



EAR AND HEARING

SURVEY HANDBOOK



**World Health
Organization**



EAR AND HEARING

SURVEY HANDBOOK



World Health
Organization

WHO ear and hearing survey handbook

ISBN 978-92-4-000050-6

© World Health Organization 2020

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. WHO ear and hearing survey handbook. Geneva: World Health Organization; 2020. Licence: [CC BY-NC-SA 3.0 IGO](https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Printed in Switzerland

Contents

Acknowledgements.....	i
Abbreviations.....	ii
INTRODUCTION	1
DEVELOPMENT AND USE OF THIS SURVEY HANDBOOK.....	2
Who can use this survey handbook?	2
When should the survey handbook be used?	3
How to use the survey handbook	3
Use of survey data	4
SECTION 1: Planning the survey.....	5
The planning team	5
Survey protocol	7
Survey aims and objectives	8
Estimating sample size	9
Survey design and methods.....	10
Cluster sampling design.....	10
Identifying the sample.....	14
Identifying staff and resource requirements	16
Developing timelines	20
Ethical issues	21
SECTION 2: Pre-survey preparations	23
Training field teams	23
Pilot and feasibility study	24
Pre-survey visit	25

SECTION 3: Conducting the survey.....	26
Home visits.....	26
Data collection tools	28
Care of persons identified with hearing loss or ear problems.....	29
Optimizing participation.....	30
SECTION 4: Data management	31
Data management plan.....	31
Minimizing errors in data entry	32
Data analysis	32
Data reporting	34
Hearing loss database	34
SECTION 5: Quality assurance	35
Prerequisites for a successful survey	35
Error sources	36
Mitigating errors.....	36
SECTION 6: Household roster and data collection form	39
Household roster form.....	39
Data collection form	40
Notes on use of data collection and household roster forms	42
SECTION 7: Protocol for rapid assessment of hearing loss	55
Aim of RAHL.....	56
Survey design and sample.....	56
Examination protocol	57
Survey team.....	58

Equipment required	58
Missed participants	58
Data entry and analysis	59
Advantages of RAHL	60
Limitations of RAHL	60
ANNEX 1: Sample size estimation and sampling	61
ANNEX 2: Minimum training requirements for non-qualified audiologists to perform hearing assessments	69
Annex 3: Tablet and Smartphone-Based Software Applications for Hearing Assessment	72
ANNEX 4: Exploring funding options – some tips	74
ANNEX 5: Mobile application and web portal for data collection.....	77
ANNEX 6: Protocol for the validation of selected software applications for assessment of hearing thresholds	80

Acknowledgements

This document is the outcome of a consultative process led by the World Health Organization and has been reviewed by the following World Health Organization (WHO) staff members: Shelly Chadha, Alarcos Cieza, Cherian Varughese, Karen Reyes and Tamitza Toroyan.

The conceptual framework and outline of the document were developed in consultation with an expert group through a series of consultations. Document review and inputs were provided by: Tess Bright, Sharon Curhan, Suneela Garg, Diego Santana Hernández, Hannah Kuper, Ricardo Martinez, Islay Mactaggart, Bolajoko Olusanya, Danuk Pallewala, Audra Renyi, Harjit Sandhu, Andrew Smith, De Wet Swanepoel, Sarah Sydlowski, Peter Thorne and Alejandra Ullauri.

The London School for Hygiene and Tropical Medicine supported this work through hosting of the consultative meetings and contribution of the section on 'Rapid Assessment of Hearing Loss'.


Sharon Curhan of Harvard University and Peter Thorne of University of Auckland made a special contribution through development of a protocol for validation of hearing testing apps. WHO would also like to acknowledge the developers of the following applications: AudCal; EarTrumpet; hearTest, Shoebox Audiometry; and uHear, for their support in testing and validation of some of these apps. The validation studies were undertaken with support of Achal Gulati and Rajiv Dhawan, New Delhi, India and Peter Thorne and Elizabeth Holt, Auckland, New Zealand.

The final protocol was field tested by Suneela Garg in New Delhi, India and Isaac Macharia in Nairobi, Kenya. A data management software application, based on the data collection form of this handbook has been developed by WWHearing to support its implementation.

Financial support for this document has been provided by the International Society of Audiology and CBM.

Abbreviations

ABR	Auditory Brainstem Response
ANSI	American National Standards Institute
AOE	Acute Otitis Externa
ARHL	Age-Related Hearing Loss
ASOM	Acute Suppurative Otitis Media
CSOM	Chronic Suppurative otitis media
CSOM	Chronic Suppurative Otitis Media
dB	decibels
dBA	A-weighted decibels
dBHL	decibels Hearing Level
DHL	Disabling Hearing Loss
DHS	Demographic and Health Surveys
DPOAE	Distortion Product Otoacoustic Emissions
EHCSAT	Ear and Hearing Care Situation Analysis Tool
EHES	European Health Examination Survey
ENT	Ear-Nose-Throat
FB	Foreign Body
GBD	Global Burden of Diseases
GHDx	Global Health Data Exchange
GHLD	Global Hearing Loss Database
IHME	Institute for Health Metrics and Evaluation
ISO	International Standards Organization
kHz	Kilohertz
NCDs	Non-Communicable Diseases
NGO	Non-Governmental Organization
OAE	Otoacoustic Emission
OME	Otitis Media with Effusion
PIN	Personal Identification Number
PPS	Probability Proportional to size
PTA	Pure Tone Audiometry



RAHL	Rapid Assessment of Hearing Loss
RN	Random Number
SI	Sampling Interval
SOPs	Standard Operating Procedures
SPSS	Statistical Package for the Social Sciences
SRS	Simple Random Sampling
STEPS	WHO's STEPwise approach
SYRS	Systematic Random Sampling
TEOAE	Transient Evoked Otoacoustic Emissions
TM	Tympanic Membrane
UNSD	United Nations Statistics Division
WHO	World Health Organization

INTRODUCTION

Reliable, standardized, population-based data on the prevalence and causes of deafness and hearing loss are scarce, especially in low- and middle-income countries. A World Health Organization (WHO) survey undertaken in 2013¹ revealed that only 30 countries (out of 76 respondents) gathered epidemiological data on hearing loss.

Information on the causes and prevalence of hearing loss essential to raising awareness of hearing loss and ear disease among WHO Member States, and to developing suitable public health strategies to address it. Since 1999, WHO's Ear and Hearing Disorders Survey Protocol has been used by a number of countries to help conduct epidemiological studies that assess the prevalence, profile and causes of hearing loss. However, in view of the many advances in diagnostic technology and software interfaces since 1999, a review of the existing Protocol – including its methodology, assessment techniques and software for data entry and analysis was considered necessary.

This survey handbook is the result of that review, and provides guidance for planning and implementing hearing loss surveys, including information on possible data collection tools. The survey handbook aims to enable countries – particularly low- and middle-income countries – to gather data by planning and implementing population-based epidemiological surveys.

The main uses of data collected by such surveys are:

- to provide an accurate picture of hearing loss prevalence in a given area, which could be a country or an area within the country (e.g. district or state);
- to provide an overview of the most common probable causes of deafness and hearing loss in the study area;
- assess global and regional prevalence and trends.

Using this survey handbook for data collection will help to ensure comparability of data collected through studies conducted in different countries and by different investigators. This will facilitate the estimation of global prevalence and the examination of hearing loss trends over time.

¹ Multi-country assessment of national capacity to provide hearing care. Geneva: World Health Organization; 2014

DEVELOPMENT AND USE OF THIS SURVEY HANDBOOK

This survey handbook was developed using a consultative process, which was coordinated by WHO's team on 'Sensory functions; Disability; and Rehabilitation' in Geneva. Following the decision to update the WHO Ear and Hearing Disorders Survey Protocol, an expert meeting was held in November 2015 to discuss the scope and nature of revisions and to review newer available technologies for assessment of hearing.

Based on the outcomes of the meeting, a validation study of software applications designed to test hearing was undertaken and its results have informed some of the methods outlined in this survey handbook. An outline of the structure and contents was developed by WHO and reviewed by experts. The initial draft was prepared by WHO with inputs from consultant epidemiologists. The expert group reviewed three drafts of the survey handbook.

The final draft was also reviewed by the WHO regional offices. It underwent field evaluation in India and Kenya in order to assess its usability and feasibility and to identify any practical difficulties encountered during implementation. On the basis of the inputs and comments received from reviewers, the survey handbook was modified and reviewed within WHO.

WHO CAN USE THIS SURVEY HANDBOOK?

This document is intended for use by anyone undertaking a study to assess prevalence of hearing loss in the population. This includes researchers, policy-makers, project managers, NGOs and others working in the field of ear and hearing care.

WHEN SHOULD THE SURVEY HANDBOOK BE USED?

The survey handbook can be used in any situation where the epidemiology of hearing loss is to be studied in a given population. The aim of such a survey would be to estimate prevalence of hearing loss and assess its probable causes in the target population.²

Such a survey may be:

- undertaken as part of strategic planning, or to inform public health initiatives;
- initiated by researchers to gather evidence for advocacy on hearing loss, for economic analysis and for the Global Burden of Disease (GBD) study;
- part of monitoring the implementation of a strategy for ear and hearing care.

Undertaking such a survey at regular intervals (5–10 years) can help to examine trends in hearing loss prevalence and causes, and to make changes to the strategic plan.

The survey handbook can also be used to guide research studies, such as:

- to determine the prevalence of hearing loss in a defined age group, e.g. adults over 50 years or children aged 5–15 years.
- to assess the prevalence and probable causes of hearing loss in a special population, e.g. schoolchildren.

HOW TO USE THE SURVEY HANDBOOK

The handbook should be read in full and used to develop project-specific protocols. Each study needs multidisciplinary expertise from the beginning of the project, and the survey investigators should include an epidemiologist and biostatistician, as well as an audiologist and ENT specialist. They should plan the study together and make decisions regarding the study design and sample; the age range to be tested; the sampling method and sample size; and data collection, management and reporting. These decisions will in turn determine logistics such as the personnel required, the type and quantity of equipment needed, and the time required to undertake and report on the survey and its budget.

² Refers to the entire group of people to which the researcher intends to generalize the study findings.

However, it is strongly recommended that the epidemiologic methodology, assessment methods, case definitions and data collection tools be implemented as they have been outlined in this survey handbook. If these are changed independently, it may not be possible to use the results for country or regional comparisons.

When required, the study can be supplemented by the collection of additional data that may be of importance to the target population, so long as this does not interfere with the primary aim and outcomes of the survey.

USE OF SURVEY DATA

Data on hearing loss prevalence and associated causes, as well as any other information gathered through this survey, should be disseminated through:

- publication in scientific, peer-reviewed journals;
- preparation and dissemination of a report that can be used for:
 - advocacy: the survey results should be graphically presented, and key messages identified. Advocacy materials, such as infographics/factsheets can be prepared based on the results. These can be used for raising awareness on this issue among policy-makers, health professionals and civil society.
 - identification of ear and hearing care needs for planning purposes: data collected will help to determine needs for ear and hearing care in the community and inform decisions regarding prioritization of services. This information can provide a strong evidence-base for policy development. The WHO ear and hearing care situation analysis tool (EHCSAT), the *WHO manual on planning for ear and hearing care strategies* and *EHCS Indicators for monitoring provision of services* provide useful tools for the planning process.³

³ See http://www.who.int/pbd/deafness/news/ear_hearing/en/
http://www.who.int/pbd/deafness/news/ear_hearing/en/

SECTION 1: Planning the survey

THE PLANNING TEAM

Once the decision to undertake a survey has been made, it is important to put together a survey planning team. The planning team (which may also be called the steering committee) must include a:

- principal investigator;
- ear and hearing care professionals (ear, nose and throat (ENT) specialists and audiologist/s);
- public health expert or epidemiologist/s;
- biostatistician/s;
- survey coordinator (responsible for managing field teams and all field work)

The planning team is responsible for designing the study; developing the specific survey protocol; developing the implementation and logistics plan; developing the budget and seeking funding; monitoring the study; and quality assurance and report writing (see Box 1 for key steps in survey planning). The team should meet at regular intervals to plan the survey and to monitor its implementation and evaluate results. All decisions made during the survey should be documented, together with the reasons for making them.

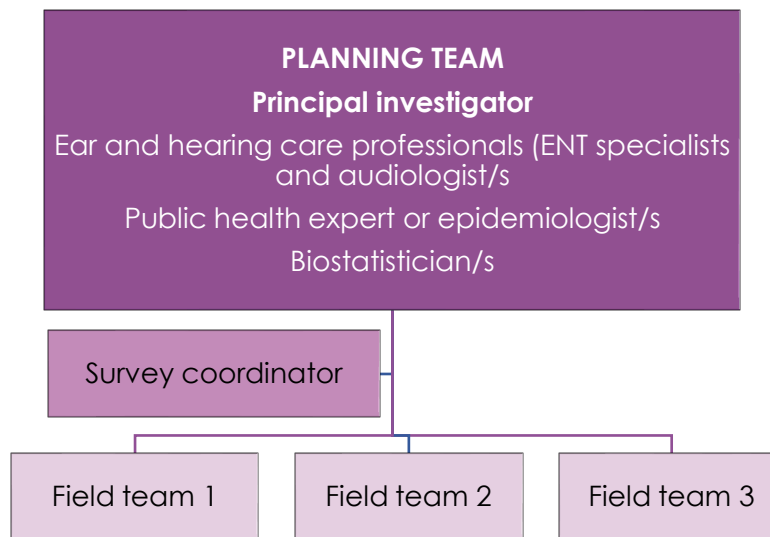
The principal investigator should assemble and chair this team and ensure that it has all the expertise needed to design, implement, and analyze the survey. The principal investigator should liaise with government departments and technical consultants and secure funding for the conduct of the survey. Some possibilities for exploring funding are given in Annex 4.

Box 1: Steps for conducting a survey*

1. Identify survey planning team members.
2. Appoint survey coordinator.
3. Identify areas (clusters) to be included in the survey and inform authorities/gain permission, if required.
4. Finalize survey design, methodology and data collection tools.
5. Develop timeline and budget, and gain financial approval/support.
6. Finalize study protocol and develop standard operating procedures.
7. Obtain ethical approval.
8. Establish size and composition of field team and determine training requirements.
9. Procure required equipment.
10. Train field teams.
11. Conduct pilot and feasibility study.
12. Make pre-survey visit to each cluster.
13. Conduct the study and collect data.
14. Follow up with study group participants, where required.
15. Data coding, entry and analysis
16. Write survey report.
17. Publish articles in peer-reviewed scientific journals and share survey results with WHO.

*Many of these steps will occur concurrently rather than sequentially.

Figure 1 Structure of the planning team



A full-time survey coordinator is the focal point for day-to-day survey management, in close liaison with the principal investigator and field teams. As such the survey coordinator must be part of all planning team meetings, and have knowledge of epidemiology and experience in field work. Ideally, the survey coordinator should be knowledgeable about hearing loss and ear diseases. In consultation with the planning team, the survey coordinator will be responsible for:

- ✓ preparing the survey protocol and defining standard operating procedures (SOPs) in consultation with the planning team;
- ✓ preparing training materials and organization of training;
- ✓ planning and supervising fieldwork;
- ✓ arranging and evaluating the pilot test;
- ✓ preparing advocacy materials to be used by field teams;
- ✓ supervising data management;
- ✓ organizing monitoring by the planning team (and external consultants, if required);
- ✓ reporting progress, problems and any deviations to the planning team.

There may be need for additional support personnel, especially in a large study. If required, an administrator may be appointed to support the survey coordinator.

SURVEY PROTOCOL

The key step in undertaking a survey is to develop a clear and detailed protocol, which is essential for a reliable and valid survey. A protocol is the document that clearly states the survey's rationale, aim and objective(s). It describes the survey design and methodology, and outlines statistical considerations. Such a protocol helps ensure uniformity in the way the survey is conducted.

The protocol should be developed by the survey planning team using a consultative process, and should include others who need to be involved in the study, an epidemiologist and a biostatistician. It is also important to include representatives of the community to be surveyed as they can help assess feasibility, highlight specific geographical and environmental considerations and recommend best practices for the population under study. Obtaining political and financial commitment by involving governments and nongovernmental partners is important to maximize the use and dissemination of survey results.

The best way to start is to conduct a protocol development workshop. All survey protocols must be approved by an appropriate ethical committee before implementation.

The parts of a protocol are listed in Box 2. Further details on a research protocol can be found at <https://www.who.int/ethics/review-committee/format-research-protocol/en/>.

