AUDIOLOGICAL PRACTICES EMPLOYED BY AUDIOLOGISTS IN THE MANAGEMENT OF ADULT PATIENTS WITH MULTI-DRUG RESISTANT TUBERCULOSIS IN SOUTH AFRICA

BY

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DECLARATION

I, Melesha Govender, hereby declare that this dissertation, which is submitted to the University of KwaZulu-Natal for the degree of Master of Communication Pathology (Audiology), represents my own work in conception and execution and that all sources and quotes that have I used, has been acknowledged.

Signed _____ at Stanger on 16th day of March 2015.

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ABSTRACT

Aminoglycosides, such as amikacin and kanamycin, are part of the treatment for Multi-Drug Resistant Tuberculosis; however, it is ototoxic and the need for audiological monitoring is, therefore, emphasised. However, there are currently no explicit guidelines for monitoring ototoxicity in the South African context. Consequently, there is no standardised method for monitoring ototoxicity; however, audiologists are providing the service. Often adaptations to international protocols make them contextually relevant. Therefore, this study aims to describe the audiological practices employed by audiologists in the management of adult patients with MDR-TB in South Africa. A descriptive survey design was used. A questionnaire was developed and included the following aspects such as: identification and criteria used for patients with MDR-TB, baseline practices, monitoring procedures and post treatment management. Ninety-three audiologists contributed data for this study. Descriptive statistics and inferential statistics were used in the analysis of data. Results revealed that 80% of audiologists are aware of international guidelines, 93% reportedly provide pre-treatment counselling; while, 87% of audiologists conduct baseline assessments prior to the administration of MDR-TB treatment. Furthermore, 19% of audiologists conduct HFA and indicated that there is a lack of high frequency audiometers due is to financial constraints. The following were cited as reasons for the modification to the international guidelines: lack of specialised equipment, time constraints and large caseloads, as well as, understaffed departments. In addition, 74% of the audiologists are able to conduct periodic assessments monthly, while 72% of audiologists conduct a full audiological assessment after the cessation of MDR-TB treatment and 96% of audiologists conduct post treatment counselling. The findings of this study may, thus, inform policy by allowing for evidence-based ototoxicity monitoring protocols in South Africa.

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CHAPTER 1

INTRODUCTION

1.1. Introduction

This chapter addresses the aspects related to the research problem and the rationale of the study. In addition, it also provides clarity on specific terminologies used in the study. Furthermore, an outline of the chapters is presented.

1.2. Study Problem

According to World Health Organisation (WHO) (2012), Tuberculosis (TB) is one of the leading infectious diseases in the world. More specifically, South Africa is one of the five countries that have the largest number of incident cases (410 00 – 520 000), mainly due to the emergence of multi-drug resistant tuberculosis (MDR-TB), which has left a strain within the health care system (WHO, 2014).

MDR-TB is defined as a resistance to isoniazid and rifampicin, which requires long-term treatment of injectable aminoglycosides (WHO, 2008), as these aminoglycosides have resilience against gram-negative infections (WHO, 2008). However, it is well known that aminoglycosides are ototoxic in nature (Jones, 2008). Therefore, audiologists need to be alerted or informed of patients who are undergoing ototoxic treatment, as they may be at risk of developing an aminoglycoside-induced hearing loss. Thus, with the high prevalence of MDR-TB in South Africa many audiologists would have to conduct ototoxicity monitoring, as these patients are susceptible to hearing impairment and would benefit from identifying hearing loss early. The sense of hearing is regarded to be one of the most important of all senses, as hearing has the ability to provide empowerment and enrichment to a patient's life (Oticon, 2000). This allows the patients to socialise, work and communicate in a relaxed

manner (Oticon, 2000). It also has the ability to keep one safe by alerting us of potential dangers that may occur (Oticon, 2000). A hearing loss may lead to an individual feeling isolated from everyday activities (Valente, Hosford-Dunn, & Roeser, 2011). Thus, the audiologist plays a key role in helping patients habituate to the auditory changes they experience. Therefore, audiologists are vital in the management of a patient undergoing multi-drug resistant TB treatment.

1.3. Rationale for the Study

Developing countries, such as South Africa, have financial constraints on their healthcare system due to the competing budgetary demands from life-threatening and/or communicable diseases (Harris et al., 2012). In addition to these constraints, there are minimal audiological services available. However, the occurrence of hearing loss, due to MDR-TB, is on the rise (WHO, 2008).

Although there are international guidelines available, there are no explicit contextually relevant guidelines for South African audiologists to utilise and it is important for audiologists to know that they are ethically obligated to follow evidence based best practice guidelines. It is the responsibility of the audiologist to provide a service that is within their scope of practice or make other arrangements to make access to the service possible (Department of Health [DOH], 2001). Furthermore, the need to develop and validate ototoxicity screening and monitoring tools for developing world countries should not be left ignored, but rather acknowledged (Harris et al., 2012).

There is also a need for further investigation on the management of hearing loss in a patient with MDR-TB, as there are no specific guidelines for managing ototoxicity. Based on

anecdotal experience, there is currently no method being utilised to protect the deterioration of a patient's hearing status against the effects of ototoxic medication in South Africa. Thus, the need for appropriate detection and management of ototoxicity is reliant on effective audiological monitoring. However, there are many unanswered questions about the tests and protocols used, and there is wide variation in results (National Health and Medical Research Council, 2002), as there are no specific protocols or guidelines for South African audiologists to utilise. However, there are audiologists who are practicing in a way that allows for maximising of resources in an effective manner to ensure a high quality of healthcare. Critical consideration needs to be taken when making adaptations to international protocols as these may not necessarily lead to the protocols being contextually relevant. Therefore, this study aims to describe these practices so that the information can be used to devise evidence-based ototoxicity monitoring protocols for patients with MDR-TB. Furthermore, the findings of this study may help motivate for a more in-depth Department of Health (DOH) and Health Professions Council of South Africa (HPCSA) ototoxicity monitoring policy, allowing for uniformity among audiologists in TB clinics in South Africa.

1.4. Terminology

Aminoglycosides: "Groups of antibiotics that are used to treat many gram-negative bacterial, staphylococcal, and mycobacterial infections" (Neely, 2008, p. 250).

High Frequency Audiometry: Encompasses air conduction threshold testing for the frequencies above 8000 Hz, ranging up to 16 or 20 kHz (American Academy of Audiology [AAA], 2009).

Multi-drug resistant tuberculosis: A resistance to isoniazid and rifampicin, which requires long-term treatment of injectable aminoglycosides (WHO, 2008).

Ototoxicity: A hearing loss or vestibular dysfunction that occurs from the use of ototoxic therapeutic drugs (Kramer, 2008).

Tuberculosis: An infectious disease of humans and animals caused by the tubercle bacillus and characterized by the formation of tubercles on the lungs and other tissues of the body, often developing long after the initial infection (American Heritage, 2008).

1.5. Outline of Chapters

Chapter 1 – Introduction

This chapter highlights the study problem, rationale for the study and provides a brief description of each subsequent chapter. Additionally, common terminologies used throughout the research study are defined.

Chapter 2 - Tuberculosis and Ototoxicity Monitoring Protocols

This chapter reviews the aspects related to the role of the audiologist in ototoxicity monitoring, with reference to the patient with MDR-TB. In addition, it focuses on the theoretical aspects of TB and MDR-TB and the guidelines for the management of the patient with MDR-TB which have been provided to South African audiologists to utilise. Furthermore, it provides insight and/or a comparison to the international guidelines available.

Chapter 3 – Methodology

This chapter provides information related to the aims and objectives of the study, the study design, sample size, sampling method, as well as, the ethical and legal considerations of the study and data collection procedure.

Chapter 4 – Results

This chapter presents the results of the study, which have been analysed using a quantitative method of analysis. The results are presented according to the objectives of the study.

Chapter 5 – Discussion

This chapter provides an explanation of the results obtained in the study with reference to relevant literature. In addition, it focuses on the audiological monitoring protocols currently employed by audiologists, as well as, the modifications made to international guidelines.

Chapter 6 – Conclusion, Limitations and Recommendations

This chapter provides a summary of the main findings of the study, limitations of the research study, as well as, the recommendations for future research.

1.6. Summary

This chapter provides a review of the study. According to the literature available, ototoxicity monitoring is regarded as an essential aspect related to the management of a patient with MDR-TB. South Africa has a high incidence rate of MDR-TB; thus, there is a great need for ototoxicity monitoring. However, there are currently no specific guidelines for South African audiologists to utilise which may hinder the process or has not made it possible to follow through with monitoring; although there are audiologists conducting ototoxicity monitoring in a ways that allows it to be contextually relevant. Therefore, this study attempts to describe the audiological practices employed by audiologists in the management of an adult patient with MDR-TB. The findings of this study may allow for evidence-based ototoxicity monitoring protocols for South Africa by informing policy.

CHAPTER 2

TUBERCULOSIS AND OTOTOXICITY MONITORING PROTOCOLS

2.1. Introduction

The ensuing chapter provides an overview of the scope of practice of the audiologist, as well as the role of the audiologist in ototoxicity monitoring, with reference to the patient with MDR-TB. In addition, the theoretical aspects of TB and MDR-TB will be discussed. Finally, the guidelines for the management of the patient with MDR-TB which have been provided to South African audiologists, will be critically examined.

2.2. Audiologist Scope of Practice

Audiology is a paramedical profession involved in all aspects of auditory impairment and their associated communication disorders (South African Association of Audiologists [SAAA], 2002). Audiologists are responsible for the identification, assessment, diagnosis and management of individuals with peripheral or central auditory impairments, balance system disorders, tinnitus and associated neural system disorders (SAAA, 2002). These professionals are trained to evaluate the range, nature and degree of hearing loss in adults and children, as well as plan, implement and participate in the management of the individual with hearing impairment. Management of a hearing impairment includes a referral for medical management or selection and fitting of suitable amplification or assistive listening devices, or a combination of these (SAAA, 2002).

According to Health Professions Council of South Africa (HPCSA) (2012) regulation, an audiological assessment should comprise of the following aspects i.e. case history, otoscopic examination, immittance (tympanometry and acoustic reflex thresholds), pure-tone

audiometry (air and bone conduction testing), speech audiometry (speech reception and speech discrimination testing), as well as special tests such as otoacoustic emissions (OAE), auditory brainstem response (ABR), and auditory steady state response (ASSR), when necessary. Audiologists also participate in the development and implementation of hearing conservation programs, through auditory training, counselling and fitting of protective devices such as ear plugs (SAAA, 2002). Furthermore, these health professionals are able to measure noise levels, recommend environmental modifications in order to reduce noise levels, as well as, partake in the management of the selection, purchase, installation, and evaluation of large-area amplification systems, when necessary (HPCSA, 2012).

In addition, audiologists are also involved in rehabilitation which consists of evaluating, selecting, verifying, fitting and dispensing of amplification and assistive listening devices (HPCSA, 2012). Also, within the scope of practice for an audiologist is the assessment of a patient with hearing loss for cochlear implants and, counselling of the patient and family/caregivers in the use of and adjustment to the assistive listening device and the related psycho-social aspects of hearing loss, or other auditory dysfunctions, as well as, processes to enhance communication competence (HPCSA, 2012). The audiologist is also involved in the consultation and provision of vestibular and balance rehabilitation therapy to persons with vestibular and balance impairments; assessment and non-medical management of tinnitus, as well as provide training for professionals of related and/or allied services when needed (HPCSA, 2012).

Although the HPCSA has provided South African audiologists with an in-depth scope of practice, little mention is made of the audiologist's role and responsibility in ototoxicity monitoring. However, the role of the audiologist in this aspect is of great value for both the

patient who is undergoing the ototoxic drug therapy as well as the consulting physician. South Africa's burden of disease is significantly higher compared to that of a developed country, which in turn suggests that there are a substantial number of individuals with poor health who may require treatment (Bradshaw et al., 2003). Treatment may be ototoxic or may have associated side effects that require monitoring; thus, audiologists need to be cognisant of their role in ototoxicity monitoring.

2.2.1. Role of the Audiologist in Ototoxicity Monitoring

One of the many responsibilities of an audiologist includes the planning and implementation of an auditory monitoring program for ototoxicity (Konrad-Martin, Wilmington, Gordon, Reavis, & Fausti, 2005). However, the continuation of the program requires a collaborative effort between the audiologist and the physicians involved; thus, a trans-disciplinary approach is needed (American Speech-Language-Hearing Association [ASHA], 1994). A trans-disciplinary approach may not only refer to the collaborative effort between all members of a rehabilitation team; it could also refer to the contribution of knowledge and skills, as well as, learning of all aspects that are required to provide the best possible services to a patient (Catlett & Halper, 1992). The process of identifying patients who are potentially at risk for ototoxicity should be initiated by the audiologist in consultation with the physicians (ASHA, 1994). The interaction between the audiologist and physician is valuable in respect to the changes that need to be made if ototoxicity is present (ASHA, 1994).

Audiological monitoring for ototoxicity is usually conducted for two purposes i.e. 1) to detect ototoxic changes that may affect the speech frequencies, which in turn affect communication and it also allows the physician to make changes to the medication that is

being used, and 2) to monitor the ototoxic changes in the patient when the treatment regimen cannot be changed or once treatment is completed (Campbell, 2004). Changes in the treatment regimen include a reduction in the dosage, the scheduled timing of the dosage, temporary discontinuation or a switch to a less ototoxic drug (Mattucci & Vasquez, 2003). If the physician has decided to change the treatment of the patient, it is imperative that the audiologist establishes a new baseline in order to properly monitor ototoxicity (Mattucci & Vasquez, 2003). Thus, the need for a policy or guidelines for monitoring ototoxicity is emphasised, as this will allow the audiologist to follow a specific monitoring protocol for purposes of standardisation and consistency. This will encourage all audiologists to use a standardised method of testing, making it easier to document the progression of ototoxicity; thus, allowing for a more efficient referral system to specialised services and to gain the epidemiological statistics needed to improve or gain further insight into ototoxicity. WHO (2012) stated that there is a lack of epidemiological statistics on ototoxicity and hearing impairment in both developed and developing countries. Due to the lack of epidemiological statistics, it becomes apparent that it would be difficult to define the incidence and prevalence within a country and effectively have an impact on the rate or proportion of steps that need to be taken during ototoxicity. However, before considering the impact of ototoxicity, one needs to understand what it is and what causes it.

2.3. Ototoxicity

Ototoxicity refers to a hearing loss or vestibular dysfunction that occurs from the use of ototoxic therapeutic drugs (Kramer, 2008). Ototoxic drugs are certain medications that have the potential to cause damage to the ear, either permanently or temporarily, which can result in hearing loss, tinnitus and/or balance disorders (Cone et al., 2011). The pathophysiology of ototoxicity implicates the destruction of the sensory hair cells in the

cochlea and vestibular labyrinths (Rotstein & Mandell, 2004). The hearing loss occurs as a result of the degeneration of the hair cells within the cochlea, which typically begins at the basal end and progresses towards the apex; thus, resulting in a high frequency hearing loss at the onset (Altena & Jager, 2002). There has, however, been discrepancy between the clinical observation of patients receiving aminoglycoside treatment complaints of developing a hearing loss and the reported incidence of hearing loss (up to 41%) (Altena & Jager, 2002). This discrepancy is most likely due to the patient not complaining of hearing loss until considerable auditory deficits occur; thus, emphasising the need for ototoxicity monitoring, as well as counselling on aspects related to ototoxicity (Altena & Jager, 2002). However, ototoxicity monitoring can only be possible if audiologists are aware of the conditions for which ototoxic medication is administered. The conditions, together with the type of medication as well as the names of the medication are indicated in Table 2.1., below.

Table 2.1

Common substances known to be associated with ototoxicity

Type/Group	**Name of Ototoxic Substances**	**Conditions**
Aminoglycoside antibiotics	Gentamicin	Chest infections, urinary tract infections or septicaemia
	Streptomycin and dihydrostreptomycin	Tuberculosis, mycobacterial infections, multi-drug resistant organisms,
	Tobramycin	Bacterial infections of the eye or eyelid
	Neomycin	Hepatic encephalopathy and hypercholesterolemia.
	Netilimicin	Enterobacterial and pseudomonas infection
	Kanamycin	Infections of the lungs, urinary tract, bones and joints, soft tissue, intra-abdominal infections, meningitis, MDR-TB and septicaemia
	Amikacin	MDR-TB, pseudomonas aeruginosa, acinetobacter, enterobacter, serratia marcescens and providencia stuartii
	Ribostamycin	Neisseria gonorrhoea, escherichia coli and streptococcus

Non-aminoglycoside antibiotics	Vancomycin,	Skin infections, bloodstream infections, endocarditis, bone and joint infections, meningitis caused by methicillin-resistant staphylococcus aureus
	Erythromycin	Bronchitis, diphtheria, legionnaires' disease, pertussis (whooping cough), pneumonia; rheumatic fever, venereal disease, and ear, intestine, lung, urinary tract, and skin infections
Loop diuretics	Furosemide and torsemide	Congestive heart failure and edema.
	Ethacrynic acid	High blood pressure and the swelling caused by diseases like congestive heart failure, liver failure, and kidney failure.
	Bumetanide	Heart failure
Chemotherapeutic agents	Cisplatin	Various types of cancers, including sarcomas, some carcinomas (e.g. small cell lung cancer, and ovarian cancer), lymphomas, and germ cell tumours
	Carboplatin	Cancer of ovarian carcinoma, lung, head and neck cancers as well as endometrial, oesophageal, bladder, breast and cervical; central nervous system or germ cell tumours; oestrogenic sarcoma, and as preparation for a stem cell or bone marrow transplant.
	Nitrogen mustard	Lymphoma
Salicylates	Aspirin	Anti-inflammatory used to lessen the chance of cardiac arrest or stroke
Anti-malarial drugs, environmental chemicals and other substances	Quinine, chloroquine lead, tin, mercury, carbon monoxide, arsenic, carbon disulfide, hexane, toluene and alcohol	Malaria and poisoning

Table 2.1. Adapted from “Ototoxicity” by Virtual Medical Centre (2008), para. 1

As indicated in Table 2.1., above, there are a large number of conditions which require ototoxic medication. One such condition is MDR-TB, for which aminoglycosides are administered.

2.3.1. Tuberculosis and Multi-Drug Resistant Tuberculosis

TB is an airborne disease caused by Bacillus Mycobacterium tuberculosis and is one of the leading infectious diseases in the world (WHO, 2012). "A relatively small portion of people infected with Mycobacterium tuberculosis will develop the TB disease; however, those individuals with Human Immunodeficiency Virus (HIV) have a higher probability of developing the TB disease" (WHO, 2012, p. 3). The TB disease typically affects the lungs; however, it may affect other sites, such as the larynx, the lymph nodes, the brain and the kidneys (WHO, 2012). There is known to be an increase in mortality rate if TB is left untreated (WHO, 2014). In addition, if TB is left untreated it may lead to the development of MDR-TB, which occurs when the treatment regimen of a TB patient is inadequate or incomplete, i.e. the patient could be defaulting on treatment regimens; thereby, allowing some of the stronger/resistant bacilli to survive and prosper (Castillo-Chavez & Feng, 1997). MDR-TB has, therefore, become an obstacle in many programmes and guidelines that have been developed for TB control (Duggal & Sarkar, 2007).

Furthermore, Duggal and Sarkar (2007) suggested that the issues surrounding the origin of drug resistance are related to the length of treatment, specifically tolerability and adherence. Thus, incomplete and inadequate treatment regimens i.e. patients who default on their TB treatment schedule, are the most important factors that lends itself to believe that MDR-TB is a man-made problem (Duggal & Sarkar, 2007). Therefore, there is a need for stringent treatment regimens that will assist in the prevention and controls measures being conducted worldwide. However, despite recent advancements in global control efforts, TB remains a major public-health burden in most developing countries, including South Africa (Aziz et al., 2006), mainly due to the emergence of MDR-TB.

2.3.2. Epidemiology of TB and MDR TB

South Africa, like many sub-Saharan countries, had an upsurge of TB cases over the past decade with the figures reported to have increased, despite improved efforts for the disease care and control (Khoza-Shangase, Mupawose, & Mlangeni, 2009). This is attributed to the alarming increase in co-infection rates with HIV and the result of low adherence to the treatment of TB in patients in South Africa (Bernard, 2011). After TB was declared a global health emergency by WHO in 1993, the mid-1990's was a period of improved efforts for the disease care, prevention and control (WHO, 2012). However, TB still continues to be a major global concern, as in 2012 an estimate of 8.6 million people had developed TB, with there being 1.3 million fatalities from the disease (WHO, 2013).

According to WHO (2012), South Africa was ranked one of the five countries with the largest number of TB cases reportedly at 0.4 million – 0.6 million (WHO, 2012). "The TB incidence rate at country level ranges substantially, with around 1000 or more cases per 100 000 people in South Africa" (WHO, 2013, p. 11). There has been a 42% increase in detected cases eligible for treatment compared to 2011, with the largest increases between 2011and 2012 noted in India, South Africa and Ukraine; with India and South Africa accounting for one-third of the global TB fatalities (WHO, 2013). Furthermore, the number of MDR-TB cases was on the increase with KwaZulu-Natal specifically being ranked as the province with the highest number of TB cases between the years 2004-2010 (Department of Health, 2011), as indicated in Table 2.2., on the next page.

Table 2.2.

Number of Patients with MDR-TB between 2004-2010

	2004	2005	2006	2007	2008	2009	2010	TOTAL
Eastern Cape	379	545	836	1092	1501	1858	1782	7993
Free State	116	151	198	179	381	253	267	1545
Gauteng	537	676	732	986	1028	1307	934	6200
KwaZulu-Natal	583	1024	2200	2208	1573	1773	2032	11393
Limpopo	59	40	77	91	185	204	126	782
Mpumalanga	162	134	139	506	657	446	312	2356
Northern Cape	168	155	188	199	290	631	353	1984
North West	130	203	225	397	363	520	158	1996
Western Cape	1085	1192	1179	1771	2220	2078	1422	10947
South Africa	3219	4120	5774	7429	8198	9070	7385	45196

Table 2.2. Sourced from "Multi-Drug Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutional Management for South Africa" by Department of Health (2011), p. 4.

The need for the development and implementation of policies in countries, such as South Africa, would assist in the reduction of the number of MDR-TB cases and prevent patients from defaulting on their treatment regimens (WHO, 2011). A high success rate of one such policy is the DOT policy (Direct Observed Treatment), as this allows for a high degree of patient compliance with treatment (Duggal & Sarkar, 2007). In 2013, less than 25% of MDR-TB cases were detected compared to the number of cases detected in 2012 (WHO, 2013). This should indicate that the understanding of the concept of MDR-TB and increased awareness has helped. This would then lead to improved knowledge and skills base, related to the aminoglycosides used in the treatment of MDR-TB, among professionals that are involved in the management of patients with MDR-TB.

