# Full Length Research Paper

# Ototoxic effects of tuberculosis treatments: How aware are patients?

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This project aimed to determine awareness of South African adults with tuberculosis (TB) of the ototoxic effects of TB medication. 60 adults undergoing TB treatment in Gauteng participated. A semi-structured interview schedule was utilized to collect data. Data analysis used descriptive statistics. Results revealed a generalized lack of awareness amongst the participants regarding TB as a disease, its symptoms and how it is contracted; with 50% of the participants lacking awareness of the importance of adherence to treatment. Furthermore, even though 63% of participants reported auditory symptoms since commencement of treatment, none of them had been referred to an audiologist or an Ear, Nose and Throat specialist for management. In fact none of the participants were enrolled in an ototoxicity monitoring programme, even though 48% of the participants with auditory symptoms reported these symptoms having an impact in their daily lives. Current findings highlight the need for comprehensive counselling and education of patients on ototoxic medications through development and implementation of ototoxicity monitoring programmes as part of patient management.

**Key words:** Aminoglycosides, ototoxicity, hearing loss, tuberculosis, streptomycin, adults, audiologist, otolaryngology.

#### INTRODUCTION

South Africa, like many sub-Saharan countries, witnessed a dramatic upsurge of TB cases over the past decade with the figures reported to have increased 2.5-fold in 2004 reaching a rate of 1468 cases per 100,000 in peri-urban areas (Lawn et al., 2006). This upsurge in the number of TB cases is expected to continue, largely due to co-infection with the HIV (Lawn et al., 2006; Clarke et al., 2006). The general public's neglect of TB control is also reported to play a role in the increased rate of TB infection. Inadequate TB control and poor adherence to treatment result in the emergence of drug resistant TB (Aziz et al., 2006).

Africa remains the global epicentre of the AIDS pandemic (UNAIDS, 2006). Sub-Saharan Africa has been reported to be more severely affected by AIDS than any other part of the world since even though this region forms 10% of the world's population, it constitutes nearly

64% of the worldwide total of infected people (Claton, 2006). South Africa's AIDS pandemic - one of the worst in the world - shows no evidence of a decline (UNAIDS, 2006). Based on South Africa's extensive antenatal clinic surveillance system, as well as national surveys with HIV testing and mortality data from its civil registration system, an estimated 5.4 million people were reported to be living with HIV in 2005, with an estimated 18.8% of adults between the ages 15 - 49 years living with the virus in 2005. Almost one in 3 pregnant women attending public antenatal clinics were living with HIV in 2004 and trends over time show a gradual increase in HIV prevalence among this group (UNAIDS, 2006). This therefore raises the importance of ensuring that management of TB patients is comprehensive and involves all team members critical to the process and this includes audiologists (Campbell, 2007).

Some of the drugs used in the treatment of TB fall under the umbrella term 'aminoglycosides' - a group of antibiotics used to fight against certain types of bacteria (Smith and MacKenzie, 1997). Aminoglycosides include amikacin, gentamicin, kanamycin, netimicin, paromomy-

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cin, streptomycin, tobramycin, and apramycin (Probst et al., 2006). These antibiotics are most notorious for being ototoxic, primarily targeting the renal and cochleovestibular system (Edmunds et al., 2006). Although the renal damage is reported to be generally reversible with cessation of treatment, both the cochlear and vestibular damage is reported to be permanent (Schacht, 1998). As a result of the known ototoxic effects of some of the medications used for TB treatment, it is crucial that patients receiving TB treatment are made aware of the ototoxic signs and when to consult an audiologist and/or otolaryngologist (Fausti et al., 2005) to undergo audiologic monitoring in order to ensure that early identification of the ototoxic effects occurs. This early identification can then be promptly followed by appropriate management in the form of rehabilitative audiology, counselling and education, as well as hearing conservation implementtation, thus highlighting the importance of the current

Treatment regimens for TB are based on whether it is a new patient or a patient requiring re-treatment (Adler, 2004). Streptomycin, a type of aminoglycoside used as part of TB treatment, was the first antibacterial agent to be used effectively against TB (Schuknecht, 1974). Not long after its first use as a treatment for TB, attention was drawn to the ototoxic side effects of streptomycin (Talaska and Schacht, 2005), when a substantial number of TB patients treated with streptomycin were found to develop irreversible cochlear and vestibular dysfunction. De Lima et al. (2006) reported on high frequency sensorineural hearing loss in 75% of TB patients they evaluated in their study. These authors maintain that when patients quit their TB treatment, they are often forced to resume it, using more toxic drugs for even longer periods of time. This increases the chances of ototoxicity. Despite its known reported ototoxic effects, streptomycin is still in use today because it is the best and most effective aminoglycoside antibiotic against TB (De Lima et al., 2006).