Box 2: Parts of a survey protocol

- Project summary
- General information (title, names, addresses)
- Background and rationale
- References (of literature cited)
- Survey aim and objectives
- Survey design and sample
- Target population
- Survey design
- Sample size
- Sampling strategy
- Methodology
- Safety considerations
- Quality assurance
- Data management
- Expected outcomes
- Dissemination of results and publication
- Duration and timelines
- Problems anticipated
- Project management including survey team and training
- Ethical considerations
- Other support
- Informed consent forms and information sheet
- Budget
- Collaborations
- Financing

SURVEY AIMS AND OBJECTIVES

The planning team should first define the aim (or purpose) of the survey, and its objectives. They must then determine the target population and geographical coverage. Ideally, a survey should aim to determine the prevalence of hearing loss in all ages in a defined geopolitical area, such as a country, state, province, district, county, block, governorate, city, town or village – and assess its probable causes.

In some cases, the survey aim may be to determine the prevalence and probable causes in hearing loss among a specific subset of the population, such as adults over 50 years or children aged 5 to 15 years, or schoolchildren.

Once the aim of the study is determined, its objectives can be defined (see Box 3 for sample survey aim and objectives)

Box 3: Aim and objectives

Aim: Determine the prevalence and causes of hearing loss among all people of X
(country/sate/county/district/town/village name)

Objectives:

Primary

- Determine the overall and age-specific prevalence of hearing loss in the population.
- Estimate the overall number of people with hearing loss.
- Estimate the prevalence of different grades of hearing loss (mild, moderate, moderately severe, severe, profound, and total).
- Determine the age-distribution of hearing loss in the population.
- Determine the prevalence in males compared with females.
- Assess the common causes of hearing loss among different age groups.
- Provide appropriate referrals, treatments or further actions.

Secondary

- To raise awareness about hearing loss in the target population.
- To identify factors that could help prevent hearing loss and inform public health strategies.

ESTIMATING SAMPLE SIZE

To calculate the sample size for a prevalence survey, the following steps should be followed, in consultation with a biostatistician (see Box 4 for an example of how to calculate a sample size):

Estimate the approximate prevalence of hearing loss in the target population: this estimate may be based on a smaller pilot study conducted in part of the population. It may also be based on available literature or results of past prevalence studies. Available regional or country estimates on hearing loss can be used in absence of previous studies and data. See Annex 1 for information on sample size estimation.

Determine the required precision of the prevalence estimate: the precision refers to how far survey estimates of hearing loss prevalence may lie from the true prevalence (also known as marginal error). Typical survey precision may range from 1% to 5%. A value of 1% is preferred for use in these surveys.

Determine the required confidence precision of the prevalence estimate: 95% confidence intervals are typical in statistical calculations. The confidence interval represents values for the population parameter for which the difference between the true parameter and the observed estimate of the parameter is not statistically significant at the X% level.

Calculate the sample size required for a simple random sample survey (as opposed to a cluster sample survey) using the required precision, confidence precision, and the estimated population prevalence of hearing loss.

Box 4: Calculating a sample size: an example

Prevalence of hearing loss is to be estimated in a country with:

- a population $N=20$ million
- estimated hearing loss prevalence $P=5.3\%$
- required precision $d=1\%$
- required confidence interval 95% (i.e. $\alpha=.05$ and $z=1.96$)
- projected participation rate $P_r=85\%$

Sample size equation: i.e. $n=1833$ people

Assuming a $P_r=.85$ i.e. the sample size is $n=1833/.85=2157$ people

This assumes that the survey is in ideal conditions, with no design effect correction required. However, design effect should be determined in consultation with a biostatistician.

Estimate the design effect: the cluster sampling design is a complex design associated with a greater uncertainty than a simple random sample. The design effect is defined as the ratio of the correct standard error to the standard error computed under the assumption of a simple random sample. In order to compensate for this, a statistician must estimate the design effect and the sample size increased in consideration of this factor.

Scientific rigour is essential to ensure reliable results that are representative of the population. Make a prior prediction of the participation rate: the participation rate refers to the percentage (proportion) of the sampling frame (eligible population) that will agree to participate in the survey. The sample size may need to be increased in consideration of the expected participation rate. It is useful to aim for 90% participation rate or higher in the survey. However, for the purpose of sample size estimation, it is prudent to be more conservative and assume an 85% participation rate. Efforts must be made to maximize participation in the survey (see Section3).

Annex 1 on sample size estimation provides links to useful online resources as well as available regional estimates that can be used to calculate sample size, as well as some sample calculations, for reference.

SURVEY DESIGN AND METHODS

Design will undermine the accuracy of its outcome. It is therefore important to plan the survey in consultation with an epidemiologist and biostatistician. The survey design must aim at extracting a representative sample from the target population.

Box 5: Definitions

- Target population:** the entire group of people to whom the principal investigator intends to generalize the study findings.
- Sample:** all households and participants who are finally included and evaluated as part of the study.
- Sampling unit:** all individual items within the sample (e.g. individuals, households). For the purpose of this survey, sampling unit refers to a household.
- Sampling frame:** a list of all sampling units that could be selected for the survey.

Source: Health research methodology: a guide for training in research methods. Geneva: World Health Organization; 2001.

Cluster sampling design

Cluster sampling design is the basic design most likely to be suitable for a population-based survey carried out using this survey handbook. The objective of this method is to choose a limited number of smaller geographic areas or population groups ("clusters") in which simple or systematic random sampling can be undertaken to select the sample. The term cluster, as used here, is a collection of sampling units, usually households.

The clusters to be included in the study should be identified using the "probability proportional to size" method (PPS) (see Box 6 for an example of how to use PPS). The lowest tier of population groupings or communities are identified prior to cluster selection. These communities could be villages, urban blocks or sections, or census enumeration areas. Ideally, detailed maps should be available of these communities, which, at least, show the boundaries of these communities. Where such maps are not available, they can be generated in consultation with local leaders.

Communities in which the cluster sampling will be done are identified by PPS. In this method the likelihood of communities being selected varies according to their size. This ensures that the sampling procedure is self-weighting and no weighting is required in the analysis. It is important that the same number of participants/households should be sampled within each selected cluster.

Identification of sample clusters

Steps to identify clusters:

1. List all communities (e.g. villages or blocks) in the target population. This can usually be obtained from a census. These communities should be listed with their populations cumulatively (it is not essential that the population figures are completely up to date, because the relative size of communities is more important than their absolute size).

Box 6: Steps for cluster sampling using the “probability proportional to size” (PPS) method

1. Calculate the sample size.
2. List all the units (e.g. villages or blocks) within the target population and their population sizes.
3. Calculate the cumulative sum of the population sizes and note it alongside.
4. Determine the number of clusters that will be sampled.
5. Divide the total population by the number of clusters to be sampled, to get the sampling interval (SI): target population/no. of clusters.
6. Choose a random number (RN) between 1 and the SI. The first cluster to be sampled will be the one which contains the corresponding (cumulative population) number.
7. Subsequent clusters will be identified by repeatedly adding the sampling interval, i.e. RN; RN + SI; RN + 2SI; and so on.
8. The clusters selected are those for which the cumulative population contains one of the serial numbers calculated in item 7. Depending on the size of the community (such as village or block), it is possible that big units will be sampled more than once.
9. Mark the sampled clusters in another column
10. Within each cluster, select secondary sampling units (households) through simple or systematic random sampling.

See Annex 1 for more information.

2. Divide the total number of the target population by the number of clusters required (see below) to give the sampling interval (SI).
3. Randomly select a number between 1 and the sampling interval (e.g. by using the first number on a banknote), and the place where this number is located in the cumulative list of the population identifies the community where the first cluster will be selected.
4. The sampling interval is then added repeatedly to identify the subsequent cluster locations.

With this method, it is possible that the same community may be selected twice if it has a population larger than the sampling interval. In this situation two (or more) clusters (subsamples) should be selected separately within the community.

Number and size of clusters

The number and size of clusters to be included must be decided carefully (see Box 7). For a given sample size, there is a trade-off between increasing the numbers of clusters, which increases the precision of the result, and increasing the size of each cluster,⁴ which is logistically easier but reduces the precision.

Box 7: Determining the total number of clusters and households

To determine the **total number of clusters** to be included, divide the total sample size by the cluster size.

To determine the **number of households** to be seen in every cluster, divide the cluster size by the average household size (i.e. the average number of members in each household).

- There is no fixed formula to determine the size of a cluster. Determine the number of individuals to be sampled from each cluster. In order to ensure that all individuals in the population have the same probability of selection irrespective of the size of their cluster, the same number of individuals has to be sampled from each cluster. In practice, the sample size included from each cluster (cluster size) should generally be the number of subjects that a team could test in 2 or 3 days. (could be about 150–200 persons). The total number of clusters would therefore be the sample size divided by the cluster size.
- The number of households to be seen in every cluster will be the cluster size divided by the average household size. As mentioned above, it is important that the same number of households should be seen in each cluster. The average household size may be available from the census or it may be necessary to sample some households to find out.
- If team size and time allow, it may be possible to increase the number of clusters and reduce the size of each cluster, and hence increase the precision of the results. Ideally, the number of clusters can vary between 30 and 50.

⁴ Size of cluster or cluster size refers to the sample size to be included from each cluster. It does not refer to the total population of that cluster or community.

- Once the clusters have been identified, a unique number should be allocated to each cluster. Where there is more than one cluster in a single administrative area, each should be allocated a unique number. See Annex 1 for more information.

Identifying the sample

The sample is recruited from the available individuals that fall within the sampling frame. It is important that the size of the sample from each cluster is consistent, i.e. the same number of people should be sampled in each cluster. After determining the number of households to be sampled within a cluster, it is important to prepare a map of the cluster, listing each household and allocating a number to each household (see Box 8).

Box 8: Steps to identify a sample

1. Note the proposed size of the sample from each cluster (x).
2. Gain information on the average size of households within the clusters (y). This information is often available through census data.
3. Divide the sample size by household size (x/y) to determine the number of households to be enlisted in each cluster.
4. Acquire or prepare a map of the cluster, listing each household, and allocate a number to each household.

Next, randomly identify the sample using one of the following approaches:

- a) Simple random sampling (SRS): this is an effective method for sampling within clusters. It can also be used for research studies when the target population is relatively small and confined to a limited geographical area. It would require that a list of all households and people residing in the area be made. Each household is then allocated a number and the sample is then selected randomly from the entire population.
- b) Systematic random sampling (SYRS) (see Box 9): this can be applied within a cluster or in a situation described for SRS (small population and limited geographical coverage). In this case, after determining the sample size and the sampling interval (N), the first household is selected randomly, and thereafter every Nth household of the cluster is

sampled. While SYRS sampling is likely to be used in most situations, at times it may mean that certain sections of the population are not suitably represented. For example, if a district consists of both urban and rural areas, a population-based prevalence survey must have proportionate representation from both areas. In this case, it would be appropriate to follow the stratified cluster sampling design.

Box 9: Steps for systematic random sampling

1. Provide an identification number to each household of the target population is eligible for inclusion in the study (i.e. the sampling frame).
2. Calculate the number of sampling units (households) to be included by dividing the sample size (for the cluster) by the average number of persons per household. This gives us the number of sampling units required.

$$\text{Number of sampling units} = \text{Sample size (for the cluster)} / \text{average household size}$$

3. Calculate the sampling interval through dividing the total number of sampling units required by the total number of households within the sampling frame.

$$\text{Sampling interval (SI)} = \text{Number of households within the sampling frame} / \text{number of sampling units required} = N$$

4. Select the first household of the sample population randomly (e.g. the random selection may point to ID 13 as the first household).
5. Select the rest of the sample population by recruiting each Nth subject from the sampling frame (e.g. if N=100 and 13 is the first house, then select 13th, 113th, 213th subject and so on).

- c) Stratified cluster sampling design: In this design, prior to selecting the clusters, the population is divided into different strata according to the characteristics under consideration (e.g. urban or rural, or according to ethnic groups). Each stratum (e.g. urban or rural) is sampled separately. The results are then weighted by their populations at the time of analysis.

- d) Multi-stage cluster sampling: this method is appropriate when surveying large populations, e.g. for a national prevalence survey. The entire target population is divided into large groups, which may correspond to geopolitical divisions such as states or counties. The required number is randomly selected. Each state/county is then further divided into smaller groups (such as blocks or villages) and the required number of these are again identified through the process of random selection. Any number of such stages can be incorporated until the required cluster level is reached. The sample can then be identified as described above.

In order to obtain a study sample that is representative of a national or large subnational population, multi-stage sampling must be incorporated. This type of sampling is complex, and there is a need to compute corresponding sampling weights (the number of individuals in the target population that each selected person in the sample represents). These will help to compensate for unequal probability of selection and must be done in consultation with an epidemiologist and biostatistician.

IDENTIFYING STAFF AND RESOURCE REQUIREMENTS

Field teams are responsible for survey implementation in the clusters. While the number of field teams and their composition depend on the survey design and size, each team should nonetheless include the following:

- A team leader, with the overall clinical and managerial skills necessary to coordinate and supervise the team's activities.
- At least one member with specialized knowledge of ear diseases and hearing assessment (e.g. a trained physician, audiologist or ENT specialist). This person may also be the team leader.
- Ear and hearing care worker/s: these individuals will undertake the ear examination and assessment of hearing loss in the field. Such persons must be trained, if required, to conduct the tests allocated to them.

- Field worker/s: these individuals will be responsible for helping with enumeration, sampling, follow-up and local interaction. It is important that field workers be recruited from within the community.
- A driver.

The same team leader and ear and hearing care workers should be responsible for carrying out the survey across multiple clusters. However, field workers should be recruited locally within each cluster, as that will ensure that there is a local coordination and know-how. It is best if a trained ear and hearing care worker is teamed up with a field worker who has local knowledge. It is ideal to have at least one person in the team who can converse in the local sign language.

Field teams must be fully trained to conduct the survey according to the survey protocol, including identification of households; induction of participants; ear and hearing examinations; referrals; and raising awareness on ear and hearing care. These tasks should be duly considered when planning the budget.

A list of equipment for conducting the survey and a detailed budget should then be developed. The budget should consider various elements, including:

- Staff costs: remuneration and per diems to be paid to all staff, including local staff hired from the community.
- Equipment, supplies and consumables (see Box 10):
 - Data collection tools: otoscope; tympanometer; otoacoustic emissions OAE machine; audiometer or alternative hearing testing software application; other tools, such as ear probes, forceps etc.