2.3.3. MDR-TB and Aminoglycosides

Aminoglycosides are used to treat many gram-negative bacterial, staphylococcal, and mycobacterial infections (Neely, 2008). Aminoglycosides are recommended, as they have a resilient action against various multi-drug resistant gram negative bacilli and are, therefore,

considered to be an important component in treating serious infections (WHO, 2008). The treatment that is vital in the management of MDR-TB are, “aminoglycosides (amikacin, kanamycin, capreomycin), fluoroquinolones (ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin, gatifloxacin), old bacteriostatic second line anti-tuberculosis agents (ethionamide, protionamide, cycloserine, para-amino salicylic acid, thiocetazone) and anti-tuberculosis agents with unclear efficacy (clofazimine, amoxicillin/clavuanate, clarithromycin, linezolid” (Duggal & Sarkar, 2007, p. 1473). The aminoglycosides (i.e. kanamycin, amikacin, capreomycin and streptomycin) are classified as a group 2 drug (meaning injectable drugs) by the World Health Organization (Seddon et al., 2012)

The first line drugs that are used to treat TB are isoniazid, rifampicin, ethambutol and pyrazinamide. However, due to MDR-TB being resistant towards isoniazid and rifampicin, chemotherapy of the condition cannot rely upon the use of these medications and, therefore, a combination of second-line drugs may be used as a treatment option. Thus, depending on the individual susceptibility of the patient with MDR-TB, first-line oral drugs must be appropriately combined with second-line injectable aminoglycosides (Duggal & Sarkar, 2007). A standardized treatment programme for all newly diagnosed patients with MDR-TB is recommended i.e. an intensive phase of six months, which includes injectable treatment consisting of five drugs; kanamycin or amikacin, levofloxacin, ethionamide, terizidone and pyrazinamide. These are taken at least six times per week during the injectable phase, followed by a continuation phase treatment with four drugs; levofloxacin, ethionamide, terizidone and pyrazinamide taken at least six times per week (DOH, 2010). Due to the use of a combination of the second-line drugs, the patient may be exposed to more side effects, as each drug presents with a different type of side effect (National Health and Medical Research

Council, 2008). In addition, the severity of cochleotoxicity and vestibulotoxicity varies among the different aminoglycosides (Jones, 2008), as indicated in subsequent discussions.

Amikacin is a semi synthetic aminoglycoside i.e. prepared by chemical synthesis from natural materials, which acts against mycobacterium tuberculosis as well as atypical mycobacteria. It has primarily been known for cochleotoxicity (Taylor & Forge, 2006). Kanamycin is an antibiotic synthesized by streptomyces kanamyceticus, which has shown activity against mycobacterium tuberculosis; however, large doses of this aminoglycoside are needed, and thus the risk of ototoxicity and nephrotoxicity is increased (Duggal & Sarkar, 2007).

The next aminoglycoside, Capreomycin is an anti-microbial cyclic peptide that is capable of destroying or inhibiting the growth of micro-organisms, which is synthesized by streptomyces capreolus and is effective both in vitro and in experimental tuberculosis (Duggal & Sarkar, 2007). It has proven its value in the therapy of resistant tuberculosis as well as with the treatment failure of tuberculosis when given with ethambutol or isoniazid; however, similar to amikacin and kanamycin, capreomycin is ototoxic but the cost of therapy is substantially higher (Duggal & Sarkar, 2007).

These second-line drugs, used in combinations, assist in the treatment of MDR-TB, which in turn has an added risk compared to that of first-line drugs. However, despite the risk, the use of aminoglycoside treatment has increased due to the rise in the incidence of MDR-TB (Harris et al., 2012). This, in turn, would result in an increase in the number of patients presenting with ototoxicity. In South Africa, a country where financial considerations play a major role in patient treatment and care, kanamycin or amikacin is more commonly

used in a clinical setting for treatment of MDR-TB, as it is considered to be the least expensive option (Taylor & Forge, 2006). There are financial constraints on health care systems in developing countries, such as South Africa due to the competing budgetary demands from life-threatening and/or communicable diseases (Harris et al., 2012). This shortfall has a great impact on services; the lack of funding greatly affects not only the coverage of services but also the quality of services that could be given to patients with MDR-TB. Due to these constraints, the use of kanamycin and amikacin will be higher, which could mean that the South African population could face an increase in the number of patients presenting with ototoxicity.

While a systematic review of international studies revealed that the incidence rates of aminoglycoside-induced hearing loss ranged between 20% to 33% (Brummett & Morrison, 1990). A study by Harris et al., (2012), revealed that 57% of their participants with MDR-TB presented with aminoglycoside-induced hearing loss. This highlights the need for an ototoxicity monitoring program in South Africa. However, in order for an audiologist to implement an effective ototoxicity monitoring program, s/he needs to fully understand the mechanism of the aminoglycoside induced toxicity.

2.3.4. Mechanism of Aminoglycoside-Induced Ototoxicity

It is suggested that about 25% of patients who are treated with aminoglycosides present with a toxicity (WHO, 2008). Aminoglycoside toxicities are known to affect mainly the kidney and ear, due to the drug concentration in the renal tubular cells and in the perilymph and endolymph of the inner ear (Roland & Rutka, 2004). Aminoglycosides are known for their toxicity to the eighth cranial nerve, i.e. both the vestibular and auditory branches; thus, resulting in ototoxicity (Altena & Jager, 2002). According to Roland and

Rutka (2004), the specific mechanisms of the hair cell toxicity is unclear; however, they are understood in the following steps:

Step One: positively charged aminoglycosides are attracted to the negatively charged hair glycocalyx present on the apical surface of the hair cells, the aminoglycoside then attaches to the stereocilia, which competes with the calcium. This leads to a reversible interference with transduction channels (Roland & Rutka, 2004).

Step Two: the entrance of the aminoglycoside into the cell is from the basal end and there is a biochemical machinery interference that occurs; however, the precise mechanism of this is hypothetical i.e. the attachment of the aminoglycoside to the phospholipids may or may not cause the membrane damage or interference with protein-producing cells (Roland & Rutka, 2004).

"Aminoglycosides gradually accumulate in the endolymph and perilymph of the inner ear and the half-life in these fluids is 5 to 6 times greater than that of plasma half-life" (WHO, 2008, p. 2). Back-diffusion is reliant on the concentration of the aminoglycoside in plasma; hence, ototoxicity is more likely to occur in patients with persistently elevated concentrations in plasma (WHO, 2008). However, even a single dose can cause ototoxicity. The vestibular and cochlear sensory cells are prone to degeneration by aminoglycosides and the changes are largely irreversible (WHO, 2008).

Injectable MDR-TB treatment has the ability to destroy the basal hair cells of the basilar membrane, which are required for high frequency hearing (Seddon et al., 2012). Thus, aminoglycoside–induced ototoxicity usually affects the high frequencies first, with later progression to the frequencies associated with speech communication (Seddon et al., 2012). According to Appana (2013), the high and ultra-high frequencies are most affected as treatment progressed; with the severity increasing from mild to profound. This suggests that

speech communication is greatly affected and that there is an increase to cochlea damage as treatment progressed. Damage to the hair cells is usually permanent. In addition, these drugs can also destroy the hair cells of the vestibule, resulting in vestibular deficits (Seddon et al., 2012). These vestibular deficits include oscillopsia during head movements and postural instability (AAA, 2009). However, these symptoms may be experienced at later stages in treatment or after the cessation of aminoglycoside treatment (Haybach, 2002).

According to Altena and Jager (2002), "ototoxicity does not appear until 5 days after the start of aminoglycoside treatment" (p. 262). However, not all reported cases of hearing loss may be due to ototoxic drugs; patients who are not receiving ototoxic drugs can have auditory changes that are considered to represent the established criteria for ototoxicity (Altena & Jager, 2002). Thus, the best way to manage ototoxicity is to identify it early and thereafter, take steps in order to prevent the progression of its effects, as appropriate changes can be made to the treatment regimen. This, therefore, emphasizes the need for audiological monitoring within the treatment regimen and consequently highlights the importance of the audiologist as part of the trans-disciplinary team managing the patient with MDR TB. An additional task of the audiologist would be the counselling of aspects such as the synergistic effects of ototoxic drugs and exposure to noise (Neely, 2008). Furthermore, the audiologist should be familiar with the risk factors associated with aminoglycoside-induced hearing loss, as it may assist with identification of at-risk patients as well as aspects of counselling that may need to be addressed.

2.3.5. Risk Factors Related to Ototoxicity

Jones (2008) reported that there is existence of specific patient risk factors for aminoglycoside ototoxicity which may be cochleotoxic or vestibulotoxic in nature,

irrespective of the ototoxicity mechanism. Gatell et al. (1987) indicated that the probability of developing ototoxicity ranged from 3% to 26%, as age increased from 14 to 90 years, whilst serum level, total aminoglycoside dose, duration of therapy, sex, peak temperature, presence of bacteria, shock, liver cirrhosis, renal failure, and development of renal toxicity did not add significantly to the prediction of auditory deficits. However, Moore, Smith, and Lietman (1984) reported that patients with auditory toxicity who had undergone aminoglycoside therapy for a longer duration were more likely to present with bacteremia and on average had a higher temperature; thus, indicating the possible sign and symptoms related to ototoxicity.

In addition, many studies have identified a number of genes associated with aminoglycoside-induced hearing loss (Seddon et al., 2012). Although these genes are uncommon, they occur in at least 1% of the South African population. These genes include A1555G, 961delT+C, T1095c, c1494T and A827G. The A1555G mutation was first described to be the most common variant. Patients who have the gene can develop a hearing loss, even in the absence of aminoglycoside treatment (Bardien et al., 2009). If this gene is detected the clinician may consider the use of other drugs or more frequent monitoring of the patient (Seddon et al., 2012).

In South Africa, there are genetic services that are available for various health purposes (Kromberg, Sizer, & Christianson, 2013). These services are usually offered at a tertiary level institution. The services include prenatal genetic diagnosis, diagnostic, predictive and carrier testing; and genetic counselling services (Kromberg et al., 2013). This does not relate to matters specific to aminoglycoside-induced hearing loss. However, although pharmacogenetic testing is not generally available, it is being introduced for the assessment of TB drugs (Kromberg et al., 2013). Presently, there are no genetic services

available in the rural areas, except for the outreach clinics that may refer to a secondary institution (Kromberg et al., 2013). Furthermore, when aminoglycosides are used in high doses, approximately 15% of all patients on the treatment who presented with hearing loss were found to carry the A1555G mutation (Nance, 2003). Conversely, Harris et al. (2012) reported that due to the rarity of mitochondrial mutations in the 12S rRNA (0.09% - 3.96%), genetic tendencies may be less likely to contribute to the risk of ototoxicity to be seen in developing countries. Audiologists, therefore, need to be cognizant of these factors, as it will allow the audiologist to identify the at-risk patients more effectively and timeously, which is considered to be one of the fundamental elements of ototoxicity monitoring, as indicated in ototoxicity monitoring guidelines by ASHA (1994).

2.4. Current International Guidelines for Ototoxicity Monitoring

ASHA (1994) developed a policy that outlined the guidelines used for the audiological management of individuals receiving cochleotoxic drug therapy. This policy clearly illustrated the role of the audiologist in the management of all ototoxic cases (ASHA, 1994). This policy highlighted the following elements:

- a specific criteria for identifying ototoxicity,
- timely identification of at-risk patients,
- pre-treatment counselling regarding potential ototoxic effects,
- baseline measures (pre-treatment or early in treatment),
- monitoring evaluations at sufficient intervals to document progression of hearing loss or fluctuation in sensitivity, and
- follow-up evaluations to determine post-treatment effects.

2.4.1. Specific Criteria for Identifying Ototoxicity

The purpose of baseline testing is to establish and document the level of hearing prior to MDR-TB treatment (ASHA, 1994). The baseline audiogram is also needed as ototoxicity is determined by comparing the baseline to a subsequent result (Konrad-Martin et al., 2005). The criteria use to indicate a deterioration in hearing during ototoxicity monitoring are defined as,

> "(a) 20 dB decrease at any one test frequency, (b) 10 dB decrease at any two adjacent test frequencies, or (c) loss of response at three consecutive test frequencies where responses were previously obtained (the third criterion refers specifically to the highest frequencies tested, where earlier responses are obtained close to the limits of audiometric output and later responses cannot be obtained at the limits of the audiometer)" (ASHA, 1994, p. 6).

In order for audiologists to provide accurate assessments and classifications of ototoxicity, clinical studies and reporting of clinical outcomes are essential, as ototoxicity grading scales need to be designed in a way that does not adversely affect the minor difference and or modifications in audiological protocols (Chang, 2011). Thus, it is crucial for an audiologist to understand the criterion that they would utilise, so as to make informed decisions on whether there has been a significant change in the patient's hearing sensitivity during the course of the MDR-TB treatment. If no criterion is followed or adhered to, audiologists would not be able to identify or make clinically appropriate decisions when there are changes to a patient's hearing status. Thus, it is important for audiologists to have explicit protocols to follow when conducting ototoxicity monitoring. Despite the lack of such protocols in South Africa, audiologists may still access international guidelines for the criteria used in the identification of ototoxicity.

2.4.2. Patient Identification

Patient identification is an essential aspect of managing ototoxicity and should be conducted as soon as possible (ASHA, 1994). However, hearing tests are usually conducted when the patient reports of communication difficulties, which would indicate that patients with MDR-TB would undergo a hearing assessment only once some degree of damage to the auditory system has occurred (Seddon et al., 2012). Patient identification can be efficiently conducted if the audiologist is aware of the associated risk factors such as the type, dosage and duration of the aminoglycoside used which, in turn, would indicate the need for ototoxicity monitoring. In South Africa, referrals to the audiology departments may be delayed due to the high HIV/AIDS co-infection rate as the focus may be placed on factors other than those related to hearing loss. Even though, hearing impairment may not be one of the major concerns, documentation or capturing of data on each patient would allow for better referral to the relevant health professional. According to Avent, Rogers, Cheng, & Paterson (2011), the monitoring of aminoglycosides is conducted via computerised methods in Australia; however, it was discovered that not all hospitals had access to computers and thus, means of providing access was reviewed. Therefore, the new policy implemented in Australia indicates that information related to monitoring should be captured only via computerised methods (Avent et al., 2011). Thus, databases which would allow medical professionals to access patients' medical history are important.

According to Nglazi et al. (2012), there are at least four data sources available in South Africa which collect information on the patients who have TB and/or HIV: (1) eKapa TB and ART database, currently being used in in the Western Cape clinics since 2009, which gathers information regarding demographics, clinical information, number of visits for TB/ HIV treatment and patient outcomes; (2) Paper-based TB registration/ the electronic version

(ETR.net), which is able to monitor TB treatment; (3) National Health Laboratory Services (NHLS) database; and (4) Patient records. These databases for both TB and/or HIV allow for a unique way of identifying patients in need of ototoxicity monitoring and should make the referral process to audiology departments in South Africa more efficient. These databases would be successful; especially if aspects related to ototoxicity monitoring would be documented. This would allow for access to patient information regarding their baseline and/or monitoring results easier to view, especially if baseline and follow-up evaluations are conducted at different institutions. However, access requires technological equipment that may not be readily available to some audiologists. In addition, the reliability of the results may be questioned due to the lack of a standard protocol for audiological monitoring in South Africa. However, any modifications made to recommended protocols could also be captured in the database for the audiologist to understand. This would then assist in providing efficient therapy for patients with MDR-TB, which usually begins with pre-treatment counselling.

2.4.3. Pre-treatment Counselling

Pre-treatment counselling should be conducted prior to administration of treatment. The physician needs to include information regarding the risks and benefits of the treatment and thereafter, the audiologist should counsel the patient of any cochlea or vestibular problem that may occur, as well as the possibility of communication difficulties (ASHA, 1994). The audiologist should also counsel the patient on the usual signs and symptoms of hearing loss, the need for communication strategies and the synergistic effect of noise exposure and ototoxic drugs (Konrad-Martin et al., 2005). All these aspects are addressed during pre-treatment counselling because the audiologist is ethically bound to provide information on the adverse effects and outcomes of treatment (AAA, 2009). However, this may not be established if the medical team viz., the physicians and nursing staff do not understand what

ototoxicity is or the importance of audiological services to a patient with MDR-TB, as has been demonstrated by Khoza-Shangase (2013). Therefore, it is imperative that the health professionals involved in the management of a patient with MDR-TB, be in-serviced about the ototoxic effects of aminoglycosides and ototoxicity monitoring in this patient population (AAA, 2009).

In South Africa, counselling may be challenging due to the language barrier between the patient and the audiologist, as patients need to ideally be counselled in their first language (van Dyk, 2008). There are currently eleven official languages in South Africa, including English, Afrikaans, Ndebele, Northern Sotho, Sotho, Swazi, Tswana, Tsonga, Venda, Xhosa and isiZulu; however, most audiologists in South Africa are trained at University in English or Afrikaans. They would, therefore, require the assistance of a translator, who would be able to rephrase the information to make it understandable for the patient (van Dyk, 2008). Nevertheless, the audiologist needs to be aware of the problems they would encounter by using a third person in the counselling process (van Dyk, 2008). Often, the translator may rephrase according to their own frame of reference, which may add prejudice or their own experiences to the information they impart to the patient. Therefore, accurately translated informational pamphlets or brochures should also be available so as to ensure that the correct information is imparted to the patient (van Dyk, 2008). However, the use of pamphlets, brochures or informational guides may also prove to be challenging, if they are not be suitable for the literacy levels of the patient. According to Statistics South Africa (2011), nationally there has been a significant reduction in the percentage of individuals who are functionally illiterate, from 33.6% in 1996 to 19.1% in 2011. However, there is still much concern on the literacy rates of the patients; thus, proving that some of the material used by audiologists may be impractical. In light of these challenges South African audiologists,

therefore, make provisions in order to overcome these challenges such as including the family or friends of the patient in the pre-treatment counselling and assessment or consider the use of visual aids. However, the use of family members and friends has been discouraged, due to the emotional ties that they have, as well as, their lack of knowledge pertaining to the information being imparted (Kale & Syed, 2010), indicating that although it may work in order to relay information, one needs to be aware of the consequences such as incorrect information and innuendo.

2.4.4. Baseline Assessment

Patients with MDR-TB, who are receiving aminoglycosides should have baseline assessments conducted prior to or within 72 hours of initial treatment (ASHA, 1994). The HPCSA guidelines indicate that patients with HIV/AIDS and TB need to have baseline assessments within 24 hours of initiation of ototoxic medication. In New Zealand, 30.4% of patients who receive ototoxic medication did not undergo baseline assessment prior to initiation of their treatment (Alchin, 2010). Therefore, it is evident that in some institutions, it may not always be possible to conduct the audiological evaluation within the 72 hour window; possibly due to lack of staff or time constraints within the audiology department (Busacco, 2009). However, this needs to be conducted in order to document the progression of the possible hearing impairment by utilising the baseline results to compare to periodic results obtained.

The baseline assessment includes an in-depth case history with a particular focus placed on the medical history of any auditory and vestibular difficulties, family history of ototoxic hearing loss, recent ototoxic medications taken and any recent exposure to noise or radiation (ASHA, 1994). Thereafter, the patient will undergo the following tests during

baseline assessment; otoscopic examination, immittance audiometry, pure-tone audiometry, speech audiometry, as well as, OAEs and/or ABR. Al-Malky, Dawson, Sirimanna, Bagkeris, and Suri (2014) indicated that the use of HFA and DPOAEs have shown an increased sensivitity for the early detection of an ototoxic drug-induced hearing loss. This test battery may be modified according to the attentiveness of the patient and are thus categorized accordingly into three groups i.e. responsive, limited response and unresponsive patients (ASHA, 1994).

Responsive patients are able to provide reliable behavioural responses; while limited-responsive patients can provide reliable behavioural responses only for short periods of time. This could be due to illness, physical conditions, or age-related factors. However, unresponsive patients cannot provide reliable behavioural responses and can only be evaluated with objective measures that do not rely on responsiveness or attentiveness (ASHA, 1994). Responsive patients undergo a full audiological evaluation, as they are able to provide a behavioural response (ASHA, 1994). However, this test battery needs to be modified for those patients with limited responsiveness in order to accommodate the needs of the patient, so as to obtain the most essential information. Thus, according to the ASHA (1994) guidelines, objective means of testing should be used to test those patients with limited responsiveness or unresponsive patient. These include OAE and ABR testing. OAE testing has been shown to be the most reliable means of detecting early cochlear outer hair cell damage (Mattucci & Vasquez, 2003). However, abnormal middle-ear function and baseline hearing loss of greater than 40 dB HL may preclude effective monitoring using OAEs (Mattucci & Vasquez, 2003). Therefore, ABR testing may be more appropriate for such cases (Mattucci & Vasquez, 2003). According to the HPCSA (2007), the use of OAEs

and ABR is a preferred method of audiological assessment for patients (adult or child) who are unable to respond during the behavioural method of testing.

In addition, while patients who are classified as responsive and limited-responsive may be able to respond during behavioural testing, the test battery needs to be conducted quickly and effectively, as these patients generally fatigue easily. When conducting pure tone audiometry that includes test frequencies from 9 kHz to 20 kHz, the duration of the evaluation can be lengthy, and may thus present as a challenge for patients who are ill, as it may affect the ability of the patient to respond reliably (ASHA, 1994). Thus, it is recommended that testing commence at the higher frequencies and thereafter, depending on patient reliability, move to the lower frequencies (ASHA, 1994). It is important to note that although it may be recommended that testing commence at higher frequencies, all test frequencies need to be evaluated in order to understand and document changes in the auditory system (AAA, 2009).

However, Fausti et al. (1992) indicated that there has been higher incidence of ototoxicity when utilizing high frequency audiometry (HFA) and it is, therefore, valuable in the early detection of ototoxicity. HFA encompasses air conduction threshold testing for the frequencies above 8000 Hz, ranging up to 16 or 20 kHz (AAA, 2009). It permits the detection of aminoglycoside-induced or cisplatin-induced ototoxic losses well in advance, even before changes are noticed in the conventional frequency range used in audiometric testing due to the effects of the drugs, which tend to affect the basal end of the cochlea first (AAA, 2009).

