WHO EAR AND HEARING DISORDERS SURVEY

PROTOCOL

FOR A

POPULATION-BASED SURVEY OF PREVALENCE AND CAUSES OF DEAFNESS AND HEARING IMPAIRMENT AND OTHER EAR DISEASES

WORLD HEALTH ORGANIZATION

PREVENTION OF BLINDNESS AND DEAFNESS (PBD)
Acknowledgement

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This protocol is in a general form which can be adapted by any country according to its needs, provided the basic data collected are not changed. It consists of the following parts:

- Part 1. Survey Methods
- Part 2. Ear Examination Form
- Part 3. Coding Instructions for the form.

Part 1 provides an overview of the principles of the survey methodology to be used. Part 2 is also available as a separate form on card. Part 3 provides detailed instructions on how to complete the form. Computer software, called "EARFORM", for entering and analysing data has been developed and a manual on how to use this software is available. All these items are distributed together as one package.

The Prevention of Blindness and Deafness Programme at WHO would like to hear of any surveys that are conducted using this protocol and would be pleased to consider including data produced by such surveys in the global database that is being constructed.

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INTERNET SITE: http://www.who.int/pbd/pdh/pdh_home.htm

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1 Please see Part 1, Section 2: Development of the protocol, for further information on this.
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1 PURPOSE OF THE WHO EAR AND HEARING DISORDERS SURVEY PROTOCOL

There is a considerable scarcity of reliable, standardised, population-based data on the prevalence and causes of deafness and hearing impairment in developing countries. This protocol describes a method using a standardised survey form and coding instructions to enable countries to carry out prevalence and causes surveys of deafness and hearing impairment, and of ear diseases.

The main uses of the data produced by such surveys will be to provide:

(1) Accurate information on the size of the problem in the country or part of the country where the survey is being conducted.

(2) An overview of the main causes of deafness and hearing impairment in the study area and the resources needed to deal with them.

(3) A source of information for prioritisation, programme planning and resource allocation.

(4) Baseline data for comparison with subsequent similar surveys to measure changes in the problem and assess the effectiveness of interventions.

(5) Information that will enable determination of the costs of deafness and hearing impairment and the costs and benefits of prevention.

(6) Accurate, standardised information that can be used to compare the prevalence and causes of deafness and hearing impairment between countries and regions. This can only be done when data is collected in a standardised way, such as through using this protocol.

2 DEVELOPMENT OF THE PROTOCOL

This has been coordinated by the Programme for the Prevention of Deafness and Hearing Impairment (now called the Team for Prevention of Blindness and Deafness) at the World Health Organisation, Geneva, and it has been reviewed by expert groups. The protocol will continue to be developed and improved by a process of consultation and field testing, coordinated by WHO.

It is strongly recommended that the data that are collected and the actual methods of collection, as set out in the ear examination form (part 2 of this protocol) and coding instructions (part 3), should not be changed independently by users of the protocol. If it were changed independently it would not be possible to use the data for inter-country or inter-regional comparisons. If other data are thought to be essential, they could be collected in addition to the data required by the protocol. However, in order to avoid overloading the survey teams, only additional data on topics of immediate interest should be collected and the temptation to collect "opportunistic" data should be resisted.
Suggestions for improvements or additions to the protocol would be welcomed by the
WHO Programme (please see the first page for contact details).

3 PLANNING THE SURVEY

3.1 Initial Considerations

A survey needs multidisciplinary expertise and the survey investigators should comprise
from the outset an epidemiologist and biostatistician as well as an audiologist and ORL
specialist. They should all plan the study together from the beginning.

It is important to determine first the aim or main question of the survey. For example the
aim might be stated as “To determine the prevalence and major causes of deafness and
hearing impairment at all ages in country X” [or district Y of country X, if it is not a national
survey]. Precise objectives can then be formulated and these will enable the key decisions of
the survey to be made. These decisions will include the overall reference population\(^2\) to be
surveyed from which the sample will be drawn; the age range to be tested; the sampling method
and sample size; and whether it is a one-stage or a two-stage survey. These decisions will in
turn determine the logistics such as the number of teams and personnel required, the quantity
of equipment needed and the transport and accommodation arrangements.

3.2 Preparation of a specific written protocol

The WHO Ear and Hearing Disorders Survey Protocol is intended as a framework or model from which each
country or organization can develop a specific survey for that country. It is
essential that, at the outset, a written protocol is produced that is specific for
the particular survey being planned. This specific protocol can become a written
handbook and record of all details and decisions for that particular survey, and
will help ensure that the survey is conducted correctly and identically by all
and that all planning decisions are implemented. It will also be useful for
collaborators, ethical committees, donors and during the analysis and write-up
phase. Time spent on a detailed protocol before the survey commences will be
amply repaid later. It should include the sections listed in box 1. The Ear Examination Form
(part 2 of this document) and the coding Instructions for the form (part 3 of this document)
should be included in this specific protocol (as items 15 and 6 respectively in box 1).

\( ^2\) Also called the target population or sampling universe.
3.3 Preliminary Assessment.

Before commencing the survey itself, it is useful to try to obtain an approximate idea of the prevalence and causes of deafness and hearing impairment in the study area. This will assist with the design of the survey, and in particular the determination of the sample size.

The main sources of such data will come from clinic-based data, school health service records, schools and other institutions for the deaf, anecdotal information from health workers, social workers and community leaders, Departments of Community Health, previous health surveys, and censuses. It must be borne in mind that such data is often biased and inaccurate and will only give a very approximate guide to the size and nature of the problem. However, in most cases, it should be possible to use the best of this information to make an approximate estimate of prevalence for sample size calculation.