Box 10: Equipment for conducting a survey (one set per field team)

- ✓ Tympanometers
- ✓ OAE machine
- ✓ Audiometer or an alternative hearing testing software application with the required hardware (device and headphones)
- ✓ Other tools, such as ear probe, forceps etc.
- ✓ Disposables (cotton wool, syringes, disinfectants)
- ✓ Ear-drops: antibiotics, wax melting
- ✓ Antibiotics
- ✓ Laptop or other devices

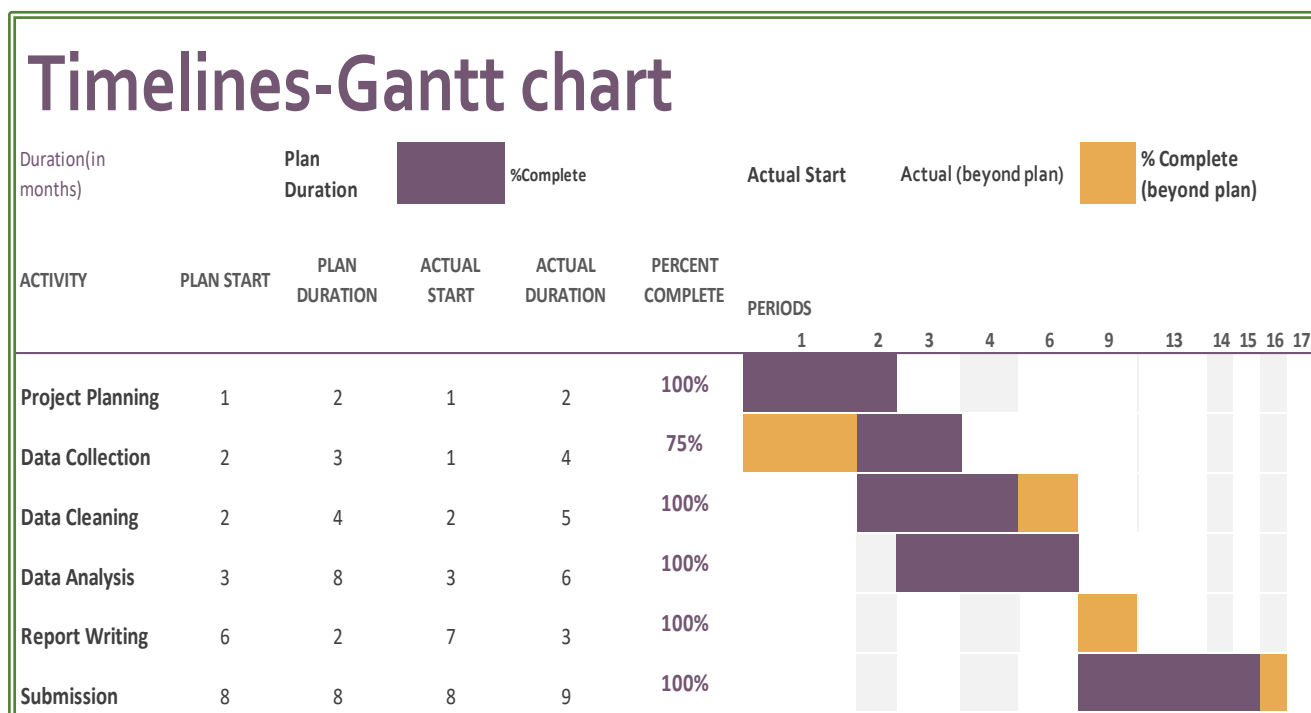
- Disposables required for examination, including cotton wool, syringes etc., and materials to clean/disinfect equipment.
 - Medicines and ear-drops for basic treatment of ear conditions, when required.
 - Laptop or tablet for data management (if appropriate).
- Printing costs: costs of printing data collection forms, information and consent documents, survey referral forms, and advocacy materials.
- Training, accommodation and subsistence costs: for training of ear and hearing care workers and sensitization of field workers.
- Transport costs: for field team, and for planning team members to monitor field activities from time to time. Transport may also be needed for participants in cases where hearing tests are not carried out in homes but at a central facility (see Section 3, subsection “Data collection”).
- Workshops and meetings for the planning team and field teams.
- Data management and analysis.
- Report preparation and dissemination, including reporting back to the community

Budget (proposed categories)			
Staff costs			
Training and sensitization			
Advocacy material preparation			
Printing			
Workshops and meetings			
Data management and analysis			
Report preparation			
Dissemination of results			
Miscellaneous			
	Cluster 1	Cluster 2	Cluster 3
Field staff			
Training			
Accommodation			
Transport			
Equipment			
Disposables			
Medicines			
Miscellaneous			

DEVELOPING TIMELINES

After finalizing the survey design and methodology, the timeline for conduct of the survey should be established. This can be documented as a Gantt chart – a chart that plots dates against tasks (see Figure 2) If required, the timeline may be adapted or modified following the pilot study or during the course of the survey.

Figure 2 Gantt Chart Example



ETHICAL ISSUES

Ethical approval must be gained from a competent authority prior to starting the study. Ethical matters should be carefully discussed by the steering committee during protocol development and all issues identified must be documented and addressed. All local rules and regulations must be followed. Common ethical considerations include the following:

- Discuss the process and procedures with the local community prior to conduct of survey. Seek the agreement of community leaders and of competent regulatory authorities (if any) for this purpose.
- Informed consent must include:
 - an information sheet provided to all participants. This sheet must clearly provide all information about the study, its procedures and the proposed use of study findings. The information sheet must be in the local language and be easy to understand.
 - a consent form in the local language should be made available, with space for the participant's signature or thumb impression. In the case of children below the legal age of consent (as determined by national or local regulations), consent must be sought from a parent or guardian. The consent form should also explain and seek permission for any minor procedures, if required (such as wax or foreign body removal). See WHO sample consent form⁵ and information sheet for guidance on how to prepare a consent form (sample form includes guidance for qualitative studies, studies involving children/minors, and gaining parental consent). The samples should be adopted and customized to suit each study's needs.

For deaf persons using sign language, the information sheet and consent form should be explained in sign language. If survey participants are unable to read, information should be verbally explained by a relative or a team member.

- Assent form: for minors (above the age of 7 years), assent should be sought in an assent form. This should be separate and in addition to the consent form.

⁵ See http://www.who.int/rpc/research_ethics/informed_consent/en/.

- Follow-up and referrals:
 - For persons identified with ear disease or hearing loss, suitable treatment should be initiated, when possible, in consultation with a team member who is authorized to prescribe such treatment.
 - Where a person requires advanced diagnosis or management, he or she should be referred to a suitable facility, which is accessible to the individual, both geographically and financially. The referral pathway must be clearly established, and linkages should be developed with the referral facilities prior to the start of the survey. Referral slips should be available at the time of assessment. This should be conveyed to all members of the survey team during training.
 - Management of the persons identified with hearing loss or ear diseases must follow local best practice.

SECTION 2: Pre-survey preparations

TRAINING FIELD TEAMS

Field teams should be trained in various aspects of the survey including the following:

- Identification of households within clusters and how to approach household members regarding their inclusion in the survey.
- Provision of information on the survey and gaining consent from participants.
- Gathering and recording information through household roster forms and data collection forms.
- Providing information and education on the principles of ear and hearing care.
- Examination of the ear using an otoscope and identification of common ear problems expected to be encountered during the survey.
- Wax and foreign body removal.
- Assessment of hearing levels.
- Tympanometry and how to record it
- Identification of cases requiring referral, including those in need of urgent medical attention.
- Referral processes.

While both health workers and field workers must be trained in in steps 1 to 5, only health workers expected to perform ear and hearing examination should be trained in steps 5 to 10. When training in ear and hearing examination, it is important to ensure that trainees' findings are accurate (i.e. are the same as those that the trainer would produce) prior to authorizing trainees to conduct examinations as part of the survey.

The [WHO Primary ear and hearing care training resource \(intermediate level\)](#) can be adapted to suit training needs. Training must include use of the specific ear and hearing assessment device/s that are to be used under the survey protocol. Any cultural sensitivities in cluster areas must be considered during training. Field workers must be recruited locally and sensitized to the needs and objectives of the survey. They should be trained in use of awareness materials and to prepare them to interact with study participants. See Annex 2 for more on training field team.

PILOT AND FEASIBILITY STUDY

Ideally a feasibility study should be carried out after the sample clusters have been identified, the protocol developed, equipment procured, and training undertaken. However, a small study may have to be done earlier in cases where this is required to calculate the sample size. This can have several purposes: to test the methodology, equipment, logistics and timing of each part of the survey and to familiarize the staff with conducting the survey. Prevalence obtained in the pilot may be useful to calculate the sample size if there is no other source for this information. Issues identified during the study should be documented and can be used to adapt and finalize the protocol. Feasibility study considerations include the following:

- It can be undertaken at any place within the target population, including a with a small number of participants, approximately equal to the size of one cluster.
- The feasibility study should be operated with the same number of staff that will participate in the actual survey field operations.
- All data collection tools and data management protocols should be tested during the pilot study, but data collected should not be used in the final survey analysis.
- Supervisory staff and trainers should be on hand to provide direct monitoring and in-the-field training, if required.
- The protocol should be adapted after the feasibility study to accommodate any lessons learned.
- Individuals who participate in this are not eligible for the full study.

Following the feasibility study, the planning team must finalize the survey protocol before its implementation.

PRE-SURVEY VISIT

Before starting the survey in any location, one or two members of the team should visit the cluster. They should undertake the following activities during the visit:

- Sensitize the community (through its leaders, whenever possible) and explain the purpose and procedures of the survey and benefits for the community. This will help to obtain consent and cooperation of the community for optimum participation.
- Map the location of potential referral facilities for those identified during the survey as needing additional care.
- Assess the situation regarding suitability of the area, including its accessibility during different seasons.
- Locate a suitable (quiet and central) site for conduct of ear and hearing assessment (see Section 3, subsection on “Data collection tools”).
- Obtain a list of households and (if possible) identify households using random selection.
- Identify field workers for the field team and train them (see Section 2, subsection on “Training field teams”).
- Secure accommodation for the field team, if required.
- Most surveys are likely to have multiple sites. Each site should be visited before the start of the survey

SECTION 3: Conducting the survey



Figure 3 Steps for conducting the survey

HOME VISITS

The field team should determine which days and the time of the day that is most suitable for visiting families and conducting the examination. They should prepare a list of households to be visited, their allocation among the field workers, and an itinerary, to ensure that all households are visited.

Based on the selection process, the field teams should make a list of all households included in the survey. Each household should be visited by a small team of two: one ear and hearing care worker and one field worker.

During this visit, they should inform family members of the purpose and procedures of the survey and seek their consent for participation. The Household Roster (part of the data collection form that aims to gather relevant basic information on the households and participants included in the sample) should be filled in during this visit.

Families should then be guided to the central location where the ear and hearing examination will take place and given a date and time for visiting the location.

DATA COLLECTION

It is important that all household members come to the central testing location, and that anyone who cannot come is either seen later or visited by the team at home (e.g. if the subject is not mobile). A list of household members, obtained from the census or compiled locally, is essential to check the names and numbers of those attending and those who fail to attend. If culturally appropriate and not perceived as unethical, a small incentive in the form of a useful gift item or monetary compensation may help ensure participation in the survey.

Every attempt possible should be made to find non-attenders. It may be necessary for the team to return later, e.g. in the evening or at the weekend if that is feasible. In any case, non-attenders and subjects who refuse to be tested should have a data collection form completed so that they can be entered into the analysis in order to calculate the non-response rates.

Data collection should be undertaken at an accessible, reasonably quiet location (test site) within the community, where two or more rooms are available for the survey team. The following steps are recommended:

- The availability and location of such a place should be ascertained during the pre-survey visit.
- The place selected should be accessible for all, including older adults and people with disabilities.
- Ideally the place should be centrally located within the community from which the sample is drawn. However, in case of a large or spread-out area, it is possible that arrangements for transporting subjects to the test site will have to be made. Alternatively, it may be required to identify more than one location in the cluster.
- It is important that the test site is comfortable and has place for a registration desk, for ear examinations and tympanometry, and a separate room where audiological testing can be undertaken.

As the ambient noise level at the time of audiological testing is required to be below 40 dBA – a factor that should be checked during the pre-survey visit as well as at the time when tests are being performed. Validated smartphone-based applications can be used to check the ambient noise level.

DATA COLLECTION TOOLS

Gathering information on, and clinical assessment of, the study group can be undertaken using the following tools.

The data collection form and household roster form are the basic tools that must be filled in completely. A standardized data collection form is provided in Section 6 of this survey handbook and should be used as such. If additional information is required, the relevant questions or examinations can be added to the data collection form as an additional section. Instructions regarding its use are provided along with the form in Section 6. Data collection includes:

- Demographic information and brief history about ear and hearing problems and use of hearing devices.
- Hearing assessment should be done before ear examination and prior to undertaking any intervention such as wax or discharge removal.
- 0–5 years of age: OAE testing should be used, combined with tympanometry. DPOAE/TEOAE test should be used and evaluated using set criteria (see data collection form, page 40 for details)
- Children above 5 years of age: audiological evaluation using audiometry undertaken in a quiet room or through use of portable audiometry or validated software applications (see Annex 3).
- In cases where wax, a foreign body or ear discharge is obstructing the ear canal and is removed, the hearing assessment should be repeated following the removal and also recorded. NOTE: pre-removal thresholds should be used for estimation of prevalence.

Ear examination: the external ear (auricle and external auditory canal) should be examined for any abnormalities. The ear canal should be inspected and then examined with the use of an otoscope. Where feasible, video-otoscopy should be done, and the images of the tympanic membrane captured. These can be later discussed with the ENT specialists before forming a firm diagnosis.

Tympanometry: to assess for middle ear abnormalities.

(Note: Care must be taken to ensure disinfection and sterilization of instruments.)

Special requests

At times, individuals from the target population who are not part of the sample may request to be examined. This may be done as a courtesy to the community and provided as an additional service. Such persons are not a part of the sample and the results should not be included in data analysis. If someone is identified with hearing loss or ear disease, due care must be taken to provide the required guidance/intervention or referral.

CARE OF PERSONS IDENTIFIED WITH HEARING LOSS OR EAR PROBLEMS

The procedure for follow up and care of persons who are identified as having hearing loss or ear problems during the survey should be decided at the time of planning the survey and these should be in line with the standards of clinical practice in the area.

All those who require further evaluation or management should be properly guided and referred to an appropriate and accessible health facility. It is important that the planning team considers and plans for these situations. Linkages should be developed with health professionals (physicians, pediatricians, otologists, audiologists) who can help to provide suitable care for those in need of it. Where financial resources are available, surgical services and hearing devices should be provided as part of the survey activities. When these are not available, efforts must still be made to link with other organizations and institutions where such services can be provided to those needing them, at reduced or no cost.

If any persons requiring urgent attention are identified by the examiners, they should be properly referred and, if possible, taken to the health facilities (with proper consent) to ensure timely attention.

OPTIMIZING PARTICIPATION

It is important to have the best possible participation rate (at least 80%) in order to have a valid survey result. Optimizing participation rates includes the following:

- ✓ A culturally sensitive understanding of the local population.
- ✓ Raising public awareness about the survey and its importance at national, community and individual levels.
- ✓ Engaging the community and local authorities in the survey. As far as possible, field workers should be hired locally in order to improve access to the population.
- ✓ Testing the community leader(s) first or before the survey and making this information public, where possible.
- ✓ Training health workers/ear and hearing care workers, and field workers in the induction of participants into the survey.
- ✓ A clear and participant selection and recruitment process. Proper information on the survey, including benefits and clear instructions as to how it will be carried out, must be provided to all participants, in a language which they can easily understand.
- ✓ Multiple attempts should be made to contact survey participants. The preferred method of contact may vary with the demographic characteristics and may include a home visit, phone call, letter or email etc.
- ✓ Flexibility in scheduling the examination by offering evening and weekend appointments and rescheduling an appointment where necessary.
- ✓ Locating the test site as centrally as possible to ensure it is accessible for all, including older adults and people with disabilities. Where the test site is far away from houses of participants, transport should be arranged.
- ✓ Where people are unable to visit the test site due to any reason, home visits and examination at home should be considered as an option.
- ✓ Treating survey participants with respect at all times, maintaining confidentiality at all costs. Photographs must never be taken without prior permission of the participants.
- ✓ Financial incentives or gifts may be considered but should take cultural norms and ethics into consideration.

SECTION 4: Data management

DATA MANAGEMENT PLAN

A data management plan is critical to the success of the survey and will have been outlined as part of the study protocol. One person must be in overall charge of data management (a data manager) and should be involved in the discussions regarding the study protocol, data collection forms, data entry and analysis. The main sources of data are likely to be the household roster forms and the data collection forms.

Proper data management includes the following:

- The data manager must ensure accuracy and consistency in data collection, recording and entry.
- All data management procedures should be included in the pilot study, so as to field test and revise them before survey implementation.

A personal identification number (PIN) should be assigned to each participant. Care must be taken to ensure that each participant receives a PIN and that only one PIN is assigned per participant, to ensure smooth data entry. The confidentiality of participants must be respected, and any clinical and personal data should be anonymized.

- The planning team must discuss and agree on the software to be used for data entry and analysis.

The data coding and terminologies noted in the data collection form should be followed, and the data manager should ensure the uniform application of this coding during data entry (see Section 7 for the Data collection form).

Data should be entered and checked continuously during data collection (preferably by two different persons). Validation and consistency checks must be made by the data manager at every step. This should be done by cross checking at least 5% of the entries against the data collection forms (where the clinical and demographic details were first noted). These methods should be clearly noted in the protocol.

Data back-up should be undertaken at regular intervals. All essential documents and files should be securely stored for a pre-agreed period of time.