According to Konrad-Martin et al. (2005), HFA has good test-re-test reliability and low false positive rates, and is, thus, recommended to be an ideal test that may be used for

reliable and sensitive ototoxicity evaluation (ASHA, 1994). However, despite there being much controversy surrounding the use of HFA, it is now well established and widely used in many departments (AAA, 2009). Hesitance to use HFA arose from the concern for excessive inter-subject variability of the threshold measure, due to the problem of standing waves in the ear canal above the resonant frequency (AAA, 2009). This, however, has deteriorated over the years due to the advancements in instrumentation (AAA, 2009); therefore, suggesting that HFA is becoming a widely acceptable practice for audiological management of patients, as HFA would be able to provide vital information for ototoxicity. However, considering the constraints that many South African audiology departments face, such as the lack of appropriate equipment (Koekemoer & Ndjeka, 2013) and adequate staff, it is likely that HFA audiometry is not routinely conducted in ototoxicity monitoring.

However, there has been a distribution of 38 mobile monitoring systems across the country of the high frequency audiometer known as the KUDUwave (Koekemoer & Ndjeka, 2013). This portable system has been used to conduct audiological monitoring for patients undergoing ototoxic treatment and is able to detect high frequency hearing losses. This would allow for an increase in decentralised management of a patient with MDR-TB from the onset of treatment (Koekemoer & Ndjeka, 2013); consequently, resulting in improved service delivery and management of a patient with MDR-TB. Although, 38 mobile monitoring systems have been distributed, this does not sufficiently cover all areas in South Africa that are affected by MDR-TB as the incidence rate of this disease is extremely high. However, the results of these tests need to be captured accurately, as the KUDUwave can be used by other professionals that may not be audiologists (Koekemoer & Ndjeka, 2013).

Furthermore, there is a need to assess tinnitus and dizziness at the outset of treatment with aminoglycosides, as it would assist with monitoring the progression of these side effects (Konrad-Martin et al., 2005). However, no formal guidelines have been developed to provide a monitoring procedure for tinnitus. Hence, it is recommended that the patient be questioned about their tinnitus at each monitoring assessment, so as to have comparative information (AAA, 2009).

Similarly, there are no specific guidelines for the assessment of vestibulotoxicity (AAA, 2009), but assessments that may be used to assess vestibular function include electronystagmography testing (ENG), rotational testing, vestibular autorotation testing (VAT), vestibular evoked myogenic potentials (VEMPs) and computerized dynamic posturography (CDP) (AAA, 2009). There are also bedside assessments that can be used to identify bilateral peripheral vestibular system impairments. These include head-thrust and dynamic visual acuity tests. However, these informal tests are sensitive to impairments of high-frequency function and ototoxic medication begins to affect the high frequencies first, which indicates a possible concern for audiologists who attempt beside balance assessments; as these tests may not be helpful in the identification of bilateral peripheral impairments (AAA, 2009).

However, vestibular tests are not widely available in South Africa and are usually found in specialised facilities (Rogers & Petersen, 2011). In addition, the personnel required generally have to be specially trained, experienced and competent individuals in vestibular testing (Rogers & Petersen, 2011). Therefore, some facilities are not adequately equipped or designed for optimal testing and more common than not, there is rarely trained staff available to conduct testing. The constraints experienced by audiology departments in South Africa,

may delay audiological monitoring and essentially the overall management of the patient. Thus, there is a need for more audiological services to be available at hospitals and primary health care centres, so as to allow for easier access to audiological services by patients requiring assessment and management. This, therefore, highlights the need for standardised programs or improved referral systems to enable audiologists to provide the best services to patients with MDR-TB.

Standardising the assessment of hearing for patients on treatment for MDR-TB is very important, as it will improve clinical case management within the TB program (Seddon et al., 2012). Every guideline should include the schedule, duration and testing method to be applied, as well as, the documentation of the configuration of the hearing loss to ensure that an informed decision can be made regarding clinical management (Seddon et al., 2012). An informed decision can be made easily or more efficiently if a patient adheres to the appropriate treatment regimen designed for them, which then allows the audiologists to prepare and schedule timeframes in order to provide follow-up evaluations needed throughout the ototoxicity monitoring process.

2.4.5. Ototoxicity Monitoring

A stringent monitoring evaluation should be conducted every 2-3 days a week as this will allow for early detection of hearing loss (Fausti et al., 1992). However, this is not always feasible; thus, it was recommended that follow-up assessments be conducted prior to each course of treatment i.e. most likely to be monthly (AAA, 2009) or follow-up evaluations are performed 24 hours prior to each course of treatment so as to allow time for any temporary threshold shift to recover (Langer, am Zehnhoff-Dinnesen, Radtke, Meitert, & Zolk, 2013). According to Venter (2011), 31% of patients receiving ototoxic treatment, do not have

follow-up assessments conducted during or after treatment in New Zealand. Watson and Selvadurai (2011) reported that patients who are currently receiving aminoglycosides should be monitored weekly, especially if treatment is more than or equal to 21 days. Alternatively, they may be assessed before each successive dose of treatment is administered.

A monitoring test battery comprises of the same audiological tests used during baseline audiometry. This test battery is usually used for patients who are responsive during behavioural testing. Patients who have limited responsiveness or patients who are unresponsive undergo objective means of testing i.e. OAE's or ABR (ASHA, 1994). Thus, information obtained from the OAE or ABR can be used to determine if there is a need for changes to be made to the patient's treatment regimen. However, a study by Seddon et al. (2012) indicated that access to ABR and OAE were most likely to be in specialised institutions; highlighting the importance of health professionals to develop an effective referral system to these specialized audiology departments. The need for ototoxicity monitoring is important; however, there is a greater need for monitoring protocols to be sensitive and reliable for the early detection of ototoxicity in the least amount of time and also allow for routine monitoring to be conducted on more patients, especially in institutions that may not have specialized equipment (Vaughan et al., 2002).

According to the HPCSA (2014), audiology departments at specialised TB hospitals in South Africa should have the following equipment for diagnostic hearing assessment; otoscopic examination, immittance measures, pure tone audiometry (air & bone conduction, un-& masked), high-frequency pure-tone audiometry, visual reinforcement audiometry, speech audiometry (un- & masked) and OAEs. However, the HPCSA guideline states that for ototoxic threshold shift monitoring, only high frequency air conduction pure-tone audiometry

and collaboration with doctors administering treatment should be conducted for patients undergoing ototoxic treatment (HPCSA, 2014). Although, this guideline indicates a standard to which audiologists need to conform to, it shows that there is a difference, compared to that of international protocols, in assessment of a patient who is undergoing ototoxic treatment. However, similar to the HPCSA guidelines is the monitoring protocol of the sensitive range for ototoxicity (SRO). This monitoring protocol is individualized to each patient's hearing configuration where, the highest frequencies with a threshold less than or equal to 100dB SPL would be tested, followed by six lower adjacent frequencies. This is known as the sensitive range for ototoxicity (SRO) (AAA, 2009).

SRO improves clinical efficacy by decreasing the test time; however, if there are notable changes in hearing sensitivity, it is recommended that a full test battery be conducted (Fausti et al., 2003). According to Fausti et al. (2003), 90% of the initial ototoxic hearing changes were detected by the use of SRO. This would indicate that if there is a shorter protocol which is able to assist an audiologist in identifying early changes to hearing it would be of great benefit. Once the aminoglycoside treatment is complete, the audiologist will need to advise the patients that they need to return for post treatment evaluations, aural rehabilitation and post treatment counselling.

2.4.6. Long Term Follow-up

The outcomes of post treatment evaluations would allow the patient to communicate effectively and/or adapt to adverse situations that the patient may be involved in with regard to communication ability and to identify hearing loss that is of late onset. Anecdotal experience revealed that post treatment management is one of the least practiced aspects of an ototoxicity monitoring program, as most audiologists may not have the time due to large

caseloads. According to Naidoo (2006), both private (70%) and public (90%) sectors provide auditory training, private (6%) and public (21%) provide speech reading, private (14%) and public (85%) provide language therapy and private (13%) and public (10%) provide manual communication. Audiologists may only perform a hearing aid fitting, which is considered to be a minute aspect of post treatment management. This indicates that there is a need to establish specific aspects that need to be addressed when providing post treatment management.

Long-term audiological follow-up is important as it will enable the audiologist to determine if the hearing loss is stable or progressive in nature (ASHA, 1994). The audiologist needs to be aware that the use of aminoglycosides can also cause delayed hearing loss (Campbell, 2011). Therefore, follow-up testing should also be scheduled a few months after drug discontinuation (AAA, 2009). Follow-up evaluations should be conducted immediately, at 3 months, 6 months and 1 year after cessation of MDR-TB treatment (Konrad-Martin et al., 2005). However, according to the HPCSA guidelines in South Africa, audiological intervention may be required until 6 week to at least six months depending on the type of ototoxic medication (HPCSA, 2014). According to Konrad-Martin et al. (2005), if the audiologist observes threshold changes during post treatment evaluations further monitoring is warranted until the hearing threshold is stabilized. Due to the changes in hearing sensitivity, weekly monitoring assessments should commence until hearing stabilizes (ASHA, 1994). If hearing stabilizes at a level significantly worse than the baseline, a complete audiological test battery is recommended (ASHA, 1994). Therefore, it is essential for the audiologist to counsel the patient, as well as their family members, to keep them informed during each aspect of post treatment. This will allow the patient and their family

members to understand the outcomes of MDR-TB treatment; thus, enabling them to cope with the changes that may take place.

There are three phases in counselling a patient undergoing MDR-TB treatment i.e. the initial phase, the post treatment phases and six month precautionary phase (Konrad-Martin et al., 2005). The initial phase is used to educate the patient on the potential adverse effects that the ototoxic medication may have on their auditory system and to establish any family history of aminoglycoside use (Konrad-Martin et al., 2005). The post treatment phase addresses aspects relating to the changes in hearing sensitivity and all other aspects related to their individualized aural rehabilitation program that would be beneficial to the patient when communicating (Konrad-Martin et al., 2005). The six month precautionary phase emphasizes the importance of hearing protection during and following treatment for at least six months (Konrad-Martin et al., 2005). Those patients who exhibit permanent hearing loss and/or a vestibular problem need to be referred; once again placing, the importance on a well-functioning referral system.

However, the lack of knowledge of the symptoms may hamper identification and subsequently have a negative impact on the appropriate referral and management of hearing loss (de Andrade, Khoza-Shangase, & Hajat, 2009). This in turn, impacts on the services that an audiologist can provide to the patient (Khoza-Shangase et al., 2009). As in the case of South Africa, counselling may occur during each visit to the audiologist and especially during follow-up treatment. The counselling would centre on the synergistic effects of noise and ototoxic treatment and would also impart that the effects of the ototoxic medication can last up to 18-24 months (Harris & Heinze, 2013). In South Africa, follow-up assessments occur at 1 month, 3 months and 6 months after completion of treatment; thereafter, the main focus

is place on amplification or communication strategies that the patient could possibly utilise (Harris & Heinze, 2013).

2.4.7. Aural Rehabilitation

If an ototoxic hearing loss results in communication deficit, the audiologist is ethically bound to begin aural rehabilitation (i.e. hearing aid evaluation, hearing aid fitting, assistive listening devices, speech-reading, audition, etc.) (ASHA, 1994). The audiologist is responsible for implementing an aural rehabilitation plan that is specific to the needs of the patient (ASHA, 2011). In the audiological management of an adult, the focus is placed on re-teaching the patient skills that have been hindered due to the hearing loss, helping the patient live with the hearing loss, optimize the use of amplification available, explore the needs of assistive listening devices, and teaching the patient communication strategies to overcome communication deficits (ASHA, 2011). The effects of an acquired hearing loss can be minimized by optimal use of amplification and a personalized aural rehabilitation program (Pienaar, Stearn, & Swanepoel, 2010).

According to a survey by Pienaar et al. (2010) patients who were hearing impaired and fitted with hearing aids were satisfied by its benefits even if the hearing aid fittings were not optimal; thus, the findings of the study advocate for the initiation of sustainable aural rehabilitation services in developing countries such as South Africa. Furthermore, the study indicated that counselling remains to be an essential aspect of an aural rehabilitation program; thus, indicating the need for audiologists to develop and implement an aural rehabilitation program that is specific for the needs of a patient with MDR-TB (Pienaar et al., 2010).

Aural rehabilitation forms an integral part of the audiological management of patients with MDR-TB, as has been stipulated in the ASHA (1994) and AAA (2009) ototoxicity monitoring guidelines. AAA (2009) position statement and ASHA (1994) clinical practice guidelines for ototoxicity monitoring and the audiological management of individuals receiving ototoxic and/or vestibulotoxic drug therapy guidelines, assist audiologists in implementing appropriate ototoxicity monitoring regimes; however, these guidelines are not based in the South African context and thus, can only serve as a guide to South African audiologists. The only context-relevant guidelines available to the South African audiologist are the policy developed by the South African National Department of Health (DOH, Management of Drug-Resistant Tuberculosis: Policy Guidelines, 2010) and the guidelines developed by HPCSA (A guideline for planning STA services at all levels of health care, 2014).

2.5. Current Guidelines for South African Audiologists

The policy developed by the Department of Health (2010), is intended for use by healthcare professionals involved in the medical management of patients with MDR-TB (DOH, 2010). It focuses on clinical management, referral mechanisms and models of care, psychosocial support to ensure prevention and control, as well as, occupational health services that need to be available to patients with MDR-TB (DOH, 2010). This policy indicates the need for uninterrupted supply of appropriate medication and stipulated that medical treatment should be conducted under direct supervision with suitable education and counselling (DOH, 2010). The management of MDR-TB is a progressive approach, which needs to be revised through evidence-based information (DOH, 2010). Supervision of this treatment regime should be conducted by a medical team, usually consisting of the following: physician, professional nurse, pharmacist, social worker, psychologist, physiotherapist and

audiologist (DOH, 2010). Therefore, the policy gives audiologists an outline of the process involved in the management of a patient with MDR-TB, as indicated in the Figure 2.1, on the next page.

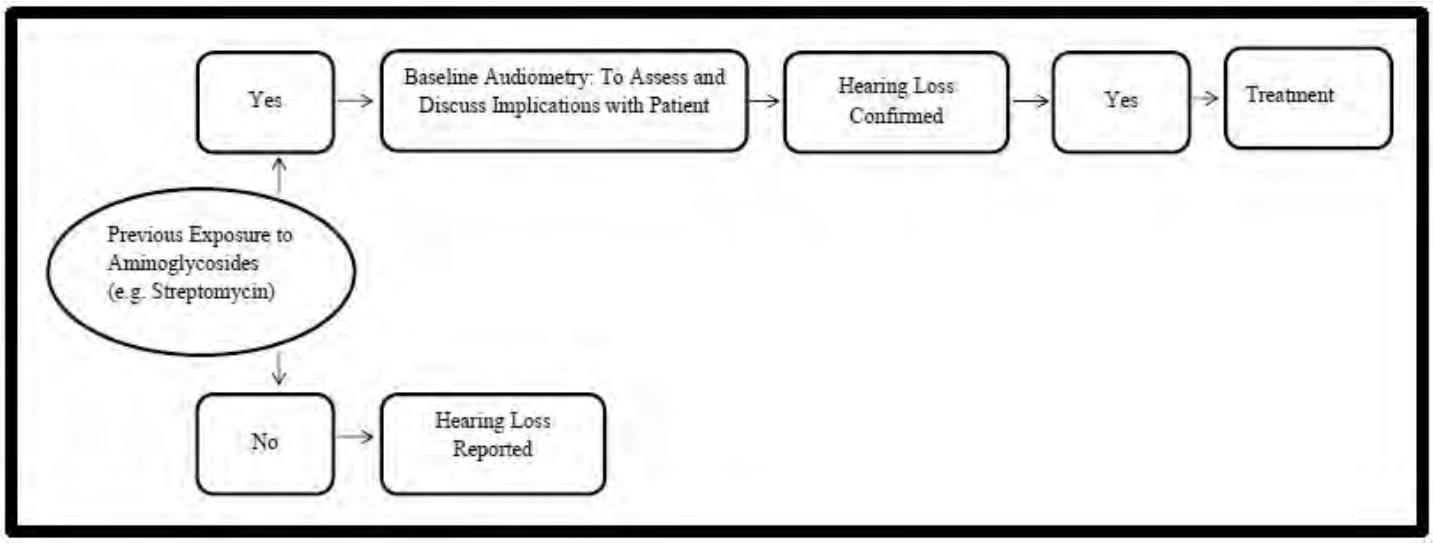

Figure 2.1. Flow diagram indicating the process of managing hearing loss in patients with MDR-TB. Sourced from "Management of Drug-Resistant Tuberculosis: Policy Guidelines" by Department of Health, 2010, *Department of Health*, p. 77.

The Department of Health policy indicates some aspects relevant to ototoxicity such as the need for baseline assessment; however, it does not reveal the test battery used for basic audiological testing or even ototoxicity monitoring. Thus, it would indicate that there is a need for the Department of Health to review and/or amend the audiological aspects of the current policy to ensure that audiologists across the country have standardised and more specific guidelines to follow in the audiological management of the patients with MDR TB.

The current HPCSA guideline was developed so as to facilitate rehabilitation service planning and implementation at all levels of health care. The guidelines contain aspects related to audiological management of a patient undergoing ototoxic treatment. This guideline is not specific to the assessment and/or management of the patient with MDR-TB. However, it does advise audiologists to be aware of the indicators related to ototoxicity, such

as, the percentage of baseline audiograms completed upon initiation of ototoxic medication (i.e. within 24 hours), percentage of patient with signs or symptoms related to ototoxicity, patients who received medical intervention within 24 hours and audiological intervention at least 6 weeks post cessation of ototoxic treatment. Furthermore, the guideline goes on to describe the different levels of care at the different institutions such as a CHC, etc. In addition, the guidelines do not mention pre-treatment counselling or the topics that need to be addressed during this crucial time in the management of a patient with MDR-TB. This guideline fails to provide audiologists with the specific test battery to utilise when conducting ototoxicity monitoring or how to assess patients who may be non-responsive. Moreover, the guideline does not mention aspects related to post treatment management with the exception of hearing aid fittings and only follow-up evaluations at specialised TB hospitals. While, this guideline serves a purpose of making speech therapists and audiologists aware of the services that are needed at the different levels of care, it is evident that specific guidelines for ototoxicity monitoring is needed, as Harris et al. (2012) indicated that the need for context relevant tools and guidelines should not be left ignored but rather acknowledged.

According to Naidoo (2006) many institutions, both public and private, may make modifications or not conduct all audiological assessments due to time constraints, lack of qualified staff or understaffed departments, lack of equipment, language barriers and the quantity of the caseloads. The researcher postulates that to overcome constraints experienced in audiology departments, changes are made to monitoring protocols such as, conducting monthly assessments instead of doing them biweekly, as well as only conducting air conduction testing or only testing the high frequencies. Hence, there is a need for the establishment of protocols for ototoxicity monitoring in South Africa that would allow the audiologist to achieve sensible and reliable results in a short period of time, which allows for

routine assessment to be conducted without having to implement any modification to the norm.

Seddon et al. (2012) reported that the proportion of patients with hearing loss seemed to be greater in programs where standardized hearing assessments have been conducted. This could indicate that clinically non-significant hearing loss is being detected when a standardised methodology is being used or that a larger number of patients with hearing losses are being missed when less robust assessments are being carried out. This suggests that the patients who undergo standardised methods of treatment benefit more with regard to hearing as it would be monitored from commencement of treatment and not when irreversible damage to the auditory system has occurred. There has been a notable lack of consensus amongst all current guidelines (Seddon et al., 2012). Although there are international guidelines available, there are no explicit contextually relevant guidelines for South African audiologists to utilise and it is important for audiologists to know that they are ethically obligated to follow evidence based best practice guidelines. This, therefore, serves as an impetus for the current study.

There is also a need for further investigation on the management of hearing loss in a patient with MDR-TB, as there are no specific guidelines or protocols for South African audiologists to use as a foundation in the audiological management of a patient with MDR-TB. Once an ototoxicity monitoring program is put into place, it will allow for early identification and appropriate changes to be made to the treatment regimes. Audiological management of hearing loss will be conducted at the early stages of deterioration and thus improve service delivery.

Furthermore, the findings of this study may help motivate for a more in-depth DOH and HPCSA ototoxicity monitoring policy, allowing for uniformity among audiologists in TB clinics in South Africa as the current policies are not explicit, in the assessment of a patient undergoing ototoxic treatment, such as, the audiological tests that are needed, the intervals in which to conduct assessment or the post treatment management of a patient. Furthermore, the availability of explicit guidelines specific for ototoxicity monitoring based in the South African context will assist in the interpretation of changes in hearing sensitivity will improve; thus, allowing for changes to treatment regimens to occur timeously and documentation of all stages of ototoxicity monitoring may assist in understanding the modifications being made in audiology department across South Africa and how it may improve service delivery.

2.5.1. Service Delivery and Its Impact on Audiological Services

Delivery of audiological services in South Africa has deteriorated, due to the many challenges faces by audiologists (Naidoo, 2006). These challenges include limited budget allocated to audiological services, poor understanding or awareness of the services provided by audiologists, by other healthcare professionals and general public (Naidoo, 2006). According to HPCSA, primary health care centres, community health care centres should be providing ototoxicity screening in South Africa. Furthermore, audiologists at district hospitals, regional hospitals, provincial/central hospital should be able to conduct baseline assessments and monitoring for ototoxicity (HPCSA, 2014); while, audiologists at specialized TB hospitals should be conducting baseline assessments and high frequency testing (HPCSA, 2014). However, delivery of audiological services is hindered by the lack of equipment, lack of training and lack of staff (Naidoo, 2006). According to Naidoo (2006), 59.14% in the public sector conduct ototoxicity monitoring, while in the private sector 54.79% conduct ototoxicity monitoring in South Africa. This suggests that approximately 40% of audiology

departments are not conducting ototoxicity monitoring which is alarming. Although, there are constraints that affect the audiological services for ototoxicity monitoring, audiologists have to overcome these barriers. According to Koekemoer and Ndjeka (2013), approximately 5000 patients per month, require ototoxicity monitoring in South Africa and on average that is around 12 tests per patient. Audiologists have used methods such as tele-audiology to provide services to patients who may not have access to audiological monitoring or have made modifications to the recommended guidelines in order to provide the best possible service to the patient. This indicates the need for standardized regimens that are context-relevant to audiologists.

