOAEs, as the target population included infants and young children. Specificity refers to the number of negatives correctly identified and sensitivity refers to the number of positives correctly identified. OAEs have been used extensively in screening programmes in infants and have a specificity exceeding 95% and sensitivity exceeding 99%, once the clinician has ruled out the possibility of middle ear dysfunction. This study incorporated tympanometry to ensure that DPOAEs were only conducted in children who had normal middle ear functioning. Tympanometry is used in the diagnostic audiological test battery as an indicator of middle ear functioning. Tympanometry has been proven to have a sensitivity of 90% and a specificity of 86% in the diagnosis of otitis media (Finitzo, Friel-Patti, Chinn, & Brown, 1992).

3.6.2 Repeatability

To ensure repeatability the researcher used strategies to reduce variation in testing. This was obtained by using the same tympanometer and DPOAE screener on all participants. The same room, with the same screening audiometric booth was used with all participants. Although outer ear testing was subjective, tympanometry may be used to confirm outer ear results (e.g. if the researcher missed a tympanic membrane perforation, tympanometry will show very high ear canal volume). Objective measures were used for middle ear and inner ear screening, to increase subject validity.

3.6.2 Observational (intra-rater) considerations

This study had one researcher, who is a trained audiologist to maintain consistency. Tympanometry results were interpreted using equipment normative data for ear canal volume, pressure and static compliance. All Type B tympanograms, that had small ear canal volumes, were repeated by repositioning the probe in the ear, to ensure that the probe was not placed against the ear canal. All refer DPOAE screening results were repeated, by repositioning the probe to ensure that it was not positioned against the ear canal.

3.6.3 Calibration of Instruments

The instruments used for tympanometry and DPOAE screening underwent annual calibration as per manufacturer's specifications. A certificate of calibration was available for confirmation.

3.7 Data Analysis

Given that the objectives in this study were to describe the presence of outer, middle and inner ear pathologies, descriptive statistics were used to analyse the data. Descriptive statistics are used to analyse data where there are known variables that need to be analysed (Botma et al., 2010). It is commonly used when there is little information known about the topic (Botma et al., 2010). The data was entered into an excel spreadsheet and participants were coded to ensure that confidentiality was maintained. The data was statistically analysed using Microsoft Excel and were represented graphically in frequencies and percentages using pie, chart and bar graphs.

Stata 13 (StataCorp, 2013) was also used to determine the relationship between HAART and CD4 percent, by calculating the regression between HAART and CD4 percent. The p-value and r-square value of regression was graphically represented using a line fit plot and probability plot *(Chapter 4)*. Level of significance was a p-value of <0.05.

3.8 Ethical Considerations

The ethical codes considered in this study included informed consent, beneficence, justice, anonymity and confidentiality (Fouka & Mantzorou 2011; Orb, Eisenhauer & Wynaden 2001; Richards & Schwartz 2002).

Autonomy refers to the ability for self-determination, and this was achieved by ensuring that informed consent and assent was obtained (Fouka & Mantzorou, 2011; Orb et al., 2001). Assent was obtained by reading the information letter, simplifying it where necessary and asking if the participant would like to participate in the study.

Informed consent is when a participant knowingly, intellectually and voluntarily agrees to partake in a study (Fouka & Mantzorou, 2011). The informed consent in this study included the provision of information on the aims, benefits, selection criteria and right to withdraw from the study at any time. Written consent was obtained from the parent/caregiver *(Annexure 5)* and verbal assent was obtained from the participants, if they were old enough to do so.

Beneficence refers to the ability for a participant to benefit from the study and to ensure that there will be non-maleficence as a result of this study; this included harm that may be caused in a physiological, emotional, social or economic manner (Fouka & Mantzorou, 2011). Non-maleficence was adhered to in this study, as participants that were uncomfortable and started crying during the testing was respected and testing was terminated. There are no known physical or psychological risks to participate in this study. The hearing screening could be considered to be invasive testing as it required the researcher to look inside the ear and to introduce air into the ear canal. During the test procedures participants were seated on the caregivers lap to ensure that they were comfortable and at ease during the testing. The caregiver kept the participants head steady during otoscopic examination and the researcher braced against the head to reduce the risk of injury to a participant during otoscopic examination. Tympanometry was not conducted on any participant who had a tympanic membrane perforation, as it could be painful and may result in the perforation expanding. A few of the participants in the study were referred to the otorhinolaryngologist (ENT) specialist, for the removal of wax and the management of otitis media.

Respect for privacy is the right of a participant to withhold any personal information from the researcher (Fouka & Mantzorou, 2011). This study respected the right of a participant to withhold personal information at any time during the study; if this information was imperative for the study, the participant was withdrawn from the study. Confidentiality is the management of personal information, in order to protect the identity of an individual (Fouka & Mantzorou, 2011). Participants in this study were coded and no names or hospital numbers were used to ensure that

confidentiality was maintained throughout the study. Personal information obtained from all participants was accessed by the researcher and supervisor and information obtained from the study was stored in the Audiology department at the hospital and were accessible to the researcher and supervisor.

Ethical approval and gatekeeper permissions to conduct this study were obtained from the Head of Paediatrics at the hospital, the Head of Paediatric Virology Clinic at the hospital and from the assistant directorate of the Speech and Audiology Department at the hospital. Once those permissions were obtained ethical approval was requested and provided by the CEO of the hospital (*Annexure 2*). Additionally permission had been granted from the University of Witwatersrand's Medical Ethics Committee (*Annexure 3*). As part of accountability reporting, all gatekeepers will receive a summary of the study findings.

3.9 Summary

This chapter has highlighted the methodological considerations implemented in this study. A detailed description of the methods and procedures were described that reveals the specific hearing screening processes followed to meet the objectives of this study. The pilot study indicated all the changes that were required prior to the actual data collection. Ethical approval for this study was granted by all relevant gatekeepers, and principles and considerations were upheld in the study.

CHAPTER 4

RESULTS

4.1 INTRODUCTION

This chapter discusses the results of the study, under the following sections, demographics, HIV viral load and CD4 percentage and ear pathologies. Each section will clarify the number of participants that were considered in the analysis of that specific section. Some of the sections considered the participant as the total number whilst other sections considered the number of ears as the total number. Results are presented in this manner as the middle ear screening could only be performed if there was no perforation or discharge from the ear. The inner ear screening could only be done if there were type A tympanograms. There was only one caregiver who did not understand English and only spoke Xhosa; a nursing staff member at the hospital verbally translated the permission letter and translated the necessary case history questions. The medical history was cross referenced with the medical records and all corresponded well.

4.2 DEMOGRAPHICS

Objective 1 of the study was to describe the demographic profile of children on HAART. Seventy seven participants formed the final sample. Age and gender were the two demographics that were considered in this study.

4.2.1 Age

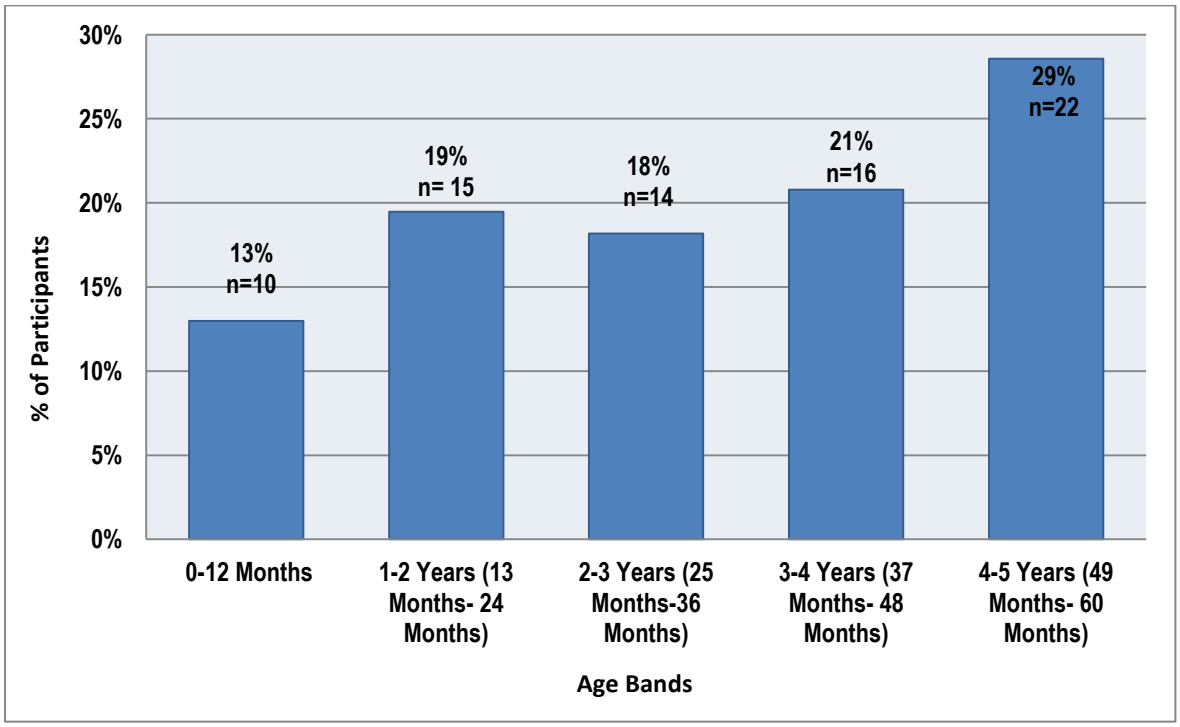


Figure 4.1 Age Distribution of Participants (n=77)