Audiological symptoms of streptomycin toxicity include: loss of hair cells in the basal region with secondary neural degeneration in the underlying portion of the cochlea with high-frequency hearing loss, tinnitus, as well as vestibular symptoms due to loss of hair cells in cristae of semicircular canals and maculae (Campbell, 2007). Patients may also present with unsteadiness, ataxia, nausea and/or vomiting (Probst et al., 2006). According to De Lima et al. (2006), healthcare workers prescribing or following up aminoglycoside treatment are expected to ask their patients about auditory and vestibular signs and symptoms in order to identify changes at an early stage; since hearing loss is gradual and irreversible. This highlights the need for healthcare workers working with TB patients to ensure that their patients are aware of symptoms of ototoxicity and that audiologic monitoring occurs as part of standard TB treatment.

Consistent with the pathologic pattern of TB are the audiologic findings of early high-frequency sensorineural hearing loss (Schacht, 1998). This hearing loss is often limited to the higher frequencies and does not usually affect lower frequencies which are utilized in conversational hearing (De Jager and Van Altena, 2002; Campbell, 2007). This therefore increases the need for patient education to ensure that hearing changes are detected early, before the configuration of the hearing loss affects the frequencies which are deemed important for speech understanding. If patients' awareness of the ototoxic potential of TB treatment is not raised, patients may not notice ototoxic hearing loss until a communication problem becomes apparent, signifying that hearing loss within the speech frequency range has already occurred. Similarly, by the time patients complains of dizziness, permanent vestibular system damage may have probably already occurred (Fausti et al., 2005).

Hearing problems due to ototoxic drugs may ensue from a few minutes to several days after drug administration (Martini and Prosser, 2003). However, late and slowly progressive hearing loss occurring several years later is reported to be possible, through synergic effects between drugs and other noxious agents (Martini and Prosser, 2003). As a result, another concern may be that noise exposure, which is a noxious agent, following treatment can act synergistically with aminoglycosides that have not fully cleared from the inner ear (Fausti et al., 2005); thereby increasing the patient's susceptibility to hearing loss for several months after completion of aminoglycoside therapy. This phenomenon again highlights the significance of patient education and provision of recommendations about avoiding excessive noise exposure during and after TB treatment.

Although attempts to achieve a drug concentration only high enough to produce an adequate clinical effect and therapeutic result are made, ototoxicity can occur even in patients who take an appropriate dose or in a single dose; thus making monitoring for ototoxicity an essential part of management for the patient undergoing treatment with ototoxic agents (Vasquez and Mattucci, 2003; Campbell, 2007). In a study conducted by De Lima et al. (2006), where hearing sensitivity of 36 cured TB patients who had been treated with streptomycin was assessed. findings indicated that 75% of the participants presented with auditory disorders. Of those patients who presented with auditory disorders, 85% presented with a bilateral sensorineural high frequency hearing loss. This is a significantly high number of patients who may not be identified if proper otolaryngological and audiological referral criteria are not in place and if patients themselves are not aware of the need for such services. These patients may also not be identified if appropriate and sensitive audiologic measures such as ultra-high frequency measures and otoacoustic emissions are not utilized in the assessment and monitoring of ototoxicity.

When life-threatening illness warrants treatment with ototoxic drugs, preserving the quality of the patient's remaining life is typically a treatment goal (Fausti et al., 2005). Aminoglycosides are infamous for their ototoxic effects; however, the prevalence of infectious, lifethreatening diseases such as TB makes their use understandable (Lonsbury-Martin and Martin, 2001). Hearing loss is indeed not a life-threatening condition; however, it is a severe threat to essential quality of life indicators unless intervention occurs early. The adverse effects of a hearing loss on cognitive-linguistic skills and psychosocial behaviour are well established (Swanepoel, 2006), as well as the serious vocational, social and interpersonal consequences for the patient (Fausti et al., 2005). Thus a discerning awareness of the consequent levels of exposure to damaging treatment is necessary to minimize risk, limit any actual hearing loss and facilitate management for the patient whose hearing is adversely affected (Lonsbury-Martin and Martin, 2001). This can only occur if the patient is educated about what to expect in as far as ear symptoms are concerned so that they are able to seek help when necessary. This is second to development of effective treatment options that are not ototoxic in nature.