Once the survey investigator has decided which population group(s) are to be sampled, the statistician advising the survey (there should always be one from the survey's inception) can begin the calculation of sample size. It should be remembered that sample size, and hence survey costs and resources required (personnel, training, equipment) will rise dramatically as more sub-groups in the population or more data than the minimum recommended on this form are included. The survey design and sample size must always take into account the rarest condition, from a public health perspective, for which an accurate prevalence is required.

3.4 Survey design.

A cluster sample design is the basic design that is likely to be the one used. The term cluster, as used here, is a collection of sampling units, usually households, which form a natural grouping or community within the population. These groupings or communities would be villages, urban blocks or sections, or census enumeration areas and the sample of households would be randomly selected from them. Ideally, detailed maps should be available of these communities, which, at least, show the boundaries of these communities. The clusters are then chosen by the method of probability proportional to size - PPS (see below).

In a large population, such as for a national survey, multi-stage sampling can also be incorporated. The population is first divided into large groups such as provinces or districts and the required number of these is randomly selected by the PPS method. The same method is then used within each large group selected, with the same number of communities being selected within each group. This may be continued for subsequent stages if necessary. The number of units required at each stage will need to be calculated by the PPS method.

If the reference population is thought to contain large variations which may affect the prevalences being measured, sampling stratified according to these variations can be incorporated with the cluster sampling method. Here, the communities are grouped into different strata according to different geographical areas, or urban and rural areas, or different social or different ethnic groups. Each stratum should, as far as is known, be internally homogeneous for the particular item being stratified. Each stratum is then an independent reference population and a separate sample survey is performed in each stratum. The results for each stratum can be combined to produce an overall result provided they are weighted according to the populations of the individual strata. This method is therefore more time- and resource-consuming than non-stratified sampling, and in many cases the basic cluster sampling method should be sufficient (further information on this method is given in Bennett et al, reference 1, section 6).

Other methods of sampling besides cluster sampling include simple random sampling and systematic random sampling. The former requires a list of all inhabitants and their
location in the reference population and this is usually not available in developing countries; it is also more time-consuming and logistically difficult than cluster sampling, although the results have greater precision. Systematic random sampling, where subjects are selected systematically, say every 10th person on a list, is only suitable in a highly organised or structured setting, such as a refugee camp.

3.5 Sampling method

Communities where the cluster sampling will be done are identified by the method of probability proportional to size (PPS). In this method the likelihood of communities being selected varies according to their size. The same number of households should be chosen from each community selected. All this means that the sampling procedure is self-weighting and no weighting is required in the analysis.

A list of all communities in the whole reference population, usually obtained from a census, should be made together with their populations, listed 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). The total population of the reference population divided by the number of clusters required (see below) gives the sampling interval. A number between 1 and the sampling interval is then randomly selected (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. 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 subsamples should be selected separately within the community.

The number of clusters required should be between approximately 30 and 50 and this number will depend partly on the total sample size required. 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 which is logistically easier but reduces the precision. In practice, the size of a cluster should generally be the number of subjects that a team could test in one or two days (usually about 200 persons). The total number of clusters would therefore be the sample population 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, the same number of house holds 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 more teams or more time are available, 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.

The same number of households should be selected randomly from each cluster site. If a list of households is available, they can be randomly selected from it. If no list of households is available, a selection team should go to a central prominent point in the community, randomly select a direction and then proceed for a randomly selected distance and select the nearest household. Ideally this procedure should be adopted for every household in the cluster, but starting from different, randomly selected points. However, it may only be practicable to use the method with one central point, and then select, say, every third or 5th household. These selections could be done in advance of the main survey team, when the household members could be sensitised about the survey at the same time.

Dwellings that contain several households can be dealt with in one of 2 ways: if there are only a few such dwellings, then all the households in such dwellings should be sampled
in order to avoid them being under-represented. If most dwellings contain several households, such as in the compounds found in some parts of Africa, each compound can be treated as a cluster and multi-stage sampling used.

If no measure of community population sizes is available at all, the PPS method cannot be used, and communities would have to be selected by simple random sampling. In this case a fixed number of households should still be obtained from each selected community, but the responses should be weighted in the analysis. This would require a count of the total number of households in each selected community.

3.6 Sample Size

The sample size calculations for a stratified multi-stage cluster survey design are complex, and dependant on the sample plan actually used. The sample size will depend on:

1. an estimate of the approximate prevalence of hearing impairment.
2. the required precision of the prevalence estimate
3. the actual sample design.

In addition the sample size may also be constrained by what is logistically possible with the resources available.

Up to 10% or more of the population may be estimated to have disabling hearing impairment whereas under 1% may be thought to have profound or severe deafness. Information gathered in the preliminary assessment will provide a guide. The estimate of disabling hearing impairment should usually be used to estimate the sample size unless it is necessary to know the prevalence of profound hearing impairment accurately with a high degree of precision.

The estimate of the prevalence of hearing impairment, and the required precision enable the calculation of the sample size that would give a confidence interval (usually at the 95% level) that is equivalent to the precision required, for a simple random sampling design. This sample size must be multiplied by a factor, known as the design effect, that is dependant on the sample design, the intraclass correlation within the clusters, and the variability among the clusters, stages or strata. The sample size for simple random sampling may be calculated using a software programs such as the population survey option of Sample Size and Power in the STATCALC choice in the Programs menu of EPIINFO-6 software, and the figure obtained multiplied by the design effect (this is generally taken to be 2, unless a formula is used to calculate it - see Bennett 1991, reference 1, section 4). Some examples of sample sizes using this programme are given in annex 1, page 14. However, for more complex designs, it is recommended that a statistician be consulted.

3.7 Personnel and Training

It is essential to determine well in advance of the survey, the numbers and skills of all personnel required, and any specific training they may need. The numbers of field workers will depend on the sample size and time required to test each subject. These may need to be determined in a preliminary pilot study.