As illustrated in Figure 4.1 the age of participants were divided into categories: 0-12 months, 1-2 years (13- 24 months), 2-3 years (25-36 months), 3-4 years (37-48 months) and 4-5 years (49-60 months). These categories were used throughout the study. The youngest participant in this study was 2 months old and the oldest participant was 4.11 years old. The average age was 2.10 years and the median was 3 years of age. The majority of participants (29%) were between 4-5 years of age; however there was a good representation of every age band in this study (figure 4.1).

4.2.2 Gender

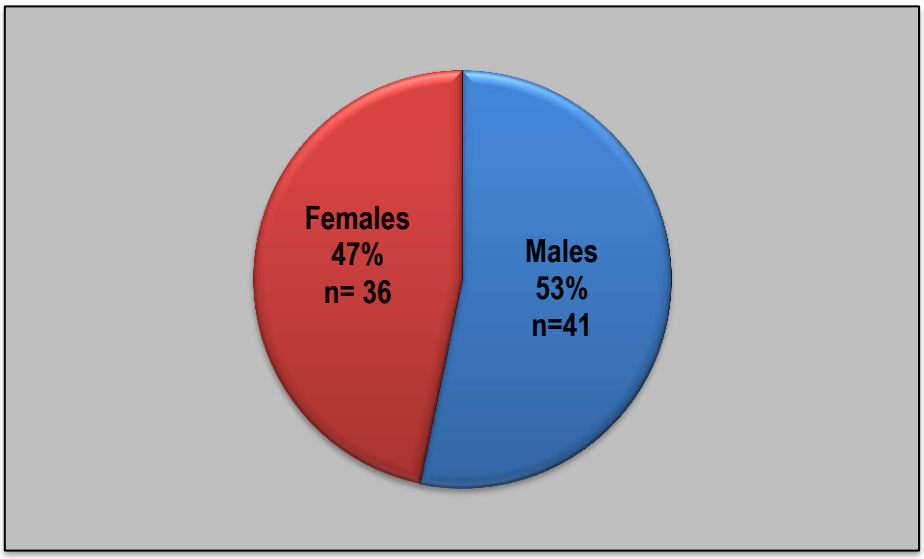


Figure 4.2 Gender Distribution of Participants (n=77)

This study had representation of both genders, with 53% male participants and 47% female participants as seen in Figure 4.2. Previous studies showed no gender difference in HIV/AIDS participants with respect to HIV/AIDS markers or hearing.

4.3 HIV/AIDS MARKERS

This section of the results will discuss in detail the HIV markers that were considered in this study. The HIV markers in this study were the duration on HAART and CD4 percent. This study considered the CD4 percent, as this is the more reliable than CD count in children less than 12 years of age (Giaquinto et al., 2008).

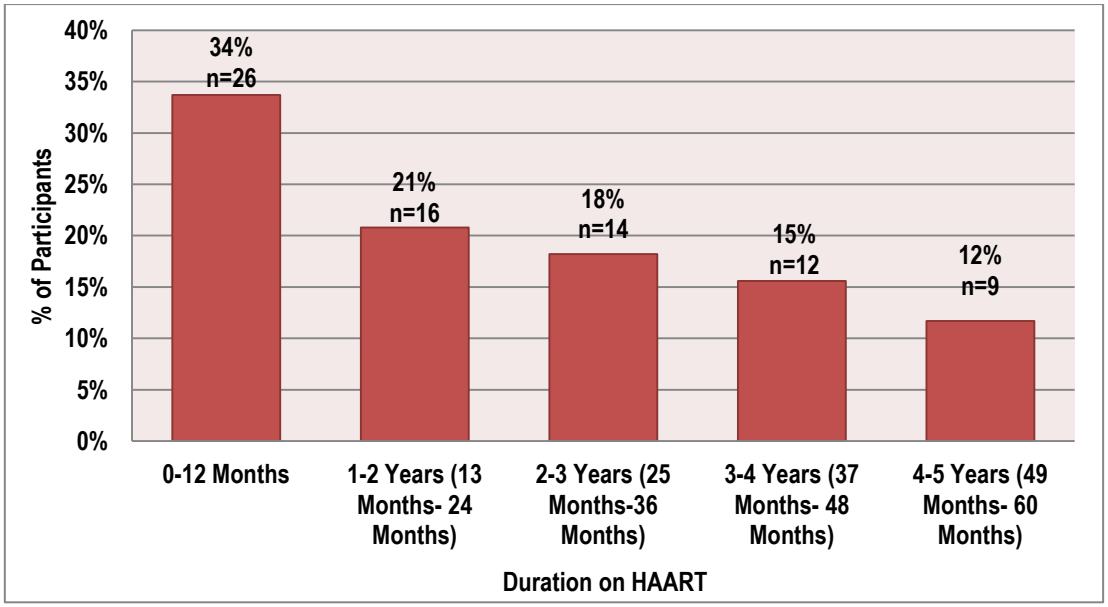


Figure 4.3 Duration on HAART (n=77)

The duration on treatment was divided into categories: 0-12 months, 1-2 years (13-24 months), 2-3 years (25-36 months), 3-4 years (37-48 months) and 4-5 years (49-60 months). The duration that participants were on HAART varied from one month to 4.5 years. Thirty three percent of participants were on HAART for 0-12 months, whilst 12% were on HAART for 4-5 years. The average duration on treatment was 2 years.

Table 4.1 Breakdown of HIV immunosuppression in Participants (n=77) (WHO, 2005)

	0 to 12 months		13-59 months	
Immune Status	CD4%	Number of children in Study	CD4%	Number of children in Study
Not significant immunosuppression	>35%	4	>25%	51
Mild immunosuppression	25-34%	3	20-24%	3
Advanced immunosuppression	20-24%	2	15-19%	4
Severe immunosuppression	<20%	1	<15%	9

In this study 71% of the participants were not significantly immunosuppressed (stage I). Severe immunosuppression (stage IV) was the next most common classification and was present in 13% of the study sample. Both mild immunosuppression (stage II) and advanced immunosuppression (stage III) was found in 8% of the participants. This could be due to the fact that the average duration on HAART of the study participants were 2 years, which could have resulted in the suppression of the virus.

4.3.1 CD4 Percent and Duration on HAART

A statistical regression was conducted to determine the relationship between CD4 percent and the duration on HAART. The regression graph shows that as the duration on treatment increased the CD4 percent also increased. The p-value of the regression test was 0.001, which indicated that it is statistically significant (that is a p-value≤0.05). The r-square value of the regression test was 13.4%, which indicates the magnitude of the relationship between CD4 percent and the duration on HAART. This indicates that the longer the participant was on HAART medication the higher the CD4 percent, as illustrated in Figure 4.4 and Figure 4.5. A higher CD4 percent indicates reduced effects of HIV on the individual. Therefore the participants in this study showed that HAART medication is effective in reducing the effects of HIV.