The issue of ototoxicity and the need for early identification of its symptoms has received wide attention within the medical fraternity, with, however, little research focusing on the patients' awareness of the side effects of the medication on their hearing, hence highlighting the importance of the current study.

#### **METHODOLOGY**

#### **AIM**

The primary aim of this study was to determine the awareness of adult patients with TB with regards to the ototoxic effects of TB treatments. There were 5 specific sub-aims to the study, namely:

- i) To find out if information was provided to adult patients with TB about the side effects involving the ear.
- ii) To identify the type of information given to the participants regarding TB and its treatment.
- iii) To establish if any of the participants presented with any reports on auditory symptoms.
- iv) To describe the perceived impact of the reported auditory symptoms on the participants' daily living.
- v) To assess recommendations made to participants regarding auditory symptoms.

This study forms part of a larger study that also investigated awareness and knowledge of health care workers of ototoxicity in TB treatment.

#### Research design

This research project took the form of semi-structured interviews, consisting of open- and closed-ended questions within a cross-sectional design. This design was deemed appropriate for the current study because it allowed for large amounts of information to

be obtained from various sources in a short amount of time (Salant et al., 1994). The participants were interviewed once on a one-to-one basis at the participating healthcare facilities since they were all still under the direct observation treatment (DOT) system.

#### **Participants**

#### Sampling procedure

A non-probability convenience sampling technique was utilized in the current study (Burns and Grove, 2001). This sampling technique was deemed appropriate as the current study was restricted to a part of the TB infected population that was readily available to participate in the study (Nieswiadomy, 2002). Participants volunteered to participate in the study following a verbal explanation of what the study entailed. Written information sheets were also provided to ensure informed consent. It is acknowledged that generalization of the findings from the current study is influenced by the nature of the sampling technique adopted in that participants were only recruited from 5 facilities (Devlin, 2006).

#### Participant selection criteria

The participant selection criteria included the following:

- i) The participants had to be on treatment for TB for the first time at the time of the study.
- ii) The participants had to be older than 18 years, with a minimum educational level of grade 10.
- iii) The participants had to have no relationship or be familiar with anyone who had been treated for TB in the past (this was to enable control for previous exposure to knowledge about TB treatment and the risks involved).
- iv) The participants had to be alert, cooperative and be able to fully participate in an interview.
- v) The participants were not to be health care professionals or be working in a health care setting.

#### Description of participants

A total of 60 participants who were undergoing TB treatment were interviewed for the current study (Table 1). The participants ranged from 22 to 53 years with a mean age of 32 years. The sample consisted of both males and females, with a slightly higher number of females.

#### Testing procedures and materials

#### Interview schedule

Semi-structured interview schedule was used to conduct the research study. A semi-structured interview schedule (Appendix A) was used to gain a detailed picture of the participant's beliefs or perceptions about information pertaining to ototoxicity which may or may not have been shared with them (Salant et al., 1994). This method gave the researchers and participants more flexibility and allowed for in-depth information to be attained. The researchers were able to follow-up particular interesting avenues that emerged in the interview and the participants were believed to have been able to provide a fuller picture of their experiences. With a semi-structured interview, the researcher has a set of predetermined questions on an interview schedule, but the interview is guided by

**Table 1.** Demographic profile of all participants in the study (N = 60).

Factor	Sub-Category	Number	Percentage
Age Range	22 to 53 years	60	(mean age:
Age hange			32 years)
Gender	Male	22	37%
	Female	38	63%

Table 2. Summary of what participants were told about TB (N =

Themes that emerged	Percentage of participants who reported this
Told about their diagnosis of TB and its infectious nature	100%
Told about TB, its symptoms and how it is contracted.	40%
Told that they have to take their medication (but only 50% reported being told about the importance of completing the TB treatment).	100%
Told that they have TB because of HIV	10%
Told about general side effects of TB medications.	6%

the schedule rather than be directed by it (Greeff, 2002).