In addition, WHO (2004) reported that healthcare systems need to be regularly assessed, in order to ensure that service delivery is of an acceptable standard. Therefore, the present study aims to describe the current practices employed by audiologists in the management of patients with MDR TB. According to Fagan and Jacobs (2009), there is a large disparity in the healthcare services between developing African nations and developed countries. However, South Africa is on its way to achieving a level of healthcare that is similar to those associated with developed countries, through the development and implementation of various white paper policies. In the meantime, there are audiologists who are practicing in a way that allows for maximizing of resources in an effective manner to ensure a high quality of healthcare. Ototoxicity monitoring protocols have been developed internationally and may, therefore, not be appropriate for the South African context. Often, adaptations to international protocols make them contextually relevant. This study, therefore, aims to document these practices so that the information can be used to devise contextually relevant evidence-based ototoxicity monitoring protocols for patients with MDR TB.

2.6. Summary

MDR-TB has become a global concern as it has impacted on the combat against TB (WHO, 2011). This chapter provided a description of TB and the development of MDR-TB. The literature review emphasized the need for guidelines and protocols, so as to provide a foundation to the audiologist, as this will improve services and efficiency of referrals between healthcare professionals. This chapter indicated the limitations of the South African health care system, compared to that of international standards with regard to the audiological management of a patient with MDR-TB. Furthermore, the policy guidelines of the DOH and HPCSA for management of patients with MDR-TB require more in-depth information so as to provide a standard method of conducting ototoxicity monitoring.

CHAPTER 3

METHODOLOGY

3.1. Introduction

This chapter provides a description of the methodology utilised in the study. It includes the aims and objectives of the study, the study design, a description of the study population, sampling technique used, data collection instruments and the procedure used to collect the data. Furthermore, a description of how the data was analysed, is highlighted. In addition, issues relating to the validity and reliability of the study, as well as the ethical and legal considerations are also discussed.

3.2. Aim and Objectives

3.2.1. Aim

To describe the audiological practices employed by audiologists in the management of adult patients with MDR-TB in South Africa.

3.2.2. Objectives

- To describe the specific criteria used for identifying ototoxicity, and the pre-treatment and baseline audiological practices employed by audiologists in South Africa.
- To describe the ototoxicity monitoring protocols, post treatment and audiological management practices employed by audiologists in South Africa.

3.3. Critical Assumptions

It was assumed that the audiologists in South Africa make modifications to the recommended AAA (2009) and/or ASHA (1994) guidelines for ototoxicity monitoring in the management of a patient with MDR-TB.

3.4. Study Design

A descriptive survey design was used in the study with quantitative methods of analysis. This study design was used, as it allowed the researcher to learn about the target population by asking relevant questions and analysing their responses using frequencies and basic statistics (Leedy & Ormrod, 2005). A survey design provides quantitative data on the trends, attitudes, or the opinions of a population by studying the sample population (Creswell, 2003). The researcher is then able to use the results of the sample to generalise or make claims about the population (Creswell, 2003).

A survey was used to attempt to provide descriptions of the audiological practices employed by audiologists in the management of adult patients with MDR-TB in South Africa. A descriptive quantitative research encompasses distinguishing the characteristics of an observed phenomenon or investigating possible correlations amongst two or more phenomena (Leedy & Ormrod, 2005). This design was appropriate for the current study because it provided answers to questions, which enabled the researcher to achieve the objectives of this study.

3.5. Study Population

The study population comprised of the 1632 audiologists in South Africa. Audiologists were selected, as the focus of this study was to describe the audiological

practices employed by audiologists in the management of adult patients with MDR-TB in South Africa. Audiologists from the private and public schools and hospitals, were targeted as the researcher could not assume that if an audiologist is currently working at a school, the audiologist does have not have any recent experience in working with patients with MDR-TB.

3.6. Sampling Technique

Purposive sampling was used in the study. Purposive sampling is a type of non-probability sampling in which the participants are observed and are selected, based on the researcher's interests about which ones will be the most useful and representative (Babbie, 2010). Purposive sampling can be very useful for situations where you need to reach a targeted sample quickly and where sampling for proportionality is not the main concern (Babbie, 2010). This type of sampling was used as it permitted the researcher to directly target the audiologists who have experience working with MDR-TB. However, like many non-probability methods, purposive sampling has the same limitations specifically i.e. the ability to generalize from the sample to the population (Johnson & Christensen, 2009).

3.7. Participant Selection

The following inclusion criteria were used for the selection of participants:

- Audiologists needed to have had a year or more of working experience, as it allowed them to be familiar with the protocols and guidelines used in their practice for audiological management of a patient with MDR-TB.
- Audiologists must have had experience in working with patients diagnosed with MDR-TB, as the research questionnaire requires a detailed account of the procedures and/or modifications that the audiologists are currently making when conducting ototoxicity

monitoring. It is, therefore, imperative that the audiologist have knowledge on this aspect as it will affect the results of the study by providing incorrect or limited information.

The following exclusion criterion was used for the selection of participants:

- Audiologists who did not have any experience in working with patients diagnosed with MDR-TB. The research study requires the audiologist to account for specific information regarding ototoxicity monitoring and MDR-TB; thus, indicating the need for the audiologist to have experience with working with this patient population.

3.8. Sample Size

Assuming that 50% of audiologists correctly follow current audiological practices, within a 7% margin of error at 80% power and probability of 95%, a sample size of 196 was required. To achieve this sample size and accommodate for a 10% non-response rate, the questionnaire was sent to all audiologists in South Africa (1632). In order to meet this target, it was assumed that 25% of the audiologists have had the experience of working with patients diagnosed with MDR-TB; thus, the questionnaire was sent to all audiologists and speech therapists and audiologists (T. Chetty, personal communication, December 4, 2013).

While 215 responded to the invitation to participate, only 205 completed the questionnaire. After applying the participant selection criteria, the study comprised of 93 participants. The reasons for the low response rates may include:

a) some participants, while having a dual qualification on the HPCSA register, only practice speech therapy,

b) some therapists who are registered with HPCSA may be practicing abroad and would not receive the invitation to participate, and

c) some audiologists may not have updated their contact details on the HPCSA database. Therefore, the exact number of audiologists practicing in South Africa could not be determined, and consequently the sample size calculation may have been affected.

3.9. Description of study participants

3.9.1. Age and Gender

Participants were aged between 22 to 41 years, with the mean age being 28 years. There were 10 males (11%) and 83 females (89%) who participated in the study.

3.9.2. Language Preference

Participants were given the option to complete the questionnaire in either English or Afrikaans. Eighty- eight participants (95%) completed the English questionnaire, whilst five participants (5%) completed the Afrikaans questionnaire.

3.9.3. Work Experience

Figure 3.1, below, indicates the work experience of the participants in the study.

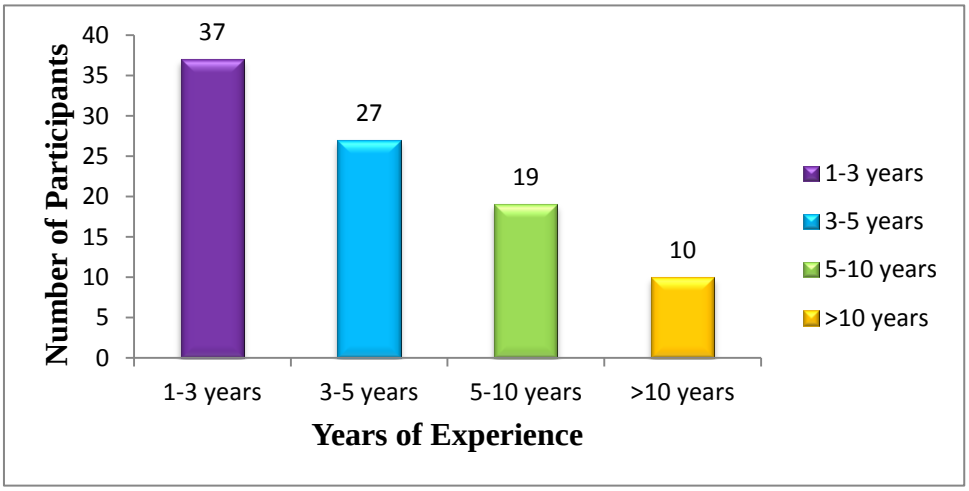

Figure 3.1. Work experience of the participants in the study

As indicated in figure 3.1., on the previous page, 37 participants (40%) had between 1 to 3 years of audiology working experience, while 27 participants (29%) had between 3 to 5 years, 19 participants (20%) had between 5 to 10 years and 10 participants (11%) had greater than 10 years of experience.

3.9.4. Types of Institution and Region of Work

Figure 3.2, below, depicts the types of institutions that participants currently work at.

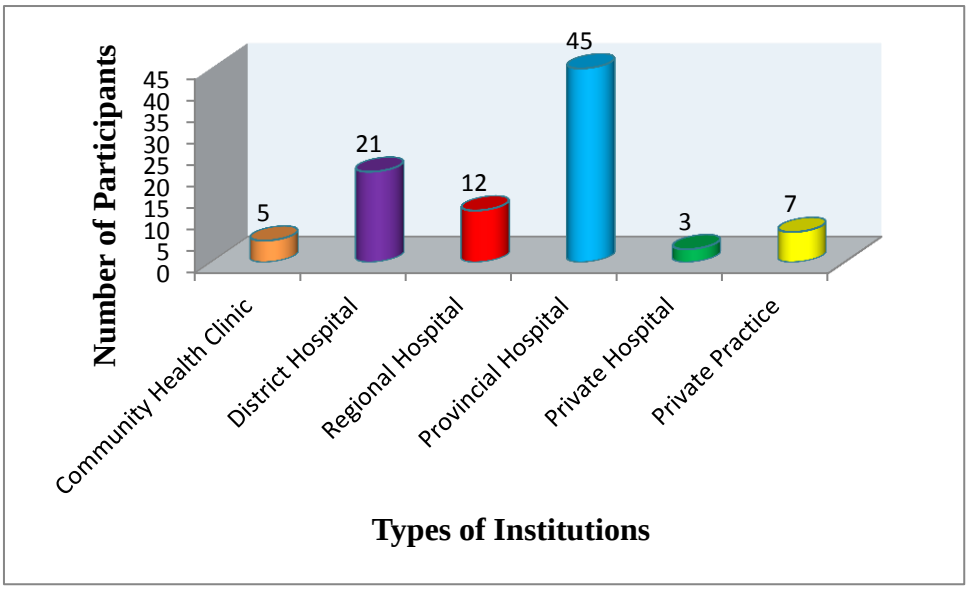

Figure 3.2. Types of institutions participants are currently employed at

As reflected in figure 3.2., above, five participants (5%) work at a community health clinic, 21 participants (23%) work at a district hospital, 12 participants (13%) work at a regional hospital and 45 participants (48%) work at a provincial hospital. In addition, three participants (3%) work at private hospitals and seven participants (8%) work in private practice. Figure 3.3., on the next page, indicates the number of participants in each province.

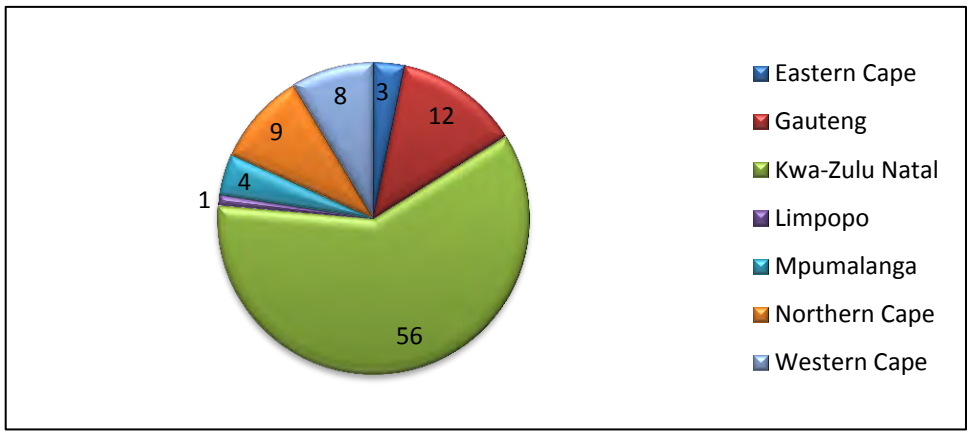

Figure 3.3. Number of participants working in each province

Fifty-six participants (60%) were employed in Kwa-Zulu Natal, 12 participants (13%) were employed in Gauteng, and eight participants (9%) were employed in Western Cape. In addition, nine participants (10%) were employed in the Northern Cape, one participant (1%) in Limpopo, four participants (4%) in Mpumalanga and three participants (3%) in Eastern Cape. No responses were collected from the North West and Free State province.

3.10. Data Collection

3.10.1. Data Collection Method

A survey method was used, as it involved acquiring information about the audiological practices employed by South African audiologists regarding ototoxicity monitoring for patients with MDR-TB. The questionnaires were accessed via survey monkey. This was a quick and effective means of reaching out to the study population. Electronic surveys have been developed as it provided the researcher with an easier way of collecting data; however, there are numerous reservations regarding issues such as the participants' willingness to fill out an electronic survey (Boyer, Olson, & Jackson, 2001). Even though there are uncertainties surrounding electronic survey, this method of distributing questionnaires is interactive and easier than completing it manually.

The advantages of using an electronic survey are as follows;

- Greater ability to present or record information,
- Electronic surveys provide the participants with a modern and interactive way of completing a survey (Boyer et al., 2001).

The disadvantages of an electronic survey are as follows;

- The lack of response as some participants may not be comfortable with completing a survey electronically,
- The traditional method of completing a survey allows the participant to browse through the survey quicker than an electronic survey,
- The response rate may be poor if the survey is detected as a computer virus or becomes spam in the participant's email (Boyer et al., 2001).

3.10.2. Data Collection Instrument

A questionnaire developed by the researcher, in consultation with the ASHA (1994) and AAA (2009) guidelines for ototoxicity monitoring, was used for the purpose of data collection (see Appendix A1 & A2). This was used to understand and/or acknowledge the audiological practices utilised by South African audiologists as compared to that of international audiologists. It helped the researcher identify the areas of ototoxicity monitoring that are being adhered to or modified by audiologists in South Africa. The questionnaire addressed aspects that included background information, baseline monitoring, periodic monitoring, post treatment as well as audiological management of the patients with MDR TB. Table 3.1, on the next page, indicates the motivation for each section of the questionnaire.

Table 3.1

Motivation for aspects in the questionnaires

Sections	Motivation
Section A: Biographical Details (13 Questions)	This section was used for administrative and statistical purposes. It allowed the researcher to establish whether an audiologist was conducting ototoxicity monitoring of patients with MDR-TB, which would aid in the inclusion criteria of this research study. This section allowed the researcher to gain insight into the types of tests that they were able to conduct, the type of equipment that they have access to and the number of institutions that conduct ototoxicity monitoring.
Section B: Ototoxicity Monitoring - Identification and Criteria Used for Patients with MDR-TB (6 Questions)	This section enabled the researcher to determine the process of early identification used by audiologists in South Africa. It helped the researcher identify if a good working relationship among staff was needed for effective ototoxicity monitoring and provided insight as to whether education and training was conducted among staff members. This section also served to inform the researcher whether there was an effective referral system used for patients with MDR-TB with regard to ototoxicity monitoring.
Section C: Ototoxicity Monitoring- Baseline Test (12 Questions)	This section was used to gain information as to whether early identification for ototoxic hearing loss was being conducted within the appropriate time frame, if audiological tests were being conducted and whether pre-treatment aspects are covered.
Section D: Ototoxicity Monitoring – Monitoring Procedures (17 Questions)	This section informed the researcher about the criteria being used for identifying specific changes in hearing. It provided an insight on the issues audiologists have with regard to monitoring schedules and the tests being used to monitor ototoxicity.
Section E: Ototoxicity Monitoring-Post-treatment Management (16 Questions)	This section helped the researcher determine the post-treatment protocols used by audiologists in South Africa and provided an insight to the scheduled interval evaluations for monitoring. It also focused on the audiological management of patients with hearing impairments, once MDR- TB treatment has ceased, with regards to amplification, assistive listening devices and aural rehabilitation.

3.10.3. Data Collection Procedure

Upon receiving ethical clearance from the University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (see Appendix B), a letter requesting the postal addresses of all audiologists was sent to HPCSA (see Appendix C). Once this information was received, the pilot study was conducted. The purpose of the pilot study was to avoid ambiguity, un-interpretable responses from participants and to assess the feasibility

of the proposed study (Leedy & Ormrod, 2005). The information document (see Appendix D1 & D2), consent form (see Appendix E1 & E2) and questionnaires were emailed to eight audiologists informing them of the study. The questionnaire was used in the pilot study and a comments form was used to record comments and suggestions (see Appendix F1 & F2). The participants, involved in the pilot study were not included in the main study. Audiologists within the Uthungulu District of Kwazulu-Natal who had previous experience working with patients with MDR-TB were selected to participate in the pilot study. Participants were between the ages of 22-35 years old and from the province of Kwa-Zulu Natal. Table 3.2., below, indicates the results of the pilot study.

Table 3.2.

Comments and Suggestions from Pilot Study

No.	Category/ Questions	Results
1	Approximately how many minutes did it take you to complete the research questionnaire?	Seven (88%) of the eight participants of the pilot study were able to complete the questionnaire within 20 minutes.
2	Did you have any difficulty understanding the instructions provided?	All (100%) participants of the pilot study indicated that questions were simple and precise; thus, allowing for clear understanding.
3	If yes, please provide me with which instruction/s and why?	N/A
4	Did you have difficulty answering any of the questions?	Seven (88%) of the eight participants indicated that there was no difficulty answering the questions.
5	If yes, please provide me with which questions and why?	One (12%) of the eight participants indicated that some questions should be open-ended as it differs from other institution such as, Questions 15.1., 16, 31 and 36.
6	Please provide any comments or suggestions that you may have for the research questionnaire.	Three (38%) of the eight participants suggested the following changes be made in order for the questionnaire to be cohesive: • Question 25: “what” was changed to “which” • Question 33: it was suggested that question 33.2 be presented before question 33.3 • Question 15.1, Question 16 and Question 31 become open-ended questions

Upon amendments of the questionnaire, following the review of the results of the pilot study, information documents (see Appendix D1 & D2) were posted to all audiologists on the HPCSA (1632) database. Once the audiologists agreed to participate (see Appendix E1& E2), they were able to complete the questionnaires. All questionnaires were self-administered. Participants were given 14 days to complete the questionnaire. If the questionnaire was not completed after 14 days, postal reminders were sent with instructions to complete and submit thee questionnaire within another 14 day period. After one month, only 33 participants had responded. Thus, due to the response rate being extremely low i.e. 33 of the 1632 audiologists (2%), the researcher had to make amendments to the recruitment procedure and obtain permission from University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (see Appendix G).

The amendment permitted the researcher to use audiology associations such as South African Association of Audiologists (SAAA) and South African Speech-Language-Hearing Association (SASLHA) to send out a broadcast email pertaining to the study and the web address to access the questionnaire. Once the broadcast email had been sent out to all audiologists on the SAAA and SASHLA databases, participants were given 14 days to complete the questionnaire online. Once the 14 day period had lapsed, reminder emails was sent once again and audiologists were given another 14 days to participate. This allowed for easier access to participants. Participants who had previously responded were urged not to complete the questionnaire again. During this time, 10 participants had contacted the researcher indicating the following reason for not participating in the research study:

1. Two respondents reported that they are currently registered as a speech therapist and audiologist according to the HPCSA database; however, they are only conducting speech therapy.

2. Four respondents indicated that they are currently not conducting ototoxicity monitoring.
3. Another four respondents indicated that they were from academic institutions.

A total of 205 participants completed the questionnaire. After applying the selection criteria only 93 participants remained. Furthermore, upon analysis of the responses, some participants failed to answer some of the questions; thus, participants' numbers may vary in some of the results presented in chapter four.

3.11. Data Analysis

The data from the questionnaires were captured on an excel spreadsheet and analysed using the STATA version 13 software. Descriptive methods of analysis were used to interpret the results. Descriptive statistics were used to describe the basic features of the study and also provided simple summaries of the sample and its measures (Donnelly & Trochim, 2006). Some of the "Yes or No" questions were tabulated or converted into graphs. This allowed for percentage counts e.g. for each province conducting MDR-TB monitoring.

Thereafter, inferential statistics was utilised in the analysis of data. This helped with understanding the current practices employed by audiologists in the management of a patient with MDR-TB (Donnelly & Trochim, 2006). The nominal variable must have only two values, such as "male" and "female" or "treated" and "untreated." (McDonald, 2009). The chi-square test is used to measure the association between two nominal variables (McDonald, 2009). The chi-square test was used to measure the association between years of experience, provinces and private practice and public institutions versus the use of international guidelines. Furthermore, open ended questions were analysed by thematic analysis. Data analysis, has taken into account that participant responses to some questions may vary due to some participants failing to answer all questions.

3.12. Reliability and Validity

"Reliability is the consistency with which a measuring instrument yields a certain result when the entity being measured hasn't changed" (Leedy & Ormrod, 2005, p. 29). "The validity of a measuring instrument is the extent to which the instrument measures what it is supposed to measure" (Leedy & Ormrod, 2005, p. 28). The questionnaire was formulated using the ASHA (1994) and AAA (2009) protocols for guidance of the different aspects that needed to be included. Extensive and thorough appraisals of associated research studies were conducted during the formulation of the questionnaire in order to ensure that relevant questions were included; thus, allowing for content validity. Content validity indicates how well the questionnaire represents the components being measured. Pre-checking was conducted by a qualified audiologist to ensure validity of the questionnaire (Leedy & Ormrod, 2005). In addition, the pilot study was conducted to determine if the questions were clear and concise; thus, ensuring that questionnaire measured what it intended to; thus allowing for construct validity. Construct validity aims to measure if the questionnaire measured what it is intended to measure (Brink, Van Der Walt, & Rensburg, 2006).

To further ensure the validity and reliability of the questionnaire, simple easy to interpret questions were used in the questionnaire (Leedy & Ormrod, 2005). The questionnaire was translated into Afrikaans by a qualified educator of Afrikaans (see Appendix H) and back translated by a first language Afrikaans speaking nurse (see Appendix I) into English., An advantage of using a questionnaire is that participants are able to remain anonymous, which results in authentic information. Participants were able to remain anonymous, as each questionnaire was individually coded with a participant number and not the participant's name. Additionally, a questionnaire allowed for a large number of participants to be targeted (Leedy & Ormrod, 2005). A disadvantage of this method is that a

poor return rate was frequently observed in questionnaires. Additionally, participants may misinterpret questions, hindering the results of the study (Leedy & Ormrod, 2005). In order to prevent this, a pilot study was conducted prior to data collection.