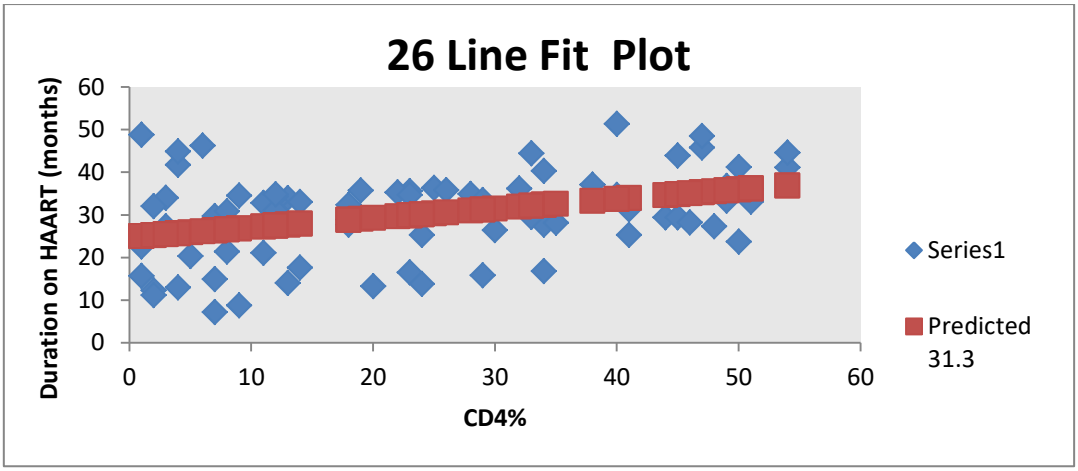


Figure 4.4 Relationship between the duration on HAART and CD4 percent

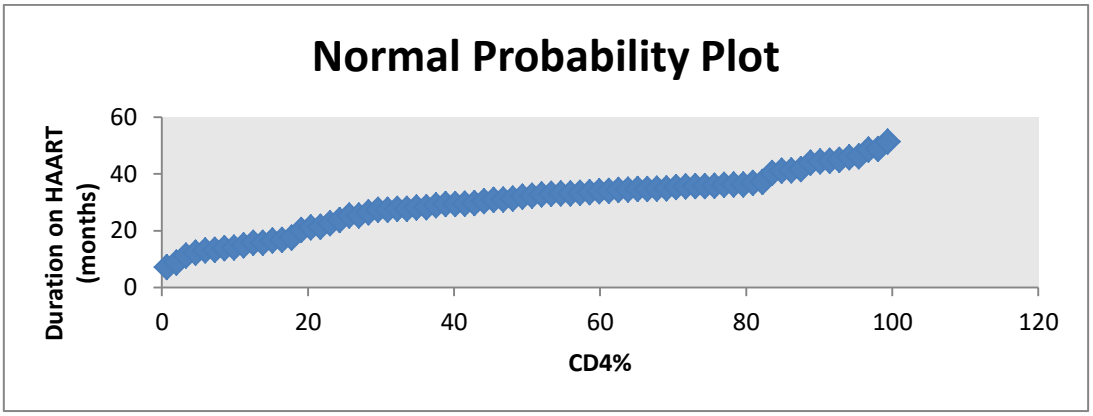


Figure 4.5 Relationship of the duration on HAART and CD4 percent

4.4 AUDIOLOGICAL SCREENING PROFILE

This section will describe the possible ear abnormalities and pathologies that were detected via hearing screening. The screening protocol involved bilateral assessment of all participants, thus n=154 ears were assessed. This section discusses ears specifically, rather than participants.

4.4.1 Outer Ear

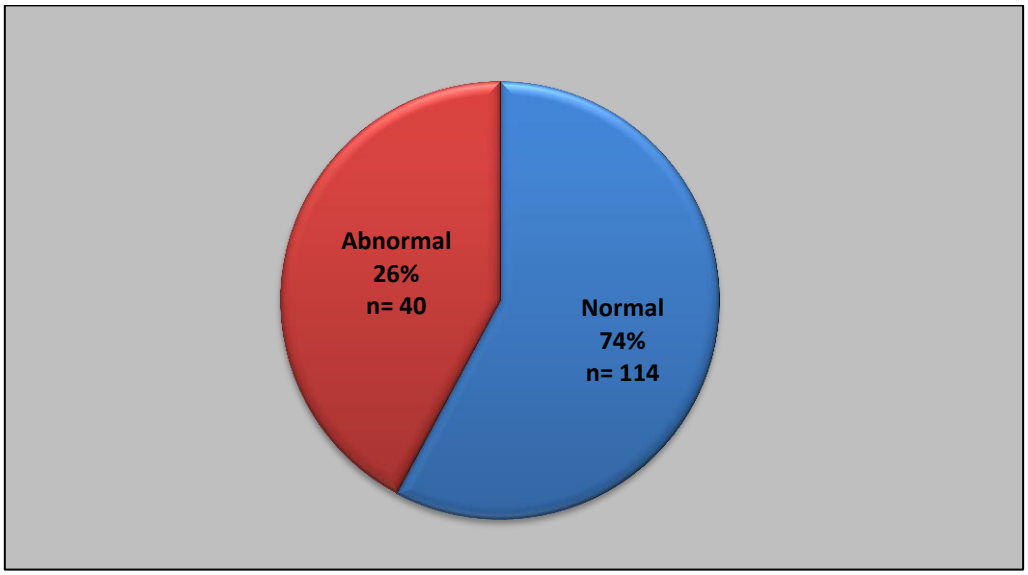


Figure 4.6 Prevalence of Outer Ear Abnormality (n=154)

Outer ear abnormalities in this study were assessed by conducting an otoscopic examination, using a hand held Welsch Allen otoscope. Normal findings represented the absence of wax, no signs of infection or foreign bodies in participant's ears. The 58% of ears had normal outer ear status, where there were no signs of abnormality. The structure of the pinna was normal in all participants bilaterally. Outer ear pathologies (42%) that were noted included occluding wax, red ear canals, bulging tympanic membranes, perforated tympanic membranes, and perforated tympanic membranes with discharge as seen in Figure 4.6.

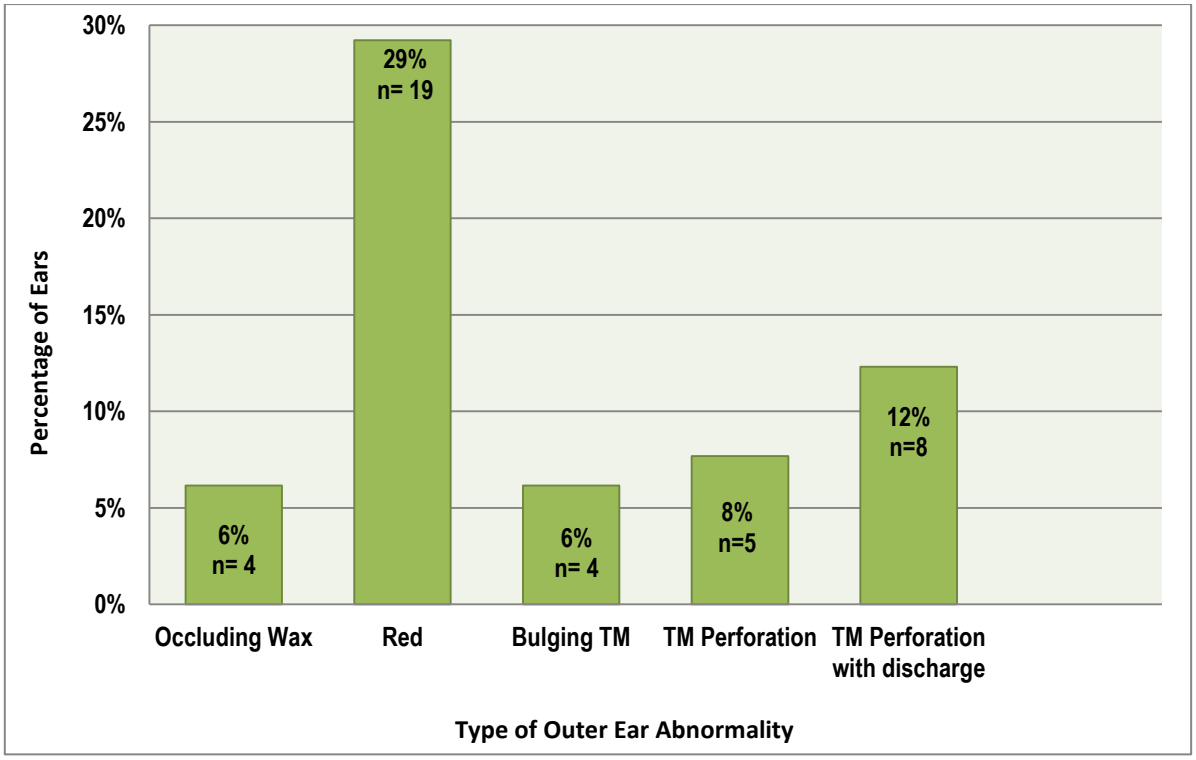


Figure 4.7 Prevalence of Specific Outer Ear Abnormalities (n=65)

Outer ear abnormalities were detected in 40 ears, with 29 participants demonstrating bilateral outer ear abnormalities and seven participants with unilateral outer ear abnormalities. Outer ear abnormalities were determined visually by the researcher using clinical judgement and experience. Redness or inflammation of the ear canal was the most prevalent outer ear abnormality and occurred in 29% of ears tested. All participants with occluding wax, Tympanic membrane perforations and discharge were referred to an ENT specialist for necessary management. Irrigation should not be conducted on children with a recent history of otitis media or with HIV/AIDS (Wilson & Roeser, 1997). Although wax management is in the scope of practise of audiologists and nurses, due to the high prevalence of otitis media in children with HIV/AIDS it is protocol at the hospital to refer them for ENT management.

