

AUDIOMETRY IN THE MANAGEMENT OF DRUG-RESISTANT TUBERCULOSIS



USAID
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 **KNCV**
TUBERCULOSIS FOUNDATION

CHALLENGE  **TB**

AUDIOMETRY IN THE MANAGEMENT OF DRUG-RESISTANT TUBERCULOSIS

VERSION 1
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Contents

Acknowledgements	3
Background	4
Hearing and Balance	4
What is hearing loss?	4
Audiometry, the audiometer and the audiogram	5
Management of hearing loss in DR-TB treatment	6
Monitoring and management of hearing during and after DR-TB treatment	6
What are the indications for stopping the SLI?	9
In case the injectable is critical to cure, what changes may be made to prevent progression of ototoxic effects?	9
What can we do for patients who have developed hearing loss?	9
Guide in the choice of audiometers	10
Challenge TB Project's recommendation for audiometry	11
Annexes	12
Annex 1: Hearing Loss Severity Grading (WHO Classification)	12
Annex 2: Hearing Loss Severity Grading (BIAP - Bureau International D'Audiophonologie)	13
Annex 3: Ear disorder severity grading scale (DMID and CTCAE)	14
Annex 4: Audiometer models	16
Annex 4A: Audiometer models that test beyond 8000 Hz	16
Annex 4B. Audiometer models that test up to 8000 Hz only	18
Annex 5: Description of testing procedure, programmatic advantages and disadvantages	20

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Background

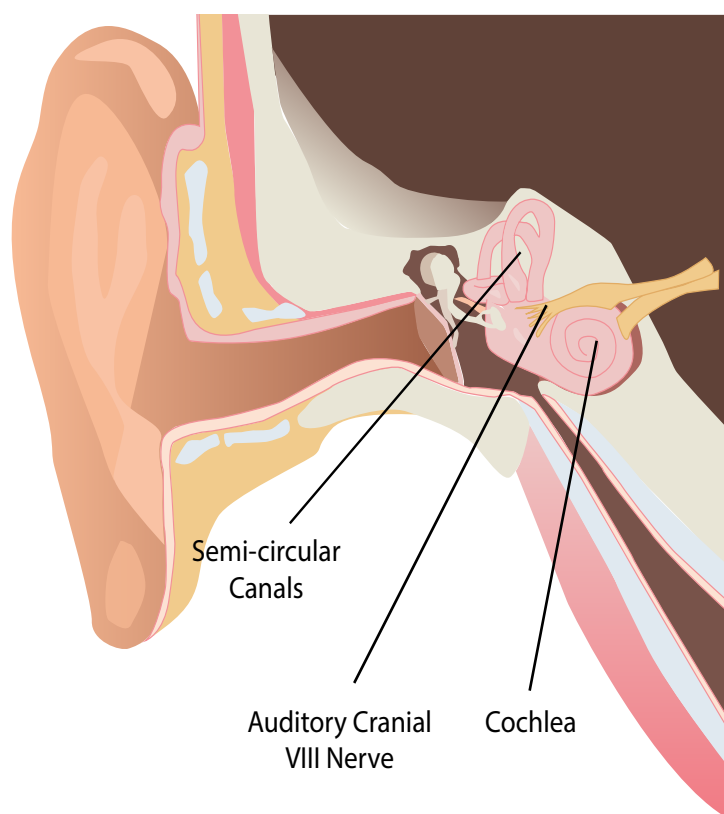
Quality of life in people with drug-resistant tuberculosis (DR-TB) can be badly affected by adverse drug reactions during treatment, and even after treatment due to sequelae from the disease and its treatment. The second-line anti-TB injectables (SLIs) are an essential class of agents in the treatment of DR-TB. Unfortunately, these drugs are known for causing adverse reactions that may have lasting effects, such as hearing loss.^{1,2} Hearing is a vital function for every individual and must be preserved. It is important to diagnose hearing loss as early as possible as it has a potential impact on children's learning and development, and, among adults, it has an impact on employment, education, and general well-being.

This guide is intended to help health providers use audiometry to make informed and patient-centered decisions to prevent and manage ototoxicity resulting from SLIs.

Hearing and Balance

The inner ear contains the sensory organs for hearing and balance. The cochlea is the hearing part of the inner ear, while the semicircular canals in the inner ear are part of our balance system. (see Figure 1: Hearing and balance functions of inner ear)

Figure 1: Hearing and balance functions of the inner ear



What is hearing loss?

Normal hearing thresholds are at 25 decibels (dB), or lower, in both ears. A person is said to have hearing loss if they are not able to hear as well as someone with normal hearing. Hearing loss may vary in severity. It can affect one ear or both ears, and can lead to difficulty in hearing conversational speech or loud sounds.³

1 Torun, T., Gungor, G., Ozmen, Y., Bolukba, I., Maden, E., Bicakci, B., & Atac, G., et al. (2005). Side effects of associated with the treatment of multidrug-resistant tuberculosis. *The International Journal of Tuberculosis and Lung Disease*: 9 (12), 1317-1377.

2 Selimoglu, E. (2007). Aminoglycoside-induced Ototoxicity. *current pharmaceutical design journal*:13(1), 119-26.

3 <http://www.who.int/mediacentre/factsheets/fs300/en/>

Damage to the inner ear (cochlea) leads to sensorineural hearing loss (SNHL), also known as nerve-related hearing loss. The possible cause or exacerbating factor in sensory hearing loss may be the toxicity of drugs including SLIs. Most of the time, SNHL cannot be medically or surgically corrected. This is the most common type of permanent hearing loss. In contrast to SNHL, conductive hearing loss is caused by a problem in the ear canal, ear drum, middle ear and little bones.