For sections A and B of the form field workers should be recruited locally so they have some local knowledge; they should be literate and have had some skills training (preferably in

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3 This software is free and can be downloaded from [http://www.cdc.gov/epo/epi/software.htm](http://www.cdc.gov/epo/epi/software.htm)
a health subject). Local primary health care or basic level health workers or top-grade school leavers are often suitable, but they will need adequate training in survey skills and audiological techniques. School leavers may also be recruited to act as field assistants to the testers.

For sections C, D and E of the form, team members will require specialist otological and audiological knowledge (further details in 1st page of coding instructions). In some communities, it may be necessary to have female staff to interview and examine female subjects.

3.8 Logistics and administration.

In any survey, it is essential to plan in detail and well in advance all aspects of study design, sample size, personnel required, training, remuneration, resources including vehicles, equipment and supplies, accommodation and subsistence. A smoothly run survey depends on detailed and properly worked-out timing of all its aspects, and a small pilot study may be needed to provide timing estimates.

A time chart should be constructed to indicate clearly the estimated starting and finishing times of each component of the survey. For a large survey, it is very helpful to appoint an administrator from the survey area to oversee all aspects of logistics and administration since the survey investigators will usually be too busy to deal with these aspects and may not have the necessary local knowledge.

3.9 Budget

Detailed advance budgeting is essential in order to minimise costs and make certain the survey proposed can be completed with the funding available. Budget elements will usually consist of (1) personnel, including remuneration and daily subsistence allowances, (2) transport costs, (3) equipment and supplies, (4) training, (5) data processing and analysis, (6) preparation of reports. In most surveys, the largest item of expenditure will be personnel costs, followed by transport costs.

4 CONDUCTING THE SURVEY

4.1 Pilot Study

It is usually necessary to conduct a short pilot study. This can have several purposes:-
to test the methodology, equipment, logistics and timing of each part of the survey and to familiarise the staff with the conduct of the survey. Prevalence obtained in the pilot may be useful to calculate the sample size if there is no other source for this information. Timings are important to work out total time for the survey and hence staffing needs. The pilot is most easily performed after the initial training of survey staff, although some elements such as timings and, if required, prevalence, may need to done earlier.

The pilot study can also provide information regarding whether or not the survey subjects should be seen by a one-stage or a two-stage approach. In a one stage approach all subjects are fully tested with all tests. This is the preferable method, but 2 stages may be used if there is insufficient time for the one-stage approach. In a 2-stage approach subjects are first screened and screen failures are then tested with all tests. The screening tests could be a pure tone of 25 dB at 1, 2 & 4 kHz for hearing, together with basic otoscopy. The screening tests
would need to be validated for sensitivity and specificity by also fully testing a proportion of subjects who passed the screening test.

4.2 Visit of advance team.

An advance team should visit the cluster site a short time in advance of the main survey team. They should sensitise and promote the survey to the community and its leaders and obtain their understanding of the purposes and needs of the survey and their consent to carry it out. They should carry out any mapping required, obtain lists of household members if available, locate a quiet site for the field testing and, if necessary, secure accommodation.

4.3 Ethical issues

From the outset, good relations should be established with community leaders and other prominent people. They will help improve community relations and can often give valuable advice and assistance. Team members must always respect local customs, and schedule visits for the convenience of subjects if possible.

For a successful survey it is essential that the community and its leaders understand why the survey is being conducted, what are the benefits for them, and that they give their fully-informed consent. In addition, arrangements must be made for appropriate treatment or referral for survey subjects found to have survey-related or other diseases. The survey should not be started if this cannot be done. However, since the main purpose of the visit is to conduct the survey, there probably will not be time to provide full-scale clinical services at the time of the visit. In any case, such services can only be properly planned by using the full results of the survey.

Health information provided by individuals is confidential and it is important that the survey team members guarantee confidentiality to survey subjects and maintain that confidentiality at all times. It should not be possible to identify survey subjects in the analysis or in the reports of results. Also no information in the data about a survey subject should be passed on to other persons or organisations without the subject’s consent.
4.4 Visit of survey team.

The minimum sized survey team should consist of one or two field-workers, a specialist audiologist/otologist, an enumerator and driver. One of these should be the team supervisor. Larger teams would be able to work faster and/or see more subjects. It is probably easier for the team to work in a central location rather than going from house to house. However it is important that all household members come to the location and that any who do not are seen later or the team visits the household if the subject is not mobile. The audiometry test site should be as quiet as possible. A flow chart of activities, (adapted slightly from that used in a recent survey) is shown in box 2. It should be noted that all subjects are given all tests. This is because the survey is designed to measure prevalences or ear diseases and hearing loss. If otoscopy and ear examination is only performed in those subjects who have audiometry, only the prevalence and causes of deafness and hearing impairment can be ascertained.

A list of household members, obtained from the census, or constructed locally, is essential to ensure that as few subjects as possible fail to attend. Every attempt possible should be made to find non-attenders. In any case, non-attenders and subjects who refuse to be tested should have part A of the form completed so that these subjects can be entered into the analysis in order to calculate the non-response rates.

It should be noted that audiometry is performed before otoscopy and removal of any wax or foreign body. This is in order to test whether and what level of actual disabling hearing impairment is present in the subject.

4.5 Age determination

It is important to ensure that the subject’s age in years is obtained as accurately as possible. In subjects who do not have birth certificates or who do not know their own age, it may be necessary to adopt other methods to ascertain age. One such method is to construct a calendar of prominent local or national events whose year of occurrence is known and then ascertain whether the subject was born before or after particular events. It should be noted that
the protocol is at present designed only for subjects aged 6 months or greater.