The information from Table 4.2 was used to determine the occurrence of outer ear abnormalities in each specific stage of HIV infection. The highest prevalence of outer ear abnormalities were present in the Stage III HIV, 67%. Stage II had the lowest prevalence of outer ear abnormalities, 17% of ears in Stage II had outer ear pathologies at the time of testing.

Table 4.2 Outer ear abnormalities compared to HIV stage

HIV Stage	No Abnormalities Detected	Tympanic Membrane Perforation	Red Ear Canals	Bulging Tympanic Membrane	Occluding Wax	Total
Stage I	85	5	14	4	2	110
Stage II	10	0	2	0	0	12
Stage III	4	4	2	0	2	12
Stage IV	15	4	1	0	0	20
Total	114	13	19	4	4	154

4.4.2 Middle Ear Pathology

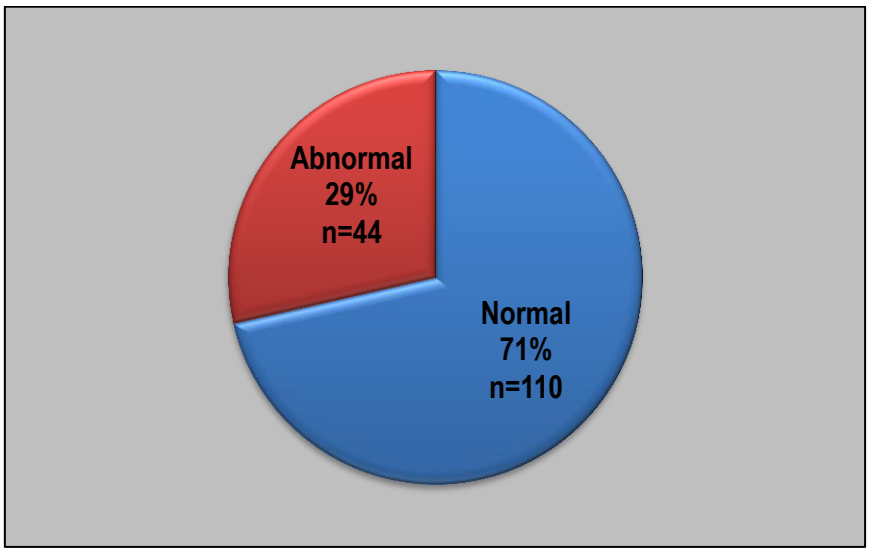


Figure 4.8 Prevalence of Possible Middle Ear Pathologies (n=154)

In this study the middle ear was assessed using a GSI Audera Screener. As the research was conducted using screening equipment, the results are indicative of possible middle ear pathology. Paediatric normative data was used and all infants under 7 months underwent high frequency tympanometry (Kei, Allison-Levick, Dockray, Harrys, Kirkegard, Wong, Maurer, Hegarty, Young & Tudehope 2003). A total of twelve ears (8%) had high frequency tympanometry (6 participants). High frequency tympanometry is a more accurate measure of middle ear function in neonates, under 7 months of age (Kei et al., 2003). This may be due to the fact that a neonate's middle ear is mass-dominated in contrast to the stiffness-dominated middle ear of adults (Holte, Margolis & Cavanaugh 1991; Keefe & Levi 1996; Meyer, Jardine & Deverson 1997 cited in Kei et al. 2003). Normal middle ear functioning was found in 71% of ears. The remaining 29% had otitis media or middle ear pathology.

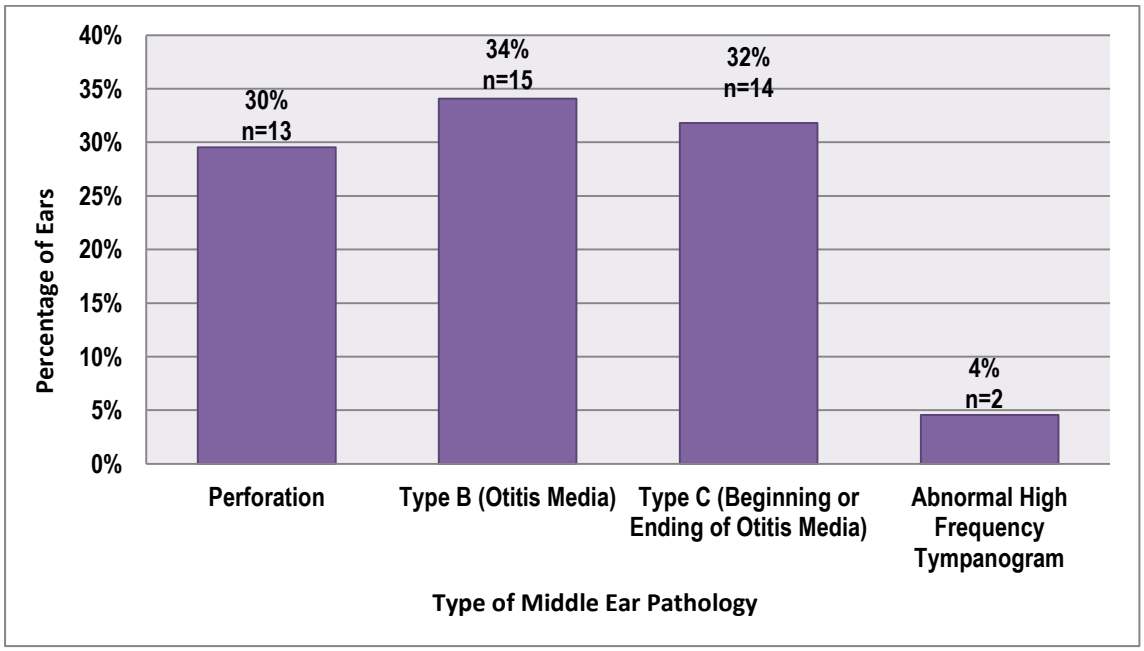


Figure 4.9 Prevalence of Specific Middle Ear Pathologies (n=44)

The results of tympanometry were further divided into specific tympanometry results. Participants who had perforations of the tympanic membrane had no history of trauma. Perforated tympanic membranes with discharge at the time of testing constituted 62% of ears and the remaining 38% had a recent history of discharge. Middle ear pathology was present if a Type B or abnormal high frequency tympanogram was obtained. Type B tympanogram indicates otitis media and a Type C tympanogram indicates the beginning or ending of otitis media or Eustachian Tube dysfunction. Two of the ears that were in participants 7 months of age or younger had unilateral abnormal high frequency tympanometry, which was indicative of middle ear pathology.

Table 4.3 Middle ear pathologies compared to HIV stage

HIV Stage	Type A Tympanogram	Type B Tympanogram	Type C Tympanogram	Could Not Test (Perforation or discharge)	Total
Stage I	82	12	11	5	110
Stage II	9	2	1	0	12
Stage III	4	1	3	4	12
Stage IV	15	1	0	4	20
Total	110	16	15	13	154

The prevalence of middle ear infections was considered in terms of HIV staging. The highest prevalence of middle ear pathologies (77%) were seen in individuals who were in Stage II HIV. The lowest prevalence (5%) of middle ear infections was in stage IV HIV. Possible middle ear infections or Eustachian tube dysfunction was most prevalent (25%) in stage III HIV and the lowest (0%) in stage IV HIV.