Audiometry, the audiometer and the audiogram

Audiometry is the procedure that tests a person's ability to hear various sound frequencies, and is used to identify and diagnose hearing loss. The test is performed using an electronic equipment called an **audiometer**. Audiometry may be done using air conduction and bone conduction tests. Both report hearing thresholds in a similar way; the difference is on how the stimulus is delivered, i.e., through the ear canal (air conduction) or through the bone behind the ear (bone conduction), as shown in the pictures below. Not all audiometers come with bone conduction testing capacity. Fortunately, screening audiometry only requires air conduction.

Air Conduction

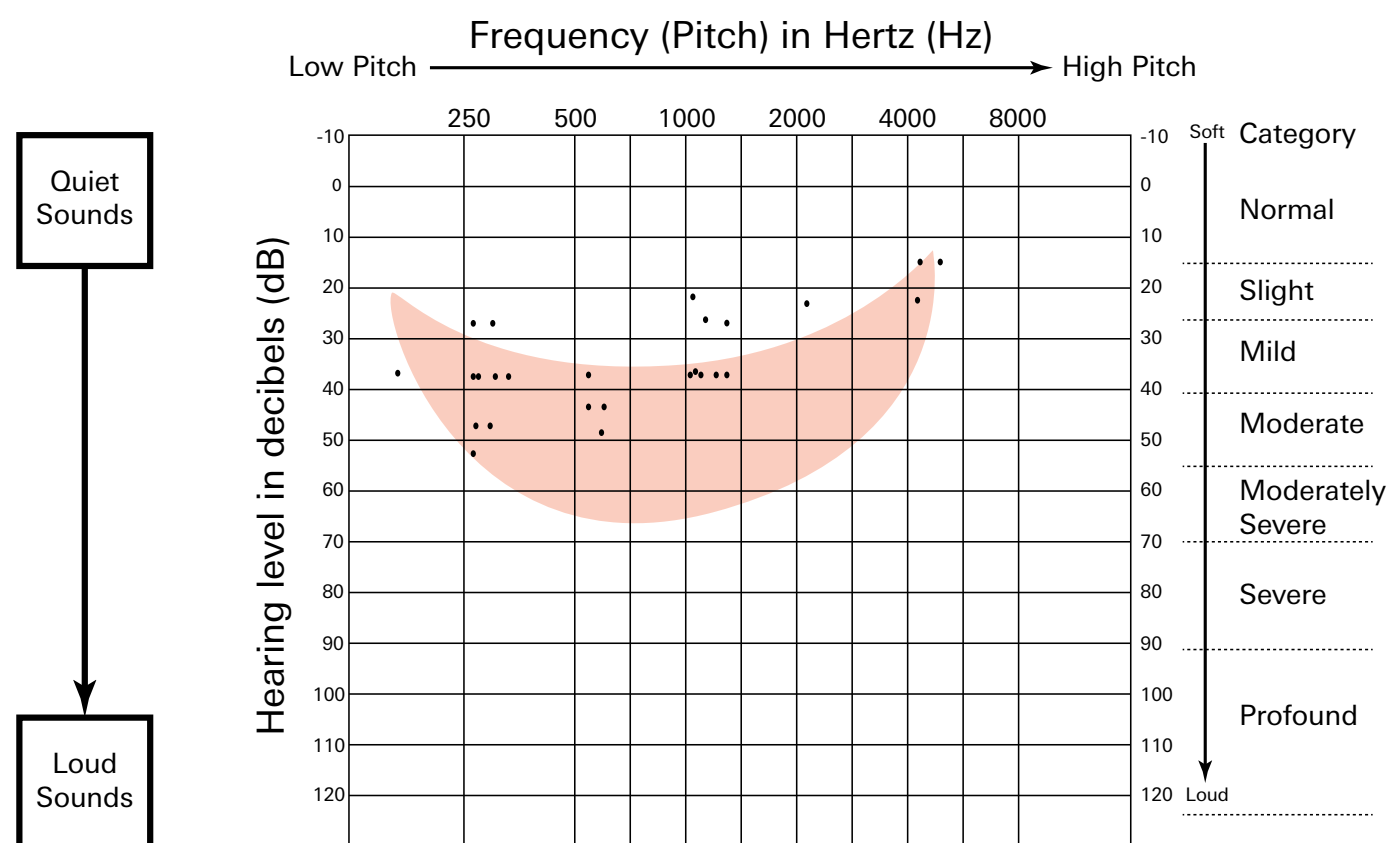


Bone Conduction



The **audiogram** is a graph showing the result of a pure tone audiometry or the hearing test which determines the faintest tones a person can hear at selected pitches or frequencies from low to high. It illustrates the type, degree, and configuration of hearing loss, where patients' responses are recorded on the graph that shows intensity levels for each frequency tested (see Figure 2: Sample of an audiogram). The frequency or pitch of a sound is referred to in Hertz (Hz). The intensity or loudness of a sound is measured in dB.

Figure 2: Sample of an audiogram



Management of hearing loss in DR-TB treatment

Ototoxicity refers to the damage to the auditory cranial nerve (VIII) causing irreversible symptoms, such as hearing loss, tinnitus (ringing of the ear), and/or other vestibular symptoms such as nystagmus, ataxia, and disequilibrium. It is a serious disability of different grades (see Annex 1: Hearing Loss Severity Grading -WHO Classification), Annex 2: Hearing Loss Severity Grading- BIAP, and Annex 3: Ear disorder severity grading scale - DMID) that must not be underestimated nor ignored. According to various reports available in literature, the incidence of ototoxicity from different causes varies from less than 10% to 50%.⁴ A decrease in hearing due to ototoxic drugs starts at high frequencies, and so does hearing loss due to advancing age. A genetic predisposition adds to the possibility of developing such a hearing loss. The risk is also greater in patients with HIV infection,^{5,6} who are seen to develop ototoxic hearing loss more frequently than non-HIV patients. The ototoxic effects of anti-retroviral therapy are also well documented.⁷

Monitoring and management of hearing during and after DR-TB treatment

Audiometry is recommended as a baseline test for all patients starting DR-TB treatment, and as a follow-up test while on the SLI. The following points will help health care providers in detecting early hearing loss using clinical awareness and audiometry to aid in decision-making regarding the use of SLI in the management of DR-TB.

