

# Guidelines for Hearing Aids and Services for Developing Countries (2<sup>nd</sup> Edition, 2004.9.)

World Health Organization Prevention of Blindness and Deafness (PBD)

## EXECUTIVE SUMMARY

These guidelines have been developed by an expert working group set up following a recommendation by the WHO—CBM Workshop on Needs and Technology Assessment for Hearing Aids Services in Developing Countries held in 1998.

Current production of hearing aids is one—tenth of the global need and only one quarter of these are distributed to developing countries. There is an urgent need to provide hearing aids and services that are appropriate and affordable for developing countries, taking into account the scarcity in resources of skills, training, services and finances in most developing countries. These guidelines set out minimum requirements and recommendations for such hearing aids and services, and are particularly targeted at manufacturers, distributors, policy makers and service providers at all levels. It is intended that the hearing aid requirements given here would enable manufacturers to produce them at low cost and in bulk with currently available technology.

The guidelines recommend that priority for hearing aids and services should be given to children with an average hearing impairment in the range 31 to 80 dBHL in the better ear in the frequency range 500 Hz to 4 kHz, followed by adults with an average hearing impairment in the range 41 to 80 dBHL in the better ear in the same frequency range. Behind the ear hearing aids should be the preferred option but body—worn aids may still be required in some situations, provided they are of similar reliability and no greater cost than behind the ear hearing aids. To ensure that a basis for specifying the electroacoustic performance of hearing aids is available a minimum performance specification is given; this does not preclude the use of higher performance aids as appropriate.

Persons with profound hearing impairment may benefit from a Cochlear implant (CI) but implantation is not recommended unless the necessary medical, technical, educational, psychological and hearing therapist resources and services are available. Also, where resources are limited, the available resources may be more effectively used to prevent a greater burden of hearing loss in more people through using less costly interventions.

Manufacture or assembly and servicing of hearing aids should be feasible in developing countries. Hearing aids and batteries that are imported from another country should be classified as medical devices in order to avoid import duty. Batteries should be zinc air or rechargeable type. The availability of a reliable supply of batteries is essential.

Earmoulds should be individually made by a two—stage syringe technique in locally established static laboratories; other methods that maintain the same quality may be used. Portable, mobile facilities may be necessary in less accessible areas. Universal or stock size earmoulds should only be used as a temporary measure. Earmoulds should be replaced at recommended intervals.

Services for providing hearing aids to users are an essential component of a hearing health system. The guidelines make recommendations for services which comprise raising awareness, identification and assessment, provision, support for users, and training.

Awareness should be raised through the promotion of prime messages about the problems caused by hearing impairment, its detection, and prevention of its effects. These messages should be targeted at particular groups in society including people with hearing impairment, parents, teachers, community and national leaders, health care and educational and other service providers, and policy makers and administrators.

Identification of hearing impairment should be done at the primary level by primary health care (PHC) workers with training and skills in primary ear and hearing care (PEHC). Persons with hearing impairment and discernible ear disease (such as otitis media) should receive medical &/or surgical treatment initially, where possible; persons in whom such

treatment fails to resolve the hearing problem and also persons who are found to have a hearing problem alone should be referred to the secondary level for hearing assessment. This should include ENT examination, frequency specific test of hearing threshold in each ear, and decision whether a hearing aid would be beneficial. It may be feasible to make available some of these functions, including provision of hearing aids, at the primary level if they cannot be developed at the secondary level.

Provision of hearing aids includes supply, pricing, distribution, delivery, and fitting. Reliable sources for the aids, batteries, earmould materials, spare parts and repair materials need to be identified and adequate systems for importation, storage, stock control and delivery should be set up. Costs should be kept low. Hearing aids and services should be provided to the user at a price they can afford or, in certain cases, they may be provided free. Hearing aid services should be designed and implemented as a low cost, sustainable, community service.

Fitting of a hearing aid with earmould and batteries should only be done following a hearing assessment. Persons doing the fitting must have received the necessary training and keep adequate records. Support for users (including their care-givers, if present) should include easily understood instruction in using and continuing to learn to use the hearing aid; care and maintenance; obtaining batteries; dealing with problems; and special instructions for parents and teachers. Follow-up should be done at secondary and primary levels and by suitable hearing-aid users in the community. There should be easy and close access to affordable services for replacement of earmoulds and batteries and maintenance and repair of hearing aids. Initial contact for these services should be with the PEHC-trained worker.

The performance of the whole programme for provision of hearing aids should be monitored and evaluated using performance and outcome indicators for achievement of specified targets. A system of quality assurance should be set up.

The guidelines list topics and equipment required for training the different categories of health worker at primary, secondary and tertiary levels; topics can be adapted according to a country's needs. Training courses, especially at primary level, should take place as close as possible to where the workers will be employed. Courses should be recognized as soon as feasible in the countries where they are conducted. At the primary level, it is likely that the PEHC-trained worker will be a CBR or PHC worker who has received additional training in PEHC with subsequent refresher training. At all levels, good trainees will become trainers, with selection of trainers occurring progressively from the basic levels. Training for trainers is essential.

Before implementing a programme for provision of hearing aids services in full, pilot project(s) should be set up to determine costs of the services, refine the model of service delivery, and assess the impact and effectiveness of the hearing aids and services being utilized.

## PREFACE TO THE SECOND EDITION

The Hearing Aids Working Group (HAWG) was set up in 1999 following a recommendation from the WHO-CBM Workshop on Hearing Aids Services - Needs and Technology Assessment for Developing Countries held in Bensheim in 1998. From its terms of reference the HAWG was charged with drawing up guidelines containing requirements and recommendations for hearing aids and services so that they are appropriate and affordable for developing countries, and so that manufacturers can produce them at low cost and in bulk with currently available technology.

These guidelines are targeted at the following groups who provide hearing aids services in developing countries:

(1) Manufacturers and distributors of hearing aids

(2) Policy makers

(3) Service providers at all levels.

Hearing aids services defined here include the design and manufacture of hearing aids, and the provision of hearing aids, ear moulds, batteries, maintenance, repair, instruction, and rehabilitation. These elements are all intimately related and hearing aids and the services to provide them in developing countries should be appropriate, acceptable, affordable, and available. The recommendations made here are the minimum required to serve the needs of most populations in developing countries.