4.4.3 Inner Ear

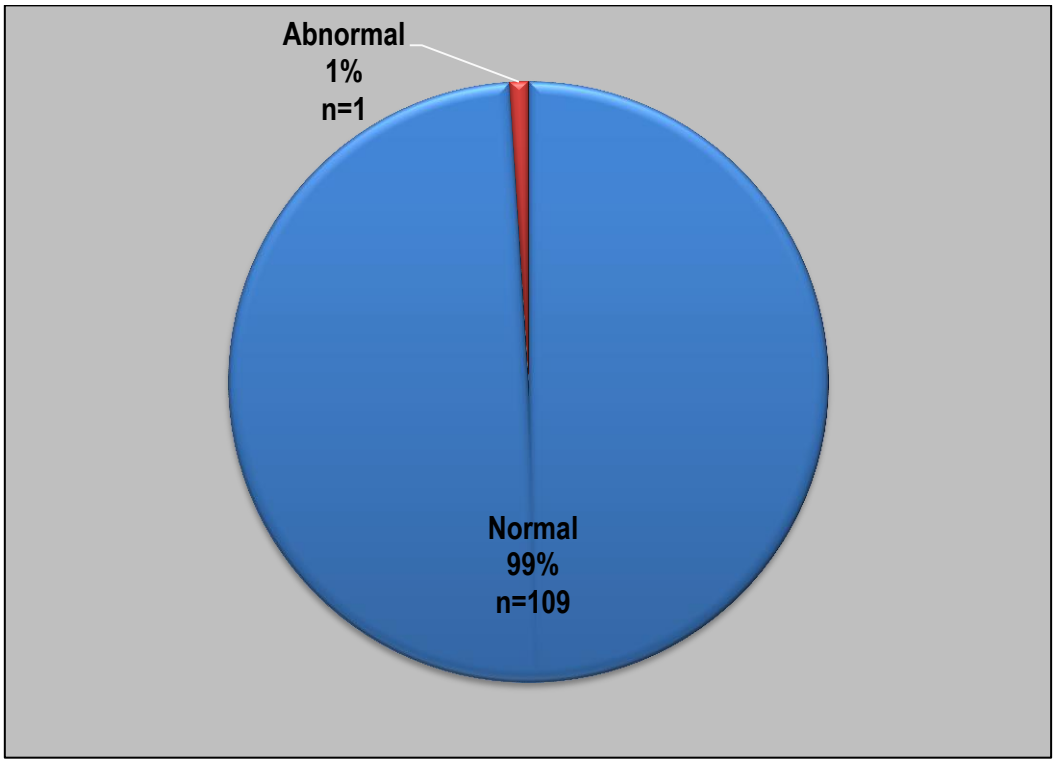


Figure 4.10 Prevalence of Possible Inner Ear Pathologies (n=110)

In this study the inner ear was measured using the GSI DPOAE Screener. This measures the outer hair cells of the cochlear, rather than the entire inner ear; however it is used for detecting the possibility of early hearing loss. DPOAE screening could only be conducted on a total of 110 ears, as it is only accurate when there are Type A tympanograms present. Six of the ears could not be tested due to the participants crying (noisy) during DPOAE screening, therefore the test had to be terminated and no results were obtained. Inner ear pathology was only detected unilaterally in one of the participants, whilst all other participants who had DPOAE screening (99%) passed bilaterally.

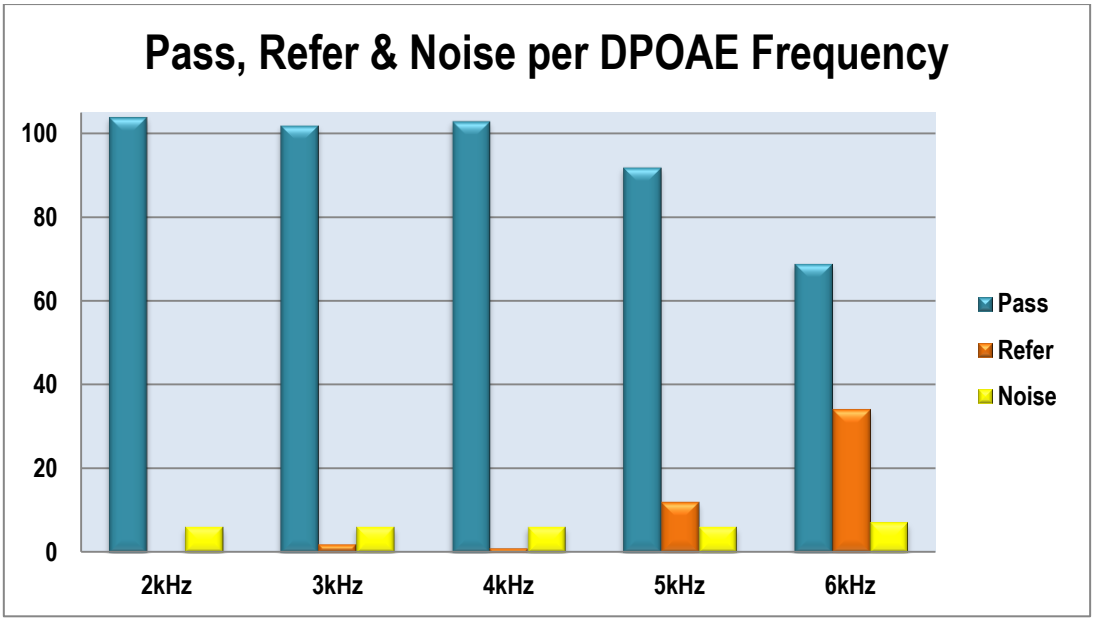


Figure 4.11 DPOAE Screening Results (n=110)

The DPOAE screening results were further analyzed into frequency specific results, as seen in Figure 4.11. The graph indicates the pass, refer and noise result that was obtained at each frequency. Noise was detected in 6 ears during DPOAE screening across from 2kHz through to 6kHz, however at 6kHz 7 ears was noisy during DPOAE screening.

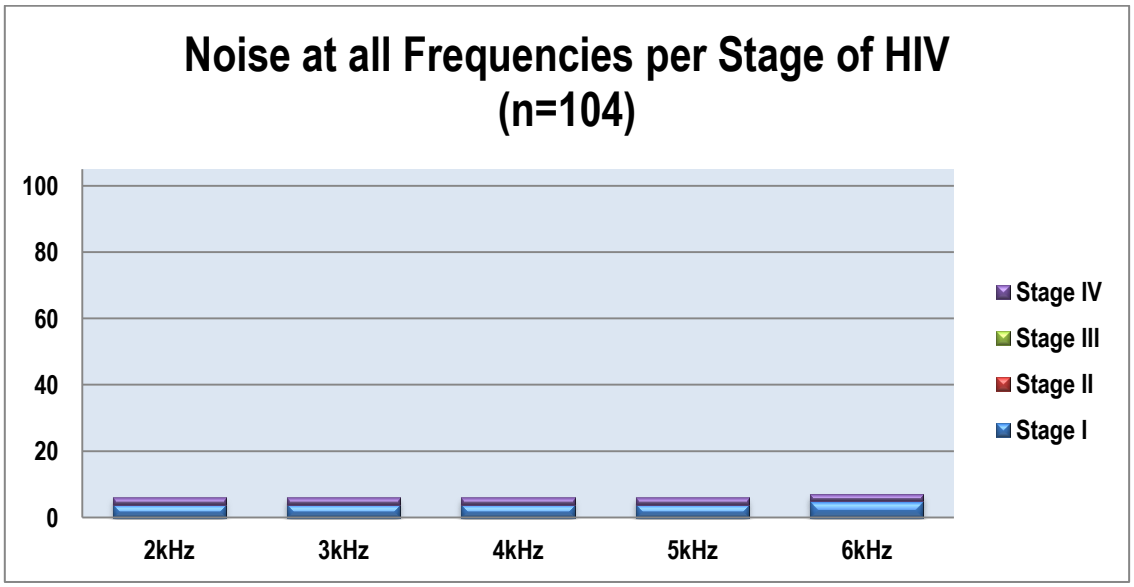


Figure 4.12 Noise detected in DPOAE screening

Noise was noted in DPOAE screening if the participant was crying or restless during testing and testing was eventually terminated and a noise result was noted. Noise responses were recorded per frequency, per ear as some of the participants were fine during most of the DPOAE screening and started crying during the screening of one ear or at one frequency. Noise was noted in participants who were in stage I and stage IV HIV. There were no noise responses obtained from participants who were in stage II and stage III HIV.