4.6 Sampling Errors and quality control.

Sampling error is the difference between the values derived from the sample population and the true values in the population. It is partly due to random sampling error which can only be minimised by increasing the sample size, and non-random errors which are potentially more serious and less easily quantifiable.

Non-random errors can be grouped as follows:-

(1) Coverage errors. These occur when population elements which 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 is also in this category.

(2) 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 measured and corrected during the survey.

(3) Processing errors. These are mainly clerical errors that occur during coding, entering or analysing the data.

The following quality-control measures can be taken to minimise non-random errors:-

(1) Sampling units should be clearly defined at all levels within the survey.

(2) Clear and detailed training and operations manuals should be developed for each survey.

(3) All field staff should be carefully trained under actual field conditions, in all aspects of their duties, and all office staff in data coding and entry.

(4) 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 of records much easier.

(5) Inter- and intra-observer variation 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.

(6) Validation of the tests used, both audiometric and otoscopic, should be carried out and their sensitivity and specificity should be measured. This can be done by comparing a number of subjects, with normal and abnormal hearing or otoscopic findings, with a "gold standard". Sensitivity is the proportion of truly abnormal subjects who are found to be so by the survey test, and specificity is the proportion of true normals who are found to be so by the test.
(7) Supervisors should make regular, announced and unannounced checks on performance of all survey procedures carried out by survey teams.

(8) Supervisors should make daily checks of that day's mapping and enumeration, and of the completed forms.

(9) A sub-sample of households should be re-checked by supervisors on a regular basis.

(10) Every effort should be made to find non-responders. There may be a higher prevalence of hearing loss amongst 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 it's first visit, a second visit should be made at an appropriate and if possible arranged time to find these subjects.

(11) Audiometric equipment should be regularly calibrated. This should be done by a laboratory at the beginning and end if a study, and on a daily basis by team members using self-calibration against their known hearing levels.

(12) Supervisors should provide field and office staff with regular feedback of their performance, and provide refresher training if necessary.

(13) If possible data should be double-entered into the computer programme used for entering and analysing the data.

5 DATA RECORDING AND ANALYSIS

A computer software programme, called EARFORM, for entering and performing basic analysis of the data has been developed together with a software manual. Data can easily be entered onto a computer representation of the form and frequencies of the main variables generated. The database file produced can also be accessed by programmes such as EPI-INFO and ACCESS (Microsoft) for more sophisticated data handling and analysis. The following specific age subsets are used in the analysis, in order to allow comparison between studies: 6 months to 4 years, 5 to 9 years, 10 to 14 years, 15 to 19 years, 20 to 24 years, 25 to 29 years and so on (the age in years is the age at the last birthday).

6 BIBLIOGRAPHY


3 Manual of epidemiology for district health management. Eds Vaughan J and


ANNEX 1: TABLE OF SAMPLE SIZES for a simple random sample with a confidence interval at the 95% level for various expected prevalences calculated from the STATCALC choice in the Programs menu of EPIINFO-6 software. The second column shows the worst acceptable levels for the given sample sizes. Thus, for example, for a 7% expected prevalence, if the worst prevalence that can be accepted can range between 6.20% and 7.80%, then the sample size, for a simple random sample design, should be 3,904 persons. If the worst prevalence acceptable can range between 6.08% and 7.92%, then the sample size should be 2,953 persons.

For a cluster sample survey the sample size shown must be multiplied by a factor, known as the design effect, that is dependant on the sample design, the intraclass correlation within the clusters, and the variability among the clusters, stages or strata. If this is not calculated, it should be taken as 2, so that the sample sizes in the table must be multiplied by 2. This will give sample sizes of approximately 8,000 and 6,000 for the 2 levels of acceptability. If each cluster contains 200 persons (the number that can be seen in 1 or 2 days), the number of clusters for the 2 levels of acceptability will be 40 and 30 respectively.

The EPI-INFO programme should be consulted for other expected prevalences, other levels of acceptability, and other confidence intervals.

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<th>Worst acceptable (± %)</th>
<th>Sample size</th>
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</table>
WHO/PDH Ear and Hearing Disorders Examination Form  Version 7.1A

A. CENSUS
1. Country Number ☐ ☐ ☐ ☐
2. Study Number ☐ ☐ ☐ ☐
3. Admin Division ☐ ☐ ☐ ☐
4. Cluster ☐ ☐ ☐ ☐
5. Household ☐ ☐ ☐ ☐
6. Person ☐ ☐ ☐ ☐
7. Optional ☐ ☐ ☐ ☐

B. HEARING EXAMINATION
(I) Hearing Assessment for children (Age 6 months to 3 years 11 months)
1. A child searches for the sound direction and his/she shows some response such as smile or pause when you call his/her name.
   - Yes ☐ No ☐ Not Done ☐
2. A child can point to a parent or brother and sister when you ask, and can speak simple word such as ‘mama’ or ‘bye bye’.
   - Yes ☐ No ☐ Not Done ☐
3. A child can answer your question for his/her name & can repeat sentences which you give.
   - Yes ☐ No ☐ Not Done ☐
4. Child reflexly blinks to loud noise
   - Yes ☐ No ☐ Not Done ☐

(II) Audiometry (Age 4 years or over)
1. Ambient noise ☐ dB(A)
2. Hearing Thresholds
   - 1 KHz ☐ 2 KHz ☐ 4 KHz ☐ 1 KHz ☐

SCREENING EXAMINER’S NUMBER ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
SCREENING EXAMINER’S REMARKS:

C. BASIC EAR ASSESSMENT
Mark all abnormal findings which apply
I. Ear Pain ☐ ☐ ☐ ☐
II. Auricle
   1. Malformation ☐ ☐ ☐ ☐
   2. Normal ☐ ☐ ☐ ☐
III. External ear canal
   1. Inflammation ☐ ☐ ☐ ☐
   2. Wax ☐ ☐ ☐ ☐
   3. Foreign body ☐ ☐ ☐ ☐
   4. Otoscopy ☐ ☐ ☐ ☐
   5. Fungi ☐ ☐ ☐ ☐
   6. Normal ☐ ☐ ☐ ☐
   7. Not seen ☐ ☐ ☐ ☐
IV. Ear drum
   1. Perforation ☐ ☐ ☐ ☐
   2. Dullness or Retraction ☐ ☐ ☐ ☐
   3. Red and Bulging ☐ ☐ ☐ ☐
   4. Normal ☐ ☐ ☐ ☐
   5. Not seen ☐ ☐ ☐ ☐
V. Middle Ear
   1. Otoscopy ☐ ☐ ☐ ☐
   2. Normal ☐ ☐ ☐ ☐
   3. Not seen ☐ ☐ ☐ ☐
VI. Others ☐ ☐ ☐ ☐
   Specify ☐ ☐ ☐ ☐

D. CAUSE OF EAR DISEASE AND/OR HEARING IMPAIRMENT
Mark all disease or impairment which apply
Normal ear and normal hearing ☐ ☐ ☐ ☐
I. Ear Disease
   1. Wax ☐ ☐ ☐ ☐
   2. Foreign body ☐ ☐ ☐ ☐
   3. Otitis externa ☐ ☐ ☐ ☐
   4. Otitis media ☐ ☐ ☐ ☐
   5. Acute ☐ ☐ ☐ ☐
   6. Chronic suppurative ☐ ☐ ☐ ☐
   7. Serous (with effusion) ☐ ☐ ☐ ☐
   8. Other ☐ ☐ ☐ ☐
II. Infectious Diseases ☐ ☐ ☐ ☐
   Specify ☐ ☐ ☐ ☐
III. Genetic Conditions ☐ ☐ ☐ ☐
   Specify ☐ ☐ ☐ ☐
IV. Non-Infectious Conditions ☐ ☐ ☐ ☐
   Specify ☐ ☐ ☐ ☐
V. Undetermined Cause ☐ ☐ ☐ ☐
   Specify ☐ ☐ ☐ ☐

E. ACTION NEEDED
Mark all action which apply
I. No action needed ☐ ☐ ☐ ☐
II. Action needed ☐ ☐ ☐ ☐
   1. Medication ☐ ☐ ☐ ☐
   2. Hearing aid ☐ ☐ ☐ ☐
   3. Language/speech rehabilitation ☐ ☐ ☐ ☐
   4. Special needs education ☐ ☐ ☐ ☐
   5. Vocational Training ☐ ☐ ☐ ☐
   6. Surgery Referral ☐ ☐ ☐ ☐
   7. Others ☐ ☐ ☐ ☐
   Specify ☐ ☐ ☐ ☐

SPECIAL EXAMINER’S NUMBER ☐ ☐ ☐ ☐
SPECIAL EXAMINER’S REMARKS:

VII. Additional Information
1. (This question to be answered for subjects reporting deafness or hearing impairment).
   Since infancy/childhood (0-14 y) ☐ ☐ ☐ ☐
   Since adulthood (15-59y) ☐ ☐ ☐ ☐
   Since age 60y+ ☐ ☐ ☐ ☐
   Uncertain ☐ ☐ ☐ ☐
2. (This question to be answered for all subjects).
   Does any brother/sister/effinger/parent of subject have difficulty hearing?
   No ☐ ☐ ☐ ☐
   Yes ☐ ☐ ☐ ☐
   Uncertain ☐ ☐ ☐ ☐

Date of version: 9.3.98
Date of printing: 15-Jul-1999
[version 7.1A]
PART 3: CODING INSTRUCTIONS
To accompany Form Version 7.1A

1. INTRODUCTION

The WHO/PDH EAR EXAMINATION FORM has been developed by the WHO Programme for the Prevention of Blindness and Deafness (PBD). It is designed for use in a survey to assess the magnitude of the problems of deafness and hearing impairment and other ear diseases in order to evolve strategies for their prevention and control.

The purposes of this form are:

(1) To be the data-collection instrument for a population-based survey of the prevalence and likely causes of ear disease and hearing impairment for people aged 6 months or above.
(2) To enable data collection in a standard way so that results can be compared amongst surveys that use this form.
(3) To gather information on otological actions needed in order to estimate the resources required to deal with these problems in the study population.

Thus, when the form is used in a survey, it is strongly urged that no changes are made to it. However, those conducting the survey may very well decide to gather additional information at the same time.

The WHO/PDH EAR EXAMINATION FORM comprises 5 different sections, as follows:

A. CENSUS.
B. HEARING EXAMINATION.
C. BASIC EAR ASSESSMENT.
D. CAUSE OF EAR DISEASE AND/OR HEARING IMPAIRMENT.
E. OTOLOGICAL ACTION NEEDED.

To complete the form, adequate training of survey team personnel is required in advance. Section A needs literate and numerate personnel. Section B needs personnel with audiometric skills to handle equipment to measure hearing, and careful observation of behavioral response of children. Section C, D and E 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 so as to be easy to fill in by marking the boxes and giving further information where indicated.

Small boxes (□) for the right (R) and/or left (L) ear should be ticked only if the condition indicated exists. If it does not exist the small box should be left blank. Larger boxes (□)
WHO Ear and Hearing Disorders Survey Protocol (Part 3: Coding Instructions for Ear Exam Form 7.1A)

require a number to be inserted as described in relevant coding instructions. Data will be processed by computer.

In the Sections, C, D and E, when the category "specify" is encountered, a detailed description or opinion of the examiner should be stated here.