Children with moderate or severe hearing impairment (In this document, the term 'hearing impairment', used by itself, denotes any or all levels of severity of hearing difficulty. These levels comprise mild, moderate, severe and profound hearing impairment. The term 'deafness' denotes profound hearing impairment.) in the better ear

should be given priority, followed by adults. Behind the ear hearing aids are the preferred option. Body — worn hearing aids are not preferred because of easy damage to leads and lack of head — turning effects; however body — worn aids may still be needed in some circumstances. Basic requirements to meet the needs of people with moderate to severe hearing losses are listed to enable manufacturers to produce hearing aids according to these recommendations.

For this second edition, the text has been reviewed by most of the original members of the Hearing Aids Working Group, and they have been joined by a new member, Professor Xingkuan Bu, from China. A number of small changes have been made to the guidelines in the light of recent developments and a statement has been added about cochlear implants.

LIST OF ABBREVIATIONS

- AC: air conduction
- AGC: automatic gain control
- BC: bone conduction
- BTE: behind the ear
- CBM: Christoffel—Blindenmission / Christian Blind Mission
- CBR: community—based rehabilitation
- dB: decibel
- dB HL: dB hearing level
- ERA: evoked response audiometry
- FM: frequency modulation radio device
- HAWG: Hearing Aids Working Group
- IEC: International Electrotechnical Commission
- ISO: International Organization for Standardization
- ITE: In—the—ear
- ITC: In—the—canal
- mA: milliamperes
- OAE: oto—acoustic emission
- OSPL: output sound pressure level
- PEHC: primary ear and hearing care.
- PHC: primary health care.
- SPL: sound pressure level
- WHO: World Health Organization

1 INTRODUCTION

WHO has estimated<sup>[1]</sup> that in 2001 250 million persons in the world have disabling hearing impairment [WHO DEFINITIONS OF DISABLING HEARING IMPAIRMENT: Disabling hearing impairment in adults should be defined as a permanent unaided hearing thresh-

old level for the better ear of 41 dB or greater; for this purpose the “hearing threshold level” is to be taken as the better ear average hearing threshold level for the four frequencies 0.5, 1, 2, and 4 kHz.” Disabling hearing impairment in children under the age of 15 years should be defined as a permanent unaided hearing threshold level for the better ear of 31 dB or greater; for this purpose the “hearing threshold level” is to be taken as the better ear average hearing threshold level for the four frequencies 0.5, 1, 2, and 4 kHz.” (Note that the term “hearing impairment” without the epithet “disabling” is taken to mean a hearing problem of any level or all levels of severity. )]; the burden is estimated to be approximately twice as large in developing countries as in developed countries<sup>[2]</sup>. Total world production of hearing aids is less than one tenth of the global need; 75 % of the annual production are distributed to North America and Europe and 25 % to the rest of the world. Japan, Australia and New Zealand account for over half of these and the remainder are distributed in developing countries<sup>[3]</sup>. Where hearing aids and services are available they are generally expensive and often inappropriate for developing countries<sup>[4]</sup>. It is important to determine accurately the extent of the need for these items in developing countries and what would be the most appropriate solutions<sup>[5]</sup>.

WHO has addressed these issues at a consultation held at the European Regional Office in 1990<sup>[6]</sup> and more recently at the WHO/CBM Workshop on Hearing Aid Services in 1998<sup>[3]</sup>. The latter meeting made recommendations on the most appropriate type of hearing aid and service provision in countries with limited resources and how these might be provided. Consensus was reached concerning hearing aids as part of a hearing health system: “A hearing aid should be regarded as only one component of a hearing health system that includes the ear mould, batteries, maintenance, repair, instruction, and rehabilitation”. Hearing aids and the services to provide them should be appropriate, acceptable, affordable, and available<sup>[7]</sup>.

The 1998 meeting recommended that a small working group of experts should be convened by WHO to develop detailed specifications for appropriate hearing aids and services for developing countries. Thus, the Hearing Aids Working Group (HAWG) was set up and commenced work in 1999.

The HAWG was asked to draw up guidelines for re-

quirements for hearing aids and their accessories and services so that they would be appropriate and affordable for developing countries, and so that manufacturers could produce them at low cost and in bulk. The group was also asked to use these guidelines to help set up a meeting with interested societies of hearing aid manufacturers to determine possibilities for future production (see Annex 1 for the group's terms of reference).

For these guidelines the Hearing Aids Working Group decided to focus particularly on the following issues: —

- to set up minimal requirements for low cost hearing aids for developing countries.
- to propose solutions for ear moulds.
- to propose solutions concerning batteries.
- to propose systems for delivery of the whole package of services.

The group decided not to address the following elements of the terms of reference: “consider and make recommendations on method and location of manufacture and assembly, bulk purchase, tendering, importation”. It was felt that these items should either be left to the manufacturer, or would vary according to the region or country concerned and would be better determined locally as an addition to the guidelines.

It should be emphasized that the purpose of these guidelines is to provide a set of minimal but appropriate recommendations for the manufacture and provision of services for hearing aids in developing countries. Setting minimum standards for the population is necessary because of the scarcity in resources of skills, training, services and finances in developing countries<sup>[8]</sup>. The guidelines are intended to be of particular interest to manufacturers and to encourage them to address the huge need in these parts of the world. The guidelines are also intended for policy makers and service providers at all levels in developing countries in order that they may develop and provide appropriate and affordable services for the provision of hearing aids.

## 2 BASIC HEARING AID REQUIREMENTS

### 2.1 Overview

The group considered the problem of specifying hearing aid performance to cover the needs of both children and adults. The consensus of opinion is that a basic specification or requirement should be produced that would enable hearing aids to be produced at low cost to meet the

needs of the majority of those with hearing impairment. It was recognized that all needs could not be met and therefore children should be given priority. Initially these should be children with an average hearing impairment in the range 31 to 80 dBHL in the better ear in the frequency range 500 Hz to 4 kHz. Next in priority should be adults with an average hearing impairment in the range 41 to 80 dBHL in the better ear in the same frequency range. These are the largest groups with hearing impairment and the ones that should benefit most from using hearing aids. However, people experiencing hearing problems at a hearing level better or worse than the above range may need hearing aids and, when appropriate, may be considered as candidates.

It should be stated that persons with profound hearing impairment may benefit from a Cochlear implant (CI). However implantation cannot be recommended unless the necessary medical, educational, technical, psychological and hearing therapist resources and services are available. Also, given the very high cost of implantation, consideration must be given, where resources are limited, to whether resources for implantation could be more effectively used to prevent a greater burden of hearing loss in more people through using less costly interventions.

Given the restrictions in resources, both in terms of skills and finance, that are likely to apply in developing countries the specifications given below, as well as service and training needs, should be seen to be the minimum to meet the needs of this population.