3.13. Ethical and Legal Considerations

- This study has taken into account ethical and legal considerations. This involved informed consent, rights to privacy, protection from harm, anonymity, and honesty between professionals (Leedy & Ormrod, 2005).
- The researcher had completed an online ethics course by the National Institutes of Health (NIH) on Protecting Human Research Participants (see Appendix J).
- Permission to conduct this research study was obtained from the University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (see Appendix B). The current study adhered to the ethical principles of the Declaration of Helsinki.
- Due to there being low response rate, the researcher had to make amendments to the recruitment procedure and obtained approval from the University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (see Appendix G).
- A letter requesting the postal addresses of all audiologists was sent to HPCSA (see Appendix C). HPCSA provided the information and the information document was sent to all audiologists, informing them of the study and the web address to access the survey.
- Information documents (see Appendix D1 & D2) contained information about the nature of the study, the requirements to complete the questionnaire, their rights as a participant to this study and access to the researcher, research supervisor and research office's contact details if they require further information. Participants received a signed copy of the information document. The following measures were taken into account for the purpose of the study. The researcher was obligated to discuss and explain the nature of the study to

the participants. Participants were informed and permitted to withdraw from the research study at any given time.

- Consent documents (see Appendix E1 & E2) were completed by all participants who were involved in the study. Each participant was able to print a signed copy of the consent form, should they wish. Anonymity and confidentiality of information was assured by allocating a number to each questionnaire; thus, no personal information was revealed. This ensured participant's right to privacy. There were no hidden agendas or misconceptions when obtaining information (Berg & Latin, 2004).
- All questionnaires, information and consent documents were available in English and Afrikaans, as these are the common mediums of instruction used in South African universities.
- Research questionnaires are locked in a cabinet and only accessed by the researcher involved in this study.

3.14. Summary

This chapter focused on aspects such as the aim, objectives and the data collection procedure of the study. A descriptive survey design was used in the study with quantitative methods of analysis. Taking into account all the ethical and legal considerations of research, an electronic survey method was used to distribute questionnaires to all audiologists in South Africa in order to realise the aims and objectives of this study. Once the participants completed the questionnaires, the raw data was captured onto an excel spreadsheet and statistical analysis was conducted with the assistance of a qualified statistician. The next chapter will provide the results of this study.

CHAPTER 4

RESULTS

4.1. Introduction

The results of the study, described in accordance to the objectives of the study, are presented in this chapter. To realize the aims of the study, statistical analysis of results was conducted. Data was analysed using the STATA version 13 software. Descriptive and inferential statistics were used in the analysis of the data. A p-value of less than 5% was considered statistically significant. During completion of the questionnaires, some participants chose to answer only those questions that they could answer or thought were relevant to them; and therefore, participant numbers may vary in the presentation of the results.

4.2. Specific Criteria/Protocol Used For Pre-Treatment and Baseline Measures

4.2.1. Access to Equipment

Of the 93 participants who had completed the questionnaire, 91 (98%) of the participants indicated that they conduct diagnostic hearing assessments, and 58 (62%) of the participants indicated that they have electrophysiological equipment at their institutions. The figure 4.1., on the next page, indicates the types of electrophysiological equipment participants have available in their departments.

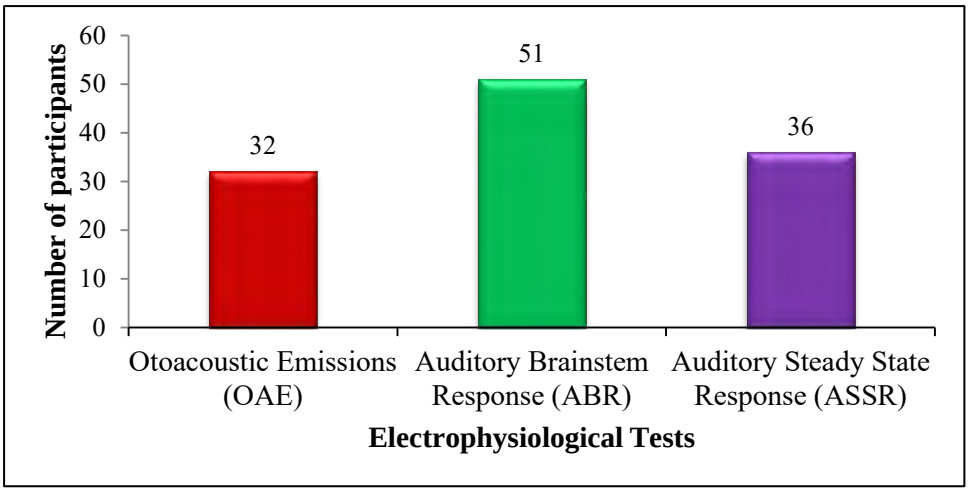

Figure 4.1. Types of electrophysiological tests available (n=58)

As indicated in Figure 4.1., above, 32 (55%) of the 58 participants have access to OAEs, 51 (88%) have access to ABR and 36 (62%) have access to ASSR.

4.2.2. Specific Criteria Used for Identifying Ototoxicity

4.2.2.1. Awareness of Current Protocols/Guidelines

Sixty-eight (73%) of the 93 participants indicated that they currently conduct ototoxicity monitoring at their institutions. In addition, there was no significant relationship (p=0.08) between the work experience of the audiologists and whether ototoxicity monitoring was being conducted. Furthermore, 74 (80%) of the 93 participants were aware of ototoxicity monitoring guidelines. In addition, those who were aware of ototoxicity monitoring protocols had been asked to choose which monitoring protocols they were aware of.

Figure 4.2., on the next page, reflects the ototoxicity monitoring guidelines that audiologists in South Africa are aware of.

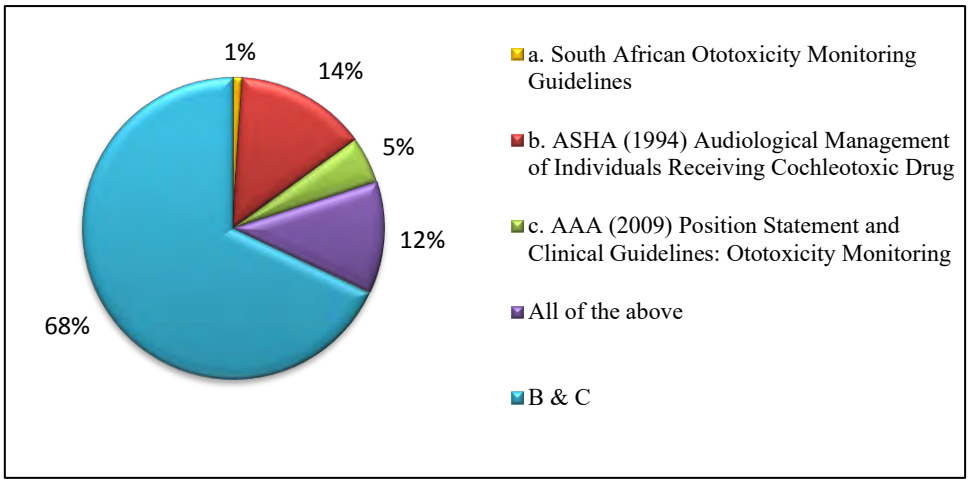

Figure 4.2. Awareness of the protocols/guidelines available (n=74)

Figure 4.2., above, indicates that 50 (68%) of the 74 participants are aware of the two recommended international guidelines used for ototoxicity monitoring. Ten (14%) participants identified the ASHA guidelines; whilst, four (5%) participants identified the AAA guidelines. Nine (12%) participants were aware of all guidelines and one (1%) participant was aware of a South African guideline. However, South Africa currently does not have specific guidelines on ototoxicity monitoring protocols.

4.2.2.2. Working Relationships and In-service Training among Staff

All 93 (100%) participants believe that the identification of a patient with MDR-TB at risk for ototoxicity depends on a good working relationship between the audiologist, physician and nurses, and that in-service training amongst the staff involved in the management of a patient with MDR-TB is beneficial. With regards to the aspects to be addressed during in-service training with staff, 74 (89%) of the 83 participants who answered this question, indicated that it should consist of, “what is ototoxicity, when does ototoxicity occur, what happens to the ear and its function, what are the ototoxic drugs involved in

MDR-TB, what are the associated auditory and vestibular problems, the need for counselling and aural rehabilitation".

Figure 4.3., below indicates the participants response on who should conduct the training.

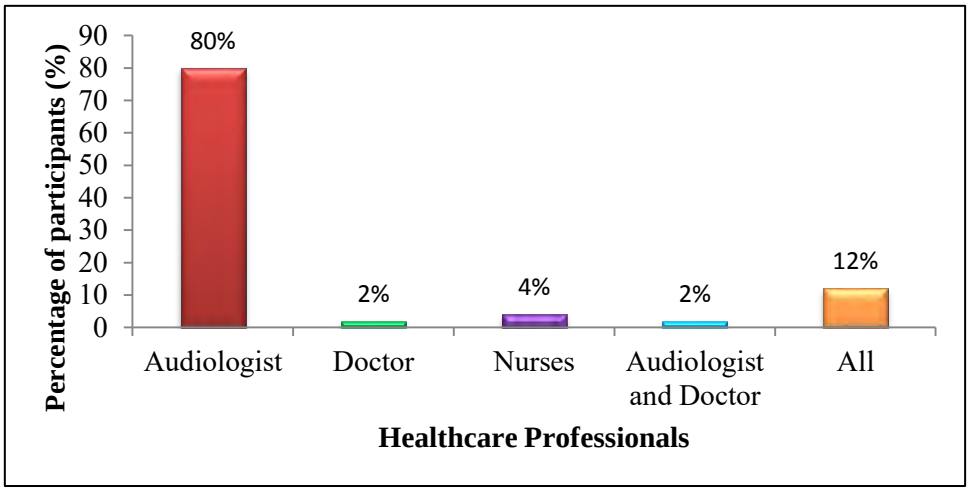

Figure 4.3. Responsibility of in-service training (n=83)

Of the 83 participants who answered this question, 66 (80%) participants indicated that the audiologist should conduct the in-service training, while two (2%) participants indicated that the doctor should conduct the training, three (4%) participants indicated that it should be the nurse's responsibility, two (2%) participants indicated that it should be both the doctor and audiologist, and 10 (12%) participants believed that all members i.e. audiologists, doctors and nurses should conduct the training.

4.2.2.3. Automatic Referrals for Ototoxicity Monitoring

Table 4.1., on the next page indicates the types of medications that may require an automatic referral for ototoxicity monitoring.

Table 4.1

Automatic referral based on the type of medication (n=83)

Medication	Frequency	Percentage
Dihydrostreptomycin, stilpain, asprin and gentamicin	1	1%
Tobramycin and kanamycin	6	7%
Dihydrostreptomycin, tobramycin, kanamycin, amikacin, and gentamicin.	76	92%

As reflected in Table 4.1., above, 76 (92%) of the 83 participants who responded to this question, believed that dihydrostreptomycin, tobramycin, kanamycin, amikacin, and gentamicin are the types of medication that would require an automatic referral for ototoxicity monitoring. Furthermore, 77 (93%) of the 83 participants indicated that if referrals are made automatically when patients are undergoing ototoxic drug treatment, there will be an improvement in the current referral system; however, six (7%) participants disagree.

4.2.3. Pre-treatment Measures

4.2.3.1. Pre-treatment Counselling

Seventy-five (93%) of the 81 participants who responded to this question, reported conducting pre-treatment counselling, whilst six (7%) participants do not conduct counselling prior to the administration of the MDR-TB treatment. The following reasons were provided for pre-treatment counselling not being conducted:

a) Patients were only referred to the audiology departments after the administration of the MDR-TB treatment.

b) Counselling is conducted by the medical personnel prior to treatment.

c) The audiologist is not involved in the management of the patient at this stage, as patients are only seen for diagnostic audiology once the treatment is completed. Baseline and monitoring evaluations are carried out at the TB facility.

d) Referrals are delayed, as patients are usually seen when they present with a hearing loss.

The 75 participants who had indicated that they do conduct pre-treatment counselling were then required to select the topics that needed to be addressed. Table 4.2., below, indicates the topics that were selected by participants as most appropriate to be covered during pre-treatment counselling.

Table 4.2

Topics covered during pre-treatment counselling (n=75)

Topics	Frequency	Percentage
Tinnitus, loss of balance, pharmacological effects, synergistic effect on ototoxicity and noise exposure, occlusion effect, hearing loss and potential effect on communication ability	45	60%
Tinnitus, loss of balance, synergistic effect on ototoxicity and noise exposure, occlusion effect, hearing loss and potential effect on communication ability	10	13%
Tinnitus, loss of balance, synergistic effect on ototoxicity and noise exposure, occlusion effect, hearing loss, potential effect on communication ability and effects of daily living.	20	27%

As reflected in table 4.2., above, 45 (60%) of the 75 participants who conducted pre-treatment counselling address topics such as tinnitus, loss of balance, pharmacological effects, synergistic effect on ototoxicity and noise exposure, occlusion effect, hearing loss and potential effect on communication ability, when conducting pre-treatment counselling.

4.2.4. Baseline Measures

4.2.4.1. Commencement of Baseline Assessment

Seventy-two (87%) of the 83 participants who responded to this question, conduct baseline assessments prior to the administration of the MDR-TB treatment, whilst 11 (13%) participants do not conduct baseline assessment. The participants indicated the following reasons for not conducting baseline assessments:

a) Patient is only referred once a complaint of hearing loss is received.

b) Shortage of staff

c) Lack of Occupational Health and Safety (OHS) infrastructure

d) One booth

e) No ventilation

f) Lack of space

g) Patient is referred from the TB hospital (out of town), which does not have an in-house audiologist; therefore, it is considered impractical to conduct a baseline assessment.

Figure 4.4., below, depicts the timeframe for conducting baseline assessment after administration of MDR-TB treatment.

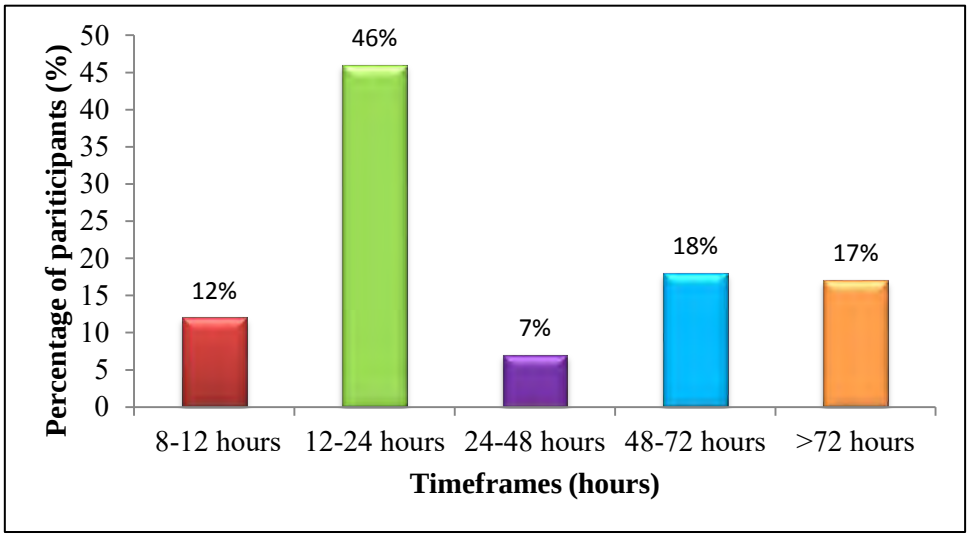

Figure 4.4. Timeframe for conducting baseline assessment (n=72)

Nine (12%) of 72 participants who responded to this question, conduct the baseline assessment within 12 hours of the administration of aminoglycoside treatment, while the majority of the participants i.e. 33 (46%) conduct the assessment within 24 hours, five (7%) participants within 48 hours, 13 (18%) participants within 72 hours, and 12 (17%) participants after 72 hours of the treatment.

4.2.4.2. Audiological Tests Used During Baseline Assessments

Table 4.3., below, represents the audiological tests that were used during the baseline assessment.

Table 4.3

Audiological tests used during the baseline assessment (n=81)

Tests	Frequency	Percentage
Otoscopic examination, immittance audiometry, air conduction testing, bone conduction testing, high frequency audiometry (HFA), speech reception testing (SRT), speech discrimination testing (SDT) and otoacoustic emissions (OAE) and auditory brainstem response (ABR)	65	80%
Otoscopic examination, immittance audiometry, air conduction testing, Eustachian tube function (ETF), speech reception testing (SRT), speech discrimination testing (SDT) and otoacoustic emissions (OAE)	10	12%
Otoscopic examination, immittance audiometry, air conduction testing, high frequency audiometry speech reception testing (SRT), otoacoustic emissions (OAE) and auditory brainstem response (ABR)	6	7%

As reflected in Table 4.3., above, 65 (80%) of the 81 participants who responded, chose the best possible option of otoscopic examination, immittance audiometry, air conduction testing, bone conduction testing, high frequency audiometry (HFA), speech reception testing (SRT), speech discrimination testing (SDT) and otoacoustic emissions (OAE) and auditory brainstem response (ABR).

4.2.4.3. High Frequency Audiometry and Re-test Confirmation

Of the 81 participants, 65 (80%) indicated that they do not conduct HFA, whilst 16 (20%) participants responded that they conduct HFA when conducting baseline assessment. Those participants who did conduct HFA were asked which frequencies above 8 kHz were tested. Figure 4.5., on the next page, indicates the frequencies tested by the participants.

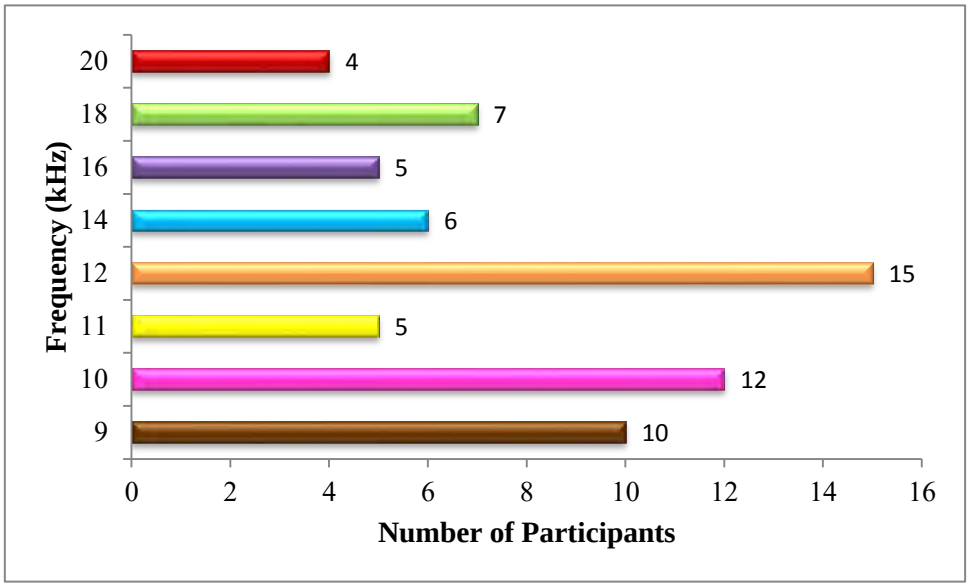

Figure 4.5. Frequencies above 8 kHz that are tested (n=16)

In figure 4.5., above, majority i.e. 15 (94%) of the 16 participants conducted pure-tone audiometry at 12 kHz. Twelve (75%) of the participants conducted pure-tone audiometry at 10 kHz. Furthermore, only 4 (25%) of the 16 participants tested at 20 kHz.

Those participants, who do not conduct HFA, had a general consensus in the reasons for not doing so. Figure 4.6., below, represents some of the reasons for not conducting HFA.

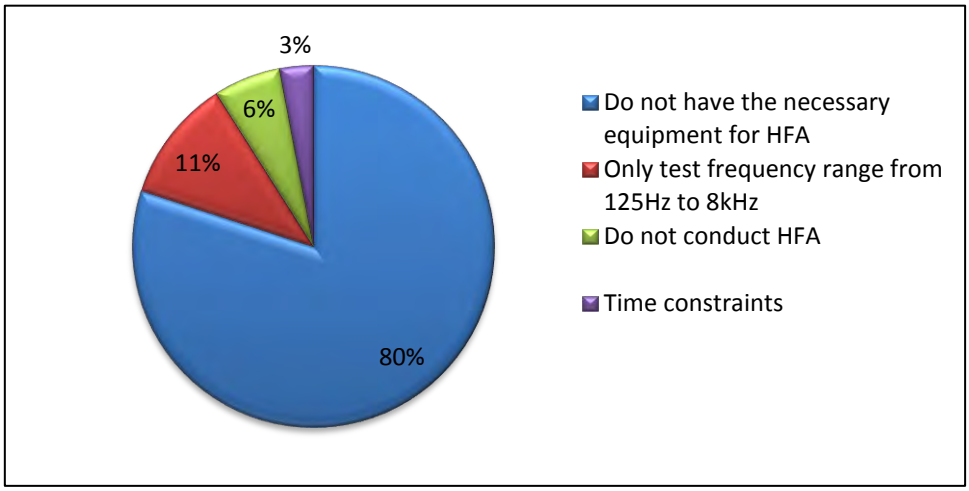

Figure 4.6. Reasons for not conducting high frequency audiometry (n=65)

From Figure 4.6., on the previous page, 52 (80%) of the 65 participants indicated that they do not have the necessary equipment needed for HFA, seven (11%) participants only test frequency range from 125Hz to 8kHz, four (6%) participants indicated that no HFA is being conducted, two (3%) participants reported that there is not enough time to conduct HFA.

Participants were asked if they perform a re-test to confirm results. Twenty (25%) of the 81 participants who responded, indicated that they do not conduct re-tests, while 61 (75%) participants perform re-tests to confirm results. Figure 4.7., below, represents some of the reason for not conducting re-tests.