4 James, A. S., Peter, G., Kayleen J., Adam, E., Anneke, C. H., & Schaaf, H. S (2012). Hearing loss in patients on treatment for drug-resistant tuberculosis. *European respiratory journal*: doi: 10.1183/09031936.00044812.

5 Harris, T., Bardien, S., Schaaf, HS., Petersen, L., De Jong, G., & Fagan, J.J. (2012). Aminoglycoside-induced hearing loss in HIV-positive and HIV-negative multidrug-resistant tuberculosis patients. *South African Medical Journal*: 102(6 pt 2), 363-6.

6 Trebucq A. Results of the Union's observational study of the 9-month MDR-TB regimen in Africa. Oral communication, the 47th World Conference on Lung Health, Liverpool, 26-29 Oct 2016.

7 Khoza-Shangase, K., Mupawose, A., & Mlangeni, N.P. (2009). Ototoxic effects of tuberculosis treatments: How aware are patients. *African journal of pharmacy and pharmacology*: 3(8), 391-399.

1. Health care providers responsible for initiating, dispensing and managing DR-TB treatment should be aware of the risk of ototoxicity, its early symptoms and signs, diagnosis, and management. This must be a part of a training program for clinical staff in DR-TB management. TB programs must have a management protocol based on the resources of the health system, with clear roles and responsibilities to ensure early detection and proper management of hearing loss.
2. Patients should be made aware of the possible adverse effects of therapy, including information about the early symptoms of ototoxicity, such as tinnitus and dizziness, and the irreversible effects, such as hearing loss and dizziness. Strengthening patient awareness regarding adverse effects may prevent deterioration of the quality of life of the patient as a result of treatment, and also have significant implications on patient adherence to the treatment regimen.^{8,9}
3. A **baseline** screening audiometry determining at least air conduction thresholds should be performed on all patients initiated on therapy that includes an SLI.
Five percent of the world's population has disabling hearing loss defined as a hearing threshold greater than 40 dB in the better hearing ear in adults, and greater than 30 dB in the better hearing ear in children due to a variety of causes. This includes one third of those over the age of 65 years; many more may have lesser degrees of loss. Hence, it is important to attain a baseline record of the hearing status of a person prior to treatment initiation.
4. Regular audiological follow up must be undertaken. Detecting changes in the pure tone threshold directly, and using serial audiograms is the most effective indication of ototoxic hearing loss.

*Ideally, since the nature of the damage done by the ototoxic medicine leads first to **high frequency** hearing loss, a high frequency audiometry is recommended with audiological testing undertaken to determine air conduction thresholds at frequencies from 125 to 20 000 Hz, at weekly intervals.^{10,11} However, in consideration of the fact that most persons undergoing treatment for DR-TB, reside in low-resource settings with lack of technical resources and personnel, an alternate management has been suggested in literature.^{12,13} This includes:*

Monthly screening audiometry including speech frequencies and higher frequency of up to 8000 Hz while on SLI. "Speech frequencies" refer to pitches of sound commonly attributed to human speech. These range from 250 to 6000 Hz. Figure 3: Audiogram (see below) is an example of an audiogram showing high frequency (8000 Hz) hearing loss of both ears due to aminoglycosides.

8 Trebucq A. Results of the Union's observational study of the 9-month MDR-TB regimen in Africa. Oral communication, the 47th World Conference on Lung Health, Liverpool, 26-29 Oct 2016.

9 Powderly WG (2003). Introduction.s J. AIDS. 33(1): S5–S6.

10 Khoza-Shangase, K., Mupawose, A., & Mlangeni, N.P. (2009). Ototoxic effects of tuberculosis treatments: How aware are patients. African journal of pharmacy and pharmacology: 3(8), 391-399.