The interview questions were developed following the aims of the study. Interview questions were divided into 5 subsections:

- A) Demographic Information: To characterize the sample, information was obtained regarding the participants' age, gender, previous exposure to TB, etc.
- B) TB treatment: This section involved obtaining information regarding participants' health, their TB diagnosis and treatment.
- C) Ototoxicity: To determine presence of any ototoxicity symptoms as well as to establish patients' awareness of these.
- D) Audiology and TB management: To determine the treatment regime that the patients were undergoing including education; possible lifestyle changes; impact of TB and its treatment on the activities of their daily living.
- E) Recommendations: To determine what recommendations the patients were given by healthcare workers as part of their treatment.

#### Validity and reliability

Prior to the conduct of the current study, the interview schedule was pilot tested with nine patients who did not form part of the main study. These patients, consisting of 5 females and 4 males between the ages of 24 and 49 years were recruited from one of the sites where the study was conducted 4 weeks before the actual study. Deficiencies in the research tool with regards to the design of some of the questions in the interview schedule were addressed. Following infection control measures proposed by Kemp and Roeser (1998), all interviews were conducted in a guiet room where each participant was seen individually. Participants were interviewed in the language they preferred including English. Other languages, other than English, used in the study included Zulu, Sotho, Xhosa and Tswana with the researchers being proficient in all of them.

To enhance the reliability of the findings, responses were transcribed by the principal researcher with re-transcription of half of the interviews performed by a second researcher. It is acknowledged that the nature of the interview did not eliminate the possibility of participants providing socially desirable answers. Furthermore, participants' educational level as well as socioeconomic status could have influenced findings as these variables were not controlled for.

#### Data analysis

Data obtained was analyzed using a qualitative statistical approach where descriptive and content analysis procedures were employed (Durrheim, 2006). The researchers transcribed the interviews and highlighted significant themes, words, phrases and statements. The researchers then grouped similar topics together to form major topics (Holstein and Grubrium, 1998). Related categories were then grouped together into the following.

#### **Ethical considerations**

Ethical clearance was obtained from the University of the Witwatersrand, Human Research Ethics Committee (medical) before the study was conducted (protocol number: M070313). The researchers ensured that permission was obtained from the relevant authorities such as the Chief Executive Officers, Matrons and Heads of departments at the research sites. The participants were then invited to participate in the study where the researcher verbally explained the purpose of the study in the participant's preferred language. Following verbal explanations, a participant information sheet was given to all participants who volunteered to form part of the study, and written informed consent to participate in the study was obtained before the participants were interviewed with an assurance that confidentiality would be maintained. Furthermore, to ensure anonymity, participants were assured that no personal or identifying information would be included in the research report as research coding numbers instead of identifying information were to be used. Moreover, participants were assured that they could stop participating in the study at any moment without any negative consequences thereby ensuring that their autonomy was not violated. Lastly, the participants were given the opportunity to request to see the research results if they were interested.

#### **RESULTS**

#### Understanding of TB as a disease

Table 2 revealed apparent inconsistency in what participants were informed regarding TB as a disease. All participants were provided with information regarding their diagnosis of TB as well as its infectious nature. However, less than half of the participants reported being educated about TB, its symptoms and actually how it was contracted. Furthermore, although all participants were told

**Table 3.** Summary of audiological data reported by participants (N = 60).

Questions	% of participants who answered Yes	% of participants who answered No	% of participants who answered Not Sure
1. Do you know what the side effects of TB medication are on the ear?	20%	70%	10%
2. Have you ever had your hearing tested	0%	100%	0%
3. Have you ever been referred to an audiologist for a hearing test since you've been diagnosed with TB?	0%	100%	0%
4. Before you had TB, have you ever experienced?			
Tinnitus (ringing or buzzing)	0%	100%	0%
Vertigo (dizziness)	10%	55%	35%
Nausea	10%	90%	0%
Hearing Loss	7%	93%	0%
5. Since you have started taking your TB medication do you experience any of the following:			
Tinnitus (ringing or buzzing)	20%	70%	10%
Vertigo (dizziness)	10%	55%	35%
Nausea	0%	90%	0%
Hearing Loss	33%	57%	10%
6. Do any of the above problems (tinnitus, vertigo, nausea, hearing loss) affect your performance of activities of daily living (n = $38$ )	32% consistently 16% sometimes	52%	0%

that they have to take their medication, only half of the participants indicated that they were informed about the importance of adherence and completion of TB treatment. Interestingly, 10% of the sample reported being told that they had contracted TB because of their HIV positive status.