These requirements do not preclude the delivery of hearing aids with more advanced specifications providing that this does not lead to increased costs and resources which then put hearing aids beyond the reach of the majority of people in developing countries.

The main recommendation is that aids worn behind the ear are likely to be the preferred option in the first instance. However, aids worn in the ear of the modular type may have potential use once the problems of large-scale fitting have been overcome. There may also be a need for body worn aids in some areas, provided they have similar reliability and less or no greater cost than BTE hearing aids. The group felt that body-worn aids would only be needed where the problems for which they are provided (low cost, ease of repair, wide availability of batteries) cannot be solved by the other hearing aids that are being recommended here. For example this may be the case in

rural areas of some developing countries where at present body—worn aids are generally preferred. ITE hearing aids and ITC hearing aids should be considered in adults as long as their reliability, stability and costs are comparable to BTE—hearing aids.

The technology to be used in the manufacture of the hearing aid is not specified as this is a matter for the manufacturers in determining the best way in which to implement the specifications.

2.2 General Specification

Hearing aids should be constructed in a form that allows for ease of servicing and with components that are readily available and will remain so for a period of at least five years. Manufacturers should provide sufficient technical details, including circuit diagrams, to permit servicing to take place in appropriate centres in developing countries.

Hearing Aids should be powered by either primary cells of the zinc air type or secondary rechargeable cells. The aids should meet the specifications below with either type of cell. Where rechargeable cells are the preferred option appropriate battery chargers should be provided together with clearly stated instructions for proper use of the cells and chargers.

Aids should be capable of operating within the specified performance over at least the temperature range 5 °C to 45 °C and a humidity range of 0% to 80%.

Aids should have the means to reduce the gain at frequencies below 750 Hz. A reduction of at least 12 dB at 250 Hz, relative to 750 Hz, should be achieved by either a pre—set or a user control. The volume control should have a range of at least 30 dB and be clearly numbered. The provision of an induction pick—up coil is optional but preferred. Preference should be given to aids with a means for controlling the level of the maximum acoustic output, preferably by means of output controlled AGC. In some countries, programmable units and trained staff are available for the HA—fitting. Hearing Aid Manufacturers should have certification to ISO 9001 on quality management systems<sup>[9]</sup>.

The hearing aid should be designed so that the risk of injury or discomfort to the user is minimized. The external parts of the hearing aid should not have any sharp edges or protrusions and should be made of materials, which minimize the risk of allergic skin reactions. The external parts should be made of durable materials and

designed and finished in a way that minimizes the noise caused by wind and/or physical contact.

Manufacturers should provide hearing aids in a few basic colours as requested by the country involved. The colour range could include skin colours, or black or grey (to match hair colour).

The number of moving parts should be minimized. Consideration was given to omitting the on/off switch and just removing the battery when the hearing aid is not being worn. However it is difficult to make a simple and effective battery drawer act as an on/off switch and the loose batteries could more easily be lost and be tempting for a young child to swallow. The battery compartment should be designed in such a way that the battery can only be inserted with the correct polarity.

For the educational setting, a direct audio input system for FM or other direct coupling could be considered<sup>3</sup> although this may add significantly to the costs of the programme and of the hearing aids themselves. Such costs may be beyond the resources available in many areas so such systems should not be considered a priority if they jeopardise the provision of the hearing aids themselves.

2.3 Electro—acoustic specification

The following specification represents the minimum performance requirements for hearing aids and does not preclude or suggest that performance values in excess of these should not be used as appropriate.

Measurements should be made in accordance with IEC60118—7: Hearing Aids Part 7: Measurement of the performance characteristics of hearing aids for quality inspection for delivery purposes<sup>[10]</sup>.

Minimum Performance Requirements	
Maximum OSPL <sub>90</sub>	118 dB (+/- 4dB)
OSPL <sub>90</sub> at 1 kHz	114 dB (+/- 4dB)
Maximum full—on acoustic gain	45— 55 dB (+5/- 0 dB)
Full—on acoustic gain at 1 kHz	42 dB (+5/- 0 dB)
Basic frequency response	200 Hz to 4500 Hz (200 Hz to 2000 Hz +/- 4dB, 2000 Hz to 4000 Hz +/- 6dB, on nominal frequency response curve)
Total harmonic distortion at 70 dB SPL input	500 Hz < 5% 800 Hz < 5% 1600 Hz < 2 %
Equivalent input noise level	< 25 dB SPL
Battery current	≤ 1 mA

2.4 Classification of hearing aids

A hearing aid should be classified globally as a medical device as in most developed but few developing countries. If so, it would avoid import duty<sup>[11]</sup>. Thus, for ex-

ample, the Medical Devices Directive of the European Union under regulation 93/42/EEC<sup>[12]</sup> regulates all non-implantable medical devices, and under its requirements hearing aids will be classified as Class 2 medical devices.

There is also a classification system for medical devices by the ISO which is ISO15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purposes of regulatory data exchange<sup>[13]</sup>. Hearing aids of all types are classified under this and therefore can be taken as medical devices.

## 2.5 Manufacture and Guarantee

Hearing aids may be manufactured or assembled nationally or regionally in a developing country or imported from the developed world<sup>[14]</sup> provided neither option affects the cost or availability of spare parts and their quality and distribution.

The cost of hearing aids is affected by the form of guarantee given to the purchaser. For bulk purchasers manufacturers may provide aids on, for instance, a 30 day return basis. This requires the purchaser to ensure that the aids are tested on delivery and any faulty aid returned in this time. Thereafter the purchaser is responsible for repairs and any subsequent guarantee given to the end user. This provides the lowest cost option but places the onus on the purchaser to inspect the aids on delivery and provide a repair service. For one or two year guarantees the costs will increase substantially and will require a system to be in place to ensure the rapid repair of aids.

For costing of hearing aids, see section 3.4.3.

## 2.6 Earmoulds

The earmould is an integral part of the hearing aid system. Individual earmoulds produced from impressions of the ear taken at primary care level using a syringe technique are required. Where no earmould manufacturing facilities are available a range of universal, or stock size, earmoulds may be used but only as a temporary measure.

Readily accessible earmould manufacturing facilities must be established as soon as possible to produce earmoulds using the two stage technique i.e. (1) making a cast of the ear impression using Plaster of Paris (partly dehydrated gypsum) or gel; (2) filling the cast with the acrylic or silicone based earmould material.

Other production methods may be used as long as high quality of the ear mould is maintained.