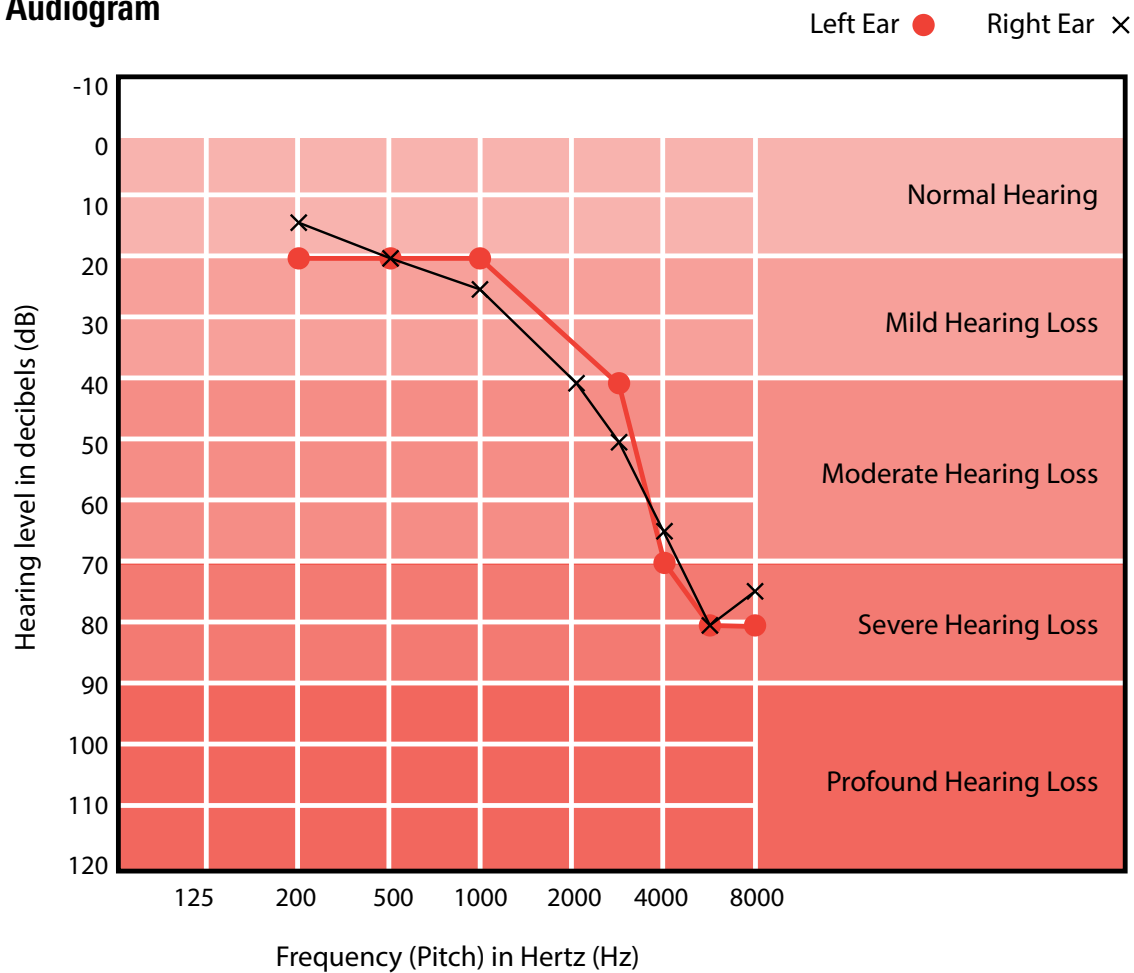
11 American Speech-Language Hearing Association. (1993). Audiological Management of Individual Cochleotoxic Drug Therapy: Ad Hoc Committee on Audiologic management of Individuals Receiving Ototoxic and/or Vestibulotoxic Drug Therapy. Available at <http://www.asha.org/policy/GL1994-00003.htm> (accessed 07 May 2013).

12 <http://www.who.int/mediacentre/factsheets/fs300/en/>

13 Department of health, Republic of South Africa. (2011). Management of drug-resistant tuberculosis: policy guidelines. Pretoria: Author. Available at <http://www.info.gov.za/view/DownloadFileAction?id=165278> (accessed 07 May 2013).



Figure 3: Audiogram



In case of the occurrence of any of the conditions mentioned below in Table 1: Ototoxicity conditions that warrant weekly audiometry, while on the SLI, and the SLI cannot be stopped as it is critical to cure, a detailed audiological assessment by pure tone audiometry should be immediately undertaken to assess the status of hearing, then increase the frequency of audiometry to weekly as indicated in the table.

Table 1: Ototoxicity conditions that warrant weekly audiometry, while on a treatment regimen including an SLI

1. Complaint of tinnitus, dizziness or vertigo, and hearing loss.
Patients are to be asked about tinnitus, and vertigo/dizziness everyday while on treatment with an SLI, whether in the clinic or on ambulatory career. These are early symptoms of ototoxicity. Hearing loss will only be appreciated by patients at a later stage, when the hearing loss has extended to speech frequencies; hence, a change in hearing or hearing loss is not a good indicator for early detection. Causes of conductive hearing loss, such as ear wax, otitis media, tympanic perforation, are to be excluded.
2. Screening audiometry suggestive of ototoxicity, based on the following criteria,¹⁴ (with changes always computed relative to baseline):
 - Decrease in hearing threshold by 20 dB or more at any one test frequency
 - Decrease in hearing threshold by 10 dB or more at any two adjacent frequencies
 - Loss of response at three frequencies where responses were previously obtained

5. Note that as the ototoxic effect of SLIs may continue to progress up to 6 months after completion of therapy^{14,15}, repeat audiometry is advisable **3 and 6 months** after completion of the SLI, if feasible.

What are the indications for stopping the SLI?

Since ototoxicity is an irreversible adverse effect of SLIs, its presence may necessitate discontinuation of the causative agent. The following are indications for stopping the SLI:

Tinnitus or unsteadiness attributable to vestibular toxicity. Persistent vertigo and ataxia an intolerable toxicity and not reversible.

- Moderate or severe hearing loss. Annex 1: Hearing Loss Severity Grading -WHO Classification, Annex 2: Hearing Loss Severity Grading - BIAP, and Annex 3: Ear disorder severity grading scale - DMID are among the available grading scales which will help grade the severity of the hearing loss. The below note * is a description of these grading scales, guiding countries in determining which one best fits their setting.
- When stopping the SLI, new DR-TB drugs, such as bedaquiline and delamanid, and repurposed drugs should be used as alternatives to the injectable agent. Knowing that there are other treatment options will empower DR-TB health providers to make patient-centered decisions when faced with ototoxicity.

* Note on the severity grading scales: The WHO Classification provides a good visual representation of severity that is easy to understand, and is applicable to both adults and children. It allows determination of hearing thresholds per frequency per ear in case of ototoxicity, and allows one to determine the average hearing threshold across frequencies per ear. The BIAP Classification grading uses sub-grades of 1st, 2nd, 3rd degrees, allowing more detailed monitoring of hearing loss over time. It also allows one to get the average hearing threshold across frequencies per ear. The DMID Classification is more comprehensive, where shifts in hearing thresholds are being used to grade severity. However, it is not as straightforward as the other grading scales. It also applies to both adults and children, and has suggestions for management.

In case the injectable is critical to cure, what changes may be made to prevent progression of ototoxic effects?

