# Standard Operating Procedure for

# Audiometry Screening

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# Standard Operating Procedures: for Audiometry Screening

## PURPOSE

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| This standard operating procedure (SOP) describes the procedures for hearing loss screening. It aims to provide more detailed information on the patient’s hearing status and to inform dosing adjustment, further referral, and follow-up. This screening test is a series of pure tones presented at decreasing decibel (dB) levels so that the softest dB level to which the patient consistently responds at each frequency may be recorded. This test is not a diagnostic test. |

## SCOPE

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| --- |
| This SOP is developed for trained healthcare workers assessing hearing loss in participants involved in the endTB observational study and clinical trials. |

## RESPONSIBLE FUNCTIONS

|  |  |
| --- | --- |
| **Function** | **Activities** |
| **Assessor** | * An audiologist to whom the patient is referred, or a study personnel who has received training on basic audiometry screening and endTB source document filling.
 |

## DEFINITIONS and ABBREVIATIONS

None

## PROCEDURE

There are two ways that an audiometry screening test can be conducted at an endTB study site:

* The patient is referred to an audiologist, who will perform the screening test following their protocol and record the results in the patient’s medical record (for endTB clinical trials, see the Audiometry section in the ***endTB Clinical Trial Worksheet Completion Guide***). Delegated data entry personnel will enter the audiometry screening results into the endTB Audiometry Form (see ***Audiometry Form Completion Guide***) for the observational study or onto the electronic case report form (eCRF) for the clinical trials.
* The patient is screened using an audiometric device at the study site, in which case a trained study personnel will perform the test and record the results in the patient’s medical record(for endTB clinical trials, see the Audiometry section in the ***endTB Clinical Trial Worksheet Completion Guide***). Delegated data entry personnel will enter the audiometry screening results into the endTB Audiometry Form (see ***Audiometry Form Completion Guide***) for the observational study or onto the electronic case report form (eCRF) for the clinical trials. The following procedures are to provide guidance for the study personnel at the site when performing the screening test.

### Equipment

* A calibrated manual pure tone audiometer with accompanying headphones; or,
* A calibrated automated pure tone audiometer with accompanying headphones (for example: Shoebox audiometer or Hearscreen audiometer).

### Choosing a test environment

The ideal test room is quiet and free of distractions. It is very important that there is no outside noise and as inside noise in the area of the test room, that will mask the test signals. If possible, turn off any fan, air conditioner, computer, or any device that may create ambient noise. For manual audiometers that are not able to monitor the ambient noise, if distracting noises occur during the test, it is advisable that the test is paused until the noise winds down.

### Screening for hearing loss

In screening for hearing loss, there are the following approaches:

* **Screening audiometry** presents tones across the speech spectrum (500 to 4,000 Hz) at the upper limits of normal hearing (25 to 30 dB for adults, and 15 to 20 dB for children). Results are recorded as pass, indicating that the patient’s hearing levels are within normal limits, or refer, indicating that hearing loss is possible and a repeat screening test or a threshold search test is recommended.
* **Threshold search audiometry** determines the softest sound a patient can hear at each frequency 50 percent of the time. This testing requires more time and expertise than screening audiometry. The American Speech-Language-Hearing Association has a recommended procedure for pure-tone threshold search tests known as the modified Hughson-Westlake method. This hearing screen presents to the listener sound levels from just audible to just inaudible. The listener’s threshold is somewhere between these two levels.

**Testing frequencies**

In the endTB project, we recommend testing at least these frequencies: 1000Hz, 2000Hz, 4000Hz, and 8000Hz. The reason for this is that hearing loss caused by injectables usually occurs at higher frequencies. When lower frequency hearing loss happens, it is often too late to preserve the patient’s hearing.

If using an automated/manual audiometer at the site, these frequencies can be added or chosen from the setting of the device. If the patient is referred out, the audiologist can be asked to include these frequencies, among others.