Initially earmould laboratories should be set up centrally to serve a district, region or county, (depending on

demand). Central laboratories can only be effective where there is a good network to bring ear impressions to the laboratory and return finished earmoulds to the hearing aid user. When the situation permits, district (secondary) level earmould laboratories (static or mobile) should be set up. Ear impressions need to be brought to the laboratory quickly since shrinkage occurs after a few days. Such centralized laboratories can be set up to produce a larger range of earmould styles of various materials. Initially it may be possible to train a local dental technician and house the earmould-making facility in a dental laboratory.

Alternatively, simpler, portable earmould making facilities can be established. The equipment and materials can be transported to where the earmoulds are required. However, the range of earmoulds styles and the materials used with this method are limited. This method is recommended for more inaccessible regions (e.g. that do not have electricity) or where a central earmould laboratory has not yet been established. They could also support the central laboratory. Instant (one stage) earmoulds would in principle be suitable for these situations where appropriate materials are available together with adequate training in their use, but further research and development for this technique is needed.

Many materials required for making earmoulds can be obtained from established dental suppliers in developing countries. Other materials need to be imported from specialist earmould suppliers in developed countries. A long-term supply of materials need to be ensured when setting up earmould laboratories.

Some equipment needed for the manufacture of earmoulds can be bought locally in developing countries from electronics or dental suppliers. Other equipment needs to be imported from specialist earmould suppliers in developed countries.

Earmoulds should, if possible, be replaced at the following intervals: —

\*for infants and young children — every three to six months

\*for older children — every six to twelve months

\*for adults — every two to three years

The need for replacement also depends on the style and material of the earmould. A leaking, hurting or broken earmould should be replaced as soon as possible.

Sufficient, on the job, practical training is required

by the person(s) who are to make these earmoulds. In the initial stages earmould manufacture may be an additional duty taken on by a primary level worker. However, as demand and services increase, dedicated earmould technicians will be required.

- ° At present most hearing aid batteries need to be imported from developed countries and should be done so duty free (this could be by countries re-classifying them as medical instruments rather than electronic consumables).
- ° Bulk purchase of batteries by districts, countries, regions, international NGOs etc can substantially reduce costs.
- ° A good distribution network is required to make batteries readily available to hearing aid users e.g. through PHC or CBR networks or commercial vendors selling at affordable prices.
- ° Batteries must be made available to the users at a price that they can afford.
- ° At least twenty zinc air hearing aid batteries will be required to power a hearing aid for one year of daily use. Battery consumption depends on length of use and power of the hearing aid, and care taken to switch off the aid or remove the batteries when not in use.
- ° New batteries should be issued in exchange for old used batteries. This enables the use of hearing aids and batteries to be monitored and can make battery disposal safer.
- ° Batteries must be stored in cool, dry conditions to prolong shelf life & avoid corrosion.
- ° All batteries should have an expiry date (printed on the packet) and should be purchased well within the expiry date.
- ° Hearing aid users should be instructed to use the correct type of batteries recommended for their hearing aid. The service provider should indicate the type, where they can be obtained and any alternative types that could be used.

Box 1 Key points about batteries

2.7 Batteries

The availability of a reliable supply of batteries is essential to the continuing use of hearing aids. Batteries may be of the primary type such as zinc air cells. These have to be replaced when exhausted.

Rechargeable batteries may be appropriate for many countries. These will last for a period of at least one year but have to be used in conjunction with a source of electrical energy to charge them. This can be a mains powered charger or a larger higher voltage battery such as a car battery; solar-powered chargers are now available. The costs of electricity for charging plus costs of the rechargeable batteries should be less than the cost of disposable batteries for the same period. User training is important to achieve maximum benefit. The further development of solar powered or battery-based battery chargers should be encouraged as well as the development of alternative energy sources.

See Box 1 for key points about batteries.

3 SERVICES.

3.1 Categories

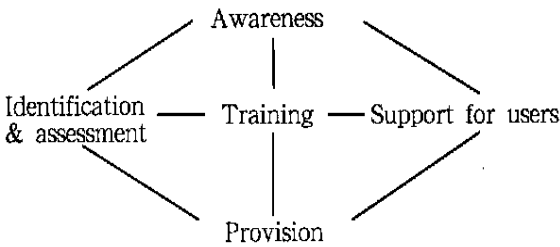


Figure 1 Categories of services

Services and their delivery can be divided into four main categories (see Figure 1). These categories are all interlinked and are dependent on each other. If just one aspect of any category is missing then the system of hearing aid provision will break down. Continuous networking, supervision and feedback is required between users and service providers at all levels.

3.2 Raising Awareness

Awareness of hearing impairment and how to prevent it<sup>[15]</sup> and deal with it needs to be raised and promoted in many groups in society<sup>[16]</sup>. Using a hearing aid should be promoted as one of the potential solutions; the subsequent demand will help to create a market which will sustain rehabilitation needs.

The prime messages for raising awareness and health promotion (see Box 2) are the same for all target groups although they need to be specifically adapted and targeted for each group.

The targets for these messages include: —

- ° society in general
- ° people with hearing impairment
- ° parents, teachers
- ° influential persons, community and national leaders
- ° professional providers of health care especially community health and rehabilitation workers
- ° providers of education and social/vocational services
- ° policy makers, administrators

Raising Awareness Programmes should operate on three levels:

1. At a National Level to influence national policy makers
2. At the provincial/district level (i.e. second tier services) to influence service providers — medical services, educational services, social services, local administration/policy services, and community health services.

3. At the primary level to inform the local community i.e. people who may have a hearing impairment.

Such programmes may be part of a larger, disability prevention programme and have a larger target population.

Hearing Impairment can...

- ° limit activities and restrict participation in daily life
- ° retard child language and educational development
- ° cause employment disadvantage and behavioural, social & emotional problems
- ° lead to large social and economic costs
- ° often be prevented

Hearing impairment and its effects are prevented by<sup>[15]</sup>:

- preventing and treating causes
  - immunization against rubella, mumps, measles, meningococcus, haemophilus and pneumococcus
  - awareness and control of the use of ototoxic drugs<sup>[17]</sup>
  - better perinatal care and management of perinatal problems
  - early identification and adequate treatment of ear disease, especially chronic otitis media & otitis media with effusion.
  - identification and treatment of syphilis
  - reducing harmful noise and controlling its effects<sup>[18]</sup>
  - publicising and providing counselling for hereditary hearing problems and their links with consanguineous marriages.
- ° early detection of hearing impairment, especially in children<sup>[19]</sup>, in order to provide rehabilitation without delay<sup>[20]</sup>
- ° proper provision of hearing aids for most people with a hearing problem
- ° giving support services in regular and special education settings
- ° vocational training, and help with and in employment
- ° enabling alternative modes of communication.