- Reduce the frequency of administration of the SLI to alternate days, or three times a week.
- Change to Capreomycin (if the patient was receiving an aminoglycoside). Capreomycin, a cyclopeptide, was associated with a comparatively lower risk of ototoxicity; however, health providers must keep in mind that this finding was derived from a small retrospective study of 50 MDR-TB patients with methodological limitations,¹⁶ and therefore is a weak basis for such a conclusion.
- Increase the frequency of audiometry to weekly and use audiometry results in deciding on possible SLI replacement with other agents.
- Monitor for worsening of symptoms of ototoxicity to guide decision-making on whether to continue retaining the SLI.
- Discuss with the patient regarding the possibility of worsening of ototoxicity while on medication and take an informed decision regarding the continuation/ discontinuation of the injectable for the management of DR-TB.

14 Prahlad, D., & Malay, S. (2007). Audiologic monitoring of multi-drug resistant tuberculosis patients on aminoglycoside treatment with long term follow-up. BMC ear, nose & Throat disorder: 7:5. Doi: 10.1186/1472-6815-7-5. <http://bmcear-nose-throatdisord.biomedcentral.com/articles/10.1186/1472-6815-7-5>

15 American Speech-Language Hearing Association. (1993). Audiological Management of Individual Cochleotoxic Drug Therapy: Ad Hoc Committee on Audiologic management of Individuals Receiving Ototoxic and/or Vestibulotoxic Drug Therapy. Available at <http://www.asha.org/policy/GL1994-00003.html>

16 Sturdy, A., Goodman, A., Jose, R.J., Loyse, A., O'Donoghue, M., Kon, O.M., & Dedicoa, M.J., et al. (2011) Multidrug-resistant tuberculosis (MDR-TB) treatment in the UK: a study of injectable use and toxicity in the practice. Audiometer models: 66(8), 1815-1820. DOI: 10.1093/jac/dkr221.



What can we do for patients who have developed hearing loss?

Advise and guide patients regarding suitable options for rehabilitation, including the following:

- Use of hearing devices, such as hearing aids and cochlear implants;
- Sign language education;
- Social and psychological support.

Suitable referral protocols must be put in place for effective management of persons developing ototoxic effects of DR-TB treatment.

Guide in the choice of audiometers

Audiometer models vary in features, such as in the frequencies at which they test for hearing loss. As mentioned above, it is ideal to have a full audiogram undertaken including all frequencies from 125 to 20,000 Hz; however, **when full audiometry is not feasible, one can do audiometry with air conduction, including speech frequencies and higher frequency of up to 8,000 Hz.**

The following are other desired audiometer features in the context of programmatic DR-TB treatment:

- **Good sound management** eliminates the need for a sound booth to do audiometry testing, and allows the test to be done in normal environments, like the clinics or patients' homes. Most audiometers nowadays have this feature either through a built-in device that alerts the tester of too much noise, or through the noise cancelling action of the respective headphones that are used.
- **Dual power supply** can either come from alternating current (A/C) or from a battery, or both. Models with a battery operation option solve the problem of interrupted electricity in the field, or having to find a power source for cord connection. Coupled with portability in size and weight, battery run models allow easy transport from clinics to the field, and from patient to patient in hospitals.
- **Connectivity to a computer.** Audiometers can either be stand-alone devices that test hearing without need for a computer, or they may have the option of connecting to a computer. Stand-alone devices require staff performing the test to manually plot patients' results on pre-printed audiogram sheets to be kept on patients' files. This is prone to error. On the other hand, models with web-based computer connectivity generate electronic recording of audiogram files that can be printed, stored on memory and organized into patient folders rather than kept as manual files. Data storage enables viewing of files at a later time, and facilitates sending of audiogram results for referral to specialists, when necessary, allowing off-site management. Moreover, new features include the ability to automatically generate frequency reports of hearing loss according to age and sex. As more and more countries are using this type of audiometer, data across countries can be pooled together electronically to generate meaningful results from a considerable population size.
- **Patient-friendly procedure.** The method of response from the patient should be one that s/he finds easy and is familiar with. If a patient has never worked with a tablet computer screen before, more so with a touchscreen, it may be challenging to subject the patient to a tablet touchscreen-based test.
- **Calibration:** Audiometers require regular calibration which, in the case of some models,

require that the headphones be shipped to the manufacturer. Country feedback on this kind of arrangement reveals interrupted audiometry testing for months while the calibration is ongoing. This is currently being addressed by Shoebox by providing service headphones to the facility to be used during the calibration period. Local and regional calibrators are also now gradually being engaged by some manufacturers to bring the service closer to the users. The annual cost of calibration for Shoebox is USD \$400 (plus shipping), a recurring cost which can be a burden to countries outside project support. Calibration is part of the so-called “concierge package” that includes training, technical support, and renewal of access to the web portal. If available, the cheaper option is regional and country calibration at a lower cost (USD \$150).

- Most audiometers require minimal **training** of peripheral health staff, which is usually provided by the manufacturer/distributor upon purchase. Routine technical support, usually distant, is often available.
- There is minimal need for **specialist interpretation**, as long as there is program consensus and guidance on what constitutes hearing loss as well as progression of hearing loss; thereby, allowing implementers to use these results for decision-making, i.e., at baseline whether to start the injectable or not, or during monitoring, whether to continue it, reduce the frequency, or altogether stop it.
- Audiometers also vary in **warranty** and **cost**.

Annex 4: Audiometer models shows samples of audiometers that may be considered for use in CTB supported countries. The choice of which model to procure is at the country’s discretion considering local scenarios, e.g., human resources, safety from theft, etc.

Annex 5: Description of testing procedure, programmatic advantages and disadvantages describes the testing procedures of computer-based and stand-alone audiometer models based on actual product demonstration, their advantages and disadvantages in a programmatic setting.

Challenge TB Project’s recommendation for audiometry

CTB’s recommendation regarding the use of audiometry aligns with the recommendation of the “WHO Companion Handbook for the management of drug-resistant TB (DR-TB),” 2016.