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

HOUSEHOLD ROSTER FORM

Before completing the Examination Form a Household Roster Form should be completed for each household. This should include all persons usually living in that household. The identification number on the Roster Form for each household and each individual should then be inserted into Boxes A.5 and A.6 respectively (see descriptions for these boxes for further explanation).

The complete number in boxes A1 to A6 forms a unique identifier number for each subject.

2. CODING INSTRUCTIONS

Section A : CENSUS

In this section each box should be filled either by a digit or a letter inside a box, according to the instructions.

<table>
<thead>
<tr>
<th>POSITION NUMBER</th>
<th>ITEM</th>
<th>INSTRUCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.1</td>
<td>Country Number</td>
<td>The UN 3 figure code must be used if data processing is to take place outside the country as per WHO region. (See Annex 1).</td>
</tr>
<tr>
<td>A.2</td>
<td>Study Number</td>
<td>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.</td>
</tr>
<tr>
<td>A.3</td>
<td>Admin Division</td>
<td>A defined geographical or administrative area such as a district which can be further sub-divided into smaller administration units. A different number should be given to each administrative division.</td>
</tr>
</tbody>
</table>
A.4 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.5 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 (see Introduction, page 2).

A.6 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 six months or more. This number should be the same as that on the Household Roster Form (see description above).

A.7 Optional
This field may be used for collection of additional information such as ethnic group, occupation, literacy, etc.

A.8 Name
The subject's name may be filled in for identification purposes but will not be coded.

A.9 Age in Years
00 = If less than 1 year. Go to Section A.10 "Age in months".
99 = If missing information.
1 to 84 = Age in years (at age last birthday).
85 = 85 or over in years.

A.10 Age in months
0 - 11 in months for child less than 1 year.

A.11 Male/Female
Mark M or F as appropriate (M = Male; F = Female).

A.12 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 subject (or parent or guardian) refuses to have any type of examination or provide any information.
Code 3 (= Absent) should be entered if the subject is a usual resident who is not present during the entire survey period.

Even if the subject is absent or refused, the census section should still be completed as far as possible and the form submitted for analysis.

A.13 Date

Date, month and year of this examination should be entered. Example: 5 October, 1994 would be 051094.
WHO Ear and Hearing Disorders Survey Protocol (Part 3: Coding Instructions for Ear)  
Exam Form 7.1A  
Section B: Hearing Examination

Section B: HEARING EXAMINATION

In a household, adults should be examined before children so that children are less frightened by the procedures.

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. This is in order to measure the actual level of disabling hearing impairment (the special examiner may request further audiology after removal for diagnostic purposes, but there is no need to record the second set of audiological results).

B.I  Hearing Examination for Children (age 6m to 3y11m)  
(if any of these tests are recorded as “yes” the child is regarded as having normal hearing)

1. A child is called by his/her own name by the tester from behind the child by at least ½ metre in a normal conversational voice. A positive response, either by turning or showing attention should be recorded as `Yes’. If the child does not respond, record `No’. If the test was not done for any reason, tick the `Not Done’ box.

2. The child is asked, in a conversational voice, to point to someone in the room known to him/her by name. If the child does this, record as `Yes’.

3. A child should be asked a simple question, for example, his/her name or the name of a brother or sister, if a correct reply is given, record as `Yes’.

4. This is a suitable test for very young children or babies. With an observer standing in front of the child, a loud noise is produced by an assistant, eg. a loud clap or 2 pieces of wood banged together behind the back of the child’s head. The baby or child should reflexly blink in response to this noise. If the baby or child does this, record as `Yes’.

B.II  Audiometry (age 4 years and over)

Pure Tone audiometry is performed for all individuals who are 4 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 4 years and over, if a child up to age 9 years cannot be tested this way, the questions given above for section B.I can be used].

B.II 1. 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. The
WHO Ear and Hearing Disorders Survey Protocol (Part 3: Coding Instructions for Ear
Exam Form 7.1A)

Section B: Hearing Examination

level of ambient noise should be recorded in the box B.II.1. 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.

Calibration

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

1. Daily self-calibration.
2. Regular audiometric calibration. Ideally every month, every 6 months acceptable.
3. Regular battery testing to make sure these are at full strength.
4. If a mains operated audiometer is used, a voltage stabiliser should be used since reduction in voltage can produce reduction in audiometer output.

Testing Procedure

The person who is 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 fit well. Each time the subject hears the sound, he/she has to respond to the tester by using a simple sign, eg. raising a hand.

B.II 2. Hearing Thresholds
1,2,4 KHz
and 1 KHz

It is important to be sure that the subject hears some sound and can hear and understand the test. 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 subject responds to the sound. Once the subject has heard a sound the threshold of hearing should then be established by decreasing thresholds by 10 dB steps and increasing by 5 dB steps until the threshold is established by subject confirming threshold on 3 successive occasions. No correction factors should be used since these will be inserted at the analysis stage if necessary.

These thresholds should be established in the same manner at 2 & 4 KHz and then finally, the threshold should be established again at 1 KHz and should be
WHO Ear and Hearing Disorders Survey Protocol (Part 3: Coding Instructions for Ear Examination Form 7.1A)

Section B: Hearing Examination

Within 5 dB of the original measurement at 1 KHz. If not, repeat the whole audiogram.

<table>
<thead>
<tr>
<th>SCREENING EXAMINER NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each screening examiner should enter his/her assigned code.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOT FULLY EXAMINED IN THIS SECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>This box should be ticked if the child was not fully examined in Section B.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SCREENING EXAMINER'S REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>The opinion of the examiner why the examination could not be completed satisfactorily. The reasons should be recorded.</td>
</tr>
<tr>
<td>Type, make of audiometer and type and make of headphones should be recorded here also.</td>
</tr>
</tbody>
</table>
Section C: BASIC EAR EXAMINATION

C.I Ear Pain
If the subject (or parent or guardian) reports any ear pain related to the external ear, ear canal or mastoid region, this should be recorded with a ✓.