#### Understanding of TB treatment and its side effects

From themes that emerged from the data analysis, it was found that although all participants were told to take their medications, only 6% of the participants indicated an awareness of possible side effects of this medication. Furthermore, although all participants indicated taking medications other than the prescribed TB medication, none of them were aware of possible side effects of any of the other medications they were on. In the current sample, 27% reported receiving antiretroviral (ARV) treatment in addition to the TB medication, however, none of them reported being aware of possible side effects of these treatments ether singly or in combination.

#### Ototoxic effects and audiological management

As far as ototoxicity assessment and management, Table

3 depicts that none of the participants had been referred for a baseline audiogram or was enrolled in an ototoxicity monitoring program. 20% of the participants indicated some awareness of what the possible side effects of TB medication are on the ear. 27% of the participants reported having experienced auditory symptoms prior to TB treatment and this number increased to 63% after commencement of TB treatment. The auditory symptoms reported included tinnitus, vertigo, nausea and/or hearing loss. Of note is the increase in reported hearing loss before and after treatment from 7 to 33%.

Of the 38 participants with auditory symptoms following commencement of TB treatment, 63% indicated that when they reported these symptoms to the healthcare workers, they were informed that the symptoms were a side effect of the TB medication and would subside after treatment, hence no recommendations were made with regards to assessment and management of these symptoms, although some of the participants were referred for cerumen management.

# Auditory symptoms and their impact on activities of daily living

Participants experiencing auditory symptoms were asked

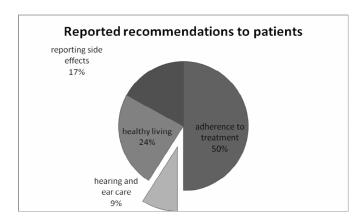


Figure 1. Reported recommendations made to participants during TB treatment.

whether the symptoms affected their activities of daily living. As shown in Table 3, 32% of the participants reported that their auditory symptoms affected their daily lives consistently, while 16% indicated that the symptoms only affected their lives sometimes. Almost half (52%) indicated that the symptoms did not affect their lives in any way. It was observed that the participants who reported that the symptoms were affecting their daily lives consistently were mostly those who experienced a hearing loss and/or consistent tinnitus. Those who reported that the symptoms only affecting their lives some-times were participants who reported only experiencing brief periods of tinnitus, with no hearing loss.

#### Recommendations made to TB patients as part of TB treatment

As can be seen in Figure 1, the main recommendation reported by participants that healthcare workers provided was compliance to and completion of treatment. Some participants (24%) reported "healthy living" as another recommendation that they received, as well as reporting of side effects such as vomiting and diarrhoea (17%). Of note is that no reports of recommendations relating to monitoring auditory function and reporting potential ototoxicity-related side-effects to the nurse or doctor were obtained. The 9% who reported having been provided with recommendations pertaining to hearing and ear care referred only to cerumen management, after those participants had reported decreased hearing.

#### DISCUSSION

It is clear from the findings of the current study as depicted in Table 2, that patients undergoing TB treatment require significant amount of education regarding the

disease itself, how it is contracted and its symptoms, as well as its treatment; including possible side effects of these treatments. The disparity in the information provided to participants in the current study is of major concern particularly since TB is an infectious condition that not only places the patient infected at risk but the general population as well. Results from the current study also indicate that there are a large number of patients who may not be receiving proper and comprehensive counselling and education with regards to their disease and the treatment they are receiving.

Consequently, patients may not be aware of the adverse side-effects to expect from their medications and the relevant professionals to consult when the need arises.