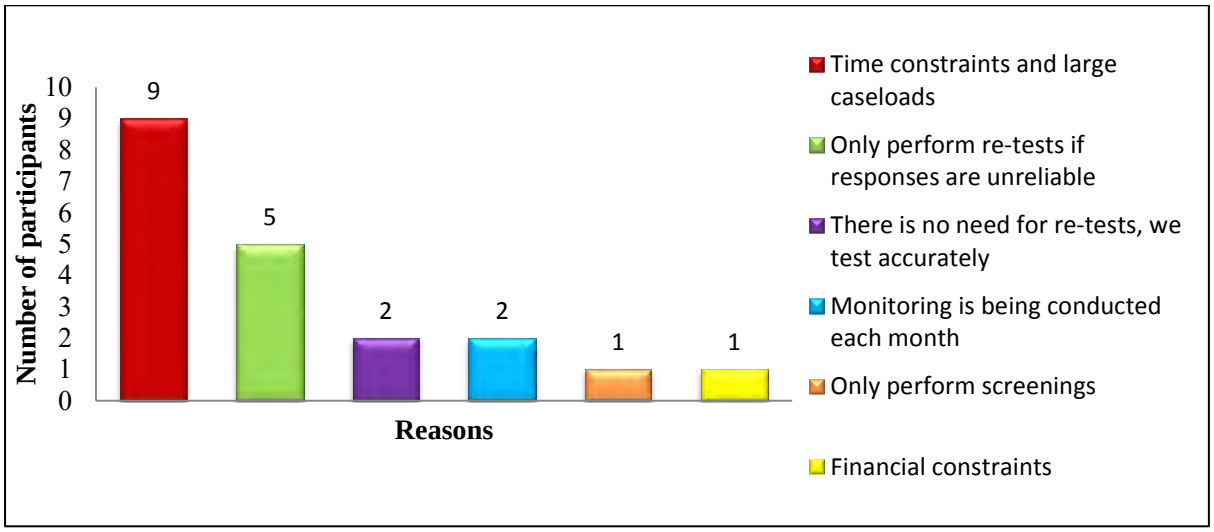

Figure 4.7. Reasons for not performing re-test to confirm results (n=20)

Nine (45%) of the 20 participants reported that there are time constraints and large caseloads, five (25%) participants indicated that they would only perform a re-test if the patient responses were unreliable, two (10%) participants reported that they do not conduct re-test as they test accurately, two (10%) participants reported that they conduct monitoring assessments, while one (5%) participant indicated that they only provide screening and one (5%) participant reported that there are financial constraints.

4.3. Ototoxicity Monitoring Procedures and Post Treatment Management

The results are presented in accordance to objective 2, which was to describe the ototoxicity monitoring protocols, post treatment and audiological management guidelines used by audiologists in South Africa.

4.3.1. Ototoxicity Monitoring Procedures

4.3.1.1. Use of Criterion to Define Ototoxic Hearing Loss

Sixty-eight (84%) of the 81 participants who responded to the question reported that they do follow a specific criterion, whilst 13 (16%) participants indicated that they do not. Furthermore, of the 13 participants who indicated that they do not use a specific criterion to define a hearing loss, seven (55%) participants reported that they were not aware of any criterion available; two (15%) participants indicated that there was no criterion available for South Africa, while another two (15%) participants indicated that it was not applicable to them and two (15%) other participants failed to answer the question.

4.3.1.2. Computation of Changes in Hearing Sensitivity

Figure 4.8., below, represents the criteria used to identify changes in hearing sensitivity.

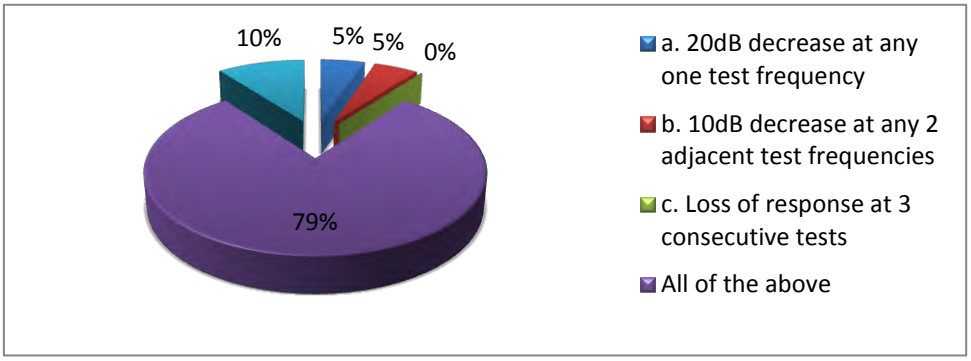

Figure 4.8. Criteria used to identify changes in hearing sensitivity (n=78)

Participants were also required to choose the correct statement that indicates changes in hearing sensitivity. Sixty-two (79%) of the 78 participants who responded to the question, correctly selected the criteria to use to identify an ototoxic hearing loss, eight (10%) participants follow A and B only, while four (5%) participants follow the 20dB decrease at any one test frequency and another four (5%) participants follow 10dB decrease at any 2 adjacent test frequencies rule.

Furthermore, 78 (99%) of the 79 participants who had responded to the question relating to computation of changes in hearing sensitivity, indicated that they use the baseline assessment results. One (1%) participant revealed that s/he does not use the baseline measures when computing changes in hearing sensitivity, as the baseline assessment has been conducted at a different institution.

When the participants were asked if they would conduct a full audiological assessment following a change in the patient's hearing sensitivity, 56 (72%) of the 78 participants who responded to the question, agreed that they would conduct a full audiological assessment, whilst, twenty-two (28%) of the 78 participants reported that they do not conduct a full assessment. Those participants, who had indicated that they do conduct a full audiological assessment, were then asked to select the tests they would use in the assessment. Figure 4.9., on the next page, represents the tests that participants would use in the assessment.

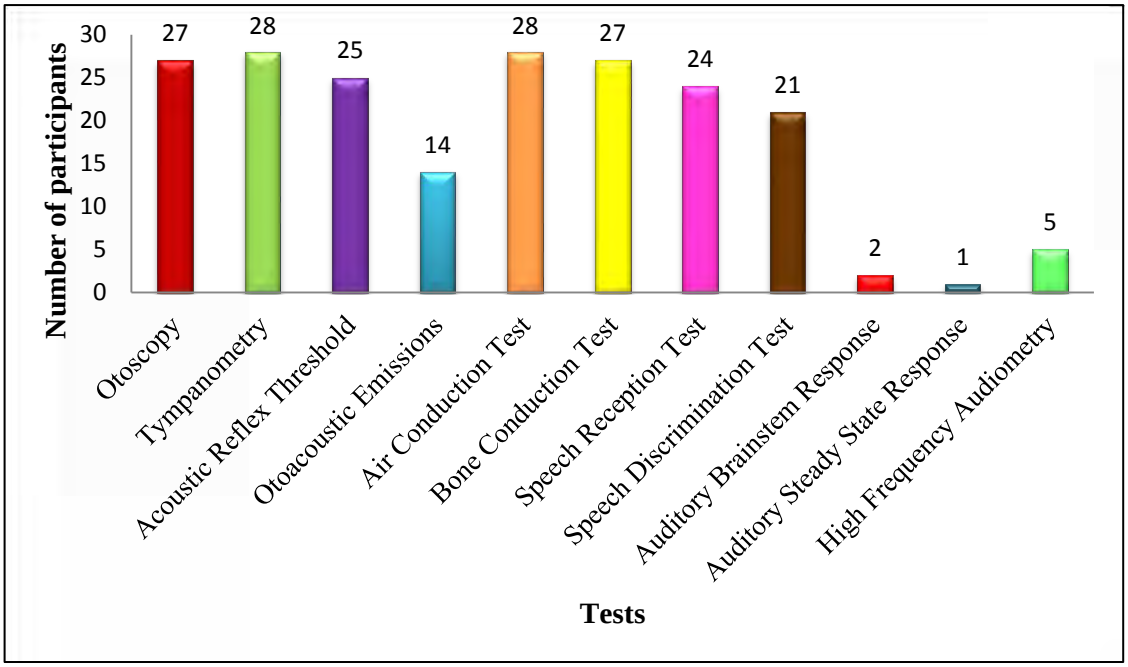

Figure 4.9. Audiological tests conducted (n=56)

Of the 56 participants who indicated that they would conduct a full audiological assessment if there were significant changes in hearing sensitivity, 27 (48%) participants would conduct otoscopy, 28 (50%) participants would conduct tympanometry, 25 (45%) participants would conduct acoustic reflex threshold test, 14 (25%) participants would conduct OAEs, 28 (50%) participants would conduct air conduction testing, 27 (48%) participants would conduct bone conduction testing, 24 (43%) participants would conduct speech reception testing, 21 (38%) participants would conduct speech discrimination testing, two (4%) participants would conduct ABR, one (2%) participant would conduct ASSR and five (9%) participants would conduct HFA.

The 22 participants who had reported that they do not conduct a full audiological test battery indicated reasons for not doing so. Figure 4.10., on the next page, presents those reasons.

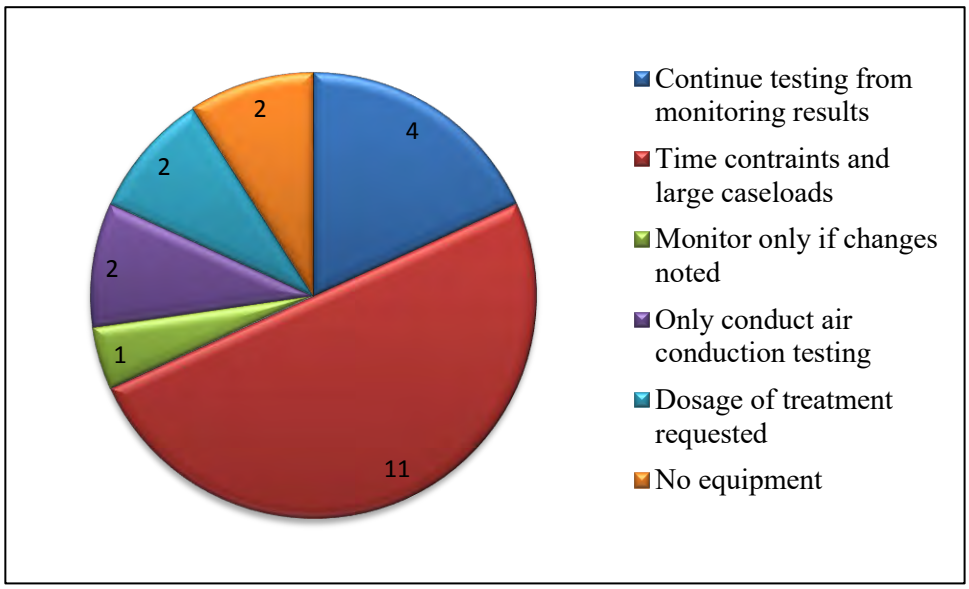

Figure 4.10. Reasons for not conducting the full audiological test battery (n=22)

Eleven (50%) of the 22 participants reported there were time constraints and large caseloads, four (18%) participants indicated that they would continue testing from monitoring results, two (9%) participants specified that there was no equipment, two (9%) participants reported they would only conduct a full audiological assessment once the dosage of the treatment is changed, two (9%) participants conduct only air conduction testing, while one (5%) participant provides monitoring if changes in hearing is noticed.

4.3.1.3. Assessment of Non-responsive Patients

Figure 4.11., on the next page, represents the type of test battery used when assessing non-responsive patients.

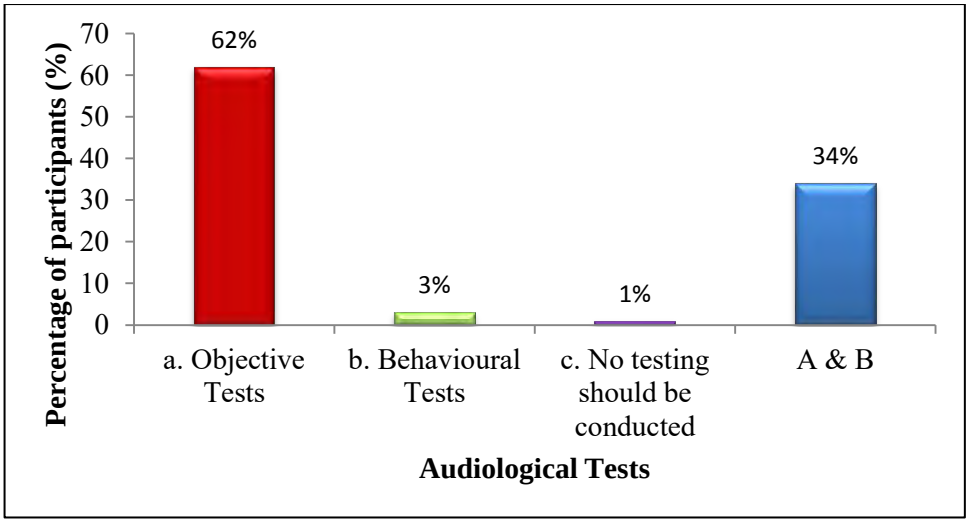

Figure 4.11. Audiological tests used to assess non-responsive patients (n=77)

Forty-eight (62%) of the 77 participants who responded to this question suggested objective means of testing, two (3%) participants indicated behavioral means of testing, one (1%) participant reported that no testing be conducted, whilst 26 (34%) participants indicated both behavioural and objective tests be conducted.

4.3.1.4. Periodic Testing of Patients Receiving MDR-TB Treatment

When asked if periodic testing is conducted after every 2-3 days per week for those patients receiving MDR-TB treatment, 70 (91%) of the 77 participants who responded, indicated that they do not, whilst seven (9%) participants reported that they do conduct the assessment after every 2-3 days per week.

The 70 participants who do not conduct the assessment after every 2-3 days per week were then asked to choose whether they conduct periodic assessments, weekly, fortnightly or monthly. Figure 4.12., on the next page, depicts the timeframe as to when periodic assessment is conducted.

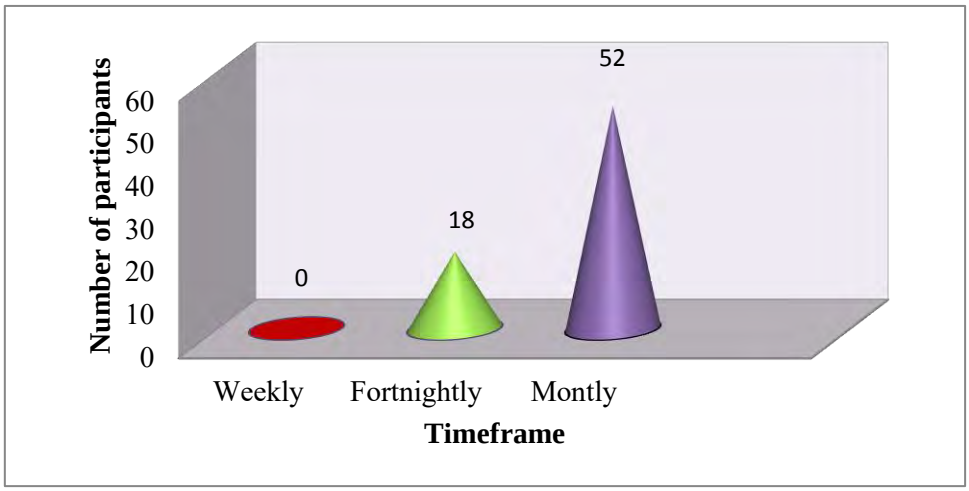

Figure 4.12. Timeframe as to when periodic assessment is conducted (n=70)

As indicated in Figure 4.12., above, 52 (74%) of the 70 participants reported that they conduct assessments monthly and 18 (26%) participants reported that assessments are conducted fortnightly.

4.3.1.5. Procedures followed if there are significant changes in hearing sensitivity

When asked if they report a significant shift in hearing threshold to the physician, 72 (94%) of the 77 participants who responded, indicated that they would; however, five (6%) participants indicated that they would not.

The 72 participants, who indicated that they would report the findings to the physician, were then asked to elaborate on the possible changes that the physician could make to the patient treatment regime. Figure 4.13., on the next page, depicts the participants' responses to the possible changes that the physician could make to the treatment regime.

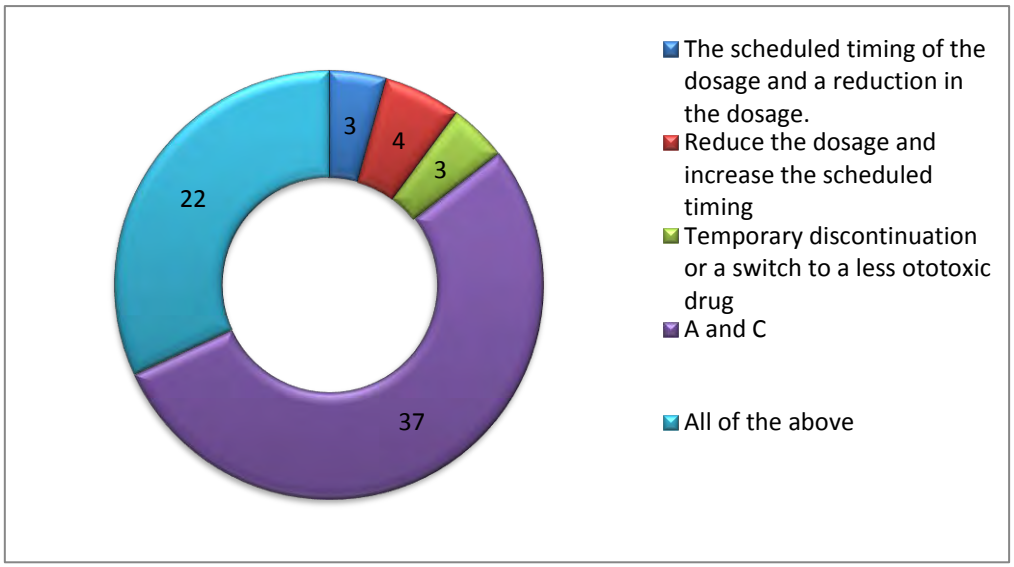

Figure 4.13. Possible changes that a physician could make to treatment regimen (n=69)

Of the 69 participants who responded to the question, 3 (4%) participants indicated that the physician would reduce the schedule timing and dosage of the treatment, four (6%) participants suggested that there would be a reduction in the dosage of the treatment and an increase in the schedule timing, three (4%) participants reported temporary discontinuation of the treatment or a switch to a less ototoxic drug. In addition, 37 (54%) participants indicated both A and C, and 22 (32%) participants indicated that all treatment options are used.

When asked if they were informed of changes in the treatment regime, 67 (88%) of the 76 participants who responded to the question, reported that they were alerted to changes, whilst nine (12%) participants reported that they were not alerted to the changes. However, they indicated that the changes are documented in the patient's TB file.

Participants were then asked if they would conduct a new baseline assessment if the drug had been changed by the physician. Forty-eight (64%) of 75 participants who responded

to the question, indicated that they would establish a new baseline, while 27 (36%) participants indicated that they would not establish a new baseline.

Figure 4.14., below, depicts some of the reasons for not conducting a new baseline measure when the physician has changed the drug used for treatment.

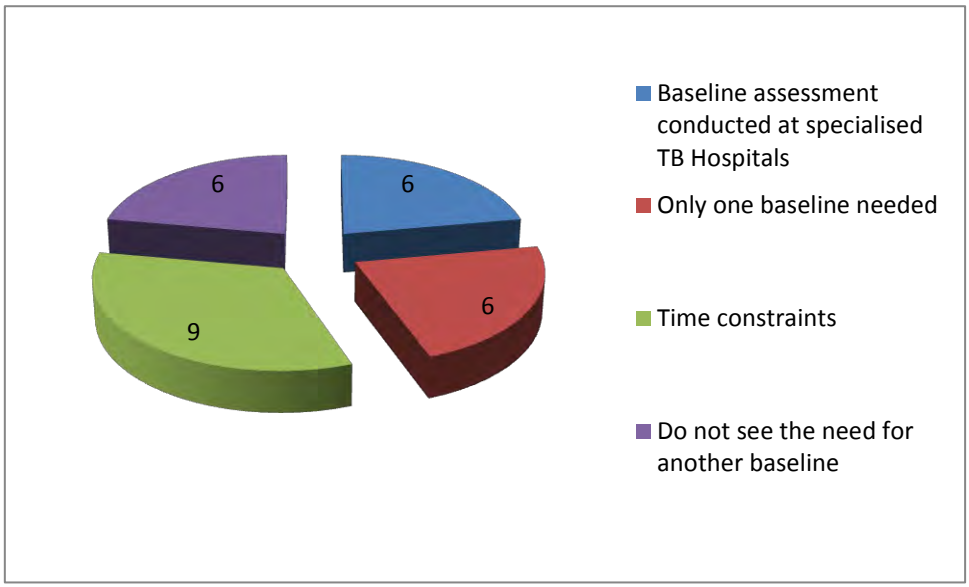

Figure 4.14. Reasons for not establishing a new baseline if treatment is changed (n=27)

Nine (33%) of the 27 participants indicated that there is not enough time to establish new baseline assessments, six (22%) participants reported that the baseline assessments are usually conducted at specialised TB hospitals, six (22%) participants indicated that only one baseline assessment is needed, whilst six (22%) participants did not see the need for a new baseline assessment.

4.3.2. Post Treatment Management

4.3.2.1. Follow-up Evaluations and Timeframes

Participants were asked if they would conduct a full audiological evaluation after the cessation of MDR-TB treatment. Fifty-three (72%) of 74 participants who responded

indicated that a full audiological assessment would be conducted after the cessation of the treatment, while 21 (28%) participants indicated that they do not conduct a full audiological assessment. However, they indicated that they would follow-up on monitoring result, only if the need arises. Figure 4.15., below, indicates the timeframe in which follow-up evaluations are conducted after the cessation of MDR-TB treatment.

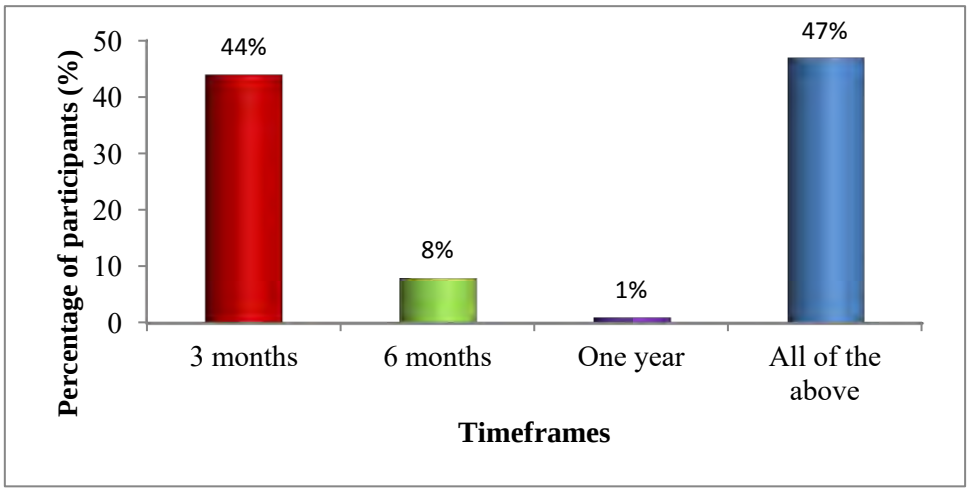

Figure 4.15. Timeframe for follow-up evaluations (n=75)

As indicated in figure 4.15., above, 33 (44%) of the 75 participants conducted follow-up at three months, six (8%) participants conducted follow-up at six months, one (1%) participant conducted assessment at one year, whilst 35 (47%) participants conducted assessments at one month, three months, six months and one year.