C.II Auricle
1. Malformation
   If the Auricle has evidence of sinuses, unusual shaped cartilages or is very small or missing, mark a ✓ in the appropriate box.

2. Auricle Normal
   Mark the appropriate box with a ✓ if the Auricle is of normal appearance without any evidence of sinuses or pits. If it appears unusual or abnormal or is missing, leave the appropriate box blank.

C.III External Ear Canal
1. Inflammation
   Mark the appropriate box with a ✓ if there is any redness or tenderness of the ear canal.

2. Wax
   Mark the appropriate box with a ✓ if unable to view the ear canal because of wax either soft or hard.

[Removed]
   Mark the appropriate box with a ✓ if the wax was removed by any member of team*.

3. Foreign Body
   Mark the appropriate box with a ✓ if there is an obvious foreign body in the ear canal. If identifiable, please describe what it is in Special Examiner’s Remarks.

[Removed]
   Mark the appropriate box with a ✓ if object is removed from ear canal by member of team*.

4. Otorrhea
   If there is evidence of any pus, mark the appropriate box with a ✓ for the appropriate ear.

[Removed]
   If the ear canal has been cleaned by a member of the team so that the ear canal is visualised mark the

* 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.
appropriate box with a √. If the ear was not touched leave box blank*.

5. Fungi
Mark the appropriate box with a √ if there is any evidence of a fungal infection. If in doubt refer to Appendix Picture 6, [Not yet available].

6. Normal
Mark the appropriate box with a √ if the ear canal is present and has no abnormalities. If there is an abnormality not listed above in C.III 1-5, record it in C.VI Others, and leave this box blank.

7. Not seen
If the external ear canal cannot be seen for any reason, mark the appropriate box with a √.

C.IV Ear drum

1. Perforation
If there is evidence of a perforation, mark √ in the appropriate box. If there is any doubt, even after ear toilet, leave blank.

2. Dullness or retraction
If the ear drum is dull or retracted and the light reflex is poor (see photograph Appendix A) [Not yet available] mark the appropriate box with a √. [These signs, when seen together with ear pain are indicative of the condition Acute Otitis Media].

3. Bulging and red
If there is evidence that the ear drum (tympanic membrane) is tense and bulging and the drum mucosa appears red, mark the appropriate box with a √. [These signs, when seen together with ear pain are indicative of the condition Acute Otitis Media].

4. Normal
If there is a good view of the Tympanic Membrane and it appears normal mark the appropriate box with a √.

5. Not seen
If the ear drum cannot be seen for any reason, mark the appropriate box with a √.

C.V Middle Ear

1. Otorrhea
If, on otoscopy, there is definitely otorrhea within the middle ear, mark the appropriate box with a √.

2. Normal
On examination with a perforation, if there is evidence that the middle ear is not inflamed and the malleus
handle is in the correct position, mark the appropriate box with a √.

3.  Not seen

If the middle ear cannot be seen for any reason (including because the drum is intact), mark the appropriate box with a √.

C.VI Others

Mark the appropriate box with a √ 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.

Normal Findings

On examination if the auricle, ear canal, tympanic membrane and middle ear appear normal mark a √ in the appropriate box. If there is any abnormality or doubt leave the box blank.

C.VII Additional Information

1.  *For subjects who report or who are reported to have deafness or hearing impairment*, tick the appropriate box according to how long the subject has had difficulty hearing.

2.  *For all subjects*, tick the appropriate boxes according to whether any of these first degree relatives have difficulty hearing. In some studies, additional information could also be collected on second or lesser degree relatives and on consanguinity.
Section D: CAUSE OF EAR DISEASE AND HEARING IMPAIRMENT

Normal ear and normal hearing
If there are completely normal findings for the ear and for hearing, mark the appropriate box with a ✓. Otherwise, leave blank. The definition of normal hearing, for the purposes of this section, is that either in section B(I) at least one 'Yes' box is ticked, or that in section B(II) no hearing threshold box is marked as 26 dBHL or greater.

D.I  Ear Disease

1. Wax
   Tick the appropriate box only if occluding or impacted wax has been found (whether or not it has been removed).

2. Foreign Body
   Tick the appropriate box if a foreign body has been found (whether or not it has been removed).

Algorithms

Algorithms are provided for the following diagnoses (D.I, 3 to 7). A diagnosis box in Section D should only be ticked if all of the listed criteria for that diagnosis have been found and all of the boxes in Sections B and C have been ticked or not ticked as listed below.

<table>
<thead>
<tr>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.I</td>
</tr>
<tr>
<td>C.II.1</td>
</tr>
<tr>
<td>C.I</td>
</tr>
<tr>
<td>C.IV.3</td>
</tr>
<tr>
<td>No perforation</td>
</tr>
<tr>
<td>No pain</td>
</tr>
</tbody>
</table>

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WHO Ear and Hearing Disorders Survey Protocol (Part 3: Coding Instructions for Ear)  
Exam Form 7.1A)  
Section D: Cause of Ear Disease and Hearing Impairment

<table>
<thead>
<tr>
<th>Suppurative Otitis Media</th>
<th>Otorrhea External ear canal and/or otorrhoea of middle ear</th>
<th>C.III.4 and/or C.V.1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Perforation</td>
<td>C.IV.1</td>
</tr>
</tbody>
</table>

ALGORITHMS - continued

6. Serous Otitis
   No pain
   No perforation
   Dullness or retraction
   Fails hearing screen (< 4 yrs)
   or
   Hearing Threshold > 25 dB for 1 or more freq (4 yrs or older)

   not C.I
   not C.IV.1
   C.IV.2
   B.I or B.II

7. Dry perforation
   No pain
   Perforation
   No otorrhea external ear canal
   No otorrhea middle ear

   not C.I
   C.IV.1
   not C.III.4
   not C.V.1

[End of Algorithms]

For sections D.II to D.V., further information (by history and/or examination) should be obtained from those subjects who appear to have a hearing impairment or deafness, in order to attempt to determine the likely cause. The definition of hearing impairment and deafness, for the purposes of these sections is that in section B(I) no box is ticked 'Yes' and at least one box is ticked 'no', or that in section B(II) at least one hearing threshold box
records a level of 26 dBHL or greater, or that one of the boxes in section C.VII.1 has been ticked.