MINIMIZING ERRORS IN DATA ENTRY

The following steps may help reduce data entry errors:

- Forms and registers should be checked for completeness and consistency before the fieldwork completion in each cluster. If there are missing data or inconsistencies, field team members should provide clarification.
- When using paper forms, the original forms and registers should be copied and kept as a back-up. The original forms and registers are sent to the data manager as soon as the field activities in one cluster are finished and must be promptly entered into the appropriate data management software.
- Data validation should be undertaken at the time of data entry. This includes checking for missing or invalid entries such as incorrect dates, numbers such as age outside plausible ranges, invalid codes and logical consistency checks.
- 5% of the data entries should be cross checked against the original forms by the data manager. Up to 1% of errors are considered acceptable. If the error rate is above 1%, data need to be re-entered

DATA ANALYSIS

Data analysis must be undertaken according to pre-determined indicators. These may include:

- Prevalence in the population.
- Prevalence in specific subsets of the population (based on the objectives of the study):
 - According to sex: males; females.
 - According to age (at last birthday): e.g. 0–4 years; 5–14 years; 15–44 years; 45–60 years; above 60 years.
 - According to geographical distribution: e.g. province A; province B.
 - According to urbanization: e.g. urban, rural, urban slums
 - Other subsets, as may be required by study objectives.
- Profile of hearing loss in the population, i.e.
 - Overall prevalence of hearing loss: to estimate this, the average hearing threshold at 0.5, 1, 2 and 4 kHz should be estimated separately in each ear; hearing threshold

above 20 dB in the better ear should be recorded as hearing loss, based on the grades in Table 1 below.

- Grades of hearing loss: mild, moderate, moderately-severe, severe, profound or complete (see Annex 7 for full classification).
- Hearing threshold above 35 dB in one ear only should be recorded as unilateral hearing loss.
- High frequency hearing threshold should also be calculated during data analysis. This is the average of hearing threshold at 4, 6 and 8 kHz, calculated separately for each ear.
- Frequency of ear diseases: e.g. impacted wax, otitis externa, otitis media (acute, chronic suppurative, non-suppurative), dry tympanic membrane perforations and foreign bodies.
- Other parameters, as required by study objectives (e.g. conductive and sensorineural type of hearing loss, if this has been studied).
- Occurrence and distribution of ear conditions in the study group.
- Correlation of hearing loss with identified ear conditions.

In the case of complex sampling such as in a multi-stage cluster, it is necessary to use the sampling weights to compensate for the study design (see Section 1, subsection on “Identifying the sample”).

Table 1: Estimating hearing loss using grade system

Grades of hearing loss	Average hearing level in better ear at 0.5, 1, 2 and 4 kHz on pure tone audiometry (PTA)
Mild hearing loss	20 to <35 dBHL
Moderate hearing loss	35 to <50 dBHL
Moderate to severe hearing loss	50 to <65 dBHL
Severe hearing loss	65 to <80 dBHL
Profound hearing loss	80 to <95 dBHL
Complete or total hearing loss/deafness	95 dBHL or greater
Unilateral	<20 dBHL in the better ear, 35 dBHL or greater in the worse ear

DATA REPORTING

A detailed report should be developed, including the following sections:

- Background and rationale
- Target population and survey area
- Survey design, sampling methods, sampling weights, and sample size
- Data collection tools, definitions
- Methodology of data collection, including details of technology and its calibration
- Detailed codification of the surveyed data
- Results
- Outcomes and suggested actions

All researchers undertaking a prevalence survey are encouraged to:

Submit findings in a peer reviewed scientific journal

Share the results or if possible, the data with the World Health Organization

(whopbd@who.int)

HEARING LOSS DATABASE

All researchers are encouraged to share the data and results of the survey with WHO. The World Wide Hearing Foundation's "WWHearing" software application can be downloaded and used for data collection, and reporting of some basic demographic information and statistics. Where agreed after seeking permission from researchers, data entered into this application can also be shared with others, including WHO. This will be used to build an online database. Details of the software application and database are annexed (Annex 5)

SECTION 5: Quality assurance

PREREQUISITES FOR A SUCCESSFUL SURVEY

The following features are essential for conducting a successful study:

- Strong commitment and leadership
- Participation of all stakeholders in the protocol development process
- Effective communication with and among the survey team, stakeholders and community
- Sufficient financial resources
- Feasibility studies to develop and test protocols, procedures and logistics
- Development of a suitable survey protocol
- Availability of technical capacity and suitable training
- Comprehensive standard operating procedures
- Timely procurement
- Strong data management
- Community participation
- Participation of state (national or subnational) authorities

ERROR SOURCES

To collect high-quality survey data, the team must consider possible sources of error and try to minimize these. Possible error sources include the following:

- Coverage errors. These occur when population elements that are not part of the target population are sampled, or when those that should be part of the sample are not sampled. Non-response due to refusal or unavailability of the subject also falls into this category.
- Observational errors. These are caused by errors in making and recording the observations and can be attributed to observer, respondent or instrument errors. Inter- and intra- observer error should be documented and corrected during the survey.
- Processing errors. These are mainly clerical errors that occur during coding, entering or analyzing the data

Information on ways to minimize errors and enhance quality assurance are listed in Section 4, subsection on “Minimizing errors in data entry”.

MITIGATING ERRORS

The following factors must be taken into account to ensure a good quality survey that produces results that are representative of the target population. These are:

- The survey team should include representation from all sectors, including ear and hearing professionals, biostatistician(s), epidemiologist(s) and the community.
- A clear survey protocol should be developed, including clearly defined standard operating procedures. Sampling units should be clearly defined at all levels within the survey.
- All field staff should be carefully trained under actual field conditions, in all aspects of their duties, and all office staff should be trained in data coding and entry.

- Pairing each survey staff member with a field team member selected from the community can help to maximize participation.
- Survey staff should sign each form and enter their survey staff number when they have finished completing the form. This encourages good work and makes checking records much easier.
- Inter and intra- observer variations should be measured and quantified. Thus at the beginning and at several points during the survey, the performance of team members should be assessed by comparing different team members testing the same subject, and comparing a particular team member testing the same subject on different occasions.
- Supervisors should make regular, announced and unannounced checks on performance of all survey procedures carried out by survey teams.
- Supervisors should make daily checks of the day's mapping and enumeration, and of

Measuring observer variations

Re-evaluate 5% of the sample (5% of the population tested). This should include 5% of those who were identified as having hearing loss as well as 5% of those who did not have any hearing loss, selected randomly. The hearing test and ear examination should be repeated by an ENT specialist or audiologist (different from the primary examiner) to confirm the clinical findings.

the completed forms.

- A sub-sample of households should be re-checked by supervisors on a regular basis.
- Every effort should be made to find non-responders. There may be a higher prevalence of hearing loss among non-responders, and if they are not found the results of the survey could be biased. If subjects are not at home when the team makes the first visit, a second visit should be made at an appropriate and if possible arranged time to include these subjects. This may include weekends because working adults may be away on weekdays.

- Equipment used for hearing assessment should be regularly calibrated, as per the requirements of the device used. When using an audiometer, this should be calibrated by a laboratory at the beginning of the study. It should subsequently be checked daily by a team member using self-calibration, against their known hearing levels.
- Background noise levels should be below 40 dBA during audiological testing, to maintain optimal test conditions in the field.
- Supervisors should provide field and office staff with regular feedback on their performance, and provide refresher training if necessary.
- Data entry and processing errors should be minimized as noted in Section 4.

SECTION 6: Household roster and data collection form

HOUSEHOLD ROSTER FORM

(To be filled in during visits to participating households)					
Cluster number and household number					
Name of head of family					
Address					
Contact number/s					
Family member's name	Age (years)	Gender (M / F)	Educational status	Occupation	PIN*
*Participant identification number (PIN) (to be allocated)					
<p align="center">APPOINTMENT SLIP TO BE HANDED OVER PARTICIPANTS</p> <p>For the ear and hearing examination, please come:</p> <p>To (venue):</p> <p>On (date and time)</p> <p>In case of any questions or concerns, please contact:</p> <p>..... (name of contact person)</p> <p>..... (contact number of contact person)</p>					

DATA COLLECTION FORM

DATA COLLECTION FORM

A. Participant demographic information (TO BE FILLED IN BEFORE TESTING)

Participant details Participant identification number (PIN) (to be allocated)	The PIN will consist of: Country number/study number/cluster number/household number/participant number
Name:	
Date of birth:	Sex:
Educational status:	None, primary, secondary, post-secondary, graduate, post-graduate
Examination status	Date/s of testing

B. History (TO BE FILLED IN BEFORE TESTING)

B1	For adults (aged above 15 years): Without the use of hearing aids or other listening devices, your hearing is: <input type="checkbox"/> 1=excellent; 2=good; 3=a little hearing trouble; 4=moderate hearing trouble; 5=a lot of trouble; 6=deaf; 7=uncertain; 8=refused For children (up to age of 15 years): Which statement best describes your child's hearing without a hearing aid or listening device? <input type="checkbox"/> 1=excellent; 2=good; 3=a little hearing trouble; 4=moderate hearing trouble; 5=a lot of trouble; 6=deaf; 7=uncertain; 8=refused	B6	Do you (does your child) use a hearing device? <input type="checkbox"/> 1=hearing aid(s); 2=cochlear implant(s); 3=yes; 4=no; 5=uncertain Other
B2	Have you experienced ringing, roaring, or buzzing in your ears or head that lasts for 5 minutes or longer, over the last 12 months? <input type="checkbox"/> 1=yes; 2=no; 3=uncertain	B7	Do you (does your child) have difficulty in hearing even if using a hearing device? <input type="checkbox"/> 1=no difficulty; 2=yes, some difficulty; 3=yes, a lot of difficulty; 4=uncertain
B3	Do you have history of discharging/drainage ears? <input type="checkbox"/> 1=yes; 2=no; 3=uncertain	B8	Are you frequently around loud sound (in your workplace or at home)? ("Loud sound" here refers to background sound such that you have to shout to be understood by someone standing an arm's length from you) 1=never; 2=once a month or less; 3=2-3 times per month; 4=once a week; 5=almost every day <input type="checkbox"/>
Supplementary questions, in case response to B1 is 3-6		B9	How frequently do you use headphones/earphones? <input type="checkbox"/> 1=never; 2=once a week or less; 3=2-3 times per week; 4=every day
B4	How long have you had difficulty in hearing? (To be answered when response to B1 is either 3, 4 or 5) 1: since birth; 2=since childhood; 3=since age 18/59; 4=since old age (60+); uncertain; 5=no difficulty <input type="checkbox"/>	B10	Did you notice the decrease in your hearing after taking any medications? <input type="checkbox"/> 1=yes; 2=no; 3=uncertain
		Supplementary question, in case response to B2 is 1	
B5	Do any relatives have difficulty in hearing? (To be answered when response to B1 is either 3, 4 or 5)	B11	Does ringing, roaring, or buzzing in your ears/head interfere with your ability to:
5.1	Brother/sister: 1=yes; 2=no; 3=uncertain <input type="checkbox"/>	11.1	sleep? 1=yes; 2=no; 3=uncertain <input type="checkbox"/>
5.2	Parent/s: 1=yes; 2=no; 3=uncertain <input type="checkbox"/>	11.2	concentrate? 1=yes; 2=no; 3=uncertain <input type="checkbox"/>
5.3	Children: 1=Yes; 2=no; 3=uncertain <input type="checkbox"/>	11.3	work? 1=yes; 2=no; 3=uncertain <input type="checkbox"/>
			perform daily activities? 1=yes; 2=no; 3=uncertain <input type="checkbox"/>

C. Hearing examination

C1	Right ear	Left ear					
OAE test (up to 5 years)	1. Pass 2 Refer	1. Pass 2 Refer					
C2 Hearing threshold evaluation in participants aged above 5 years (insert actual value)							
Frequency (Hz)	500	1000	2000	4000	6000	8000	Ambient noise level:
Hearing threshold right ear (dB)							Screening examiner's number:
Hearing threshold left ear (dB)							Not fully examined in this section:
							Screening examiner's remarks:

D. Ear examination findings Code to be entered: 1=yes; 2=no; 3=uncertain

		Right	Left			Right	Left
D1	Auricle malformation			D3	Tympanic membrane		
D2	External ear				Perforation		
	Wax				Dull and retracted		
	Wax removed				Red and bulging		
	Foreign body (FB)				Normal		
	FB removed				Not seen		
	Inflammation of ear canal			D4	Middle ear		
	Inflammation of ear canal treated				Otorrhoea		
	Otorrhoea				Cholesteatoma		
	Otorrhoea removed				Normal		
	Fungus (Otomycosis)				Not seen		
	Fungus treated			D5	Others:		
D6	Tympanometry: Code: 1=A; 2=B; 3=C; 4=A _s ; 5=A _D ; 6=uncertain; 7=test could not be performed				Screening examiner's number:		
					Not fully examined in this section:		
					Screening examiner's remarks:		

E. Probable cause of hearing loss (in case of hearing threshold above 20 dB in one or both ears)

		Right ear 1=yes; 2=no; 3=uncertain	Left ear 1=yes; 2=no; 3=uncertain
E1	Unknown		
E2	Wax		
E3	CSOM		
E4	OME		
E5	AOE		
E6	ASOM		
E7	FB		
E8	ARHL		
E9	Other		

Examiner's comments

F. Action needed

Code 1=yes; 2=no

F1	No action
F2	Medication advised
F3	Refer for further evaluation
F4	Refer for urgent evaluation

NOTES ON USE OF DATA COLLECTION AND HOUSEHOLD ROSTER FORMS

Data collection form

The data collection form is a standardized tool for gathering and recording information during the survey. The data collection form:

- (1) is the data-collection instrument for a population-based survey of the prevalence and likely causes of hearing loss;
- (2) enables data collection in a standard way so that results can be compared amongst surveys that use this form;
- (3) helps gather information on the otological actions needed in order to estimate the resources required to deal with these problems in the study population.

It is therefore vital that no changes are made to the form when are used in a survey. However, those conducting the survey may very well decide to gather additional information at the same time and this can be added as a supplement to this form.

Household roster form

When visiting the household, a Roster form (page no. 43) should be completed, one for each household. This should include all persons usually living in that household. The personal identification number (PIN) should be allocated and noted on the Roster Form for each individual within a household. This same PIN will be inserted into the data collection form (see description of PIN below). A copy of the data collection form should be handed to members of the household and provide information regarding place and time of data collection.

The WHO Ear and Hearing Survey Data collection form comprises six different sections, as follows:

- Demographic information
- History
- Hearing examination
- Basic ear assessment
- Cause of ear disease and/or hearing loss
- Action needed

To complete the form, adequate training of survey team personnel is required in advance. Section A and B need literate and numerate personnel. These sections can be filled in either during the household visit or when participants report to the test site. Subsequent sections should be filled in at the test site. Section C needs personnel with audiometric skills to handle equipment to assess hearing. Section D, E and F should be completed in all cases by personnel with experience of work as ENT specialists or health workers with higher level specialist ENT training.

The form must be completed according to the coding instructions. The form is designed to be easy to fill in by marking the boxes and giving further information where indicated.

When the category “specify” is encountered, a detailed description or opinion of the examiner should be stated.

During the survey, the availability of services for ear care, such as provision of medication, wax removal or counselling would be desirable.

A: DEMOGRAPHIC INFORMATION

A unique PIN number should be allocated to each individual. This PIN number will consist of a series of numbers, filled in boxes A1 to A5, which form a unique identification number for each participant.

In this section each box should be filled either by a digit or a letter inside a box, according to the instructions below. The PIN number should be pre-allocated on the data collection forms to avoid duplication.

Allocating a PIN number

The PIN consists of: Country number/study number/cluster number/household number/participant number

NUMBER	ITEM	INSTRUCTIONS
A.1	Country number	The UN 3-figure code must be used if data processing is to take place outside the country. Refer https://www.nationsonline.org/oneworld/country_code_list.htm
A.2	Study number	A reference number to be given to each study conducted within the country. This code, as well as the country code, should preferably be stamped on forms prior to data collection.
A.3	Cluster	This is a grouping of households, such as a village or an enumeration area. A different number should be given to each cluster within each of the administrative divisions.
A.4	Household	Household is the smallest group where people live together, such as a family. The number inserted should identify each household within the cluster. This number should be the same as that on the Household roster form
A.5	Person	The number inserted should identify each person who is a usual resident within the household. Usual resident is defined as a person having resided in the household for a total period of 6 months or more. This number should be the same as that on the Household Roster Form (see description above).
A.6	Name	The participant's name may be filled in for identification purposes but will not be coded.
A.7	Date of birth	This should be entered in the format dd/mm/year. Example: 5 October, 1994 would be 05/10/1994
A.8	Male/Female	Mark M or F as appropriate (1=Female; 2=Male)
A.9	Educational status	Highest educational level should be noted starting from high school 1=high school student; 2=high school graduate; 3=university graduate; 4=post-graduate studies completed; 5=unknown; 6=not applicable (in case of a child below high school level); 7=school drop out
A.10	Exam status	1=examined, 2=refused, 3=absent Code 1 (=examined) should be entered if either complete or partial examination has been performed. Code 2 (=refused) should be entered if the participant (or parent or guardian) refuses to have any type of examination or provide any information. Code 3 (=absent) should be entered if the participant is a usual resident who is not present during the entire survey period. Even if the participant is absent or refused, the census section should still be completed as far as possible and the form submitted for analysis
A.11	Date	Date, month and year of this examination should be entered in the format dd/mm/year.