Audiometry determining air conduction thresholds is recommended as a baseline test for all patients starting DR-TB treatment on an SLI, then monthly while on the SLI, and weekly in case of the occurrence of any of the following, and the SLI is judged to be critical to cure and cannot be stopped:

1. Complaint of tinnitus, dizziness or vertigo, and hearing loss;
2. Screening audiometry suggestive of ototoxicity, based on changes computed relative to baseline;
 - Decrease in hearing threshold by 20 dB or more at any one test frequency
 - Decrease in hearing threshold by 10 dB or more at any two adjacent frequencies
 - Loss of response at three frequencies where responses were previously obtained

Audiometry is also advised **3 months and 6 months** after completion of the SLI, if feasible.



Annexes

Annex 1: Hearing Loss Severity Grading (WHO Classification)

http://www.who.int/pbd/deafness/hearing_impairment_grades/en/

Disabling hearing loss: refers to hearing loss greater than 40 dB in the better hearing ear in adults and greater than 30 dB in the better hearing ear in children.

Note: While audiometric descriptors may provide a useful summary of an individual's hearing thresholds, they should not be used as the sole determinant for the provision of hearing aids. The ability to detect pure tones using earphones in a quiet environment is not in itself a reliable indicator of hearing disability. Audiometric descriptors alone should not be used as the measure of difficulty experienced with communication in background noise, the primary complaint of individuals with hearing loss.

Figure 4: Hearing Loss Grades

40 dB	41-60 dB	61-80 dB	Over 81 dB
Slight/Mild	Moderate*	Severe	Profound
A person with this level of hearing loss will have trouble hearing and understanding soft speech, speech from a distance or speech against a background of noise.	A person with this level of hearing loss will have trouble hearing regular speech, even at close distances.	A person with this level of hearing loss may only hear very loud speech or loud sounds in the environment, such as a fire truck siren or a door slamming. Most conversational speech is not heard.	A person with this level of hearing loss may perceive loud sounds as vibrations

*In the case of moderate hearing loss, the range for children is 31-60 dB.

Annex 2: Hearing Loss Severity Grading (BIAP - Bureau International D'Audiophonologie)

BIAP Recommendation n° 02/1 bis, AUDIOMETRIC CLASSIFICATION OF HEARING LOSS

Speech is made up of both acute and low-pitched sounds of highly-varied acoustic power. It cannot be measured by means of a single average acoustic level.

After a clinical examination, an audiometric measuring can be done in satisfactory acoustic conditions. It shows a loss in dB, compared with normal hearing level (dB H.L.), with reference to ISO standards. An average tone loss is calculated, taking as a starting point the loss in dB at various frequencies: 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. A frequency which is not perceived is considered as a loss of 120 dB. The total amount is calculated, divided by 4 and rounded up to the nearest unit. In the event of an asymmetric hearing loss, the average loss level, expressed in dB, is multiplied by 7 for the "good" ear and by 3 for the "bad" ear. The total is then divided by 10.

I. Normal or subnormal hearing	II. Mild hearing loss	III. Moderate hearing loss	IV. Severe hearing loss	V. Very severe hearing loss	VI. Total hearing loss - Cophosis
1. Average tone loss					
< 20 dB.	Between 21 and 40 dB.	<u>1st degree:</u> Between 41 and 55 dB. <u>2nd degree:</u> Between 56 and 70 dB. Some daily life noises are still perceived.	<u>1st degree:</u> Between 71 and 80 dB. <u>2nd degree:</u> Between 81 and 90 dB.	<u>1st degree:</u> Between 91 and 100 dB. <u>2nd degree:</u> Between 101 and 110 dB. <u>3rd degree:</u> Between 111 and 119 dB.	> 120 dB.
2. Sound and speech perception					
Mild tone disorder with no social consequences	Speech perceived if voice is <u>normal</u> , difficulties arise if voice is low-pitched or distant from the subject. Most of the daily life noises are perceived.	Speech is perceived if the voice is <u>loud</u> . The subject understands better what is being said if he can see his/her interlocutor.	Speech is perceived if the voice is <u>loud</u> and <u>close to the ear</u> . Loud noises are perceived.	Speech is not perceived. Only very <u>loud noises</u> are perceived.	<u>Nothing</u> is perceived

Annex 3: Ear disorder severity grading scale (DMID and CTCAE)

Table 2: Ear disorder severity grading scale (version 4.0; date 4 July 2016)

Principally based on DMID Nov 2007 and CTCAE v.4.03 14-Jun-2010

Grade 1	Grade 2	Grade 3	Grade 4
A. Hearing loss			
Definition: characterized by partial or complete loss of the ability to detect or understand sounds resulting from damage to ear structures			
ADULTS enrolled on monitoring program on a 1,2,3,4,6 and 8k Hz audiogram			
Threshold shift of 15 -25 dB averaged at 2 contiguous test frequencies in at least one ear or subjective change in the absence of a Grade 1 threshold shift.	Threshold shift of >25 dB averaged at 2 contiguous test frequencies in at least one ear.	Threshold shift of >25 dB averaged at 3 contiguous test frequencies in at least one ear. Therapeutic intervention indicated.	Profound bilateral hearing loss: Threshold >80 dB HL at >2 kHz Non-serviceable hearing
ADULTS not enrolled on monitoring program			
N/A	Hearing loss but hearing aid or intervention not indicated; limiting instrumental activities of daily living (IADL)**	Hearing loss with hearing aid/ or intervention indicated; limiting self-care ADL.*	N/A
CHILDREN enrolled on a monitoring program on a 1, 2, 3, 4, 6 and 8 kHz audiogram			
Threshold shift >20 dB at 8 kHz in at least one ear	Threshold shift >20 dB at 4 kHz and above in at least one ear.	Threshold shift >20 dB at 3 kHz and above in at least one ear; Hearing loss sufficient to indicate therapeutic intervention, including hearing aids. additional speech-language related services indicated.	Pediatrics not enrolled: Audiologic indication for cochlear implant and additional speech-language related services indicated.
B. Tinnitus			
Definition: characterized by noise in the ears, such as ringing, buzzing, roaring or clicking			
Mild symptoms Intervention not indicated	Moderate symptoms Limiting instrumental ADL**	Severe symptoms Limiting self-care ADL*	N/A
C. Vestibular disorder			
Definition: characterized by dizziness, imbalance, nausea, and vision problems			
N/A	Symptomatic Limiting instrumental ADL**	Severe symptoms Limiting self-care ADL*	N/A

***Activities of daily living (ADL):- Self-care**

ADL (Self-care) are a series of basic activities performed by individuals on a daily basis necessary for independent living at home or in the community. There are many variations on the definition of the activities of daily living but most organizations agree there are 5 basic categories.