A teacher who suspects a child has a hearing problem must refer him/her for proper hearing assessment.

A child with a hearing problem may need additional help in regular school or special education.

People with hearing impairment: —

- ° should be encouraged to seek help from the appropriate services in the community
- ° need informing about how to cope with it
- ° may need help to obtain appropriate education/employment
- ° may require poverty relief due to limited employment potential
- ° have special needs which should be included in local policies and community services (e.g. ear health care services, educational assistance, assistive services, disability relief)
- ° should be encouraged and trained to set up support groups

Box 2 Prime messages for raising awareness

A variety of health education materials should be developed and different media utilized according to the group being targeted. Training in awareness-raising should be given for all professional care providers, including community health workers. Material to be presented by the primary level worker should be mainly verbal, supported by other methods used and understood by the community

(e.g. pictures, booklets, video/TV, sign language etc).

3.3 Identification and assessment

This includes an initial screening-type test at the primary level to identify those people who may have a hearing problem and/or other ear disease (for example chronic otitis media<sup>[21]</sup> or otitis media with effusion). This test could be used as part of a population screening programme or the same type of test used by a health worker on request for any infant, child or adult who presents with suspicion of hearing loss.

Following identification, an assessment of hearing function is required. This assessment may take place at primary or secondary level depending on what facilities and infrastructure are available. Assessment involves finding the type, degree and shape of hearing loss and whether a hearing aid is beneficial. As a result of the identification and assessment some people will also need referral to other services, e.g. medical, social, educational.

The categories of personnel who perform these functions are given in section 3.4.4, and their training for primary and secondary levels in sections 4.1 and 4.2 respectively.

3.3.1 Primary Level Identification

A simple and straightforward screening procedure is useful to allocate the person presenting at a health centre or for screening each member of a target population into one of four groups. The groups are (1) hearing problem and discernible ear disease that is treatable by medical &/or surgical means, (2) hearing problem and no such ear disease, (3) such ear disease and no hearing problem, (4) no such ear disease and no hearing problem (see Figure 2).

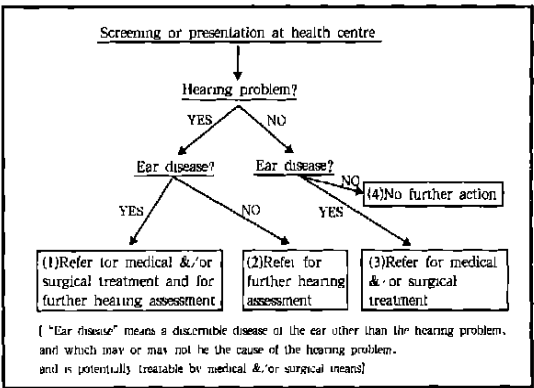


Figure 2 Primary level identification

In group (1), if medical and/or surgical treatment



results in no hearing problem and no ear disease, then no further action is needed. If treatment does not resolve the hearing problem then further hearing assessment is required. If medical/surgical treatment is not available at the primary level for someone in this group, he or she would first have to be referred to the secondary level for treatment.

In some cases, such as in a child in order to avoid loss of auditory sensory input<sup>[22]</sup>, whilst appropriate treatment is being sought hearing aids could be considered on a temporary basis, but only if the ear is not infected and is not actually or likely to be discharging.

The screening procedure should include a combination of the following:

- a short questionnaire concerning ear and hearing health
- ear examination, preferably with an otoscope
- a simple hearing test, whose performance characteristics are known and proven
- for infants: questionnaire to parents regarding response to sound and development of speech
- voice test for older subjects

The screening procedure should be followed by a hearing assessment that could include an OAE test prior to an assessment of hearing thresholds at recommended frequencies by air-conduction pure tone audiometry in an appropriate acoustic environment.

Each stage of the procedure should include a sheet giving the minimum data required and there should be detailed instructions for the procedure.

The procedure should be carried out by a trained primary level worker, in the community who is here called a primary ear and hearing care (PEHC) — trained worker (see Figure 3 and Figure 4). This person in most countries will not be a dedicated health worker who only deals with PEHC, even though it would be preferable in order to fully address this subject. It is more likely that the PEHC-trained worker will be a CBR or PHC worker who has received additional training<sup>[23]</sup>. The amount and content of such training that this person receives will determine the level at which he or she functions. A recent workshop on PEHC<sup>[24]</sup> recognized 3 levels of worker who could provide PEHC services. In this workshop they were called the community health worker, the Nurse practitioner/clinical assistant, and the PHC worker with special training and skills. The level of service provided would

depend on the amount of training received. Not all of these categories may be available in a particular programme (and they may have different titles).

If PEHC — trained workers do not exist, the PHC or CBR worker would refer ear and hearing problems directly to the secondary level where the hearing assessment and hearing aid provision would be done by the audiology technician (see Figure 3). If there is no secondary level, primary health care workers would have to be trained to refer cases directly to the tertiary level, if feasible.

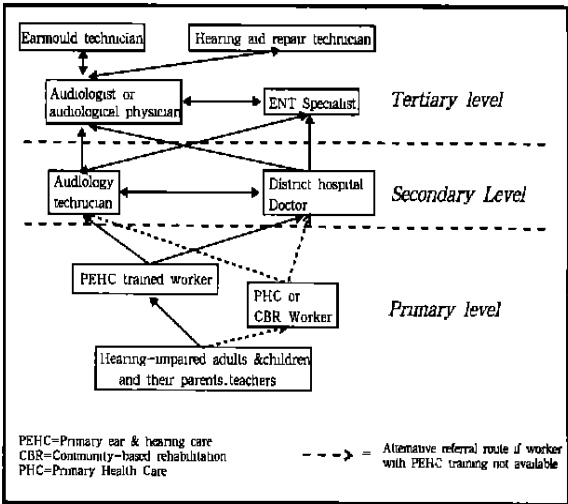


Figure 3 Routes for referral

3.3.2 Hearing Assessment

Those people found to have a possible hearing problem through failing the primary level identification should be referred for an ear and hearing assessment (see Figure 3 for routes for referral; these may vary in different programmes and according to staff categories available).

This assessment should be carried out at the secondary level, when these facilities and personnel are available. When secondary level facilities are not available the primary level worker should be trained to carry out a hearing assessment (see section 4.1.2). Facilities may be shared amongst a group of communities or take the form of mobile services<sup>[25]</sup>.