B: HISTORY

The following questions can be used to gather baseline information regarding participants' hearing status and history of risk factors.

The core questions (B1–3) must be asked of all participants. The supplementary questions (B4–11) need to be asked as indicated.

These questions should be administered as such. The code (i.e. number 1–8) should be entered in the box opposite the question in the data collection form. If required, supplementary questions can be added.

These questions can be asked either during the household visit or when the participants are at the test site.

CORE QUESTIONS	
B1	<p>For adults (above 15 years of age):</p> <p>Without the use of hearing aids or other listening devices, your hearing is:</p> <p>1=excellent; 2=good; 3=a little hearing trouble; 4=moderate hearing trouble; 5=a lot of trouble; 6=deaf; 7=uncertain; 8=refused</p> <p>For children (up to 15 years of age):</p> <p>Which statement best describes your child's hearing without a hearing aid or listening device?</p> <p>1=excellent; 2=good; 3=a little hearing trouble; 4=moderate hearing trouble; 5=a lot of trouble; 6=deaf; 7=uncertain; 8=refused</p>
B2	<p>Have you experienced ringing, roaring, or buzzing in your ears or head that lasts for 5 minutes or longer, over the last 12 months?</p> <p>1=yes; 2=no; 3=uncertain</p>
B3	<p>Do you have history of discharging/draining ears?</p> <p>1=yes; 2=no; 3=uncertain</p> <p>Supplementary questions, in case response to B1 is 3–6</p>
B4	<p>How long have you had difficulty in hearing? (To be answered when response to B1 is either 3, 4 or 5)</p>

	1: since birth; 2=since childhood; 3=since age 18/59; 4=since old age (60+); uncertain; 5=no difficulty
B5	Do any relatives have difficulty in hearing? (To be answered when response to B1 is either 3, 4 or 5).
5.1	Brother/sister: 1=yes; 2=no; 3=uncertain
5.2	Parent/s: 1=yes; 2=no; 3=uncertain
5.3	Children: 1=yes; 2=no; 3=uncertain
B6	Do you (does your child) use a hearing device? 1=Hearing aid(s); 2=cochlear implant(s); 3=yes, other; 4=no; 5=uncertain
B7	Do you (does your child) have difficulty in hearing even if using a hearing device? 1=no difficulty; 2=yes, some difficulty; 3=yes, a lot of difficulty; 4=uncertain
B8	Are you frequently around loud sound (in your workplace or at home)? ("Loud sound" here refers to background sound such that you have to shout to be understood by someone standing an arm's length away) 1=never; 2=once a month or less; 3=2-3 times per month; 4=once a week; 5=almost every day
B9	How frequently do you use headphones/earphones? 1=Never; 2=once a week or less; 3=2-3 times per week; 4=every day
B10	Did you notice the decrease in your hearing after taking any medications? 1=yes; 2=no; 3=uncertain Supplementary questions, in case response to B2 is 1
B11	Does ringing, roaring, or buzzing in your ears or head interfere with your ability to: 11.1 sleep? 1=yes; 2=no; 3=uncertain 11.2 concentrate? 1=yes; 2=no; 3=uncertain 11.3 work? 1=yes; 2=no; 3=uncertain 11.4 perform daily activities? 1=yes; 2=no; 3=uncertain

C: HEARING EXAMINATION

A hearing examination should take place at the test site and be carried out by a trained person. If occluding wax or a foreign body or pus is present, audiometry should be performed without removing it, and the results recorded in the boxes in Section B of the form. This is in order to measure the existing level of hearing (before any intervention). (The examiner may request further audiology after removal for diagnostic purposes, but there is no need to record the second set of audiological results.)

In cases where wax, a foreign body or ear discharge is obstructing the ear canal and is removed, the hearing assessment should be repeated following the removal and also recorded. However, the pre-removal thresholds should be used for estimation of prevalence.

As hearing assessment is to take place prior to removal of ear wax or discharge, it is advisable to use supra-aural or circum-aural headphones with audio-cups and not to insert earphones for the hearing assessment.

Ambient noise: The testing must be performed in as quiet a room as possible. Ambient noise is recommended not to exceed 40 dBA measured by a sound level meter or a validated software application.⁶ The level of ambient noise should be recorded in the relevant box in section C of the data collection form. Even if ambient noise is higher than 40 dBA, hearing testing should continue, and the results, including the level of ambient noise, should still be recorded in the boxes. All equipment used in testing should be assigned a unique number and this number should be noted in every data collection form.

- | | |
|--------------|---|
| C.1 | Hearing examination for children (age up to 5 years): otoacoustic emission (OAE) testing should be undertaken in children up to 5 years of age. |
| C.1.1 | Type of OAE test to be used: While either Distortion Product Otoacoustic Emissions (DPOAE) or Transient Evoked Otoacoustic Emissions TEOAE can be used for hearing screening, it is recommended to use DPOAE as part of this survey protocol, for consistency. |
| C.1.2 | Test procedure: The test procedure will depend on the equipment being used. It is important for the testers to familiarize themselves with the relevant equipment and to follow the relevant test procedure. |
| C.1.3 | Pass/refer criteria: will depend on the equipment being used. It is important for the testers to familiarize themselves with the relevant equipment and its pass/refer criteria |
| C.1.4 | Recording results: the test result should be recorded as a “pass” or “refer” for each ear separately. If the child has a “pass” result in both ears, this should be recorded. The final of the two results should be recorded in the data collection form (separately for each ear) as 1=pass; 2=refer; 3=could not be performed. If for any reason the test cannot be administered, or if the child fails the OAE test in either ear, the child should |

⁶ Validated sound level apps can be used such as: NIOSH SLM, SPLnFFT, Noise Hunter, NoiSee or SoundMeter (<http://scitation.aip.org/content/asa/journal/jasa/135/4/10.1121/1.4865269>).

be re-evaluated on another day. When this is not practical, the repeat OAE test should be attempted the same day.

Note: When the child repeatedly fails the OAE test, the child must be referred for an Auditory Brainstem Response test (ABR) which should be done for diagnostics purposes.

C.2 Audiometry (age 5 years and over)

Pure tone audiometry is performed for all individuals who are 5 years of age and over. The system and method must be uniform throughout each survey. The hearing examination procedure should be carefully explained to each person. Although every effort should be made to use pure tone audiometry in children aged 5 years and over, if a child cannot be tested this way, OAE test (section BI) can be used.

C.2.1 **Ambient noise**

See previous section.

Calibration

The audiometer needs to be calibrated regularly to ensure reliability. Portable audiometers should be calibrated as follows:

1. Daily biologic calibration check.
2. Regular audiometric calibration, at least every 6 months.
3. Regular battery testing to make sure they are at full strength.
4. If an audiometer requiring power connection is used, a voltage stabilizer should be used since reduction in

voltage can produce reduction in audiometer output

Testing procedure

The person who being tested should be seated with his/her back to the control panel and examiner. Each ear should be tested separately, the right ear first. If possible, noise-excluding headsets should be used. The headphones should be well fitting. Each time the participant hears the sound, he/she should respond to the tester by using a simple sign, e.g. raising a hand.

C.2.2 **Hearing thresholds**

0.5, 1, 2, 4, 6 and 8 KHz

Therefore, the presentation of sound at the start of the test should be 60 dBHL at 1 KHz. If there is no response to this threshold, it should be increased in 10 dB steps until the participant responds to the sound. Once the participant has heard a sound, the threshold of hearing should then be established by decreasing thresholds by 10 dB steps and

		<p>increasing by 5 dB steps until the threshold is established by participant confirming threshold on three successive occasions. No correction factors should be used since these will be inserted at the analysis stage if necessary.</p> <p>These thresholds should be established in the same manner at 0.5, 2, 4, 6 and 8 KHz and then finally, the threshold should be established again at 1 KHz and should be within 5 dB of the original measurement at 1 KHz. If not, repeat the whole audiogram.</p> <p>Hearing thresholds should be entered for each frequency in both ears separately in the data collection form. Any threshold above 20 dB HL is considered indicative of hearing loss.</p> <p>Each screening examiner should enter his/her assigned code.</p>
C.2.3	Screening examiner number	
C.2.4	NOT FULLY EXAMINED IN THIS SECTION	This box should be ticked if the participant was not fully examined in Section C.
C.2.5	SCREENING EXAMINER'S REMARKS	This is the opinion of the examiner as to why the Examination could not be completed satisfactorily. The reason should be recorded. The equipment number should be noted here.

D: EAR EXAMINATION

D.1	Auricle	
	1. Auricle malformation	Examine the auricle to look for any malformations, such as small sized or absent pinna, or presence of sinus/es in front of the pinna. Enter the appropriate code: 1= malformation of auricle; 2=no malformation; 3=uncertain
D.2	External ear canal	
	1. Wax [Removed]	1=yes; 2=no; 3=uncertain Mark the appropriate box with a tick if the wax was removed by any member of team*.
	2. Foreign body Removed]	1=yes; 2=no; 3=uncertain If identifiable, please describe what it is in Special Examiner's Remarks. Mark the appropriate box with a T if object is removed from ear canal by member of team**.
	3. Inflammation [Treated]	Is there any redness or tenderness of the ear canal 1=yes; 2=no; 3=uncertain Mark the appropriate box with a "T" if treatment has been given for the ear canal inflammation.
	4. Otorrhea	Look for evidence of any pus in the ear canal. 1=yes; 2=no; 3=uncertain. If the ear canal has been cleaned by a member of the team so that the ear canal is visualized, mark the appropriate box with a "T". If the ear was not touched leave box blank.
	5. Fungus	Look for any evidence of a fungal infection. 1=yes; 2=no; 3=uncertain Mark the appropriate box with a "T" if treatment has been given for the fungus in ear canal.

** The special examiner for Section C may wish the subject to have repeat hearing thresholds for diagnostic purposes after the removal of wax, or a foreign body, or pus. These repeat hearing thresholds should not be recorded in the boxes in Section B.

- . D.3 Tympanic membrane: Examine the tympanic membrane with the use of an otoscope and look for evidence of any abnormality such as perforation, dullness or retraction, bulging and red tympanic membrane. Enter the number corresponding to the findings, as given below. If the tympanic membrane is normal or if it cannot be clearly examined, this should be noted.

1. Perforation	1=yes; 2=no; 3=uncertain
2. Dullness or retraction	If the tympanic membrane is dull or retracted and the light reflex is poor, mark yes. 1=yes; 2=no; 3=uncertain
3. Bulging and red	Look for evidence that the tympanic membrane is tense and bulging and the drum mucosa appears red. These signs, when seen together with ear pain are indicative of acute otitis media. 1=yes; 2=no; 3=uncertain
4. Normal	If the eardrum appears normal, mark yes 1=yes; 2=no; 3=uncertain
5. Not seen	If the tympanic membrane cannot be examined respond yes: 1=yes; 2=no

- D.4 Middle ear: In case of a perforation of tympanic membrane, examine the middle ear mucosa through the perforation and note the findings as follows:

1. Otorrhea	If, on otoscopy, there is definitely otorrhea within the middle ear, enter 1=yes; 2=no; 3=uncertain
2. Cholesteatoma	Examine for evidence of cholesteatoma 1=yes; 2=no; 3=uncertain
3. Normal	If no abnormality is identified 1=yes; 2=no; 3=uncertain
4. Not seen	If the middle ear cannot be seen for any reason, respond yes: 1=yes; 2=no

- D.5 Others If there is any other abnormal finding related to any part of the ear or mastoid region and specify these findings in the space provided.
- D.6 Tympanometry This should be conducted using a portable tympanometer. Participants with canal inflammation or with impacted wax, blood, pus discharge, debris, foreign body or growth in the external auditory canal should be excluded from this test. The type of curve (A, B, C, A_s or A_D) should be determined and recorded as follows:
1=A; 2=B; 3=C; 4=A_s; 5=A_D; 6=uncertain; 7=test could not be performed
- D.7 Examiner number Each screening examiner should enter his/her assigned code.
- D.8 Not fully examined in this section This box should be ticked if the participant was not fully examined in Section D.
- D.9 Examiner's remarks This is for the opinion of the examiner as to why the examination could not be completed satisfactorily. The reasons should be recorded.

E: PROBABLE CAUSE OF HEARING LOSS

This section should only be filled for those participants where an abnormality was identified during ear or hearing examination. If none is found, this section should be left blank.

The definition of normal hearing, for the purposes of this section, is that *either* in section C.2, the OAE test result is pass in both ears; *or* that in section C.3 no hearing threshold box is marked as 26 dBHL or greater.

Common ear diseases that are encountered should be documented (and coded). The following case definitions and codes should be applied. Examination of ear should be undertaken by an experienced otoscopist and whenever possible, any diagnosis of ear conditions be made in consultation with a special examiner trained in identification of ear problems. The survey protocol does not aim to identify and document the cause of hearing loss in each person identified as having hearing loss. It aims only to document those problems which are evident upon examination of external ear and tympanic membrane.

- E.1 None identified (unknown) 1=yes; 2=no

E.2 Impacted wax (wax) 1=yes; 2=no; 3=uncertain

In cases where wax is encountered in the ear canal, written consent for wax removal should be obtained from the adult participant/child's guardian before an attempt is made by a trained person to remove it. If wax cannot be removed and it was completely obstructing the view of the tympanic membrane, it should be noted as a diagnosis of impacted wax. In those cases where the wax can be easily removed from the canal with the help of a probe and the tympanic membrane is clearly visible, it is not considered to be impacted and such cases should not be classified as impacted wax.

E.3 Chronic suppurative otitis media (CSOM) 1=yes; 2=no; 3=uncertain

Recurrent or persistent ear discharge lasting for more than 2 weeks and the presence of a central perforation are criteria for diagnosis of chronic suppurative otitis media of the tubotympanic (safe) type.⁵ Active ear discharge is a requirement for this diagnosis. History of ear discharge, with evidence of cholesteatoma, marginal or attic perforation or evidence of retraction pocket, point to a diagnosis of atticoantral (unsafe) type of CSOM.

E.4 Otitis media with effusion (OME) 1=yes; 2=no; 3=uncertain

Dull, retracted tympanic membrane with reduced mobility and/or evidence of fluid in middle ear, along with a type B tympanogram are considered indicative of OME.

E.5 Acute otitis externa (AOE) 1=yes; 2=no; 3=uncertain

Signs of inflammation of the external auditory meatus with or without ear discharge and fungal debris are indicative of otitis externa.

E.6 Acute suppurative otitis media (ASOM) 1=yes; 2=no; 3=uncertain

Diagnosis of ASOM is made on the basis of redness, bulging or acute discharging perforation of the tympanic membrane, mostly with a history of acute ear pain.

E.7 Foreign body in the ear (FB) 1=yes; 2=no; 3=uncertain

This is the presence of any external object or creature in the ear.

E.8 Age-related hearing loss (ARHL) 1=yes; 2=no; 3=uncertain

It should be suspected as the probable cause in people above the age of 60 years with no history of childhood hearing loss or other risk factors.

E.9 Any other: (to be noted) Examiner's comments:

Comments from examiner regarding probable cause of hearing loss and any specific factors worth noting.

F. Any further action required should be noted in consultation with a doctor trained to make the decision for medication and referral.

SECTION 7: Protocol for rapid assessment of hearing loss

(written by Tess Bright and Hannah Kuper,
The London School for Hygiene and Tropical Medicine)

A tool for rapid assessment of the prevalence of hearing loss is useful for settings where data are needed quickly, or where time- or cost-related factors are barriers to carrying out a full epidemiological survey. Rapid assessment provides a quicker and cheaper option that can serve to:

provide an estimate of hearing loss prevalence in people aged 50 years or older;

give an indication regarding hearing loss prevalence in the community;

serve as a first step to the planning of, and raising resources for, an in-depth survey, as outlined in this survey handbook.

This section provides an outline of the RAHL concept and methodology.