1. Personal hygiene - bathing, grooming and oral care
2. Dressing - the ability to make appropriate clothing decisions and physically dress oneself
3. Eating - the ability to feed oneself though not necessarily to prepare food
4. Maintaining continence - both the mental and physical ability to use a restroom
5. Transferring - moving oneself from seated to standing and get in and out of bed

Whether or not an individual is capable of performing these activities on their own or if they rely on a family caregiver to perform the ADLs serves a comparative measure of their independence.

****Instrumental ADL (IADL)**

IADLs are actions that are important to being able to live independently but are not necessarily required activities on a daily basis. The instrumental activities are more subtle than the Activities of Daily Living (Self-care). They can help determine with greater detail the level of assistance required by an elderly or disabled person. The IADLs include:

1. Basic communication skills - such as using a regular phone, mobile phone, email or the Internet
2. Transportation - either by driving oneself, arranging rides or the ability to use public transportation
3. Meal preparation - meal planning, preparation, storage and the ability to safely use kitchen equipment
4. Shopping - the ability to make appropriate food and clothing purchase decisions
5. Housework - doing laundry, cleaning dishes and maintaining a hygienic place of residence
6. Managing medications - taking accurate dosages at the appropriate times, managing re-fills and avoiding conflicts
7. Managing personal finances - operating within a budget, writing checks, paying bills and avoiding scams.



<https://www.payingforseniorcare.com/longtermcare/activities-of-daily-living.html#title2>



Other ADL checklists (Katz index of Independence in Activities of Daily Living and Lawton-Brody Instrumental Activities of Daily Living Scale, are available at:

https://clas.uiowa.edu/socialwork/sites/clas.uiowa.edu.socialwork/files/NursingHomeResource/documents/Katz%20ADL_LawtonIADL.pdf



Annex 4: Audiometer models



Annex 4A: Audiometer models that test beyond 8000 Hz

Model and Price	Technical Specifications			Remarks	Link
	Specifications	Power	Dimensions / Weight		
MAICO MA 42 Price: Contact company 	Masking signals Freq modulation: Pulse Tone 0.25/0.5 s on time; warble tone 5% sinus rate 5Hz Freq range: 125 Hz – 8,000 Hz (8,000 Hz – 16,000 Hz optional) Hearing level range: 5 dB, 2 dB or 1 dB level steps Stimulus: Pure tone, pulse tone, warble tone	100 - 240 V~ 50/60 Hz ± 10 %	W x D x H: 13.4" x 7.9" x 3.2" 2.7 lbs	Ideal for on the go hearing healthcare professionals	http://www.maico-diagnostics.com/us/products/audiometers/ma-42/
KUDUwave TM Pro Price: Contact Company 	<ul style="list-style-type: none"> -Records patient response times, ambient noise levels, and other tests -Tests are done quickly with accuracy -Customized tests for MDR-TB ototoxicity monitoring -Needs a computer to run software Freq up to 16,000 Hz 		Include headset, which is a clinical audiometer, two Insert earphones, a bone conductor and an Ambient noise SPL meter – all in one place	<ul style="list-style-type: none"> -Used in Botswana and South Africa rural clinics to monitor for ototoxicity in MDR-TB patients -Complies to South Africa standards -FDA approved 	http://www.emoyo.net/en/the-kuduwave-difference/

<p>ShoeBOX Audiometry for iPad Free Software</p> 	<ul style="list-style-type: none"> -Free software that you download via iTunes onto an iPad -Need a Clearwater Clinical account to access the app -Will need to invest in a pair of audiological headphones -Tests patients in with a game and the responses are interpreted by the health care professional -Cloud based patient data management system Freq up to 16,000 Hz 	Recharge iPad	N/A Used on iPad	<ul style="list-style-type: none"> -FDA and Health Canada approval -Can be used by health professionals without audiology training -Used in 16 countries 	<p>https://www.clearwaterclinical.com/</p> <p>https://itunes.apple.com/us/app/shoebox-audiometry/id873272921?mt=8</p>
<p>HearTest Price: Contact company</p> 	<p>Sennheiser HD 202 II Ear coupling: supraaural Frequency response: 18-18000Hz Sound pressure: 115 dB Harmonic distortion: <0.5% Cable Length: 3m Weight: 130g</p> <p>Sennheiser HD 280 PRO Ear coupling: circumaural Frequency response: 18-25000Hz Sound pressure: 102 dB Harmonic distortion: <0.1% Cable Length: 3m Weight: 220g Both use cloud data management</p>	Mobile, battery operated	Smart phone and set of headphones	<ul style="list-style-type: none"> -Meets international standards for audiometry -Being used by an endTB project -Average screening test is 54.5 seconds 	<p>http://www.hearscreen.com/</p>