Hearing assessment should include:

- Brief case history
- Ear, Nose and Throat specialist assessment if available or assessment by a medical officer if not.
- Frequency specific test of hearing threshold level in each ear.
- Shape, degree, classification and cause of hearing loss
- Interpretation of hearing test results and decision

whether hearing aid would be beneficial (see section 3.4 for provision of a hearing aid)

° Referral to other services where necessary (e. g. social/ educational services)

In addition countries should be encouraged to develop the following audiology facilities:

- frequency— specific test of hearing threshold levels in each ear using air and bone conduction to determine type and degree of hearing loss
- tympanometry to determine function of middle ear.

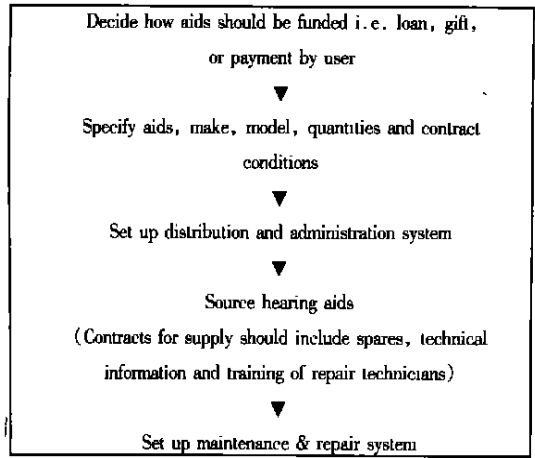
For some cases, such as very young children, assessment should preferably take place at tertiary level centres using hearing tests appropriate for the developmental level of the child. Oto— acoustic emission testing may be useful at this level. Countries without such facilities should be encouraged to develop these services. However some tests for young children may be suitable to carry out at a more basic level (e. g. speech reception testing, play audiometry and free— field audiometry, use of hand held sound generators with calibrated output levels when presented at set distances).

Reassessment should be carried out every few months in children (depending on age of the child), and after 4 ~5 years in adults (the general life— span of a hearing aid).

3.4 Provision of Hearing Aids

3.4.1 Components of Provision Process

Provision includes supply, pricing, distribution, delivery and fitting of hearing aids. (see Box 3 and Box 4)



Box 3 Supply of hearing aids

3.4.2 Supply and distribution of hearing aids

Prior to services being set up to fit users with hearing aids, a reliable source of supply needs to be established for the hearing aids themselves, batteries, earmould ma-

terials, and spare parts and materials for repair or replacement of defective devices.

If hearing aids are to be imported, then a reliable and safe method of shipment is required which allows all items to enter the country without being detained at customs. Shipment can be done in bulk. Hearing aids should be checked after arrival in country and before being fitted to the user. Sufficient stocks of all items should be kept in order to meet the demand and hence minimize the time between assessment and fitting and the time required for repair or replacement.

All hearing aids should be ordered with an adequate stock of spare parts (a repair laboratory having been set up and a technician trained). A record should be kept of all parts replaced and this will assist in re— ordering spares, and indicate which parts are required most frequently.

The amount of earmould material required can be approximately calculated using the number of hearing aids fitted and the rate of replacement of earmoulds. The number of batteries required can be calculated using the average battery life and the number of users).

All items, hearing aids, batteries, spare parts and earmould materials should be stored at all times, including during shipment, in cool and dry conditions.

The process by which a hearing aid reaches its eventual wearer varies depending on whether the distribution service is completely state operated, under controlled conditions from the state or under a completely private commercial system.

State operated services put out tenders for the bulk purchase of hearing aids and distribute the hearing aids to the end user through various locations (see section 3.4.5). The hearing aids and the service that goes with them e.g. batteries, repairs, replacement are provided free of charge or on a nominal charging basis.

Private commercial services, which exist in most countries, distribute the hearing aids through dispensers who purchase the aids either directly from manufacturers or from a wholesaler. The hearing impaired person then either pays the whole cost of the aid and service to the dispenser, or may be covered in some countries for part of the cost by an insurance scheme, which may operate under compulsory government legislation. In this system the cost of batteries, repairs etc would depend on local arrangements.

It should be noted that potential hearing aid users should always have a hearing assessment before being fitted with a hearing aid (see section 3.3.2) and the hearing aid should be fitted by trained personnel (see section 4).

3.4.3 Costs of hearing aids and services

To reduce costs, hearing aids can be purchased in bulk by countries, districts, or regions such as through governmental and non-governmental agencies. Hearing aids and services for them should be provided to the user at a price that he or she can afford<sup>29</sup>. Governments of some developing countries may agree to share in the costs of hearing aids and services or provide them free. A low cost hearing aid should be carefully marketed, especially in countries where more sophisticated models are already available. Affordable hearing aids must not be made available to unscrupulous individuals who may sell them to users for large profits.

Affordable hearing aid services should be considered as a community service and be structured so that financially they are low cost yet sustainable.

3.4.4 Setting up a hearing aid provision service

Identify hearing problem at primary level (see section 3.3.1)



Assess ear & hearing

See section 3.3.2 (include suitability for an aid e.g. no wax or discharge; shape, degree, classification cause of hearing loss)



Assess subject's suitability for a hearing aid

(user's motivation, skills and family support to use an aid)



Take ear impression (syringe technique for individual moulds)



Send impression to earmould laboratory without delay.



Make individual earmould

(or use stock or temporary mould if no laboratory available)



Get earmould to audiology technician



Deliver hearing aid & batteries



Fit hearing aid to user

Fit earmould, modify if necessary; fit hearing aid, adjust settings, instruct user (section 3.5.1 & Box 5) Ensure battery supply and contacts for maintenance/ repair, replacement of earmoulds.



Arrange follow up visit(s) (section 3.5.2 & Box 6).

Box 4 Stages in provision of a hearing aid and earmould to a person with a hearing problem

The main stages in a service for identification and provision of a hearing aid and earmould to a person with hearing loss are shown in Box 4.

A simplified chart showing the ideal staff categories required to set up such a service is shown in Figure 4 and their training is described in section 4. The health worker who provides the services for primary level identification has been described in section 3.3.1. The rest of the stages would normally take place at the secondary and/or tertiary levels.

Where secondary level services are not available, hearing aids could be provided at the primary level, as long as secondary level services are intended or starting to be developed. In this situation it may be possible to have distribution and delivery of hearing aids, earmoulds and batteries done in combination with other programmes such as community-based rehabilitation (CBR), or blindness prevention.