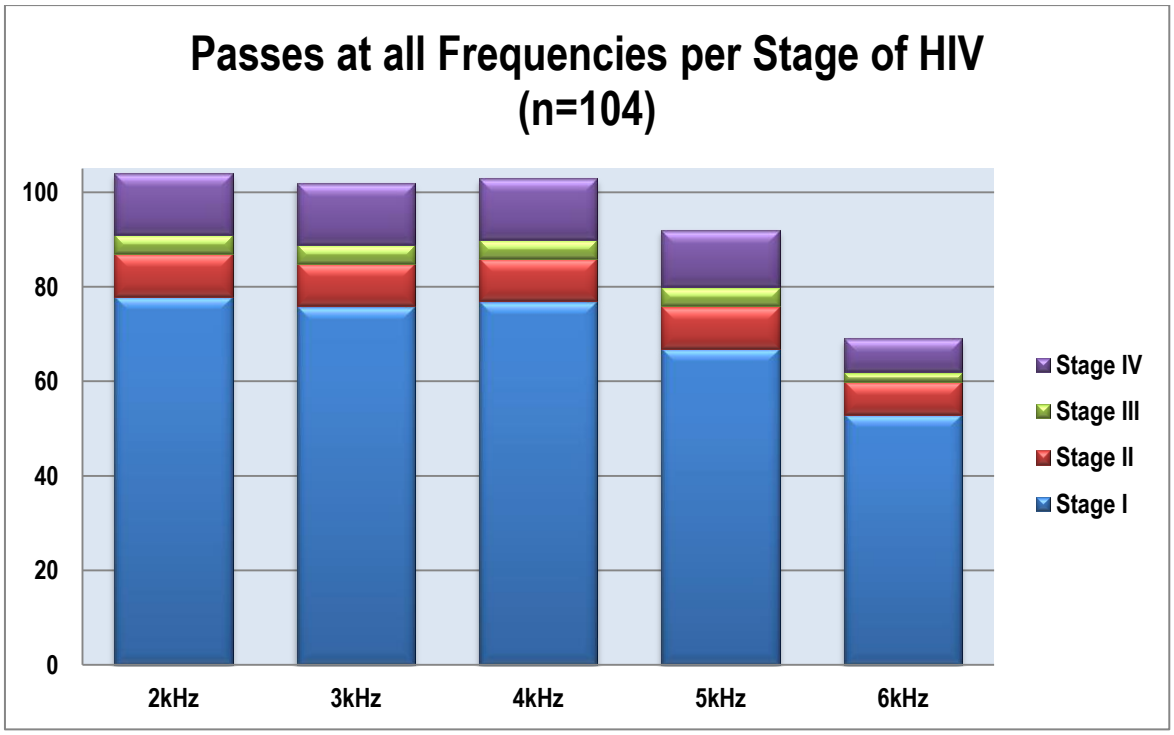


Figure 4.13 Passes in DPOAE screening

When considering the pass results at DPOAE screening, the six participants who were crying throughout the frequency range were discarded and not considered in the participants when considering pass and refer results, therefore the total number of ears were reduced to 104 ears. However the one participant who was crying

during 6kHz only, in one ear was considered and the noise was interpreted as a refer result.

More pass results were obtained at low frequencies when compared to high frequency DPOAE screening. Low frequency DPOAE (2kHz- 4kHz) passes were between 98% and 100%, whilst there was an 88% pass at 5kHz and only a 67% pass at 6kHz. This trend shows that as the frequency increases the pass rate in DPOAE screening decreases, indicating possible high frequency cochlear damage.

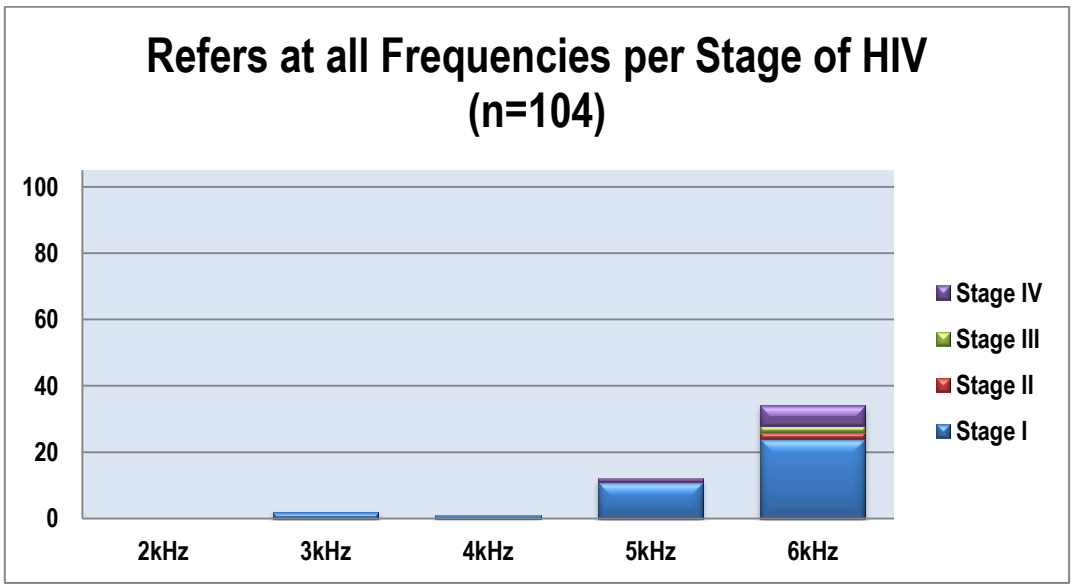


Figure 4.14 Refers at DPOAE frequencies

The DPOAE screening refer results highlight the trend that there were more refer results obtained at high frequencies. The refer results further emphasize the relation that was described earlier, as the frequency increases the number of refer results from DPOAE screening increases, thus highlighting the possible high frequency damage of the cochlear.

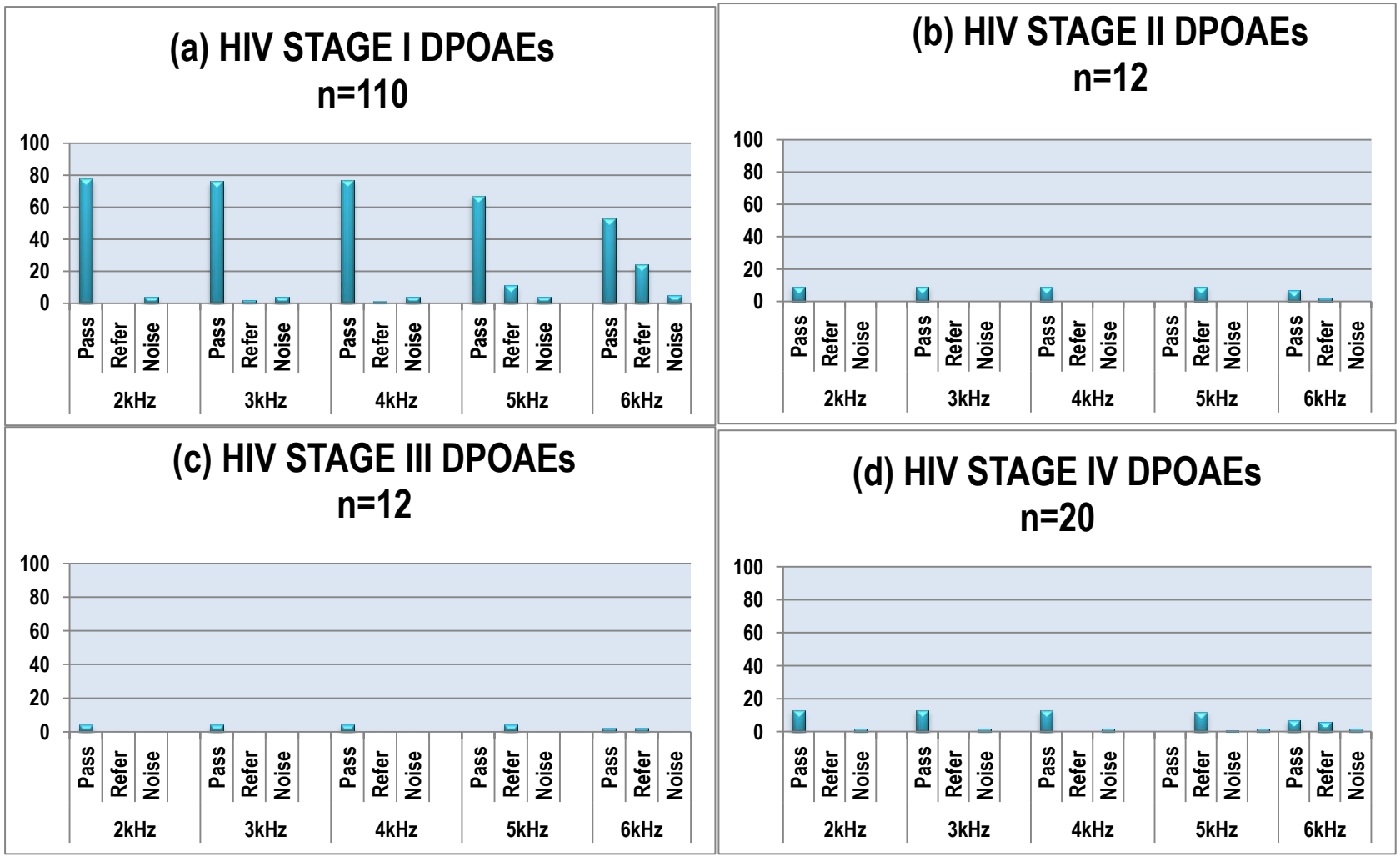


Figure 4.15 HIV stage vs DPOAE screening

The DPOAE screening results were separated into HIV stages to determine if there were any differences that could be related to the HIV stage. As the HIV staging was not considered in the inclusion criteria there was not an even distribution of participants across the stages of HIV. However when looking at the trend between the stages it was seen that irrespective of the stage of HIV, there were more DPOAE refer results obtained at high frequencies when compared to low frequencies, where all ears obtained pass results.