Rapid assessment: the concept

RAHL provides a cheaper and quicker alternative to a full epidemiological survey by:

- Restricting the sample to people aged 50 years and older: the age restriction is based on evidence that over 75% of people with hearing loss are aged 50 or older. Due to the higher prevalence of hearing loss in this group, the sample size needed is drastically reduced.
- Simplified examination protocol: the use of validated smartphone/app-based tools offers a cheaper and quicker means for prevalence assessment.
- Simplified two-stage sampling method.
- Simple standardized analyses.

AIM OF RAHL

To estimate the prevalence of hearing loss in people above 50 years and its probable causes
To make projections regarding the prevalence of hearing loss in the entire population

SURVEY DESIGN AND SAMPLE

Sample size is estimated locally based on the approximate prevalence of hearing loss in the target population i.e. people above 50 years of age (see Section 1, subsection on “Estimating sample size” for details of sample size estimation). Given the high prevalence of hearing loss in this age group, a much smaller sample size is expected as compared to a full population-based survey including all age groups.

Survey design: A cluster design is recommended (see Section 1, subsection on “Survey design and methods”). Each cluster should comprise 50 sampling units (50 individuals above the age of 50 years). The total number of clusters will depend on the sample size required based on the expected prevalence.

Sampling strategy: A two-stage sampling procedure is recommended.

First, the required number of clusters will be selected through probability proportionate to size (PPS) sampling using the most recent national census or similar source of population data. The next step is to select households within clusters. This can be done by a compact segment sampling method (see Box 11).

Box 11: Compact segment sampling

Each cluster should be divided into segments of approximately 50 people aged ≥ 50 years. For example, if a cluster includes 200 people aged ≥ 50 years then it should be divided into four segments.

One segment should be chosen at random by drawing lots, and all households in the chosen segment visited, until 50 people aged ≥ 50 years are identified. If the segment does not include 50 people aged ≥ 50 years, then another segment should be chosen at random and sampling continued until 50 people are identified and examined.

EXAMINATION PROTOCOL

Data collection should be done by going from house to house and seeking out all household members aged 50 years or above.

Following enumeration and obtaining basic demographic information for each participant, all participants should undergo a hearing assessment. In the case of rapid assessment (in contrast to the recommendations made in Section 3 of the survey protocol), all examinations should take place in the participant's home at the time of enumeration. There are two stages to a hearing assessment under the Rapid Assessment Hearing Loss protocol: 1) hearing assessment; 2) assessment of probable causes of any hearing problems.

Step 1: Perform a hearing assessment

All eligible participants should be assessed by a trained data collector using validated, automated audiometry software. The chosen system must be able to determine hearing thresholds at 500–8000 Hz. Details of suitable software applications evaluated by WHO are provided in Annex 3.

Background noise should be measured and recorded before each assessment either within the mobile testing application (as some have inbuilt noise monitoring capabilities) or using a separate sound-level meter app. Information is available on page no. 44 the data collection form.

A pure tone average of thresholds at 0.5, 1, 2, 4, 6 and 8 kHz in the better ear should be obtained to determine the hearing threshold and estimate any degree of hearing loss, in line with the WHO definitions (see Section 4)

- Before the survey takes place, calibrate the chosen mobile-based audiometry.

Step 2: Assess probable causes of any hearing loss

All participants should be examined by a trained local clinician (audiologist, ENT specialist or ENT clinical officer) using otoscopy. However, where this is not feasible, video-otoscopy (can be smartphone-based) with remote interpretation is acceptable.

In addition, a questionnaire should be administered for those identified as having hearing loss to assist in the determination of the probable causes (see Section B of the data collection form).

SURVEY TEAM

A RAHL team should consist of the following members:

- Team leader
- Ear and hearing care workers (one of them may be team leader)
- Field workers
- Driver

It is also desirable to have one person with specialized knowledge about ear diseases and hearing loss, such as an ENT specialist or audiologist, as part of the team. If possible, one member of the team should be conversant in the use of local sign language

EQUIPMENT REQUIRED

Otoscope

Hearing testing software applications with required hardware

Other tools (such as ear probe, forceps etc.)

Disposables

Eardrops and other medicines

Tablet for data collection

Missed participants

Persons above the age of 50 years that could not be examined during the first visit must be followed up and arrangements made to ensure their inclusion in the sample. This is especially important as it may be more likely to find older individuals at home compared to other eligible community members. This is essential in order to ensure that a representative sample is included.

DATA ENTRY AND ANALYSIS

Where possible, data collected should be entered directly into a mobile application (such as Open Data Kit). Where not possible, data must be collected using paper forms. Data should be double-entered, with the two versions compared to establish accuracy. Consistency checks should then be run to ensure that data are feasible (e.g. no cause of hearing loss should be included for people with normal hearing).

Data should be analyzed as recommended to allow comparison of data. The main study outcomes for the RAHL are:

- Overall prevalence of hearing loss (mild, moderate, severe and profound) in persons aged 50 years and above (with 95% confidence intervals). Prevalence of moderate or higher grade of hearing loss in persons aged 50 years and above (with 95% confidence intervals).
- Probable causes of hearing loss in study population.
- Data should be disaggregated by age (50–59; 60–69; 70–79; 80+; above 100), gender, education, rural/urban locations and any other relevant parameter.

Data can also be extrapolated to provide prevalence estimates for the entire population using the following steps (see Box 12 for an example):

Note the prevalence of hearing loss in population aged 50 years or above, determined through the RAHL survey: a

Note the proportion of population aged 50 years or above, from available census or population information: b

Note the population of interest (either 1 million people or for the defined geographic population): Total population: c

Estimated proportion of hearing loss in those aged ≥ 50 (out of the total population)^{§§}: 75%

Calculate the number of people aged ≥ 50 with hearing loss in the population (d) = $a*b*c$

Box 12: Extrapolating estimated prevalence among persons aged 50+ to entire population: an example

Note the prevalence in population aged ≥ 50 , determined through the RAHL survey: $a = 0.15$

Note the proportion of population aged ≥ 50 , from available census or population information: $b = 0.10$

Note the population of interest (either for 1 million people or for the defined geographic population): $c = 1\,000\,000$

Estimated proportion of hearing loss in ≥ 50 (out of the total population): **75%**.

Number of people aged ≥ 50 with hearing loss $d = (0.15*0.10*1\,000\,000) = 15\,000$

Number of people with hearing loss in population $e = 1/0.75 * (0.15*0.10*1\,000\,000) = 20\,000$

Prevalence of hearing loss in the population $e/c = 20\,000/1\,000\,000 = 2\%$

Calculate the total number of people with hearing loss in the population (e) = $1/0.75 * (a*b*c)$
= $1/0.75*d$

Estimate the prevalence of hearing loss in the population = e/c

ADVANTAGES OF RAHL

- Requires fewer resources and time.
- Provides a valid assessment of hearing loss prevalence in population aged ≥ 50 .
- Provides an assessment of probable causes of hearing loss in population aged ≥ 50 .
- Provides an estimate of hearing loss prevalence in the entire population.

LIMITATIONS OF RAHL

Children and adults aged below 50 years are not assessed in the survey, therefore enough evidence needs to be gathered by comparing the RAHL tool and the survey protocol for all age groups, carried out simultaneously in the same geopolitical areas, in order to be able to extrapolate valid and reliable hearing loss prevalence estimations for each age group (particularly for infants and children), based on the results obtained with the RAHL tool for the 50+ age population.

Unless care is taken, sampling may capture only those older adults that are at home, excluding adults aged ≥ 50 years who are working.

ANNEX 1: Sample size estimation and sampling

This annex provides useful online resources to assist in sample size calculation, and complex sampling techniques and weighting. It also provides WHO regional estimates of hearing loss prevalence that can be used for sample size calculation, in absence of suitable local, national or regional published estimates on hearing loss prevalence.

Available online resources

1. WHO STEPS: WHO's STEPwise approach ("STEPS") supports countries in computing national/subnational prevalence estimates of non-communicable diseases (NCDs) and their risks factors. STEPS comprises several practical resources and tools, including the [STEPS manual](#), which sets out the steps for accomplishing a national/subnational survey. It includes sampling size guidelines, comprehensive explanations, and sampling size determination examples (see pages 86 to 93). The resources include a [sample size calculation tool](#)^{***} that can be easily applied to determine the sample size for a study to determine hearing loss prevalence in the population.

The STEPS resources also include a [sampling spreadsheet](#) that can help biostatisticians and epidemiologists to:

- determine the probability proportional to size (PPS) sampling
- undertake simple random sampling
- weight the data.

Steps of the sampling procedure and related examples are provided on pages 85 to 113 of the manual.

^{***} STEPS sample size calculator and sampling spreadsheet is available at <http://www.who.int/ncds/surveillance/steps/resources/sampling/en/>, accessed 3 October 2019.

2. Demographic and Health Surveys Program (see [DHS](#)) collects and disseminates nationally/regional representative data on several health and related topics, and has developed several tools and resources to undertake a national survey (see [survey data](#)). It includes a comprehensive [Survey Household Manual](#) which explains the steps for performing a national/subnational survey, including sample size calculation, and examples (see pages 7 to 12); sampling techniques with excel templates for stratified PPS sampling or equal probability systematic sampling (pages 52 to 70); and a full glossary of complex sampling terms (see pages 80 to 87).
3. The Demographic and Social Statistics Division of the UN (see [UNSD](#)) collects, compiles and disseminates official statistics on a wide range of social and demographic topics, and develops standards, guidelines and methods. UNSD has developed several tools and resources to accomplish effectively a national survey (see [survey's publications](#)), including a comprehensive [Survey Household Manual](#). The manual explains the steps for performing a national/subnational household survey, including sample size calculation, and examples (pages 34 to 42); as well as sampling techniques and examples for stratified PPS sampling or equal probability systematic sampling (see pages 25 to 72).

WHO regional estimates

In 2012, WHO developed estimates of the number of people with hearing loss globally. These estimates are based on a meta-analysis of population-based studies of hearing loss prevalence in different countries, and were adjusted for population changes in 2018 (*available at <https://www.who.int/deafness/estimates/en/>*).

Table 1.1 provides the key prevalence statistics in different regions, while Table 2 provides a list of the countries included in each region. Sample size estimation requires an initial estimate of hearing loss prevalence. Ideally such a figure should be sought in published peer reviewed literature that provides a valid assessment of hearing loss prevalence in the target population. Alternately, such data can be obtained through a pilot study in the target population. Where none of these is available, data from sources listed below can be used, in consultation with a biostatistician for estimation of sample size, directly using the formula provided in Section 1,

"Survey design and methods" subsection of the handbook, or through the [sample size calculation tool](#).

Sources of global and regional hearing loss estimates

1. *WHO global and regional estimates on prevalence of hearing loss (these are summarized in Table 1.1 and Table 1.2)* Fuller estimates are available at <https://www.who.int/deafness/estimates/en/>.
2. *The Institute for Health Metrics and Evaluation (IHME) GBD Global/Regional/Country estimates on prevalence of hearing loss (choose context impairment and impairment hearing loss under the "[estimates GHDx tool](#)").*
3. *Stevens G, Flaxman S, Brunskill E, Mascarenhas M, Mathers CD. Global and regional hearing impairment prevalence: an analysis of 42 studies in 29 countries. European Journal of Public Health. 2013;23(1):146–15.*

Table 1.1: WHO 2018 estimates for prevalence of disabling hearing loss (DHL)* in regions of the world

	Prevalence of DHL in the world (%)	Prevalence of DHL in high-income countries (%)	Prevalence of DHL in the Central/Eastern Europe, Central Asia region (%)	Prevalence of DHL in the Sub-Saharan Africa region (%)	Prevalence of DHL in the Middle-East and North Africa region (%)	Prevalence of DHL in the South Asia region (%)	Prevalence of DHL in the Asia-Pacific region (%)	Prevalence of DHL in the Latin America and Caribbean region (%)	Prevalence of DHL in the East Asia region (%)
0–14 years total	1.73%	0.50%	1.55%	1.93%	0.92%	2.39%	2.02%	1.60%	1.28%
0–14 years male	2.13%	0.62%	1.91%	2.38%	1.13%	2.94%	2.49%	1.98%	1.56%
0–14 years female	1.31%	0.38%	1.16%	1.47%	0.69%	1.80%	1.53%	1.21%	0.95%
15–34 years total	1.73%	0.39%	1.30%	1.93%	0.79%	2.24%	1.84%	1.33%	1.15%
15–34 years male	2.13%	0.49%	1.60%	2.39%	0.98%	2.76%	2.27%	1.65%	1.40%
15–34 years female	1.31%	0.30%	0.98%	1.46%	0.59%	1.68%	1.40%	1.01%	0.86%
35–64 years total	6.53%	2.18%	6.55%	8.30%	3.69%	9.96%	8.42%	6.27%	5.84%

35–64 years male	7.92%	2.69%	7.96%	10.06%	4.48%	12.02%	10.22%	7.67%	7.10%
35–64 years female	5.13%	1.67%	5.28%	6.62%	2.83%	7.81%	6.68%	4.94%	4.53%
65 or more years total	33.17%	18.36%	36.56%	44.38%	26.40%	48.85%	43.69%	38.47%	33.71%
65 or more years male	37.73%	21.03%	41.47%	50.30%	30.82%	54.59%	49.24%	43.52%	38.28%
65 or more years female	29.43%	16.23%	33.73%	39.60%	22.58%	43.51%	39.46%	34.53%	29.50%
15 years or more (all adults)	7.64%	5.36%	9.95%	6.47%	4.08%	9.36%	8.62%	7.67%	8.03%
15 years or more (all adults male)	8.56%	5.82%	10.14%	7.41%	4.66%	10.69%	9.62%	8.50%	9.10%
15 years or more (all adults female)	6.72%	4.93%	9.79%	5.55%	3.48%	7.96%	7.65%	6.87%	6.93%
All ages total	6.12%	4.57%	8.36%	4.55%	3.17%	7.37%	6.90%	6.18%	6.85%
All ages male	6.86%	4.93%	8.45%	5.25%	3.64%	8.44%	7.71%	6.85%	7.72%
All ages females	5.36%	4.21%	8.27%	3.85%	2.67%	6.22%	6.10%	5.53%	5.93%

* Disabling hearing loss refers to hearing loss above 40 dB in the better hearing ear in adults and above 30 dB in the better hearing ear in children.

Table 1.2: Countries included in the regions listed in Table 1.1

East Asia region
Democratic People's Republic of Korea, China (including Chinese Taipei, Hong Kong SAR (China), Macau SAR (China))
Asia Pacific region
Cambodia, Cook Islands, Fiji, French Polynesia, Indonesia, Lao People's Democratic Republic, Kiribati, Malaysia, Maldives, Marshall Islands, Micronesia (Federated States of), Myanmar, Nauru, Niue, Palau, Papua New Guinea, Philippines, Samoa, Solomon Islands, Sri Lanka, Thailand, Timor-Leste, Tonga, Tuvalu, Vanuatu, Viet Nam
South Asia region
Afghanistan, Bangladesh, Bhutan, India, Nepal, Pakistan
Central / Eastern Europe and Central Asia region
Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Mongolia, Tajikistan, Turkmenistan, Uzbekistan, Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, Macedonia (Former Yugoslav Republic of), Montenegro, Poland, Romania, Serbia, Slovakia, Slovenia Belarus, Estonia, Latvia, Lithuania, Moldova, Russian Federation, Ukraine
Middle East and North Africa region
Algeria, Bahrain, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Occupied Palestinian Territory, Oman, Qatar, Saudi Arabia, Syrian Arab Republic, Tunisia, Turkey, United Arab Emirates, Yemen
Sub-Saharan Africa region
Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Seychelles, Somalia, South Africa, Sierra Leone, Sudan, Swaziland, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe
Latin America and Caribbean region
Argentina, Antigua and Barbuda, Bahamas, Barbados, Belize, Bermuda, Brazil, British Virgin Islands, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Netherlands Antilles, Nicaragua, Panama, Paraguay, Peru, Puerto Rico, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela (Bolivarian Republic of)
High-income countries
Andorra, Australia, Austria, Belgium, Brunei Darussalam, Canada, Cyprus, Denmark, Finland, France, Germany, Greece, Greenland, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Malta, Monaco and San Marino, Netherlands, New Zealand, Norway, Portugal, Singapore, Spain, Sweden, Switzerland, United Kingdom, United States of America

Complex sampling design data analysis software

The analysis of complex sampling design survey data has to be done using statistical software that takes into account the characteristics of the sample design. These designs usually include features such as multiple stages of sample selection, clustering, stratification, and unequal probabilities of selection. The packages listed (alphabetically) here are those frequently used to accomplish this task:

Epi Info is a public domain suite of interoperable software tools designed for the global community of public health practitioners and researchers. You can use StatCalc calculator to compute sample size (see [samplesize](#)). It can perform complex survey data manipulation (see [tutorial](#)). More information about the software can be found at [Epi Info](#).