4.3.2.2. Aural Rehabilitation and Post treatment Counselling

When asked if there was a difference in the audiological management of a child compared to that of an adult, 71 (95%) of the 75 participants who responded, indicated that there is a difference, whilst four participants (5%) disagreed. Participants then had to select the best possible management for an adult patient. Table 4.4., on the next page, provides the results of the participants choice of management for an adult patient.

Table 4.4

Audiological management of an adult patient (n=74)

Topics	Frequency	Percentage
Hearing aids, assistive listening devices, counselling both to the patient and their family.	5	7%
Hearing aids, assistive listening devices, counselling both to the patient and their family, and audition.	2	3%
Hearing aids, assistive listening devices, counselling both to the patient and the family, communication strategies, audition; speech-reading and possible support groups available.	55	74%
A and B	12	16%

Majority of the participants i.e. 55 (74%) of the 74 participants indicated that hearing aids, assistive listening devices, counselling both to the patient and their family, communication strategies, audition, speech-reading and possible support groups is the best possible management for a patient who has completed MDR-TB treatment.

When participants were asked if they conduct counselling after the cessation of MDR-TB treatment, 72 (96%) of the 75 participants who had responded, indicated that they do, while 3 (4%) participants do not. The participants indicated the following reasons for not conducting post treatment counselling:

a) "Patients defaulted appointments and only return for disability grants when the hearing loss has progressed"
b) "We see patients on a referral basis ONLY. Some of the questions are therefore not applicable. The patients are managed by the professor of pulmonology and are technically all supposed to be seen at the TB hospitals regionally. We do not book them for follow-ups/baselines etc."
c) "Don't see the patients except for fitting with amplification"

Participants were then required to select the most appropriate topics that would be addressed during post treatment counselling. Table 4.5., below, indicates the responses of the participants relating to post treatment counselling topics.

Table 4.5

Topics covered during post treatment counselling (n=72)

Topic	Frequency
What is ototoxicity and the effect it has on the ear, how to optimize the use of amplification, the variety of assistive listening devices available and the use of audition and speech reading to cope with communication breakdown.	9
Nature and etiology of the hearing loss, the effects that the hearing loss has on daily living, how to optimize the use of amplification, the variety of assistive listening devices available and the use of audition and speech reading to cope with communication breakdown.	44
All of the above	19

Forty-four (61%) of the 72 participants who responded to this question, indicated that the "nature and etiology of the hearing loss, the effects that the hearing loss has on daily living, how to optimize the use of amplification, the variety of assistive listening devices available and the use of audition and speech reading to cope with communication breakdown", was the most relevant of topics to address during post treatment counselling.

Figure 4.16., on the next page, depicts the responses regarding who should conduct post treatment counselling.

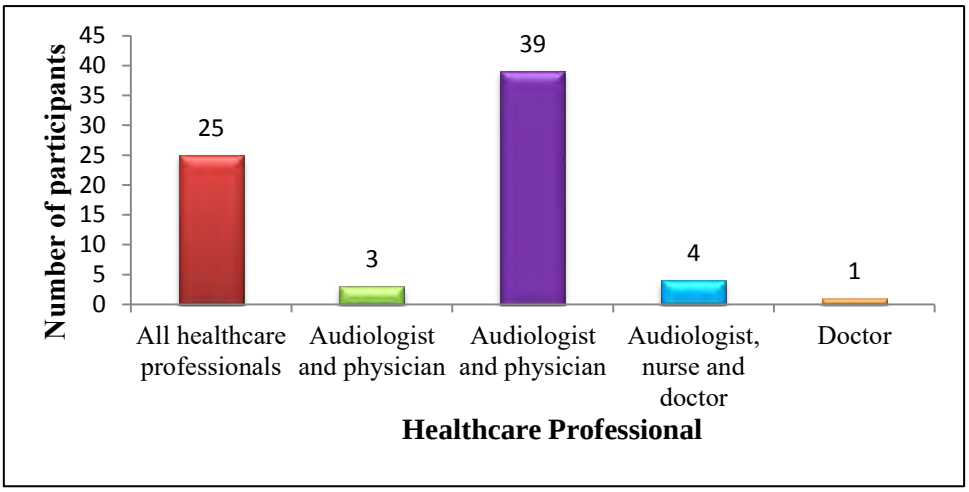

Figure 4.16. Responsibility for conducting post treatment counselling (n=72)

Of the 72 participants who responded to the question, 39 (54%) responded that it should be the audiologist, 25 (35%) participants reported that it should be all healthcare professionals, four (6%) participants indicated that it should be the audiologist, nurse and doctor, while three (4%) participants suggested that it should be the audiologist and the physician, and one (1%) participant reported that it should be the doctor.

When asked if counselling should be conducted in the home language of the patient 67 (89%) of the 75 participants who responded, indicated that counselling should be conducted in the home language of the patient, whilst eight (11%) participants indicated that it does not need to be conducted in the home language of the patient.

Participants were further questioned as to whether informational pamphlets or brochures were given to patients as part of the counselling process. Sixty-one (81%) of the 75 participants indicated that they do, while 14 (19%) participants indicated that they do not provide any informational materials. The main reason for not distributing informational

material was due to there being no specific pamphlets or brochures related to ototoxicity and hearing loss.

4.3.2.3. Modifications to International Ototoxicity Monitoring Protocols

Seventy-two (97%) of the 74 participants who responded, indicated that ototoxicity monitoring would be easier for audiologists if there were South African guidelines and/or protocols available, while two (3%) participants did not believe so. Participants were then required to state if they make modifications to the recommended guidelines. Forty-two of the 74 participants (57%) reported that they do make modifications to the recommended guidelines, while, 32 participants (43%) indicated that they do not make any modifications. Participants then had to choose one or more options or state the types of modifications they make to the recommended guideline as depicted in Figure 4.17., below.

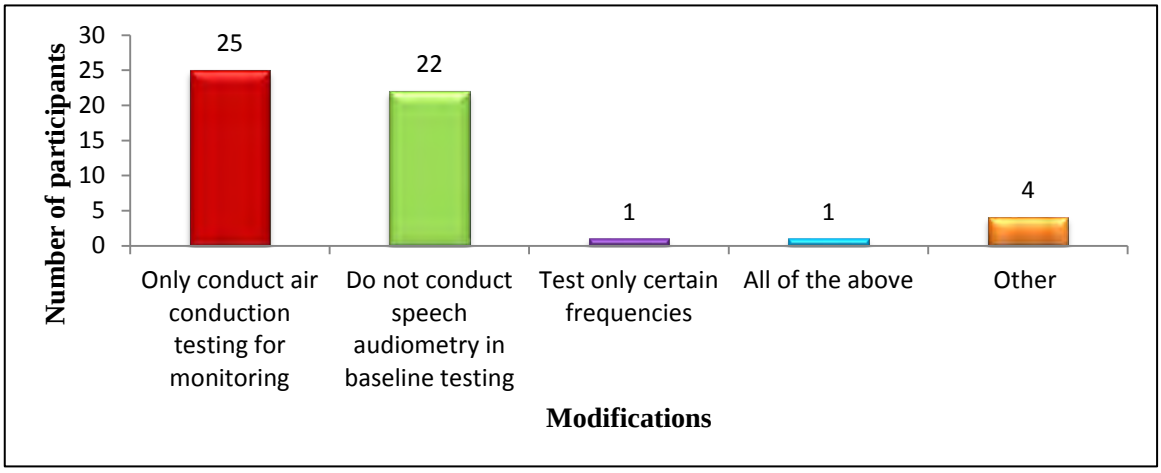

Figure 4.17. Modifications made to the international guidelines (n=42)

Twenty-five (60%) of the 42 participants indicated that they only conduct air conduction tests, 22 (52%) participants reported that they do not conduct speech audiometry; one (2%) participant indicated that only certain frequencies are tested, one (2%) participant indicated that they do all the modifications stated and four (10%) participants who had

chosen other indicated that they do not conduct immittance audiometry. Furthermore, participants were then asked the reason behind performing modifications to the recommended guidelines. Figure 4.18., below, depicts the reasons for the modifications made to international protocols. Participants were able to choose more than one option.

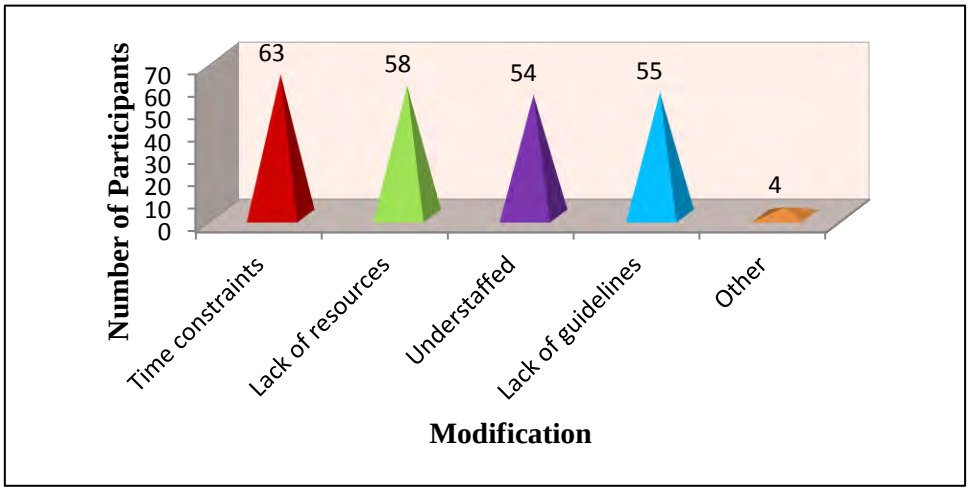

Figure 4.18. Reasons for modifications to international guidelines (n=74)

Sixty-three (85%) of the 74 participants indicated that it is due to time constraints, 58 (78%) participants reported that it is due to lack of resources, 55 (74%) participants suggested that it is due to lack of guidelines and 54 (73%) participants indicated that it is due to departments being understaffed. Four (5%) participants reported that the main reason is that ototoxicity monitoring is not practiced as often and that the recommended guidelines are not suitable for the South African context.

Questions 11, 12, 12.1, 13, 14, 15, 15.1., 16, 17, 18, 19, 20, 21, 22, 23, 24, 24.1., 25, 26, 27, 28, 29, 30, 31, 33, 33.2., 33.3.; were used to determine if participants were following international guidelines. Of the 93 participants who completed the questionnaire, only 58 participants had completed all the questions mentioned above. Thirty-five (60%) of the 58 participants are currently following international guidelines.

Further analysis of results in the current study have indicated that there is a significant (p=0.023) relationship between work experience and the use of international guidelines i.e. newly qualified audiologists are following international guidelines. There was also a significant relationship (p= 0.005) between the province in which audiologists work and the use of international guidelines. Furthermore, there was a significant correlation (p=0.024) between the type of institutions at which the audiologists work and the use of international guidelines, with participants in the public sector aligning more to international guidelines.

4.4. Summary

This chapter presented the findings of the study. Salient findings were that 80% of audiologists are aware of international guidelines, 93% reportedly provide pre-treatment counselling; while, 87% of audiologists conduct baseline assessments prior to the administration of MDR-TB treatment. Furthermore, 19% of audiologists conduct HFA and indicated that there is a lack of high frequency audiometers due is to financial constraints. The following were cited as reasons for the modification to the international guidelines: lack of specialised equipment, time constraints and large caseloads, as well as, understaffed departments. In addition, 74% of the audiologists are able to conduct periodic assessments monthly, while 72% of audiologists conduct a full audiological assessment after the cessation of MDR-TB treatment and 96% of audiologists conduct post treatment counselling. These findings will be discussed in relation to the available literature in the next chapter.

CHAPTER 5

DISCUSSION

5.1. Introduction

The study aimed to describe the audiological practices employed by audiologists in the management of adult patients with multi-drug resistant tuberculosis in South Africa. The results presented in the previous chapter will now be discussed in accordance to the objectives of the study and with reference to appropriate literature.

5.2. Pre-treatment and Baseline Measures

Ototoxicity monitoring is an essential aspect in the management of a patient with MDR-TB, due to the high incidence rate of this disease in South Africa (Bardien et al., 2009). Results from the current study have shown that of the 205 participants, 93 (45%) indicated that they conduct audiological monitoring of patients with MDR-TB. According to WHO (2013), South Africa is one of the five countries that have the largest incidence of TB cases. Therefore, it can be assumed that there will also be a large number of people on aminoglycoside treatment. This consequently indicates that there should be ototoxicity monitoring programs to monitor the audiological status of these people, due to the ototoxic nature of aminoglycosides (Duggal & Sarkar, 2007). However, with only 93 participants reporting that they conduct monitoring to patients with MDR-TB, it can be deduced that a large number of patients do not receive this audiological service.

In order for audiologists to provide ototoxicity monitoring, they would require a set of protocols or guidelines to assist them. The findings of the current study revealed that 80% of the participants were cognisant of ototoxicity monitoring protocols. Currently South Africa does not have explicit ototoxicity monitoring guidelines for audiologists to use; however,

there are two detailed international protocols, i.e. the audiologic management of individuals receiving cochleotoxic drug therapy (ASHA, 1994) and the position statement and clinical guidelines: ototoxicity monitoring (AAA, 2009). The findings of the current study revealed that majority of the participants (63%) were aware of these protocols. This indicates that audiologists in South Africa may follow these international guidelines as it is readily available to them; however, it is important to note that 1% of the participants are in the belief that there are specific ototoxicity monitoring guidelines available in South Africa. However, this participant could be referring to the guideline for planning STA services at all levels of healthcare by HPCSA (2014). This suggests that there is a need for the participants to obtain guidance and training regarding ototoxicity monitoring, and the need for awareness related to MDR-TB and ototoxicity monitoring.

In addition, 20% of the participants reported that they were not aware of any ototoxicity monitoring criteria/guidelines; however, this would then indicate that this may be one of the contributing factors for not conducting ototoxicity monitoring. This indicates that the participants may not have received sufficient training on ototoxicity monitoring, and it may even indicate their lack of interest, as there are continuing professional development activities related to ototoxicity monitoring. In addition, this information is available on the internet. Moreover, the results suggest that audiologists need to be proactive in accessing information related to their expertise. Results of the current study revealed that recently qualified audiologists are aligning to the international guidelines. The researcher speculates that this could be due to the more recent audiology curriculum placing emphasis on ototoxicity monitoring, due to the high burden of disease in South Africa. In addition, the findings revealed that more audiologists in the public sector align to international guidelines. The researcher postulates that this could be due to newly qualified audiologists still being

employed in the public sector, while those audiologists in private practice have more audiology work experience. Ototoxicity monitoring is within the scope of practice of an audiologist, with the planning and implementation of the program being one of their responsibilities (Konrad-Martin et al., 2005).

ASHA (1994) indicated that a collaborative effort needs to be made for the implementation and continuations of a program to be a success which suggests that there is a need for a good working relationship among healthcare professionals. This is emphasised by the finding of the current study, as all participants indicated that the identification of the patients at risk for hearing loss depends on a good working relationship among all health professionals. This, however, would only be possible if health professionals understand what ototoxicity is and the importance of audiological services to a patient with MDR-TB, as has been demonstrated by Khoza-Shangase (2013). Therefore, it is essential for health professionals managing patients with MDR-TB to be in-serviced about ototoxicity in this patient population (AAA, 2009), as has been agreed by all the current study participants.

The findings from the study revealed that 89% of the participants indicated that the topics that should be incorporated when conducting in-service training with staff should include; “what is ototoxicity, when does ototoxicity occur, what happens to the ear and its function, what are the ototoxic drugs involved in MDR-TB, what are the associated auditory and vestibular problems, the need for counselling and aural rehabilitation”. This is needed as all healthcare professionals who are involved in the management of a patient with MDR-TB would understand the need for ototoxicity monitoring; hence, assist with early identification of patients who are at risk of developing ototoxicity. This indicates that although the participants are aware of the importance of in-service training as well as appropriate topics

that need to be addressed during in-service training, they may not necessarily be conducting in-service training, as a study by Khoza-Shangase (2012) illustrated that 74% of the healthcare workers indicated that they lacked awareness in terms of ototoxicity and the symptoms that a patient may present with as a consequence of ototoxic treatment.

Furthermore, as reflected in figure 4.3., on page 62, majority (80%) of the participants suggested that the audiologist should conduct this in-service training, however, 2% of the participants suggested that it should be the doctor, 4% of the participants reported that it should be the nurses, 2% of the participants indicated that it should be both the audiologist and the doctor, whilst 12% of the participants believe that it should be the responsibility of all healthcare professionals. Although, it is important for all healthcare professionals to conduct in-service training so as to improve trans-disciplinary skills and knowledge base of ototoxic drugs, it is the responsibility of the audiologist to provide awareness related to ototoxicity. Thus, suggesting that all in-service training related to ototoxicity monitoring should be conducted by the audiologist (AAA, 2009), as the audiologist is the professional most closely involved in the assessment of ototoxicity and who should be the most knowledgeable about signs and symptoms, as well as, the ototoxic medication. This is re-iterated by the findings of the current study, which revealed that 92% of the participants selected the correct group of ototoxic medication. This revealed that the participants are aware of the types of ototoxic medication used in MDR-TB treatment that would require monitoring, and this information should be relayed to the nurses and physicians through in-service training. If there is adequate in-service training, it is likely that there would be more referrals of patients who are undergoing ototoxic drug treatment. Furthermore, 93% of participants believe that patients who undergo ototoxic drug treatment should be automatically referred for audiological monitoring and this would result in an improvement to the current referral system. As

medical practitioners are responsible for providing comprehensive healthcare services to all patients who require medical care, this would then include ototoxicity, as ototoxicity results from the use of often life threatening treatment (Khoza-Shangase & Jina, 2013). However, 7% of the participants disagreed; this could indicate that that these participants are concerned that some healthcare professionals may lack the knowledge of the symptoms or signs associated with ototoxic drugs which may then lead to inappropriate/unnecessary referrals to audiology departments (de Andrade et al., 2009); highlighting, again the importance of in-service training. If healthcare professionals are knowledgeable about ototoxicity in the MDR-TB patient population, patients will be referred to the audiology department prior to commencement of treatment, as this will allow the audiologist to conduct pre-treatment counselling.

Pre-treatment counselling is an essential aspect of ototoxicity monitoring as it allows the audiologist to establish rapport with the patient. It allows the patient and their family to feel actively involved in the treatment process. Results of the current study revealed that 93% of the participants conduct pre-treatment counselling. The reason cited for the lack of pre-treatment counselling, was that patients were only referred to the audiology department after the commencement of the MDR-TB treatment. This indicates that due to there being a break between services in ototoxicity monitoring, the participants may have to conduct counselling during the follow-up evaluations, or it is likely that the pre-treatment counselling may not be conducted or may be conducted by medical staff. However, pre-treatment counselling related to aspects of ototoxicity needs to be conducted by the audiologists, as audiologists are obligated to provide information regarding the adverse effect of ototoxic treatment on their auditory and vestibular system (AAA, 2009).

According to ASHA (1994), pre-treatment counselling should include the clinical notes of the physician involved in the management of a patient with MDR-TB, regarding the risks and benefits of the ototoxic treatment and the audiologists should counsel on aspects such as the signs and symptoms of cochlear damage and the possible communication difficulties that the patient may incur. The finding of the current study revealed that 60% of the participants chose the similar topics as suggested by ASHA (1994). This indicates that while majority of the participants (93%) are conducting pre-treatment counselling, a large percentage of them do not address all of the relevant aspects. Pre-treatment counselling is the time in which you are able to prepare the patient and their family for the possible changes to the livelihood of the patient that may occur due to changes in hearing sensitivity. It also provides an opportunity for the audiologist to explain to the patient with MDR-TB, the need to conduct a baseline assessment.

The need for a baseline assessment is to document the hearing status of the patient prior to the administration of the MDR-TB treatment (ASHA, 1994). Results of the current study revealed that 87% of the participants conduct baseline assessment prior to the commencement of MDR-TB treatment. This indicates that majority of the participants who conduct ototoxicity monitoring are following the international protocols, as audiologists need to establish the current hearing status prior to any effects experienced during treatment (Konrad-Martin et al., 2005). The reasons cited for not conducting baseline assessment include delays in referrals, lack of resources and/or staff and patients are assessed at specialised TB institutions. This indicates that audiologists are facing challenges that prevent them from conducting baseline assessments. These challenges include, baseline assessments being conducted at different institutions and handover or access to the results is not available to them or the patient is only referred for an audiometric evaluations if a hearing impairment

is noted by the physician. Furthermore, those patients who have baseline assessment conducted at specialised TB institutions need to have well documented audiograms and summary of results in their TB files if they are then going to be referred to another institution. According to the AAA (2009) and ASHA (1994) guidelines, baseline assessments should be conducted within 72 hours after the administration of the ototoxic treatments. As depicted in figure 4.4., on page 65, only 17% of the participants are not compliant in this regard. This indicates that these patients were not being correctly monitored and this could affect the outcomes of the results. This would further suggest that timely assessment requires a highly efficient patient identification and/or referral system (AAA, 2009), which again emphasises the importance of in-service training and a trans-disciplinary approach to patient management.

According to AAA (2009), the following tests are recommended during baseline assessments, "pure tone thresholds in the conventional frequency range, HFA, tympanometry, speech audiometry, and testing of OAEs" (p. 5). As reflected in Table 4.3., on page 66, 80% of the participants are knowledgeable of the audiological tests that are to be used during baseline measures. This indicates that majority of the participants are aware of the types of tests that are necessary when conducting ototoxicity monitoring. Furthermore, this indicates that there has been improvements in testing patients who present with ototoxicity, as until very recently, only conventional testing methods, i.e. the puretone audiometric testing was used; however, recently, more specific information is gained by use of HFA and OAEs which would allow for early detection of an ototoxic hearing loss (Venter, 2011). Thus, making baseline audiometry a crucial aspect for the successful implementation of an ototoxicity monitoring programs as the patient would undergo accurate evaluations (ASHA, 1994).