The heterogeneity in the responses from the current sample highlights the lack of consistency in the treatment protocols followed by all patients and raises the need for the dissemination of a more uniform information treatment plan to ensure patients' understanding which may aid in enhancing adherence to treatment. Patient awareness has been seen to have a positive effect on success treatments. Furthermore, the fact that all participants were on medications other than TB treatment and were not aware of ototoxic side effects raises a concern since concomitant use of other medications with ototoxic drugs can exacerbate the symptoms of ototoxicity in terms of presentation and progression of the symptoms (Fausti et al., 2005). Awareness of this information is crucial to the patients' empowerment enhancing their ability to be actively involved in their care and treatment. Several authors have reported on the ototoxicity of ARVs (Christensen et al., 1998; Williams, 2001; Simdon et al., 2001; Rey et al., 2002) and a combination of these two forms of treatment may prove more ototoxic, hence alerting patients to this possibility and ensuring that their hearing is monitored should form part of the comprehensive management of the patients. Besides improving quality of life of the patients, improved patient awareness regarding side effects has been proven to enhance adherence to treatment and contributes positively to the patients' recovery period.

The fact that no ototoxicity monitoring plans were instituted for any of the participants in the current study may speak to the lack of audiological resources that developing countries such as South Africa may have (Swanepoel, 2006; Khoza et al., 2008). Lack of baseline and subsequent hearing monitoring for patients on ototoxic medications may hinder efficacious and comprehensive management of patients which leads to delayed identification and management of hearing difficulties. Audiological referral protocols have been found to be deficient in adult cancer chemotherapeutic state clinics in South Africa (de Andrade et al., 2009) and the same conditions may be influencing referrals of patients with TB for audiological assessment and management found in the current study. The current study clearly indicates a need for establishing such referral protocols with 63% of participants indicating auditory symptoms following commencement of TB treatment. Since the main auditory symptom reported was hearing loss (33%). prompt referral to audiologists may improve the patient's quality of life if this hearing loss was managed early. The high prevalence of reported auditory dysfunction in the current study is consistent with literature reports on ototoxicity related to TB treatment (De Lima et al., 2006; Campbell, 2007). Tinnitus and dizziness are reported to usually be the first symptoms of ototoxicity and in many cases precede a hearing loss (Catlin, 1981). Health care workers involved in TB treatment should increase their own awareness of ototoxic symptoms of TB medications so they are in a better position to appropriately advise patients who report these symptoms. The current study indicated that when 63% of the participants with auditory symptoms reported these to their health care providers. none of them had been referred to an audiologist or an ear, nose and throat specialist for investigations; only cerumen management at a local clinic was recommended.

Although only 33% of participants reported hearing loss as a symptom of auditory dysfunction following TB treatment in the current study, it should be noted that no formal audiometry testing was conducted and so there may be under-reporting of hearing difficulties by participants. This belief is based on the fact that hearing loss is typically evident to the individual, once the hearing loss is severe enough to affect the speech frequencies essential for speech perception (Konrad-Martin et al., 2005); and in the case of ototoxicity, the high frequencies are affected first with progression to lower speech frequencies occuring later (De Jager et al., 2002) and so most participants in the current study may not have reported the hearing loss because it was at the initial stages of ototoxic hearing loss.

Findings from the current study, with regards to the impact of auditory symptoms on daily activities, support the importance of ensuring that these symptoms are addressed as part of the main management as these results indicate that patients' quality of life is impacted upon consistently as reported by 32% of the participants in the study. Failure to identify and address side effects of medications not only impacts on quality of life but may also have significant implications for patient adherence to the treatment regimen which is critical for proper control of infectious diseases such as TB (Powderly, 2003). The fact that 52% of participants reported no impact on their daily lives is consistent with literature which states that the degree to which an individual's impairment impacts on their daily life is based on a variety of variables and as a result different individuals may be affected differently by the same impairment Catlin (1981).

Nevertheless, pharmaco-vigilance in the form of moni-

toring all side effects of treatment modalities should not be sidelined in any treatment plan – monitoring and managing effects of the disease itself and side effects of anti-TB drugs should be one of the cornerstones of any successful and efficacious treatment plan. It is believed that monitoring and managing side effects of anti-TB treatment will enhance the success of the treatment programmes that the government is implementing, since adherence to treatment has been shown to be closely linked to the side effects of drugs implemented (Powderly, 2003).

Lastly, findings from the current study highlight the importance of the provision of follow-up recommendations to patients to ensure that holistic management is provided. The fact that only half of the sample was informed about the importance of adherence to medications and only 9% had any input on ear care highlights the need for enhanced awareness amongst the health care professionals themselves. Furthermore, dissemination of this information to the patients needs to form part of the treatment plan that all patients undergo to ensure better success and improved benefit from medical intervention.