R is an open-source software environment for statistical computing and graphics for several research fields. You can use the [samplesize4surveys](#) library to compute sample size (see [samplesize4surveys](#)). It can perform complex survey data manipulation (see [tutorial](#)). More information about the software can be found at [R Project](#).

SAS/STAT is a software suite developed by SAS Institute for advanced analytics, multivariate analyses, business intelligence, data management, and predictive analytics. It can perform complex survey data manipulation. Examples of such procedures are: `surveymeans`, `surveyfreq`, `surveylogistic`, `surveyreg`, etc. (see [tutorial](#)). More information about the software can be found at [SAS/STAT](#).

Statistical Package for the Social Sciences (SPSS) software is a popular statistical package developed by IBM that can perform complex data manipulation and analysis, such as sample size calculator and complex sampling functions that take into account complex sampling design. Examples of such procedures are: `csplan`, `csselect`, `csdescriptives`, `csglm`, etc. (see [tutorial](#)). More information about the software can be found at [SPSS](#).

Stata is a general-purpose statistical software package focused on research for data management, statistical analysis, graphics, simulations, regression, and custom programming.

It can perform complex survey data manipulation. Examples of such procedures are: svy:means, svy:regress, svy:logit etc. (see [tutorial](#)). More information about the software can be found at [STATA](#).

SUDAAN is a statistical software package for the analysis of correlated data, including correlated data encountered in complex sample surveys. It can perform complex survey data manipulation. Examples of such procedures are: crosstab, regress, logistic etc. (see [tutorial](#)). More information about the software can be found at [SUDAAN](#).

ANNEX 2: Minimum training requirements for non-qualified audiologists to perform hearing assessments

SCOPE

This annex outlines the minimum training required to perform an ear and hearing assessment during the conduct of the prevalence survey using this handbook.

It is essential that staff assessing subjects during the survey should have clearly identified roles and responsibilities and should receive appropriate training. This is vital for improving the reliability of survey outcomes, and ensuring that subjects are informed and advised correctly of their test results and intervention options.

Ideally, such training should be gained through accredited courses. However, where such trained staff and accredited courses are not available, survey planners can use the guidance provided here to train the survey staff. Training should be practical and include “hands-on” experience under the supervision of qualified and experienced tutors.

Staff should also be trained to raise awareness as part of the survey’s activities. Training may cover any cultural sensitivities specific to areas under coverage.

TOPICS TO BE COVERED IN TRAINING

1. Knowledge of ear and hearing loss (impairment)
 - Structure and function of the ear, including how sounds travel along the auditory pathway.
 - The different types and levels/classification of hearing loss, and its common causes.
 - Common ear problems and diseases, such as wax, otitis media, foreign bodies etc.

- Risk factors for hearing loss (impairment) and advice on preventative measures.
- Communication needs of hearing impaired people.
- Confidentiality, informed consent and record handling.

2. Testing procedures and limitations*

Pure-tone audiometry	Principles of pure-tone audiometry and a recommended procedure	Contraindications for audiometry	Correct method for pure-tone a-c threshold determination. The audiogram and interpretation of results
Tympanometry	Principles of tympanometry and a recommended procedure	Contraindications for tympanometry	Correct method for tympanometry The tympanogram and interpretation of results
Otoscopy	Theory and practice of otoscopy	Relevant health and safety issues, e.g. discharging ears	Interpretation of results, effect of presence of wax on results

*Trainees should be sensitized to factors that could affect the reliability or validity of the test results.

3. Calibration of equipment, especially audiometers and tympanometers
4. Assessment of ambient noise levels using either:
 - Sound level meters (validated apps for assessment of environmental sound levels e.g. [NIOSH NLM](#); SPLnFFT, Noise Hunter, NoiSee or SoundMeter).⁺⁺⁺
5. Gaining informed consent and completing the data collection form (adults and children)

⁺⁺⁺ Available at <http://scitation.aip.org/content/asa/journal/jasa/135/4/10.1121/1.4865269>.

- Provision of required information regarding the survey, with the information sheet provided.
- Gaining consent from subjects and parents/guardians.
- Recording participant's history relating to ear and hearing problems using the data collection form.

6. Data recording

- Accurate recording of data on the data collection form
- Input of data into database

7. Explanation of results and advice to patients

- Testers should be able to explain results of examinations and test procedures, and advise on intervention options.

8. Referral procedures

Testers should be aware of when and where to refer patients (e.g. ENT, audiologist) with consideration given to national and local protocols, and whether patients are already receiving care for the condition found. A list of referable conditions and which practitioner is most appropriate for a referral should be understood.

Resources

- BSA 2016 – Minimum Training Guidelines: [Basic Audiometry & Tympanometry – Minimum Training Guidelines](http://www.thebsa.org.uk/Basic-Audiometry-Tympanometry-Minimum-Training-Guidelines). British Society of Audiology. www.thebsa.org.uk.
- Tolonen H (Ed.) European Health Examination Survey (EHES) Manual. Part A. Planning and preparation of the survey. 2nd edition. Helsinki: National Institute for Health and Welfare; 2016 (<http://urn.fi/URN:ISBN:978-952-302-700-8>, accessed 10 July 2019).
- Primary ear and hearing care training resource (Student's workbook – intermediate level). Geneva: World Health Organization; 2006

Annex 3: Tablet and Smartphone-Based Software Applications for Hearing Assessment

Introduction

In 2015, WHO identified three smartphones- and tablet-based manual threshold pure-tone audiometry (PTA) applications (apps) that could be used for hearing assessment in population surveys. This was done initially through a review of available apps and portable equipment verified in small studies.¹¹ Two of these apps and their key features are listed in Table 1, with permission from their developers.

Table 1: Summary of features

	Frequencies tested	Decibel range	Pure tones	Separate right and left side testing	High environmental noise warning	Software compatibility	Headsets
Audcal	0.5, 1, 2, 3, 4, 8 kHz	0–75 dB	Yes	No	Yes	iOS	To be used with Apple earbuds
hearTest	0.125–16 kHz	0–90 dB	Yes	Yes	Yes	Android	Comes with calibrated headphones

¹¹ Bright T, Pallawela D. Validated smartphone-based apps for ear and hearing assessments: a review. JMIR Rehabil Assist Technol. 2016;3(2):e13. Published 2016 Dec 23. doi:10.2196/rehab.6074.

A study was undertaken to determine the validity and test-retest reliability of the three apps by comparing these apps against conventional pure-tone audiometry using a diagnostic, calibrated audiometer. The study was done in two different settings:

- Field setting: where hearing assessment was undertaken in a quiet room (not a sound booth) using community health workers. Overall, 200 subjects were tested using the apps.
- Clinical setting: where hearing assessment was undertaken in a sound booth and by audiologists. A total of 50 subjects participated in this study.

Table 2 summarizes the findings of the study.

Table 2: Findings of WHO hearing app validation study			
	Test-retest reliability in field and clinical settings	Validity ¹² in field setting (testing in a quiet room)	Validity ¹ in clinical setting (testing in a sound booth)
Audcal	Very good	Targets met	Targets not met
hearTest	Very good	Targets met	Targets met for all frequencies except 6 kHz

Acknowledgement: We would like to express our gratitude to the software developers of these apps for providing the required hardware and software for us to undertake our study.

¹² Clinical targets for determining validity in field and clinical settings: 90% within 10 dB and 80% within 5 dB (Table 1) and across all frequencies tested.

ANNEX 4: Exploring funding options – some tips

It is important to consider funding opportunities during survey planning. However, in many countries it may be difficult to secure funding for a purely academic public health research. As donors are increasingly interested in seeing real, measurable social impact and investing in activities that lead to transformative and sustainable change, it is important to:

- be aware of the potential funder's priorities, and to familiarize yourself with the types of research projects they have supported in the past;
- research the potential donor and understand their funding interests and objectives. It is essential to do initial background research first and if possible to speak directly with the donor prior to applying; take time to really listen to the donor and their objectives, and ask lots of questions.
- be flexible and open to adapting your proposal to the donor's specific needs. At times it may be relevant to add to the study aims and objectives depending on the priorities of the potential funder. Additional objectives could include:
 - access to services;
 - investigating barriers to services;
 - cost-effectiveness of screening/surveys/services.

However, there should be no flexibility in terms of the study methodology and its academic rigour.

Framing the funding case

The ultimate objective of the prevalence survey is to generate actionable prevalence data that can be used for advocacy and to develop evidence-based policies. In your funding proposal, highlight the possible social impact and practical outcomes of the project.

Relevant information that should be included in the proposal include:

- The number of people that will be examined.
- The number of people likely to be referred to an ENT specialist/audiologist for further testing.
- Services that will be provided through the survey, e.g. wax removal, treatment of acute ear infections, hearing aid fitting among other things. Adding information on the number of people likely to benefit from these services is important.
- Estimate of the project cost per person screened¹³ – if possible suggest ways to increase the cost-effectiveness.
- Get your potential donor excited about the research project by highlighting the paucity of prevalence data in the field of hearing loss. Explain that the prevalence study is a first step for many countries to start increasing interventions, since without an accurate estimate of hearing loss prevalence, governments struggle with policy and resources allocation. As a researcher, you are proposing to provide that catalytic data to really make an impact.

Potential donors:

- International aid agencies (starting with your own country)
- Research funding institutions
- Local government
- High net-worth individuals who are likely to have a personal interest in the field of hearing loss

Outline of the funding proposal

Many donors will have their own format for making a funding proposal. However, where such a format is not provided, the proposal can be structured using the following sections:

- Cover letter: a brief introduction to the project highlighting why it is necessary, and its potential impact
- Title page

¹³ To obtain this number, simply divide your total budget by the number of people you plan to screen.

- Executive summary: one page summary of the need for, and goals of, the survey; its potential impact and how it fits the funding agency's priorities
- Institutional background: information about the institution leading the research, including contact details of the institution and the principal investigator
- Introduction: a brief overview of the problem and how the survey would contribute to addressing it
- Aims and objectives
- Implementation plan
- Implications for future policy development and research
- Budget
- Others: CVs, survey team, detailed protocol

The points listed under "Framing the funding case" should be kept in mind while drafting the proposal.

Request in-kind contributions

Consider working with field partners that will share resources. For instance, local ENT doctors, audiologists or other partners may consider providing their car free of charge. Some partners may consider hosting international researchers in their homes, instead of having researchers pay for extended stays in hotels. Local NGOs may wish to partner in the study and provide local facilities and serve as part of the team without any financial compensation. The key to in-kind contributions is to ask for help: in the new sharing economy, people are more open than ever to share their resources for the common good.

Be resourceful

Ask your project team members how each person can individually help lower the overall costs of conducting the survey.

Don't give up

Fundraising can be a difficult process and rejection of a proposal is common. When a proposal is rejected, always ask the donor about the reasons in as much detail as possible. This will help improve your proposal and strategy. The most successful fundraisers are those that persevere.

ANNEX 5: Mobile application and web portal for data collection

World Wide Hearing Foundation International (World Wide Hearing or WWH), a non-profit organization that provides access to affordable hearing aids and hearing care, has created a mobile data-collection application combined with a web portal for data aggregation to simplify carrying out WHO hearing loss prevalence studies. The WWH app is Android-based, free of charge and can be used both online and offline to capture patient data using the WHO hearing loss data collection form.

By replacing the traditional paper-based data collection system with a mobile, Android-based application, prevalence studies can be conducted more time- and cost-effectively by reducing the need for manual data entry and transcription. Furthermore, the web-based administrator portal enables researchers and/or project leads to track progress and data collection in real time.

The WWHearing mobile application

The WWHearing mobile application uses the latest version of the WHO data collection form for hearing loss prevalence studies. This data collection form includes the following sections:

- Consent to participate in the study
- Patient history questionnaire
- Hearing examination
- Tympanometry
- Ear examination
- Causes of hearing loss/recommended action questionnaires.

All of these sections can be filled out on a single Android device or by different team members on multiple devices. If the devices have an active Internet connection during field tests, the

app will sync data between the different Android units, giving team members access to previously recorded data from other devices.

If an Internet connection is not available during field tests, tested persons will be given the same patient ID on different devices so that the datasets can be matched.

The hearing examination section gives three different options for data entry:

1. Otoacoustic emission (OAE) test for children up to 5 years of age.
2. For people aged 5 years and older:
 - Manual data entry of hearing thresholds from any audiometer.
 - For people aged 5 years and older:
 - Automatic data entry using a third-party, Android-based hearing threshold application. Currently, the WWH app can automatically integrate data collected with hearTest.¹⁴

Administrator portal

After syncing the mobile devices online, data collection can be instantaneously tracked through the web portal. For easy and prompt data analysis, collected raw data can be downloaded daily from the data server.

The administrator web portal allows not only the tracking of the study's progress, but also the setting up of the study's test clusters.

¹⁴ hearTest is a threshold-seeking hearing loss app. When using the hearing threshold app option, the hearTest external app is launched and a hearing test can be performed. The results from this hearing test app are automatically imported into the GHLD app. Any other test similar to hearTest could be used.

How to access the app and administrator web portal

Type	Link/contact
WWH app	This Android app can be downloaded through the Google Play Store at: https://play.google.com/store/apps/details?id=com.qochealth.android.wwhi.ghld
Web Portal	The Administrator web portal can be accessed at: https://globalhearingloss.org
User accounts and info	For support, questions and creation of user accounts, please contact: ghld-support@wwhearing.org

Global hearing loss database

The WWH app and administrative web portal are part of a larger initiative by World Wide Hearing to create a Global Hearing Loss Database (GHLD). This is an open-access initiative that aims to aggregate data across countries and regions for the public good, namely to help increase hearing loss interventions, research, policy-making, and – more broadly – advance the field of hearing loss.

ANNEX 6: Protocol for the validation of selected software applications for assessment of hearing thresholds

AIM OF THE PROTOCOL

This protocol aims to guide the validation process for any hearing testing software applications identified for use during a hearing survey. This protocol was developed to test the accuracy and reliability of three apps, but can be adapted for testing further apps, as required. This protocol was developed by WHO, with contributions and support from Dr Peter Thorne (University of Auckland, New Zealand); Dr Sharon Curhan (Harvard Medical School, United States of America); and Dr Tess Bright (London School of Hygiene and Tropical Medicine, United Kingdom).

STUDY OUTLINE

Overview: Assessment of accuracy¹⁵ and logistical challenges of identified hearing test software applications (apps).¹⁶

Aim: To independently assess the validity and reliability of three different software apps on a cohort of subjects using conventional pure-tone audiometry as the gold standard.¹⁷

Study questions

- How well does each app perform at determining hearing thresholds compared to gold standard methods?
- How well does each perform with respect to reproducibility¹⁸ (test-retest reliability)?

¹⁵ Accuracy of a measurement: the degree of closeness between several measurements of a quantity and that quantity's actual (true) value.

¹⁶ 3 software applications have been identified in the literature (Shoebbox audiometry, AudCAL, HearScreen).

¹⁷ Gold standard: Pure-tone audiometry conducted in a quiet space or a sound booth depending on the setting (see "Study setting" section).

¹⁸ Reproducibility of a measurement: the ability of a measurement to be replicated.

- Are the software applications valid tools for assessment of hearing thresholds in the field¹⁹ compared with portable audiometry for the purpose of conducting ear and hearing surveys?

Target

- Identification of hearing thresholds (in decibels) at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, (and if available, at 6000 Hz, 8000 Hz) and their average²⁰ in each ear tested.

Study design

- Prospective diagnostic study

Study population

- Persons aged 4 years and older

Study setting

- Setting 1: Community. This assessment will be conducted at an identified place within a village or block. This may be a community hall or school room engaged for the purpose of this assessment.
 - A portable audiometry unit²¹ will be set up, and carefully calibrated prior to testing, to facilitate the conduct of the pure-tone audiometry.
 - The ambient noise levels will be measured and testing will only be conducted if the ambient noise levels are below a certain threshold (see next section on "Ambient noise").
- Setting 2: Clinic. This assessment will be conducted at an audiology clinic.
 - Pure-tone audiometry and app testing will be conducted in a sound booth.
 - The audiometer will be carefully calibrated prior to start of testing.