D.II Infectious Diseases

Further information should be obtained (by questioning or otherwise) from subjects with deafness or hearing impairment if there is any history of a particular infectious illness present prior to deafness.

For example:

- Rubella
- Meningitis
- Chicken Pox
- Herpes Zoster
- Syphilis
- Mumps
- Measles
- Tuberculosis
- Malaria
- Pneumonia
- Cytomegalovirus
- Toxoplasmosis
- Typhoid

Tick the appropriate box if an infection is thought to be the cause and specify the particular infection in the space provided.

D.III Genetic Conditions

In subjects with deafness or hearing impairment consideration with further information should try to establish if there are any physical characteristics which are unusual and are observed on the subject.

For example:

- Unusual physical characteristic common to subject and parents, eg. colour of hair.
- Craniofacial or skeletal disorder, eg. dwarfism, shape of ears, saddle nose.
- Changes in skin pigmentation, eg. albinism, abnormal digits, skin patches (cafe au lait spots).
- Any eye disorder, eg. different colour pupil, obvious blindness.
- Cardiovascular abnormalities, eg. cyanosis of lips, oedema of peripheral structure.
- Endocrine disorders, eg. goitre from Pendred's Syndrome.
- Other conditions such as Down's Syndrome.
- Close parental relationship (specify relationship).
If the hearing loss is thought to be due to a genetic condition, the appropriate box should be ticked and the disorder specified in the space provided.

Further questions of those with a deafness or hearing impairment should be asked to establish whether there is any medical or occupational reason for this hearing loss. For example:

- Diabetes.
- Thyroid Disease, e.g. Myxoedema or Cretinism.
- Pituitary Disease, e.g. Acromegaly.
- Exposure to loud noise at work over a period of time.
- Treatment with medication for either a short or long-term period for illness which appears to be related to the onset of the hearing loss.
- Exposure at work to dangerous chemicals particularly eg. thio-cyanates or solvents or live in close proximity to a chemical factory.
- Any known neurological condition possibly progressive, eg. Multiple Sclerosis, Ataxia, Parkinsons Disease.
- Recent pregnancy.
- Presbyacusis

If the hearing loss is thought to be due to a non-infectious condition, the appropriate box should be ticked and the disorder specified in the space provided.

Tick the appropriate box if the subject has deafness or hearing impairment but the cause has not been determined.
Section E : ACTION NEEDED

This Section is included in order to assess resource requirements. Therefore, the examiner should determine what action is needed according to what is best for the subject, whether or not that action is available for the population.

The examiner should then tick the appropriate box having considered all the information collected in the questionnaire.

E.I  No action needed

E.II  Action needed

1. Medication

2. Hearing aid

3. Language/speech rehabilitation

4. Special needs education

5. Vocational Training

6. Surgery Referral

There is no obvious reason for further treatment.

Subject has an infection or metabolic condition that requires treatment.

Subject has a significant hearing loss and the hearing requires amplification for day to day communication.

There is obvious delay or abnormal speech which may be the result of hearing impairment and speech therapy might be able to improve speech.

There is obvious developmental delay either physically or mentally which requires specialised help.

The subject has significant hearing loss without any physical limitations and requires help in seeking appropriate employment.

Examination shows evidence of an infective process or significant middle ear effusion, and if surgical correction of this process would clear up infection and/or improve hearing, this should be marked as requiring non-urgent surgery.

If the subject has a significant persistent temperature and evidence of cerebral involvement or evidence of active cholesteatoma in the attic region of the middle ear the subject should be marked as requiring urgent surgery.
<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIAL</td>
<td>Each special examiner should enter his/her assigned code.</td>
</tr>
<tr>
<td>EXAMINER’S NUMBER</td>
<td></td>
</tr>
<tr>
<td>SPECIAL EXAMINER’S REMARKS</td>
<td>There is space here for any remarks by the special examiner.</td>
</tr>
</tbody>
</table>
### UN 3-Figure Codes as per WHO Region

#### AFRICAN REGION

<table>
<thead>
<tr>
<th>Country</th>
<th>Code</th>
<th>Country</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algeria</td>
<td>012</td>
<td>Ethiopia</td>
<td>230</td>
</tr>
<tr>
<td>Angola</td>
<td>024</td>
<td>Gabon</td>
<td>266</td>
</tr>
<tr>
<td>Benin</td>
<td>204</td>
<td>Gambia</td>
<td>270</td>
</tr>
<tr>
<td>Botswana</td>
<td>072</td>
<td>Ghana</td>
<td>288</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>854</td>
<td>Guinea</td>
<td>324</td>
</tr>
<tr>
<td>Burundi</td>
<td>108</td>
<td>Guinea-Bissau</td>
<td>624</td>
</tr>
<tr>
<td>Cameroon</td>
<td>120</td>
<td>Kenya</td>
<td>404</td>
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*WHO Ear and Hearing Disorders Survey Protocol (Part 3: Coding Instructions for Ear Exam Form 7.1A)*

*Section E: Action Needed*

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