#### Instructions to patients before performing audiometry

1. Introduce one’s self and verify the subject’s name and date of birth. Subject identifiers must match the clinical chart.
2. Explain the procedure to the patient. **Assessor** can refer to the instruction below to guide patients before the test begins:
	1. Perform a visual inspection of the ears. If there is any ear discharge or wax that blocks the ear canal, either consider putting off the test and refer patients to an audiologist for checkup before re-attempting the test.
	2. Place the headphones on the patient’s head; make sure you place the **red** headphone on their **right** ear and the **blue** one on their **left** ear.
	3. Ensure that the headphones are secure on the patient’s head. If they are loose, please prompt the patient to tighten the band by adjusting the sliders on each side until they fit securely.

*\*Headphones placement is very important in hearing screening. Healthcare worker should understand and let the patient know that the audiometric headphones, cushion, and headband were not designed for comfort. The correct placement is for the opening of the ear canal to be centered under the cutout in the earphone cushion for the headphones diaphragm.* ***Assessor*** *must ensure that no hair gets under the headphones cushion and earrings are removed before testing if they interfere with the headphones.*

* 1. Proceed with the test, record the results in the patient’s medical record (for endTB clinical trials, see the Audiometry section in the ***endTB Clinical Trial Worksheet Completion Guide***) and capture the data in the ***endTB Audiometry Form*** for the observational study, or onto the eCRF for the clinical trials.

### Assessment of hearing loss

After the hearing screening is done, assessment of hearing loss must be conducted by the patient’s treating physician or a well-trained clinician, hereafter referred to as **assessor**.

There are two types of assessment throughout the course of treatment: the baseline assessment at the baseline visit, and the threshold shift assessment at the monitoring screenings that follow.

#### Baseline assessment

When the **assessor** acquires the baseline audiogram, he or she will decide if hearing loss is detected based on the average threshold value calculated after the results have been retrieved. This average is calculated by the sum of all threshold values divided by the number of frequencies being tested.

For example, an adult patient had an audiometry screening at baseline visit with the readings below:

* 1000 Hz: 5 dB (Left); 10 dB (Right)
* 2000 Hz: 15 dB (Left); 35 dB (Right)
* 4000 Hz: 25 dB (Left); 50 dB (Right)
* 8000 Hz: 35 dB (Left); 70 dB (Right)

This patient’s baseline threshold for the left ear will be:

 (5+15+25+35) dB ÷ 4 = 20 dB

This patient’s baseline threshold for the right ear will be:

 (10+35+50+70) dB ÷ 4 = 41.25 dB

Based on the calculated threshold value, refer to the classification table below for detection of hearing loss in each ear at baseline.

Classification of hearing loss:

* Normal: 0 to 20 dB
* Slight impairment: 21 to 40 dB
* Moderate impairment: 41 to 55 dB
* Moderate severe impairment: 56 to 70 dB
* Severe impairment: 71 to 90 dB
* Profound impairment including deafness: 91+ dB

 **Assessor** shall record this **baseline assessment result** into the Audiogram form.

#### Subsequent hearing assessment

For each hearing screen that follows the baseline, the assessor will be able to detect if there is a threshold shift from the baseline results. These threshold shifts shall affect subsequent treatment decisions.

A threshold shift is calculated by comparing the subsequent audiogram to the baseline audiogram at 2 or 3 contiguous test frequencies. **Assessor** shall refer to the **endTB Clinical Guide for New TB Drugs** or the **MSF Severity Grading Scale** for more details.