#### Conclusion

The results of this study indicate that there is a lack of awareness of ototoxicity amongst patients receiving TB treatment and that health care workers may not be disseminating this information to the patients to empower them to become more actively involved in their own treatment plans. Patients are not fully aware of the symptoms of ototoxicity and as a result symptoms may persist without the patient receiving any form of audiological and otolaryngological evaluation, monitoring and management. Where patients report side effects such as tinnitus, vertigo, nausea and hearing loss; these symptoms are reportedly attributed to side-effects that will wear-off and no further investigations are recommended.

Although health care workers are responsible for imparting knowledge to patients about ototoxicity and the importance of having their hearing tested and monitored by an audiologist; availability of resources such as audiologists and audiological testing facilities as well as otolaryngologists in clinics where ototoxic medications are used is just as important. Health care facilities involved in treating patients with TB need to ensure that patient education regarding all side effects of drugs being used forms an important part of the treatment plan. This can only happen if all facilities involved in treating TB patients implement and properly manage ototoxicity-monitoring programs as part of their treatment plans.

The results of this study, though significant, should be interpreted with caution due to some methodological limitations that were identified in the design of the study.

These limitations include the fact that the sample size was small and only included a few sites involved in TB treatment in Gauteng; hence the results may not be the same in other institutions and other provinces. A larger sample size would have influenced the ability to generalize the findings to a wider population; therefore an implication for future studies. Furthermore, the study only targeted patients from public institutions. And lastly, the auditory symptoms and the quality of life reports were based on patient reports only and not on formal validated outcome measures; therefore findings may have been different if all participants had undergone formal investigations.

Nevertheless, findings from the current study highlight the need for intensified efforts into patient education as well as in development and implementation of ototoxicity monitoring protocols in institutions that manage conditions where ototoxicity of treatment is an established risk. This is over and above intensified efforts into research and development of drugs that are not ototoxic in nature. A closer working relationship between the audiologists and healthcare workers involved in TB treatment needs to be established with audiologists ensuring pre-treatment assessments with monitoring for all patients enrolled in these treatments. These assessments should include ototoxicity sensitive measures such as ultra-high frequency testing as well as the use objective and less time-consuming tests such as otoacoustic emissions. Some implications for future research include replication of the current study in larger sample sizes at various sites across the different South African provinces as well as in private practice.

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# Appendix A.

## Interview Schedule: Ototoxicity and TB

Demographic Information.

Gender:	Male:	Female
Age		
When diagnosed?		

#### Information on TB

	Yes	No
1. Were you told what TB is?		
2. What were you told about TB?		
3. Do you know how you get TB?		
4. How did you get TB?		
5. Do you know the signs of TB?		
6. If yes what are the signs of TB?		
7.Were you given information about the types of TB		
8. What are the types?		
Additional information		

#### Medicine

	Yes	No
9. Did you receive any medication for TB?		
10. If yes what were told about the medication?		
11. Do you know what the side effects of TB medication are?		
12. What were you told about the side effects of the TB treatment?		
13.Are you taking other medications beside TB medication		
14. If yes what are you taking the medicine for?		
15. What advice or warning were you given, when you were handed the medicine?		
Additional information		

#### Audiological Information

	Yes	No
16. Have you ever had your hearing tested		
17. Have you ever been referred to an audiologist for a hearing test since you've been		
diagnosed with TB?		
If yes, why were you referred?		
18. Do you know what the side effects of TB medication are on the ear?		
19. Before you had TB, have you ever experienced?		
Tinnitus (ringing or buzzing)		
Vertigo (dizziness)		
Nausea		
Hearing Loss		
20. Since you have started taking your TB medication do you experience any of the		
following:		
Tinnitus (ringing or buzzing)		
Vertigo (dizziness)		
Nausea		
Hearing Loss		
21. If you answered yes to any of the above what have you done about it?		
22. If you did do something about it, what steps were taken to assist you?		
23. Do any of the above problems (tinnitus, vertigo, nausea, hearing loss) affect your		
performance of activities of daily living		
If the answer is yes, please elaborate		
Sometimes?		
Always?		
Inconsistently?		