Whichever level hearing aids are provided at, persons must be designated who will administer the distribution and keep records of all hearing aids (make, model, serial number, date of delivery, name of user, cost/ payment made) delivered to those who fit them.

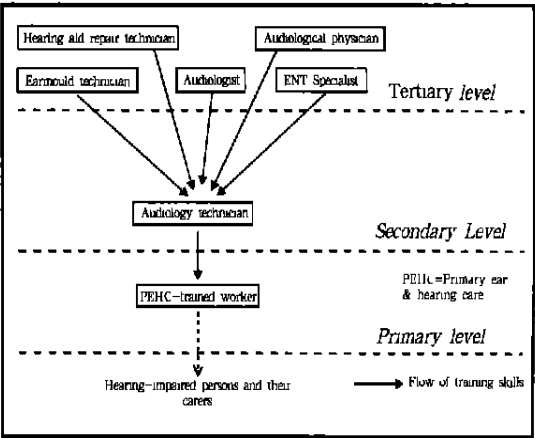


Figure 4 Staff categories for hearing aid services

- \*How to use the aid (i.e. inserting earmould and wearing aid, changing batteries, use of volume control, on/off switch and any other user controls), provide written or pictorial instructions, involve family or friend
- \*Encouragement of realistic expectations
- \*Suitability of hearing aid to user
- \*When to use / not use the aid
- \*Encouragement to continue with learning to use the hearing aid
- \*Special instructions for child users for parents, teachers
- \*Care and maintenance of aid (changing batteries, washing the earmould, storage)
- \*Where & how to obtain new batteries
- \*Trouble-shooting — what to do, who to contact when problems with the aid occur

Box 5 Instruction topics for the user

3.4.5 Fitting Hearing Aids

Hearing aids should only be fitted following a hearing assessment<sup>[27]</sup>. A hearing aid should be fitted together with an earmould, some batteries, a case for the hearing aid, a dehydrating agent to prevent moisture corroding the hearing aid and battery, and simple instructions in pictures and text. Young children should be provided with a suitable harness to prevent damage or loss of the aid.

The actual fitting of the hearing aid can be done in any of a number of possible locations (e. g. home, school, clinic, CBR or PHC centre, hospital) provided that all personnel fitting hearing aids have received the necessary training (see section 4) and have access to the results of the recent hearing assessment (see section 3.3.2).

Records of all hearing aids should be kept by the personnel fitting them (i. e. date of fitting, users name and address, make, type, model of hearing aid and earmould fitted, serial number of hearing aid, user settings). This information may also be required for guarantee purposes.

3.5 Support for users

As used in this section, "users" refers to the hearing aid users and their care givers, e. g. parents, family, teachers, social workers. "Support" includes initial instruction given when the hearing aid is fitted and follow-up.

3.5.1 Instructions for the user

These instructions (see Box 5 for topics) should be given to the user and his/her carer when the hearing aid is fitted and repeated as often as necessary during 'follow-up'.

Instructions must be given in a format that is easily understood, using a combination of verbal instructions in the local language (including local sign language), booklets, information sheets, pictorial instructions and demonstrations.

Instructions should be given by a trained secondary level worker who fits the hearing aid. If there are no secondary level personnel, then the hearing aid should be fitted and instructions given by the primary level worker. Hearing aid users require a 'learning' or adaptation period' during which repeated instructions and support are needed. This learning period may last from a few weeks to some months. Where appropriate, users should be issued with individual record cards.

3.5.2 Follow-Up

\*Hearing tactics; training the user to use their residual hearing and the hearing aid more effectively

\*Identification of users having difficulties with their hearing aid, earmould, batteries; they may require the following:

- reinstruction on use and care of the aid
- replacement due to loss or breakage
- advice on realistic expectations (user & carer)
- trouble shooting and potential solutions

\*Attention to the special needs of children e. g. acceptance of aid, need for more information, support and other services

\*Establishment of local support groups using skills & experience of existing hearing aid users.

\*Links with other services for deaf and hearing impaired people

\*Provision of replacement batteries, earmoulds, and hearing aids as required

\*Referral to other services e. g. reassessment, medical, social educational.

\*Use of record cards with each aid for individual problems and "report-back" cards by the aid fitter for potential collective problems.

\*Expectations of users and their family

\*Hearing aid maintenance, repair or replacement

Box 6 Items to be done at follow-up

Follow-up helps to encourage better use of the hearing aid, provides ongoing support and deals with problems that may arise (see Box 6).

Follow-up should be provided by primary and secondary level workers and also other experienced hearing aid users.

Follow-up should be provided in the community<sup>[28]</sup> (i. e. at primary level) and should be pro-active. It should be directed to users, parents, teachers, carers.

It may need to be in the form of outreach, going out to the consumer, rather than waiting for the user to attend a centre.

3.5.3 Hearing aid maintenance, replacement, repair

All users must have easy and as close as possible access to affordable services for the replacement of batteries, earmoulds, and the maintenance and repair of hearing aids.

Some countries operate a replacement system for hearing aids in place of a system of repair and return of the hearing aid to the same user. In principle, this allows quicker replacement of malfunctioning hearing aids and makes for easier repair and replacement.

Users should be made aware of the ongoing costs of wearing a hearing aid when the aid is issued. Batteries should be readily available at all levels including the primary level, from the PEHC-trained worker or other designated person (e. g. parent or teacher of a child with hearing impairment). This designated person should ob-

tain batteries (on a sale or return basis) from a central supplier (e.g. tertiary level audiology centre or hearing aid supplier).

Earmoulds will need to be regularly replaced, especially for young children. The PEHC worker should take an ear impression for a new earmould when required and is then responsible for sending the impression to the laboratory without delay and collecting the finished earmould and fitting it to the user. Sometimes new earmoulds may need to be modified, in which case the user may need to see the earmould technician directly.

With regard to hearing aid maintenance and repair, initial contact should be with the PEHC-trained worker. These workers should be able to carry out basic troubleshooting procedures to identify and solve minor problems with hearing aids (and earmoulds) e.g. replace earmould tubing. If the hearing aid needs to be repaired the primary level worker is responsible for taking or sending the broken hearing aid to the repair technician, collection of the repaired hearing aid and returning it to the user.

The availability of aids for loan to regular users whilst theirs is away for repair is recommended. Hearing aids considered beyond repair should be kept centrally with a view to providing spares for other aids of the same or similar types.