4.5 SUMMARY

The results of this study indicated that there were wide ranges of possible ear pathologies that were detected by hearing screening. Possible outer ear abnormalities were identified in 26% of ears. Possible middle ear pathologies were identified in 29% of ears and possible inner ear pathologies were identified in 1% of ears. However the DPOAE screening found that 11% of ears referred at 5kHz, whilst 31% of ears referred at 6kHz. This could be indicative of early cochlear damage.

CHAPTER 5

DISCUSSION

In this study, the researcher intended to address the issue of hearing loss in children living with HIV/AIDS. The question of whether a hearing screening profile is necessary for children diagnosed with HIV/AIDS currently on HAART, framed the inquiry for this study, and is discussed here in the context of empirical literature.

Hearing loss in children has detrimental effects, as children learn and develop communication through hearing (Diefendorf, 2002; Northern & Downs, 2002). Many factors, including middle ear infections, infections of the central nervous system or deficits of the neural system, affect hearing and contribute to hearing loss in this population (Northern & Downs, 2002; Shaw, 2012). Increased susceptibility to hearing loss occurs in children who are compromised, as that of children diagnosed and living with HIV/AIDS. This diagnostic group of children are more susceptible to ear infections, resulting in a conductive hearing loss, and if untreated, can progress to sensorineural hearing loss (Northern & Downs 2002; Shaw 2012; Matas, Iorio, Succi 2008). HIV/AIDS may also affect the central nervous system and auditory neural pathways (Shaw, 2012) which may ultimately result in a hearing loss.

There are currently no specific guidelines for hearing screening in persons living with HIV/AIDS. There is however speculation from authors such as Khoza-Shangase (2011) who suggest the possibility of use of HAART causing ototoxicity in adults. This was also confirmed by studies that detected early cochlear damage by

DPOAEs and high frequency hearing loss detected by pure tone audiometry (Harris et al., 2012; Ranjan & Bhat, 2008).

This study was thus positioned to address this concern for the paediatric population, by initiating a study that considered screening for children living with HIV/AIDS on HAART. The key findings of this study indicate that a significant number of participants presented with otitis media or with early signs of otitis media. Moreover there was an increase in refer results at high frequency DPOAE screening. As the frequency of DPOAE screening increased the rate of refer results also increased. These are discussed in detail below.

In hearing screening practices, it is essential that the screening protocol is sensitive, specific and reliable (Konrad-Martin, Gordon, Reavis, Wilmington, Helt & Fausti 2005). This study considered objective testing measurements such as tympanometry and DPOAEs to determine the presence of hearing pathology in the outer, inner and middle ears of children living with HIV/AIDS.

Outer ear pathologies in this study were described by the presence of impacted wax and redness or inflammation of the outer ear, by an otoscopic examination. Impacted wax can result in a conductive hearing loss. A conductive hearing loss caused by impacted wax can reduce speech intelligibility and thus impair the discrimination of speech, making it difficult for the child to comprehend all speech phonemes. Redness and inflammation of the external auditory canal may be indicative of otitis externa either with or without otitis media. Otitis externa can result in a child becoming irritable and unwell, thus making it difficult for the child to sleep and learn

or explore their environments in a younger child. This inevitably impacts on the child's daily activities and quality of life. A perforation of the tympanic membrane can be caused by trauma or otitis media. None of the participants in this study had any exposure to trauma, thus all perforations in this study were a result of otitis media. In this study, 6% of the ears tested had a perforation with discharge in the ear canal. This indicates pathology in both the outer and middle ear; which could result in a conductive hearing loss. However a hearing loss as a result of discharge and tympanic membrane perforation will be more significant than a conductive hearing loss caused by impacted wax and will have more severe consequences on the child. The child is likely to have more difficulty discriminating speech and will struggle in the classroom environment in the presence of background noise. In children living with HIV/AIDS, who have tympanic membrane perforations and discharge, it is often necessary to consider the use of bone conductor hearing aids to reduce the impact of hearing loss. Previous studies done in HIV-infected individuals (adults and children) highlighted similar findings, where discharge and perforations were found in a small percentage of participants (Chandrasekhar et al., 2000; Ndoleriire et al., 2013).

Middle ear pathology in this study was determined by Type B and C tympanograms. Type C tympanograms indicate the possible beginning or ending of an episode of otitis media or Eustachian tube dysfunction. Eustachian tube dysfunction is more common in children under six years of age, due to anatomical differences and may result in otitis media (Bluestone & Doyle, 1988). Otitis media is a common childhood disorder, with a high incidence of 80% of children under three years of age (Al-Mazrou et al., 2014; Takahashi, 2012). The presence of otitis media can result in

conductive or mixed hearing loss if left untreated for prolonged periods. Children living with HIV/AIDS are even more susceptible to otitis media (Karpakis et al., 2007; Shapiro & Novelli, 1998) which could be attributed to recurrent illnesses from a compromised immune system (Shapiro & Novelli, 1998). Previous studies have also revealed that children living with HIV/AIDS are more prone to otitis media, when compared to non-immunocompromised children (Weber et al., 2006). This study correlates with previous findings as a significant number of ears tested in this study, presented with otitis media.

The severity of hearing loss is dependent on the severity of the infection. Otitis media can affect either the outer or middle ear or both the outer and middle ear. If the outer and middle ears are both affected then the degree of hearing loss will be more severe. However if only one part of the ear is effected there will be less impact on hearing, resulting in a milder hearing loss.

Inner ear pathology in this study was measured using DPOAE screening, which is used to measure outer hair cell functioning of the cochlear. Damage in the outer hair cells of the cochlear will result in a sensorineural hearing loss, which is permanent and will require the use of hearing aids and possibly Frequency Modulated (FM) systems in the classroom environment. Even though DPOAEs measure the functioning of the outer hair cells in the cochlear, it can detect hearing loss even before it can be detected in conventional pure tone audiometry (Khoza-Shangase, 2011; Ranjan & Bhat, 2008). Thus DPOAEs are an effective (quick and objective) screening measure, particularly in infants and young children. DPOAEs have been used in previous studies and were absent even when pure tone audiometry revealed

normal hearing in a group of adults living with HIV/AIDS (Ranjan & Bhat, 2008). An interesting finding in this study is that all participants passed DPOAE screening in the low frequencies, however some referred at high frequencies. The highest frequency tested (6kHz) had the most refer results, followed by 5kHz. There have been studies that were conducted in adults living with HIV/AIDS, on ARVs, that showed similar findings where participants had a higher incidence of high frequency hearing loss (Harris et al., 2012; Khoza-Shangase, 2011). The previous study suggests that HAART may have ototoxic effects, due to the high frequency hearing loss that was prevalent in participants of that study (Khoza-Shangase, 2011).

It is imperative to note that this current study had screening DPOAEs and even though all referred DPOAEs were repeated for reliability, it cannot be used to conclude that there are signs of a high frequency hearing loss. Rather it is merely an indication that there is possibly a high frequency hearing loss that requires further audiological investigations in this diagnostic group. The early detection of possible hearing loss is crucial as it may indicate ototoxic effects in children on HAART. Future research should conduct diagnostic hearing tests in children living with HIV/AIDS on HAART, to determine if there is also a trend of ototoxicity in this population. The antiretroviral guidelines used when this study was conducted suggested that all children under five years of age should receive HAART once diagnosed with HIV, which has recently changed to include the use of HAART in all children under the age of 10 years old (World Health Organization, 2015). This thus makes it crucial to identify whether there are any ototoxic effects of HAART in children, as there will be more children placed on HAART irrespective of their CD4%. Due to the high number of children who will be on HAART, hearing screening should

be conducted to ensure the early identification of any possible hearing loss or recurrent otitis media which will result in prolonged hearing loss. Hearing screening will allow for quick testing in a large population, making it easy to identify the need for further hearing testing. There should be careful consideration when selecting the type of hearing tests that should be included in the screening protocol to ensure that there is some measure of detecting early cochlear damage, as this study as well as previous studies indicates early cochlear damage.

CHAPTER 6

CONCLUSION

6.1 INTRODUCTION

This chapter will discuss the conclusion, as well as the significance of this study. It will also consider the limitations of the study and a way forward for future research in the field.