¹⁹ Field refers to a community setting as recommended in the Ear and Hearing Survey protocol.

²⁰ Average hearing threshold will be calculated for frequencies of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

²¹ Portable audiometry unit: this equipment will be carefully calibrated and conducted in a quiet room.

Ambient noise

- Setting 1: Testing will be conducted in a quiet room and the ambient noise levels will be below 40 dBA.²²
 - This level will be assessed using suitable sound-level measurement iOS-based applications.²³
 - Each app has a mechanism of testing ambient noise and does not function in noisy situations. This will be adhered to for each individual app.
- Setting 2: Testing will be conducted in an audiology clinic.
 - The ambient noise levels will be measured and testing will only be conducted if within American National Standards Institute (ANSI) standards.²⁴

Sampling

- Consecutive: every person that meets the inclusion criteria will be included in the study until the sample size is complete.

Inclusion criteria

- All persons aged 4 years and older that present for testing.

Exclusion criteria

- Congenital or acquired ear deformities that prevent adequate earbud insertion.
- Occluding cerumen or active ear drainage on otoscopy examination or any other physical or mental disability where air conduction audiometry is not possible, and/or the use of earphones is not possible.
- Visual impairment that precludes the use of index tests.

²² A 40 dBA level has been used based on the Occupational Safety and Health Administration (OSHA) recommendations

(https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9739) from the United States Department of Labor and the American Academy of Audiology (AAA) Childhood Hearing Screening Guidelines (<http://www.audiology.org/publications-resources/document-library/pediatric-diagnostics>).

²³ SPLnFFT, Noise Hunter, NoiSee or SoundMeter

(<http://scitation.aip.org/content/asa/journal/jasa/135/4/10.1121/1.4865269>).

²⁴ **ANSI S3.1-1999 (R2003)** American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms.

- Participants or legal guardian not willing to give consent for inclusion in the study.
- Participants aged under 4 years.
- Participants who are unable to follow simple commands, unable to remain alert during the duration of the hearing test or unable to press the button on the touch-screen device.

Sample size

- $N = 120^{25}$

Who will conduct the testing?

1. All tests will be performed by an audiologist or audiology technician under the supervision of an audiologist.
2. All 3 app-based hearing tests will be performed on all participants.
3. Some participants will undergo the app-based hearing tests twice (to determine test reproducibility).

Test order

- There will be two designated testers²⁶ (Tester 1 and Tester 2) performing the testing.
- There will be one group (designated as Group 1).
- Group 1: 120 participants will undergo testing with the 3 apps and pure-tone audiometry.
 - The index tests will be performed in random order by Tester 1.
 - The pure-tone audiometry will be performed by Tester 2.
 - The order of index tests and pure-tone audiometry will be randomized for each patient.
 - Tester 1 and Tester 2 will be blinded to each other's results.
 - The first 75 participants will undergo re-testing with one of the apps after at least 10 minutes rest. This will be performed sequentially in order of subjects as

²⁵ A number of 100 participants is the sample size needed to assess the accuracy within 7 dB of the measurement that gives 80% power at the 0.05 level of significance (two-paired sample t-test). We propose $N = 120$ for each app since we expect that in about 20% of the sample the data may not be collected according to the plan or at all (depleted phone batteries, environmental constraints not respected, etc.).

²⁶ Testers will be audiologist or trained audiology technician under the supervision of an audiologist.

they are tested: app 1, app 2 and app 3, until each app has been re-tested 25 times each.

- For example, Participant 1 may test app 1, app 2, app 3, pure-tone audiometry, and then app 1 again. Participant 2 may test app 1, app 3 pure-tone audiometry, app 2 and then app 2 again. Participant 3 may test pure-tone audiometry, app 1, app 3, app 2 and then app 3 again. This is to ascertain the reproducibility of testing for each app.²⁷
- After 60 participants (i.e. half) have been tested, the testers will then switch roles and Tester 1 will perform the pure-tone audiometry and Tester 2 will perform the index tests.

Test procedure

- Each app will be tested in accordance with each app's specific instructions.
- The appropriate headphone (or transducer) will be used in accordance with each app's specifications and calibrated as directed.
- Please refer to the relevant apps for further details on test procedure.

What will be recorded?

- The following will be recorded for all participants:
 - Demographic data: name, date of birth, sex, contact information
 - participants will be anonymized
 - History of known ear disease:
 - ear infections (yes/no)
 - tympanic membrane perforation (yes/no)
 - history of hearing loss (yes/no)
 - history of tinnitus (yes/no)
 - any other disease/s?
 - Otoscopy examination performed by the audiologist prior to testing:

²⁷ 25 subjects will undergo testing with each app twice. This number is required for the "test-retest reliability" assessment, to assess reproducibility of each app (another measure of precision).

- cerumen (yes/no). In cases where the cerumen is occluding the canal, the subject will be excluded from the study
- tympanic membrane (TM) perforation with discharge (yes/no)
- TM perforation without discharge (yes/no)
- cholesteatoma (yes/no)
- canal atresia (yes/no)
- retracted TM
- other (describe):
- Ambient noise levels will be recorded and testing will only proceed if below a specified level (40 dBA):
 - if ambient noise levels are above this level, then testing shall not proceed until it is below 40 dBA
- Hearing threshold with each of the app-based hearing tests, for each ear separately. Hearing threshold will be determined separately in each ear, at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz (and 6000 Hz and 8000 Hz if possible).
- Type of earphone/headphone used for each test.
- Hearing threshold on pure-tone audiometry will be determined for each ear separately at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz and 8000 Hz.
- The tester shall fill out a questionnaire on the proforma after each test for each participant. This questionnaire will pertain to the ease of testing, time taken, issues faced, battery life, interference due to noise etc.

Data

- For each participant, test results will be recorded for each ear separately.
- Data will be compiled and entered in the format provided.
- Data will be shared with WHO.

Data analysis

- Software for statistical analysis will be used.
- The following software (one or in combination) may be used in analysis: IBM SPSS Version 20.0; SAS University Edition 2016 and MS Excel 2010.
- Other software for statistical analysis may be used.

- Mean and standard deviations should be calculated for each frequency. Calculation of the mean differences between the threshold measurements obtained in each ear and at each frequency should be calculated by pure-tone audiogram and each app.
 - At least 90% of all threshold measurements obtained should be 10 dB or closer than that obtained by pure-tone audiometry to be considered valid.
 - At least 80% of all threshold measurements obtained should be 5 dB or closer than that obtained by pure-tone audiometry to be considered valid.
 - Further statistical analysis may be performed.
- Test-retest reproducibility would be assessed by comparison of thresholds obtained from the first and second use of the app by the same subject in the same ear.
 - At least 90% of all measurements obtained by each app should be within 5 dB of each other.
 - If the above results are not obtained, then the app would be deemed unsuitable for use.
 - Further statistical analysis may be performed.

Ethical issues

- The study must be approved by the Institutional Ethics Committee.
- Informed consent must be taken for all participants. For those below the age of 18 years, consent from a legal guardian will be required.
- All those identified as having hearing loss or ear disease during the study will be referred for further assessment.

Test procedure for each participant

Step 1. Each participant will be registered and details on page 1 of the “Participant Proforma” form filled out. If participants meet the inclusion criteria and are not excluded as per the exclusion criteria, then an identification number will be assigned. This is to anonymize participants in the study results.

Step 2. Each participant is then randomized to either be tested with the apps first or tested with pure-tone audiometry first. After testing within either group, the participant then

proceeds to testing with the other test/s that have not been performed yet. Regarding testing with the apps, the order of testing of the 3 apps shall be randomized from one participant to the next.

Community setting

Step 2a. Testing with apps for setting 1 (community).

- (i) Testing will be performed by an audiologist or audiology technician under the supervision of an audiologist.
- (ii) Testing shall take place in a quiet room. Ambient noise levels will be assessed using suitable sound level measurement iOS-based applications²⁸ and should be below 40 dBA. Testing will not proceed until levels are below 40 dBA.
- (iii) Once the room is ready for testing, participants will be asked to sit down and their identification number confirmed.
- (iv) Headphones/transducer shall be placed on each participant and ensured that they are appropriately fitted:
 - AudCal: Apple headphones
 - ShoeBox: TDH-50 (60 ohm), E-A-RTONE3A or BC-71 (Pro edition) (calibrated headsets provided with the testing device will be used)
 - HearScreen: Sennheiser HD 280 Pro (calibrated headsets provided with the testing device will be used)
- (v) Instructions given by each app will be followed in a step-wise manner to conduct each test and data entered for each category in the participant proforma.
- (vi) Testing will be repeated (up to 3 times) if the app registers that ambient levels are too loud and the results are not valid. Steps to ensure a quiet room will be taken.

Step 2b. Testing with pure-tone audiometry for setting 1 (community).

- (i) Testing will be performed by an audiologist or audiology technician under the supervision of an audiologist.

²⁸ Either SPLnFFT, Noise Hunter, NoiSee or SoundMeter
(<http://scitation.aip.org/content/asa/journal/jasa/135/4/10.1121/1.4865269>).

- (ii) Testing shall take place in a quiet room. Ambient noise levels will be assessed using suitable sound level measurement iOS-based applications²⁹ and should be below 40 dBA. Testing will not proceed until levels are below 40 dBA.
- (iii) Once the room is ready for testing, participants will be asked to sit down and their identification number confirmed.
- (iv) Calibrated headphones shall be placed on each participant with a check to ensure they are appropriately fitted.
- (v) Pure-tone audiometry will be conducted in accordance with standard protocol for identification of hearing thresholds as set out by the International Standards Organization (ISO).³⁰

Clinical setting

Step 2a. Testing with apps for setting 1 (clinic).

- (i) Testing will be performed by an audiologist or audiology technician under the supervision of an audiologist.
- (ii) Testing shall take place in a sound booth with noise levels within ANSI recommendations.
- (iii) Participants will be asked to sit down and their identification number confirmed.
- (iv) Headphones/transducer shall be placed on each participant with a check to ensure they are appropriately fitted.
 - a. AudCal: Apple headphones
 - b. ShoeBox: TDH-50 (60 ohm), E-A-RTONE3A or BC-71 (Pro edition) (calibrated headsets provided with the testing device will be used)
 - c. HearScreen: Sennheiser HD 280 Pro (calibrated headsets provided with the testing device will be used)
- (v) Instructions given by each app will be followed in a step-wise manner to conduct each test and data entered for each category.

²⁹ Either SPLnFFT, Noise Hunter, NoiSee or SoundMeter
(<http://scitation.aip.org/content/asa/journal/jasa/135/4/10.1121/1.4865269>).

³⁰ ISO 8253-1:2010.

- (vi) Testing will be repeated (up to 3 times) if the app registers that ambient levels are too loud and the results are not valid. Steps to ensure a quiet room will be taken.

Step 2b. Testing with pure-tone audiometry for setting 2 (clinic).

- (i) Testing will be performed by an audiologist or audiology technician under the supervision of an audiologist.
- (ii) Testing shall take place in a sound booth with noise levels within ANSI recommendations.
- (iii) Participants will be asked to sit down and their identification number confirmed.
- (iv) Calibrated headphones shall be placed on each participant with a check to ensure they are appropriately fitted.
- (v) Pure-tone audiometry will be conducted in accordance with standard protocol for identification of hearing thresholds as set out by the International Standards Organization (ISO).³¹

Step 3. After testing of the apps and pure-tone audiometry is performed and data collected, the first 75 participants within the study shall undergo repeat testing with one of the apps only. Each app will be re-tested 25 times and data recorded for each participant.

Step 4. After each test is performed, a short questionnaire shall be completed on the proforma for each participant. After test results are collected for each participant, data shall be entered into an Excel spreadsheet provided by WHO and this will be shared with WHO

³¹ ISO 8253-1:2010

Participant Proforma for Evaluation of Study Apps

Participant details

Name:	
Age:	
Gender:	Male/Female (please circle)
Address:	
Contact number:	
Date/s of testing	

History

History of hearing loss:	Yes/No
History of ear infections:	Yes/No
History of tinnitus	Yes/No
History of tympanic membrane (TM) perforations:	Yes/No
History of ear disease: (please specify)	Duration: Symptoms:

Ear Examination

Cerumen:	Yes/No , If occluding, then patient is excluded from study
Perforation with discharge:	Yes/No
Dry perforation:	Yes/No
Cholesteatoma:	Yes/No
Canal atresia:	Yes/No
Retracted TM:	Yes/No
Any other (describe):	

Exclusion Criteria: (please tick box if present)

- Congenital or acquired ear deformities that prevent adequate earbud insertion ☐
- Occluding cerumen or active ear drainage on otoscopy examination ☐
- Any other physical or mental disability where air conduction audiometry is not possible, and/or the use of earphones is not possible. ☐
- Visual impairment which is inconsistent with the use of index tests ☐
- Participants or legal guardian not willing to give consent for inclusion in the study ☐
- Participants aged less than four years ☐

Participants who are unable to follow simple commands, unable to remain alert during the duration of the hearing test or unable to press the button on the touch-screen device

If no exclusion criteria ticked above, then please assign participant IDENTIFICATION NUMBER (ID No.) here and proceed to testing:

ID no.

Participant Identification Number:.....

Results for App (please fill in the app name)

Was the ambient noise level (as assessed by the app*) too loud at one or more frequencies? Yes/No

Each app detects the ambient noise level and can indicate if it is too noisy for suitable conduct of the test. The ambient noise levels should be below the indicated levels during the test. In case the test is conducted in a noisy environment, this should be indicated in the results.

Frequency (Hz)	500	1000	2000	4000	6000 (if applicable)	8000 (if applicable)
Hearing Threshold Right Ear(dB)						
Hearing Threshold Left Ear (dB)						

Q.1. Time taken to perform test (in minutes and seconds):

Q.2. Were there any special requirements?

Q.3. Any hindering factors? (e.g. short battery time, noisy environment, etc)

Q.4. Any complaints or concerns from the subject?

Q.5. Any other comments?

* Each app detects the ambient noise level and can indicate if it is too noisy for suitable conduct of the test. The ambient noise levels should be below the indicated levels during the test. In case the test is conducted in a noisy environment, this should be indicated in the results

Frequency (Hz)	500	1000	2000	4000	6000 (if applicable)	8000 (if applicable)
Hearing Threshold Right Ear(dB)						
Hearing Threshold Left Ear (dB)						

Please fill the following questions out before participant proceeds to next step.

Q.1. Time taken to perform test (in minutes and seconds):

Q.2. Were there any special requirements?

Q.3. Any hindering factors? (e.g. short battery time, noisy environment, etc)

Q.4. Any complaints or concerns from the subject?

Q.5. Any other comments?

Results for App (please fill in the app name)

Was the ambient noise level (as assessed by the app) too loud at one or more frequencies? Yes/No

Frequency (Hz)	500	1000	2000	4000	6000 (if applicable)	8000 (if applicable)
Hearing Threshold Right Ear(dB)						
Hearing Threshold Left Ear (dB)						

Please fill the following questions out before participant proceeds to next step.

Q.1. Time taken to perform test (in minutes and seconds):

Q.2. Were there any special requirements?

Q.3. Any hindering factors? (e.g. short battery time, noisy environment, etc)

Q.4. Any complaints or concerns from the subject?

Q.5. Any other comments?

Pure Tone Audiometry Results				Participant Identification Number:.....		
Frequency (Hz)	500	1000	2000	4000	6000	8000
Hearing Threshold Right Ear(dB)						
Hearing Threshold Left Ear (dB)						

Q.1. Time taken to perform test (in minutes and seconds):

Q.2. Were there any special requirements?

Q.3. Any hindering factors? (e.g. short battery time, noisy environment, etc) subject?

Q.4. Any complaints or concerns from the subject?

Q.5. Any other comments?

Note: this section is applicable to first 75 participants only						
Repeat test results for App(please fill in the app name)				Participant Identification Number:.....		
Frequency (Hz)	500	1000	2000	4000	6000	8000
Hearing Threshold Right Ear(dB)						
Hearing Threshold Left Ear (dB)						

Q.1. Time taken to perform test (in minutes and seconds):

Q.2. Were there any special requirements?

Q.3. Any hindering factors? (e.g. short battery time, noisy environment, etc) subject?

Q.4. Any complaints or concerns from the subject?

Q.5. Any other comments?



World Health Organization
Department of Noncommunicable Diseases

20 Avenue Appia
1211 Geneva 27
Switzerland

<https://www.who.int/health-topics/hearing-loss>