#### Threshold shift reporting and grading example (Adult)

Take the same example of the above-mentioned adult patient, whose baseline and follow-up audiometry readings are listed below:

|  |  |
| --- | --- |
| **Baseline** | **Follow-up Visit X** |
| * 1000 Hz: 5 dB (Left); 10 dB (Right)
* 2000 Hz: 15 dB (Left); 35 dB (Right)
* 4000 Hz: 25 dB (Left); 50 dB (Right)
* 8000 Hz: 35 dB (left); 70 dB (Right)
 | * 1000 Hz: 10 dB (Left); 30 dB (Right)
* 2000 Hz: 20 dB (Left); 40 dB (Right)
* 4000 Hz: 30 dB (Left); 75 dB (Right)
* 8000 Hz: 40 dB (left); 80 dB (Right)
 |

Sample calculation of the threshold shift and the classification of hearing loss grade in each ear, according to the MSF severity grading scale, is demonstrated below:

|  |  |  |
| --- | --- | --- |
|  | **Left**  | **Right**  |
|  | Follow-up audiogram - baseline audiogram = threshold shift  |  | Follow-up audiogram - baseline audiogram = threshold shift  |  |
|  **1000 Hz**  |  10 dB - 5 dB = **5 dB** |  ① | 30 dB - 10 dB = **20 dB** | ① |
| **2000 Hz**  | 20 dB - 15 dB = **5 dB** | ② | 40 dB - 35 dB = **5 dB** | ② |
| **4000 Hz**  | 30 dB - 25 dB = **5 dB** | ③ | 75 dB - 50 dB = **25 dB** | ③ |
| **8000 Hz**  | 40 dB - 35 dB = **5 dB** | ④ | 80 dB - 70 dB = **10 dB** | ④ |
| **Average threshold shift** | **Average at 2 contiguous frequencies:*** (① + ②) ÷ 2 = **5 dB**
* (② + ③) ÷ 2 = **5 dB**
* (③ + ④) ÷ 2 = **5 dB**

**Average at 3 contiguous frequencies:*** (① + ② + ③) ÷ 3 = **5 dB**
* (② + ③ + ④) ÷ 3 = **5 dB**
 | **Average at 2 contiguous frequencies:*** (① + ②) ÷ 2 = **12.5 dB**
* (② + ③) ÷ 2 = **15 dB**
* (③ + ④) ÷ 2 = **17.5 dB**

**Average at 3 contiguous frequencies:*** (① + ② + ③) ÷ 3 = **16.67 dB**
* (② + ③ + ④) ÷ 3 = **13.33 dB**
 |
|  |  Report the highest value of average change of the two ears as the threshold shift in the study-specific forms, as needed Average at 2 Contiguous frequencies is 17.5 dB Average at 3 Contiguous frequencies is 16.67 dB |

Based on this patient’s average threshold shifts at 2 and 3 contiguous frequencies, his/her degree of hearing impairment could be graded as grade 1 by the definitions below:

|  |  |
| --- | --- |
| [ ]  **Normal** | Threshold change <15 dB averaged at 2 contiguous test frequencies. |
| [x]  **Grade 1** | 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. |
| [ ]  **Grade 2** | Threshold shift of >25 dB averaged at 2 contiguous test frequencies in at least one ear. |
| [ ]  **Grade 3** | Threshold shift of >25 dB averaged at 3 contiguous test frequencies in at least one ear; therapeutic intervention indicated. |
| [ ]  **Grade 4** | Threshold >80 dB HL at 2 kHz and above. |

## REFERENCES

* Hearing measurement. <http://www.who.int/occupational_health/publications/noise8.pdf>

## SUPPORTING DOCUMENTS

* endTB Clinical Trial Worksheet Completion Guide (endTB Site Study Document)
* endTB Audiometry Form Completion Guide
* endTB Clinical and Programmatic Guide for Patient Management with New TB Drugs. Version 4.0. January 2018. <http://endtb.org/guide>
* MSF Severity Grading Scale (PV-TB-D12) <http://endtb.org/resources/pharmacovigilance>

## APPENDIX

|  |  |
| --- | --- |
| **Number** | **Title** |
| A1 | How to use Shoebox |
| A2 | How to use a manual audiometer |
| A3 | How to use Hearscreen |