6.2 GENERAL CONCLUSIONS

This was a prospective quantitative descriptive study to determine the prevalence of possible ear pathologies in children with HIV/AIDS on HAART. The study had a total of 77 participants, 154 ears, between the ages of 1 month to 4.5 years. The three different parts of the ear, namely: outer, middle and inner ear were all assessed individually. The possible outer ear abnormalities that were found in this study were: tympanic membrane perforations, discharge, redness and inflammation of the ear canal, bulging tympanic membrane, and occluding wax. The middle ear pathologies in this study were: Type B tympanograms and Type C tympanograms, which were indicative of otitis media or the starting or ending of an episode of otitis media. The inner ear was measured using DPOAE screening and the results were recorded for each frequency. DPOAE is not a complete assessment of the inner ear, but rather a measurement of the outer hair cell functioning within the cochlear. DPOAE results showed that none of the participants referred screening at low frequencies; however there were participants who referred high frequency (5kHz and 6kHz) DPOAE screening. This is a significant finding as it correlates with studies that were

conducted in adults. Referring DPOAE screening at high frequencies indicate early signs of cochlear damage and early signs of hearing loss, thus hearing screening is important in children living with HIV/AIDS and should form part of routine screening in this population.

6.3 SIGNIFICANCE

This study shows that audiological findings are similar in children and adults who are HIV infected and are on HAART. This study suggests that children have similar cochlear effects as their adult counterparts and indicates that it is important to conduct routine hearing screening and diagnostic hearing tests, as there may be hearing deficits which may result in language and cognitive delays, if not identified and managed early.

6.4 LIMITATIONS

This study included one audiometry screening session for each participant and did not include a follow-up session. This resulted in DPOAE screening being limited to participants who did not have outer or middle ear pathologies on the day of testing. This study did not include pure tone screening or a control group. A limitation could be that convenience sampling was used in this study. The participants in this study were all African in race, except one coloured participant, as that was the demographics of patients that attended the virology ward during data collection.

6.5 FUTURE RESEARCH

As the findings of this study suggest that there are possible ear pathologies that are present in the outer, middle and inner ear; it indicates the need for diagnostic audiology testing, including diagnostic DPOAEs, to be conducted in this population. A longitudinal research study that follows up with the children once they have been on treatment for three months, six months and twelve months could be useful in determining if there is any further evidence to suggest possible ototoxicity in children on HAART.

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ANNEXURE 1 Plagiarism Declaration





PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I **Kuraisha Trishel Naidoo** (Student number: 764 940) am a student

registered for the degree of Child Health-Neurodevelopment in the academic year 2016.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission

and/or without acknowledging the original source) is wrong.

- I confirm that the work submitted for assessment for the above degree is my own unaided

work except where I have explicitly indicated otherwise.

- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against

me if there is a belief that this is not my own unaided work or that I have failed to

acknowledge the source of the ideas or words in my writing.

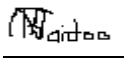
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Kuraisha Trishel Naidoo

ANNEXURE 2 Ethical Clearance

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. L. Mngomezulu
Office of the Director: Clinical Services
Tell: (011): 488-3365
Fax: (011): 488-3753
27th October 2014

Ms. KT Naidoo
Department of Speech Pathology and Audiology
University of the Witwatersrand

Dear Ms. Naidoo

RE: "A hearing profile of children who have HIV/AIDS, on highly active ARV medication that undergo hearing screening at the HIV/acquired immunodeficiency Virus Clinic should hearing screening form part of routine screening at Paediatric HIV/Acquired immunodeficiency Virus Clinics"

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic 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 sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

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

Supported / ~~not supported~~

Dr. M.I. Mofokeng
Director: Clinical Services
DATE: 27/10/2014

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 28/10/2014

ANNEXURE 3 Human Research Ethics Clearance Certificate

R14/49 Ms Kuraisha Trishel Naidoo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140884

NAME: (Principal Investigator)	Ms Kuraisha Trishel Naidoo
DEPARTMENT:	Faculty of Health Sciences Charlotte Maxeke Johanesburg Academic Hospital
PROJECT TITLE:	A Hearing Profile of Children who have HIV/Aquired Immunodeficiency Virus on Highly Active ARV Therapy Medication that undergo Hearing Screening at the HIV/Aquired Immunodeficiency Virus Clinic. Should hearing Screening Form Part of Routine Screening...
DATE CONSIDERED:	29/08/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dhanashree Pillay
APPROVED BY:	Professor Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	19/11/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

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

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly r**

Naidoo — 20 November 2014

Principal Investigator Signature — Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

ANNEXURE 4: Questionnaire

SECTION 1- BIOGRAPHICAL INFORMATION

Age:_____ Gender: Male/ Female Race:_____

D.O.B:_____ When was HAART started:_____

PLEASE COMPLETE THE FOLLOWING QUESTIONS IN AS MUCH DETAIL AS POSSIBLE.

SECTION 2- MEDICAL HISTORY

1. Does the child currently have any signs of ear infection, for example pain, discharge, tugging or banging the ears?

___ Yes
___ No
If yes:
Which ear?
_____

How often does this occur?
___ Daily

___ Every second day

___ Once a week

When last were there signs of ear infections?

2. Has the child had any surgery to the ear?

___ Yes
___ No

If yes:
What surgery was it?
___ Grommets

___ Mastoidectomy

___ Tympanoplasty

___ Unsure

When was the surgery?

__ In the last year?

__Two years ago?

__ Three years ago?

3. Has the child ever had meningitis

___ Yes

___ No

4. Has the child ever had tuberculosis (TB)

___ Yes

___ No

If yes, when and how long was treatment taken for?

_____

5. Has the child been diagnosed with any medical condition or syndrome?

___ Yes

___ No

If yes, specify

_____

THE FOLLOWING SECTIONS WILL BE COMPLETED BY THE RESEARCHER.

SECTION 3- SECTION 5 ARE CLINICAL FINDINGS

SECTION 3- VIROLOGY INFORMATION

Viral Load	CD4 Percentage	CD4 Count

SECTION 4- OTOSCOPIC EXAMINATION

Right Ear	Findings	Left Ear
	No abnormalities detected (NAD)	
	Tympanic membrane (TM) not visualized	
	Red	
	Bulging TM	
	TM Perforation	

	Minimal wax	
	Occluding Wax	
	Impacted Wax	

SECTION 5- TYMPANOMETRY

Right Ear			Findings	Left Ear		
Ear canal volume	Pressure	Compliance		Ear canal volume	Pressure	Compliance
			Type A			
			Type B			
			Type C			
			Type As			
			Type Ad			
			CNT- State why			

SECTION 6- DISTORTION PRODUCT OTOACOUSTIC EMISSIONS

Right Ear	Findings	Left Ear
	2 kHz	
	3 kHz	
	4 kHz	
	5 kHz	
	6 kHz	
	Overall Result (Pass/ Refer)	
	CNT- State why	

ANNEXURE 5 Information Sheet for the Parents

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Tel: (+27) 117172040

INFORMATION SHEET FOR THE PARENTS

Dear Sir/Madam

I, Kuraisha Trishel Naidoo am currently a masters' student at the University of Witwatersrand. I am conducting research on the ear pathologies in paediatrics on Highly Active Antiretroviral Therapy (HAART) medication. The aim of the study is to determine the prevalence of ear pathologies present in a group of paediatrics that are currently on HAART. The title of the study is "A profile of the hearing integrity of children who are HIV positive currently on HAART medication".

In order for your child to be part of this study they need to attend the virology clinic at CMJAH. The child will be required to be screened by the audiologist, which is routinely done at the virology clinic. During the hearing screening the audiologist will do tests to check for infection in the ears and test the hearing. The child does not need to respond to the tests and may be asleep.

There are no known risks to the study and you and your child will have the right to withdraw from the study at any time, with no consequences. During the data collection I will need to access your child's patient records, including their blood test results. The ethical codes followed in this study include informed consent, beneficence, justice, anonymity and confidentiality.

Should there be any queries please contact me or one of the research supervisor. I look forward to your favourable response.

Yours sincerely

_____

Miss K. T. Naidoo Telephone: 083 257 3998

(Researcher) E-mail: kuraisha1@gmail.com
Bachelor of Communication Pathology- Audiology (UKZN)

Ms. D. Pillay Telephone: 011 717 4564

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Bachelor of Communication Pathology- Audiology (UKZN)
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Faculty of Health Sciences
Private Bag 3 Wits, 2050
Tel: (+27) 117172040

INFORMED CONSENT FORM

If you are willing for your child to be a part of this study please complete the consent form below.

I_____(full name) parent/caregiver of _____(child's name) have read and understand the research information document. I fully understand what is expected from my child. I hereby give consent for my child to be a participant in this study.

☐ I agree for my child to participate in the study

☐ I agree for the findings to be used in research with my child's name with-held

☐ I acknowledge that I can withdraw from the study at any time, with no consequences and that if I choose to withdraw, the findings will not be used.

_____

Parents'/Caregivers' signature