However, majority of the participants (80%) do not conduct HFA as there is a lack of high frequency equipment in audiology departments. This indicates the constraints experienced by audiology departments relating to HFA and its use in South Africa. HFA enables the audiologists to gain threshold information from 8 kHz to 20 kHz, which is the frequency region to be initially affected by the use of aminoglycosides, as demonstrated by Appana (2013). This indicates that it is imperative that HFA be included in the assessment as it includes the upper regions of hearing which is not usually tested during conventional audiometric evaluation (Venter, 2011). However, there is a lack of the necessary specialised equipment required to conduct HFA due to financial constraints (Koekemoer & Ndjeka, 2013). This was substantiated by the findings of the current study, as depicted in Figure 4.6., on page 67, which cited the lack of high frequency audiometers as one of the main reason for not conducting HFA. In addition, service delivery is greatly affected, as specific results related to higher frequencies are able to provide early identification of an ototoxic hearing loss which would reduce the number of patients who are referred to audiology department once irreversible damage to their auditory system has occurred (Konrad-Martin et al., 2005).

Furthermore, the findings of the current study, as reflected in Figure 4.5., on page 67, revealed that 94% of the participants tested at 12 kHz and 25% of the participants tested at 20 kHz. This indicates that some audiologists may have standard audiometers, with an extended frequency range of up to 12 kHz, which would allow many audiologists to test in that frequency range. Furthermore, this may indicate that the participants are using the $\frac{1}{6}th$-octave test protocol, which provides earlier detection of ototoxicity (Fausti et al., 1994). Compared to testing in $\frac{1}{6}th$-octave steps above and below 8 kHz, testing conventional frequencies alone resulted in initial ototoxic hearing change being missed or detected later (Fausti et al., 2003). This would then delay the management of a patient with MDR-TB, which needs to be

identified early as these patients, due to fatigue and illness, may not be consistent during conventional test frequencies and may require re-test of frequencies.

Re-tests are essential to confirm results of patients that may respond inconsistently during behavioural testing (ASHA, 1994). The findings of the current study revealed that 75% of the participants conduct re-tests. As depicted in Figure 4.7., on page 68, reasons cited for not conducting re-tests include financial constraints, time constraints and large caseloads, participants reporting that they test accurately, participants reporting that they conduct only monitoring assessments, or only conducting screening. Furthermore, five (25%) participants reported that they only conduct re-tests when patient responses are unreliable. According to Naidoo (2006), service delivery of audiological services are hindered by factors related to budget cuts, lack of staff and lack of awareness of the need for audiological services. This would then indicate that the constraints experienced in audiology departments would lead to higher caseloads, lack of upgrading the department and lack of employment for audiologists, which further, indicates that the implementation of a successful ototoxicity monitoring program would be disrupted.

5.3. Ototoxicity Monitoring Procedures and Post Treatment Management

The use of a criterion, available in the international guidelines, enable audiologists to clearly define an ototoxic hearing loss and provides a way of assisting the audiologist in making informed decisions about the management of a patient with MDR-TB. Results of the current study revealed that 84% of the participants are following a criterion when defining an ototoxic hearing loss. The need for a criterion decreases the occasional false-positive identification which delays detection of the ototoxic process (Konrad-Martin et al., 2005). Of concern is the 16% of participants who do not use a criterion, due to them not being aware of

a criterion and none being available for South Africa. This, therefore, indicates that some participants need to become aware of the resources they have available, albeit international. If a criterion is not being used, a question arises – "How is ototoxic hearing loss being calculated?"

According to ASHA (1994), the following indicates ototoxic hearing loss: (a) 20 dB decrease at any one test frequency, (b) 10 dB decrease at any two adjacent test frequencies, or (c) loss of response at three consecutive test frequencies where responses were previously obtained. The findings in the current study, as reflected in Figure 4.8., on page 69, revealed that 79% of the participants, who responded to the question, correctly selected the criterion to utilise to identify an ototoxic hearing loss. The use of a criterion is essential as it would allow audiologists to make clinically appropriate decisions based on the progression of the hearing loss, as well as, assist in conveying information to the physician on the severity of ototoxicity that the patient may exhibit.

The computation of the changes in hearing sensitivity provides a method of noticing if changes to the treatment regimen need to be made. The methods suggested in the recommended guidelines, i.e. comparing the baseline assessment to that of the follow-up evaluation, allows the audiologist to use a standard method of determining the effect of the ototoxic drugs on the auditory system. The findings of the current study revealed that 99% of the participants use the baseline assessment when computing changes in hearing sensitivity. Computation of the changes in hearing sensitivity during each follow-up assessment is calculated in conjunction with the baseline assessment results (ASHA, 1994). This is done, so as to document the changes from before the commencement of treatment till the cessation of the ototoxic treatment. This indicates that the participants are following the recommended

international guidelines and it is important as, this would define if there are changes to hearing sensitivity and determine if the audiologists needs to inform the physician of the changes and make relevant changes to treatment regimen (Konrad-Martin et al., 2005). Once there is change to the patients hearing status, a full audiological evaluation is required, as changes in hearing sensitivity may be a result of middle ear pathologies (ASHA, 1994).

Therefore, participants were asked if they would conduct a full audiological assessment if there was a change in the patient's hearing sensitivity. Seventy-two percent of the 78 participants who responded indicated that they would conduct a full audiological assessment. Those who do not conduct a full audiological assessment cited the following reasons: insufficient time and large caseloads. In addition, the participants indicated that they would continue from the baseline assessment results, as shown in Figure 4.10., on page 72. According to Venter (2011), audiologists often indicate that time constraints, cost effectiveness and efficiency are the common challenges that are faced when implementing a successful ototoxicity monitoring protocol. These have been reported on the basis that it is a hindrance to audiological services that would need to be implemented; however, little is done to overcome these constraints by higher management in New Zealand (Venter, 2011).

In addition, the findings of the current study, as illustrated in Figure 4.9., on page 71, revealed that majority of the participants utilise the basic audiological test battery as the full audiological test battery for monitoring ototoxicity, with 25% and less of the participants using electrophysiological tests. This indicates that many audiology departments in South Africa do not possess specialised equipment such as, ABR, ASSR and HFA. This poses a challenge to service delivery (Naidoo, 2006), especially when assessing non-responsive patients. This is further reflected in the study by Seddon et al. (2012), who indicated that

specialised audiological equipment is available at specialised institutions. From anecdotal experience, audiologists generally refer these patients to these specialised institutions which, results in a delay in monitoring ototoxicity due to the institutions having waiting lists for specialised electrophysiological testing, especially needed for a non-responsive patient.

The assessment of a patient with limited responses or no response requires some modification that needs to be made to the test battery used. According to ASHA (1994), both behavioural and objective means of testing need to be utilised. However, only objective tests may be used to assess a non-responsive patient. The current study, as reflected in Figure 4.11., on page 73, indicates the 34% of the participants reported that they would use objective and behavioural tests and 62% of the participants indicated that an objective test be used when assessment a non-responsive patient. While the participants acknowledge the objective tests need to be used when assessing non-responsive patients, one's attention is drawn back to the lack of these specialised equipment at the different institutions. This indicates that non-responsive patients may not necessarily be receiving appropriate audiological services and intervention.

According to the international guidelines, patients who are undergoing ototoxic treatment need to be monitored 2-3 days per week (ASHA, 1994). In this way any changes to the auditory system would be detected early and thus the treatment regimes would be amended to suit the needs of the patient. However, a resounding 91% of the participants reported that they do not conduct assessment 2-3 days per week. This is understandable as audiology departments have a number of challenges; one being the caseload and time constraints they experience that would not allow these assessment to occur so often. This is further supporter by Venter (2011), which indicated that only 31% of the patient being

monitored for ototoxicity would have follow-up assessments. Thus, as depicted in Figure 4.12., on page 74, 56% of the participants reported that they conduct assessments monthly and 26% of the participants reported that it is conducted fortnightly. From the anecdotal experience of the researcher, patients usually take their MDR-TB treatment either 3-5 times a week; however, patients are usually booked monthly for their follow-up evaluation. This indicates that South African audiologists are modifying the recommended guidelines in a way that does not reflect negatively on the audiological services provided but rather in a way of relating to the South African context.

One of the main reasons for ototoxicity monitoring is to alert the physician if there have been significant changes to hearing sensitivity. In this way, the audiologist is viewed as an integral component in the team when it comes to the management of a patient with MDR-TB. The study revealed that 94% of the participants indicated that they would alert the physician if there are changes to the hearing status. In this way, the audiologist is able to convey information to the physician on the progression of ototoxicity so that the physician would be able to make appropriate changes to the treatment regime, such as reduction in the dosage, the scheduled timing of the dosage, temporary discontinuation or a switch to a less ototoxic drug (Mattucci & Vasquez, 2003).

Audiologists need to be cognisant of the treatment options the physician has when changes in hearing sensitivity are noted. This is reflected by approximately 54% of the participants, as reflected in Figure 4.13., on page 75, who selected the correct option.

In turn, audiologists need to be aware of any changes that the physician may make to the treatment regime; however, the results of the study revealed that 88% of the participants

were alerted to any changes made by the physician. This indicates that audiologists are an essential component in the management of a patient with MDR-TB and physicians are documenting detailed results in the patient TB file, as well as, indicating that audiological monitoring is required in order to track ototoxicity. It is important for an audiologist to be alerted as this may affect the ototoxicity monitoring program they may have in place for the patient (Mattucci & Vasquez, 2003). For instance, if the physician has decided to change the type of drug of the patient undergoing MDR-TB treatment, the audiologist needs to conduct a new baseline assessment (ASHA, 1994). According to the results obtained in the study, only 64% of the participants indicated that they would establish a new baseline measure. However, 36% of the participants reported that they would not conduct a new baseline measure as they could simply use the initial baseline and that they did not see the appropriateness of conducting another baseline assessment as they have one already. This indicates that these audiologists do not fully understand the need for conducting a new baseline measure or may not be aware of the purpose related to its establishment. Thus, accurate monitoring of the patient hearing status would not be documented and changes to hearing sensitivity in follow-up evaluations would go unnoticed which may lead to the failure of an ototoxicity monitoring program.

The follow-up evaluations are required so as to monitor if the changes to the hearing sensitivity have stabilised following the cessation of treatment (ASHA, 1994). Thus, there is a need for a full audiological evaluation to be conducted after the cessation of MDR-TB treatment. According to the study, 72% of the 74 participants, who responded, indicated that they would conduct a full audiological assessment; this indicates that these audiologists are following the international guidelines. Follow-up evaluations are usually conducted at 3 months, 6 months and one year after treatment has ceased (ASHA, 1994). The finding from

the current study, as shown in Figure 4.15., on page 77, revealed that 47% of the 75 participants who responded to this question conduct the assessment at those recommended timeframes. This further indicates that the participants are following international guidelines, as HPCSA indicated that rehabilitation after the cessation of treatment extends from 6 weeks to 6 months (HPCSA, 2014); however, this is a fairly new guideline that some audiologists may not be aware of.

Aural rehabilitation forms an essential part in the management of a patient with MDR-TB. Adult aural rehabilitation programs differ from children programs as adults may present with hearing impairment later on in life and have already developed speech and language skills (Alpiner & McCarthy, 2000). According to the study, 95% of the 75 participants, who responded to this question, indicated that there is a notable difference between the aural rehabilitation programs of a child compared to that of an adult.

According to Alpiner and McCarthy (2000), these general steps need to be included in an adult rehabilitation program:

a) The assessment of hearing and the impact of hearing loss.
b) Hearing aid evaluation, its use and/or need for assistive listening devices
c) Audition and speechreading
d) Development of an individualised aural rehabilitation program which includes both the patient and family members.

This was evident in the study, as reflected in Table 4.4., on page 78, as 74% of the 74 participants who responded to this question, indicated that “hearing aids, assistive listening devices, counselling both the patient and the family, communication strategies, audition; speech-reading and possible support groups available” should be covered during aural

rehabilitation. This would then indicate that those patients with MDR-TB would be receiving sufficient audiological management following the identification of a change to their hearing status that would allow them to accept and adapt to these changes more easily than those who do not have support. Furthermore, supporting a patient through counselling remains to be an essential aspect of an aural rehabilitation program; thus, indicating the need for audiologists to develop and implement an aural rehabilitation program that is specific for the needs of a patient with MDR-TB (Pienaar et al., 2010).

Post treatment counselling is an essential aspect in the management of a patient with MDR-TB, as this will allow the patient to cope with the changes in hearing sensitivity caused by the MDR-TB treatment (Alpiner & McCarthy, 2000). The study revealed that 96% of the 75 participants, who responded to this question, indicated they would conduct post treatment counselling; however, the 4% of participants reported that they would not conduct post treatment counselling due to patient defaulting on appointments or only attending the clinic when hearing aids are to be fitted. Those who do conduct post treatment counselling indicated that the nature and etiology of the hearing loss, the effects that the hearing loss has on daily living, how to optimize the use of amplification, the variety of assistive listening devices available and the use of audition and speech reading to cope with communication breakdown, were the most relevant topics to be addressed during post treatment counselling. This would assist the patient by improving their skills and help the patient optimise the use of their amplification (Alpiner & McCarthy, 2000). The audiologist needs to understand the needs of the patient and assist them appropriately.

Post treatment counselling is important; however, counselling should be conducted by all professionals involved in the management of a patient with MDR-TB (AAA, 2009). Each

healthcare professional should counsel the patient on aspects related to their treatment. Thus, the current study, as depicted in Figure 4.16., on page 80, revealed that 54% of the participants indicated that counselling related to ototoxicity should be conducted by audiologists. Although, audiologists have the expertise to provide counselling related to ototoxicity, especially once cessation of MDR-TB treatment, no mention of post treatment counselling is evident in the HPCSA guidelines. However, the international guidelines emphasised that audiologists play a key role in the facilitation of post treatment counselling so as assist the patient with communication problems they may exhibit due to the MDR-TB treatment (ASHA, 1994).

In South Africa, there are many languages, which may pose as a challenge to audiologists by creating language barriers and make the management of a patient with MDR-TB more difficult. It is by right of the patient to have services rendered to them in their home language (van Dyk, 2008). Thus, the findings of the study revealed that 89% of the participants indicated that they would conduct counselling in the home language of the patient. Furthermore, a patient is entitled to information relating to their treatment they are receiving (DOH, 2001). This would include both verbal and written form of information (DOH, 2001). Thus, the study revealed that 81% of the participants provide pamphlets or brochures to their patients. However, accurately translated informational pamphlets or brochures are needed in order to provide correct information (van Dyk, 2008). Moreover, the use of pamphlets, brochures or informational guides may also prove to be challenging, if they are not be suitable for the literacy levels of the patient.

5.4. Modifications to Recommended Ototoxicity Monitoring Protocols

Context-relevant standards allow for easier implementation as it will support the need of the professionals and the patients involved in the process of MDR-TB management. According to the study, 97% of the 74 participants, who responded, indicated that ototoxicity monitoring would be easier for audiologists if there were South African guidelines and/or protocols available. This indicates that the participants have noted that international guidelines may not be suitable for the South African context and thereby would attempt to make modifications to these guidelines to make them contextually relevant. Thus, 57% of the 74 participants indicated that they do make modifications to the international guidelines. The modifications, as illustrated in Figure 4.17., on page 81, include not conducting speech audiometry, only testing certain frequencies and not conducting immitance audiometry. This has an impact on the program as a standard protocol is not being followed and would then impact on the results obtained from the patient. The information obtained from the patient indicates the progress or stabilisation of ototoxicity. The use of standardised methods of testing make it easier to document the progression of ototoxicity; thus, allowing for a more efficient referral system to specialised services and to gain the epidemiological statistics needed to improve or gain further insight into ototoxicity (Mattucci & Vasquez, 2003). Furthermore, standardised methods of testing would improve clinical case management within a TB program, as it would provide the schedule timing of administration of treatments or the possible changes that occur if there is progression in ototoxicity (Seddon et al., 2012).

The findings of the study also revealed that 60% of participants are currently following international guidelines. This indicates that most participants are using and possibly modifying the current international guidelines in order to provide the services to patients with MDR-TB.

5.5. Summary

This study aimed to describe the audiological practices employed by audiologists in the management of an adult patient with MDR-TB in South Africa. Pre-treatment counselling, baseline practices, follow-up evaluations and post treatment sum up the basis of an ototoxicity monitoring program. Majority of the participants (92%) have been able to identify those patients who would require ototoxicity monitoring and 93% provide pre-treatment counselling.

With regard to baseline practices, 80% of participants follow the international guidelines even though many constraints are experienced within audiology departments. Although, a large percentage of participants are able to conduct the baseline assessment, it is clear that follow-up evaluations may not be conducted as frequently. Furthermore, HFA is lacking in South Africa, as 80% of the participants are unable to conduct this test due to the lack of equipment. The findings of the current study revealed that 91% of the participants were not able to meet the requirements of the international guidelines of conducting monitoring evaluations after every 2-3 day per week. Once again, indicating that due to the constraints experienced in audiology departments ototoxicity monitoring may be hindered or implemented with modifications that are suitable to the South African context.

This chapter discussed the results of the study in relation to literature. From the above discussion, it is apparent that the aims of this study were realised. Nevertheless, there were limitations of this study which will be discussed in the following chapter. Reference to future clinical and theoretical implications will also be made.

CHAPTER 6

CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

6.1. Introduction

This chapter provides a summary of the main findings of the study, highlights the limitations of the research conducted, as well as, the recommendations for future research.

6.2. Summary of Main Findings

While South Africa currently does not have specific guidelines for ototoxicity monitoring, there are audiologists who are practicing in a way that allows for maximising of resources in an effective manner to ensure a high quality of healthcare. Therefore, this study aimed to describe the audiological practices employed by audiologist in the management of a patient with MDR-TB, as the findings may be used to inform policy for a contextually relevant evidence-based ototoxicity monitoring program for patients with MDR-TB. The findings of this study revealed that audiologists do not conform to all aspects of the AAA (2009) and ASHA (1994) ototoxicity monitoring protocols and are, thus, making modifications. A summary of the finding is listed below:

- For an audiologist to have a foundation of where to begin to develop and implement an ototoxicity monitoring protocol, they would require guidelines. In this regard, 74 (80%) of the 93 participants are aware of the international ototoxicity monitoring guidelines. This indicates that some audiologists are currently following the international guidelines that are available to them; however, it also suggests that due to the audiologist utilising international guidelines, modifications are made to ensure that it is suitable for the South African context.

- Seventy-six (92%) of the 83 participants were able to identify the types of treatment that are ototoxic.
- Seventy-five (93%) of the 81 participants conduct pre-treatment counselling. However, the researcher cannot assume that the patient receives sufficient information related to the treatment of MDR-TB and the associated symptoms. Pre-treatment counselling aids in adherence to medical treatment, as well as, attendance to follow-up evaluations and acceptance to changes in the auditory system that may occur.
- The use of HFA is an essential test used in ototoxicity monitoring; however, 65 (80%) of 81 participants reported that they do not conduct HFA, due to the constraints within the audiology department, such as lack of equipment, time constraints and the lack of context-relevant ototoxicity monitoring programs.
- Results of the current study revealed that 70 (91%) of the 77 participants do not conduct follow-up evaluations after every 2-3 days per week. This may be due to time constraints, increased workload, lack of trained staff and resources. However, majority of the participants i.e. 52 of the 70 participants (74%) conduct follow-up evaluations monthly.
- The type of modification that is commonly made to the recommended ototoxicity monitoring protocol is that the participants only conduct air conduction testing or do not conduct speech audiometry. The reasons for the modification of the international guidelines are time constraints, high caseloads and lack of resources.

6.3. Limitations of the study

The study set out to describe the audiological practices employed by audiologists in the management of a patient with MDR-TB in South Africa. The findings of this study need to be considered in relation to identified limitations of the research:

- The low response rate to the research study, with 93 participants being included in the study. Some participants, while having a dual qualification on the HPCSA register, only practice speech therapy and some therapists that are still registered with HPCSA may be practicing abroad. Therefore, the exact number of audiologists practicing in South Africa could not be determined.
- Participants' numbers vary in reporting of results as some participants failed to respond to some of the questions. This has been identified as possibly affecting the reliability and validity of the findings.
- Majority of the participants were also from Kwazulu-Natal, and therefore results cannot be generalised to the broader audiology community of South Africa.
- More information such as the impact of the modification to international guidelines related to the South African context and its benefits should have been addressed, as this would have provided insight into its application to the South African context.

6.4. Recommendations for Future Research

6.4.1. Research Implications

- A qualitative research method using telephonic interviews, such as that conducted by Venter (2011) would allow audiologists at specialised TB hospitals to elaborate on the need for ototoxicity monitoring, the modifications and its benefits to the patient.
- Conduct audiological testing with the modifications that have been mentioned in this research study and evaluate the effectiveness of the ototoxicity monitoring program in this regard.

6.4.2. Clinical Implications

- Pre and post treatment counselling is considered to aid or assist the patients in adherence to MDR-TB treatment. Therefore, all audiologists should ensure that patients with MDR-TB are counselled. This should be looked into and address in a multi-disciplinary team.
- Audiologists should utilise HFA and SRO in the South African context, as these have proven to be effective means of ototoxicity monitoring.
- Audiologists should work together to develop a contextually relevant pamphlet on ototoxicity, which should be available in the 11 official languages.

6.5. Summary

This final chapter has presented the main findings of the research study, limitations of the research and recommendation for future studies. South Africa is one of the countries that has the highest MDR-TB infection rates which has put strain on the healthcare system. This highlights the use of more aminoglycosides and thus put these patients at risk for developing an ototoxic hearing loss. This, therefore, indicates the need for ototoxicity monitoring in South Africa, so that patients may benefit from the services provided, by being involved in the process of making an informed decisions. However, there are currently no specific guidelines for ototoxicity monitoring in South Africa. However, there are audiologists who are practicing in a way that allows for maximising of resources in an effective manner to ensure a high quality of healthcare. Therefore, this study aimed to describe these practices so that the information can be used to devise contextually relevant evidence-based ototoxicity monitoring protocols for patients with MDR-TB. Furthermore, the findings of this study may help motivate for a more in-depth Department of Health (DOH) and HPCSA ototoxicity monitoring policy, allowing for uniformity among audiologists in TB clinics in South Africa.

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