Annex 4B. Audiometer models that test up to 8000 Hz only

Model and Price	Technical Specifications			Remarks	Link
	Specifications	Power	Dimensions / Weight		
MAICO MA 25 List: \$933 	Rise/Fall Time: ~3 msec Distortion: 0.5% typical, 2.5% max Crosstalk: -100 dB max On/Off ratio: >80 dB Freq modulation: +/-5% rate at 5Hz Freq range: 125-8000 Hz Hearing level range: -10-100 dB HL, in 5 dB steps Stimulus: Pure tone, pulse tone, warble tone	AC Power cord or 3 AA batteries	8.9" W x 7.1" D x 2.2" H	Ideal for school health care professionals, physicians, and audiologists	http://www.maico-diagnostics.com/us/products/audiometers/ma-25/
MAICO MA 27 List: \$1,146 	Freq range: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz Hearing level range: -10 to 100 dBHL, in 1 and 5 dB steps	117 volts AC, 220 volts AC available	14" wide x 7" high x 17" deep\ 5.28 lbs including power supply, headset, and audiogram pad	Ideal for school health care professionals, physicians, and audiologists	http://www.maico-diagnostics.com/us/products/audiometers/ma-27/

<p>GSI 18 Price: Contact company</p> 	<p>20 to 50 msec Rise/Fall Time:~20-50 msec Distortion: <2.5% Freq modulation: +/-5%, 5 Hz Freq range: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz Hearing level range: -10 to 90 dBHL, 5 dB steps Stimulus: Continuous, pulsed (2.5/sec)</p>	<p>Power cord or 5 AA batteries, lasting up to 10 hours of testing</p>	<p>12.6" (w) x 8.8" (d) x 3.2" (h) 2.5lb</p>	<p>Ideal for schools, industry, and physician's office for screening</p>	<p>http://www.grason-stadler.com/solutions/audiometer/gsi-18/</p>
<p>MAICO MA 40 Price: Contact company</p> 	<p>Rise/Fall Time:35 msec Distortion: 5% typical, 3% max Crosstalk: -100 dB min On/Off ratio: >90 dB Freq modulation: +/-5% rate at 5 Hz Freq range: 125-8000 Hz Hearing level range: Stimulus: Pure tone, pulse tone, warble tone</p>	<p>117/234 volts AC, 50/60 Hz, 25W</p>	<p>12.5" W x 6.25" H x 15.5" D 16.5lbs</p>	<p>Made for rugged environments</p>	<p>http://www.maico-diagnostics.com/us/products/audiometers/ma40/</p>
<p>MAICO MA 1 List: \$714</p>	<p>Rise/Fall Time:35 msec Distortion: 0.5% THD typical, 3% THD max Hearing level range: 15 to 50 dB HL, 5 dB steps Stimulus: Continuous</p>	<p>2 AA batteries</p>	<p>W x L x D: 2.5" x 6" x 7/8" 2.1 lbs includes case</p>	<p>-Hand held -Ideal for school health care professionals, physicians, and audiologists</p>	<p>http://www.maico-diagnostics.com/us/products/audiometers/ma-1/</p>

For more models and companies: <http://www.e3diagnostics.com/home/products-menu-order-list/audiometer>

Annex 5: Description of testing procedure, programmatic advantages and disadvantages

Type of audiometer and procedure	Advantages	Disadvantages
<p>Tablet-based audiometers Example: Shoebox audiometer.</p> <p>Procedure: The individual puts on the headphones and starts to “play a game” on the iPad by placing a finger on a center button of the screen, dragging it to the green circle at the right hand top if they hear a sound, and to the red circle on the right bottom if they do not hear a sound. This is done at each frequency and dB, and independently for both ears.</p> <p>With an software downloaded upon purchase and installed in the tablet, audiogram results are electronically plotted and stored and an entire audiogram result may be generated after each test.</p>	<ol style="list-style-type: none"> Most advanced model; the only peer-reviewed^{17,18}, audiometer used extensively in TB research over the last 2.5 years (The UNION in 8 sites) Efficient data management <ol style="list-style-type: none"> Electronically records audiogram results, eliminating manual plotting of results by staff on paper; allows data storage and transmittal to specialists, when needed Can automatically generate frequency reports of hearing loss according to age, and sex. Meaningful data from countries can be consolidated to inform global policy Has web-based connectivity that automatically uploads files to its portal, allowing internet-based data viewing and management from a central location Allows printing of audiograms and filed, if desired Portability: Very light and handy Efficient on staff: no need for manual plotting and staff need not generate sound stimulus to administer the test User-friendly to the computer-literate, including children. 	<ol style="list-style-type: none"> Unfamiliar procedure: most TB patients have not used a computer, and the required touch screen response (dragging the button depending on sound stimulus); one or more trial runs needed for familiarization, otherwise results may be inaccurate. The iPad is an attractive device and raises concern on theft in the field. Relatively more costly.

17 Yeung J, Javidia H, Heley S, et.al. The new age of play audiometry: prospective validation testing of an iPad-based play audiometer. J Otolaryngol Head Neck Surg. 2013; 42:21-28

18 Thompson GP, Sladen DP, Borst BJH, et. al., Accuracy of a tablet audiometer for measuring behavioral hearing thresholds in a clinical population. Otolaryngol Head Neck Surg. Nov 2015;153(5):838-842

2. Stand-alone audiometers

Procedure: The individual puts on the headphones, while holding a device in one hand with a button connected to the audiometer. A member of staff manually “generates” a sound at each frequency and dB, and upon hearing the sound, the patient presses the button with their thumb. The member of staff then plots the results on a pre-printed audiogram paper at each point in the test, in case of models with no software installed. This procedure is done independently for both ears.

1. **Familiar procedure** (pressing on a button): easy to follow
2. Some are **battery operated**: eliminates need for electricity in field and the use of wires that limit mobility
3. **Simple data management:**
 - a. Special software (in some models) allows automatic electronic storage of results, eliminating manual plotting on paper by staff
 - b. Stored data/results can be transmitted to specialists
4. Some have a built-in **printer**
5. Comparatively **less costly**.

1. For models that require manual plotting of results, more staff time is required, and the plotting may be prone to error.
2. Audiograms with no options for electronic storage are paper-based and thus, need manual filing, are non-transmittable electronically to specialists
3. Staff is needed during entire test to generate sound stimulus



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