In order for all these services to work efficiently, there needs to be good networking between the primary level services and the earmould and hearing aid repair laboratories. Therefore, these laboratories, together with the hearing aid supplier/distributor should ideally be located at the same site. They should be established nationally initially but subsequently should be set up in different parts of the country.

3.6 Evaluation / Quality Assurance

The service and delivery system should be continuously monitored and regularly evaluated. Key performance indicators for the service components and outcome indicators<sup>[29]</sup> for overall success of the hearing aid service should be specified. Targets should be specified.

The data for monitoring and evaluation should be collected initially by the primary level worker using simple output and outcome measures<sup>[30,31]</sup> and then analysed by the district health centre and at secondary and tertiary levels.

Examples of such data would be:  
How many hearing-impaired persons are there in

the local community?  
How many hearing aids have been fitted?  
How many people continue to use their hearing aid?  
(the return of flat batteries in exchange for new ones can also be used to monitor aid usage)  
What are the reasons that others with a hearing problem have not acquired hearing aids?  
For those who have been fitted with a hearing aid, simple measures of reduction in 'disability' should be determined (e.g. does a child respond to sound when previously it did not? Have specific communication problems been solved? Is a child making better progress at school?).

When feasible, a quality assurance system should be put in place to help ensure that hearing aids, ear moulds, and batteries as well as services, procedures and reporting are of the highest quality<sup>[32]</sup>.

4 TRAINING

The following items are proposed for inclusion and adaptation into training courses according to a country's needs. It will be important that training courses are given recognition in the countries where they are carried out.

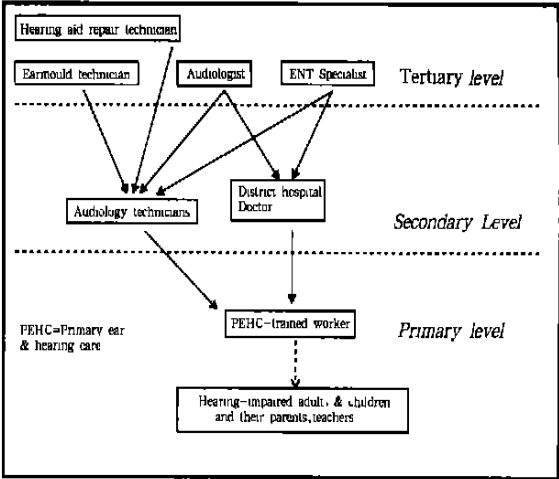


Figure 5 Staff categories and their trainers

The diagram (Figure 5) shows relevant existing staff categories and the categories whom they train (shown by connecting arrows). It should be noted that in this and other diagrams showing staff categories not all countries may have the categories shown; in this situation the category nearest in function should be identified or consideration given to creating the categories referred to in this document.

4.1 Primary Level

4.1.1 Training for a PEHC-trained Worker

This section describes the particular training in pri-

primary ear and hearing care (PEHC) that would be required at the primary level to provide a service for provision of hearing aids. Such training should be included in existing primary health care programmes<sup>[33]</sup> and consist of an initial 3-week training course in the community in the local language followed by supervision, networking and refresher courses. It is likely that the PEHC-trained worker will be a CBR or PHC worker who has received additional training. As a primary level worker becomes progressively better-trained in this field he or she will become progressively more dedicated to providing services for ear and hearing care. Further information on objectives, principal elements and outcomes-based training programmes for PEHC are contained in the report of a recent workshop on this subject<sup>[24]</sup>.

The position of PHC worker who has received additional training in ear and hearing care should be recognized within the country's health system.

Training topics:

- ° Basic anatomy/physiology of ear, acoustics, causes of deafness and hearing impairment, ear diseases
- ° Basic hearing test, questionnaire, ear examination
- ° Effects of deafness and hearing impairment on speech communication
- ° Problems of people with hearing impairment and their needs
- ° Social implications of deafness and hearing impairment
- ° Guidelines on treatment, referral, hearing aid use, maintenance
- ° Including ear and hearing care into existing primary health care programmes
- ° Data collection/record keeping

Trainers

Training for trainers is essential. Selection of trainers generally occurs from bottom-up progressively moving up each level; eventually some from the top level may need overseas training.

Qualified trainers are required from the first available level (local, regional, national, or from another country if no trainer available in country). e.g. an audiology technician to train PEHC workers, if no audiology technician is available, then an audiologist would train primary ear care workers.

Cascade effect: trainer trains primary care level workers, some of whom become trainers themselves. As

primary ear care workers gain knowledge and experience, some may be trained as audiology technicians and become trainers themselves. As audiology technicians gain knowledge and experience some may be trained as audiologists and become trainers themselves.

Training should take place in the locations of the PHC worker. The training programme should be recognized nationally and the WHO training package<sup>[34]</sup> should be used.

#### 4.1.2 Training required where secondary level does not exist

If no services have been set up at the secondary level, it may be possible to provide additional training to a PHC worker to perform some of the functions of an audiology technician until secondary-level services are instigated. The designated PHC worker would already have some experience and would be trained to assess hearing and fit hearing aids in his/her community under the supervision of the tertiary level. Training time should be a minimum of 6 weeks.

Training topics: (In addition to Primary Level training):

- ° Assessment of hearing
- ° Additional training in data collection
- ° How audiological equipment should be calibrated and maintained (day to day care & maintenance of equipment — knowledge of full calibration is not necessary)
- ° Hearing aid function and use
- ° Hearing aid fitting (if this is not available at the secondary level)
- ° Hearing aid basic adjustment
- ° Hearing aid instruction
- ° Hearing aid trouble-shooting
- ° Other common ear disorders such as tinnitus and balance problems.

Trainer

An audiology technician from another district could train PEHC workers but if none were available, then a tertiary-level audiologist should train them (from that or another country).

## 4.2 Secondary Level

### 4.2.1 Audiology Technician

The trainee should have completed at least secondary school education and should have some previous experience of working with hearing-impaired persons. An existing PEHC-trained worker would be suitable. This staff

person in this category may be called an audiometric technician in some places.

Training programme

The initial training course should be a minimum of three months, followed by practical/supervised training. Refresher Courses should be held. Formal appropriate training should lead to a recognized qualification (some developing countries may find it difficult to provide formal recognition at first ).

Training should preferably be located in a secondary centre and should be in the national language.

Training topics:

°All topics listed above for primary level (sections 4. 1. 1; Training for a PEHC — trained Worker and 4. 1. 2 Training required where secondary level does not exist ).

°Management/ supervision

°Training methods

°Making earmoulds and identifying their problems (for when the ear mould technician is not available)

°Book— keeping, stock records, administration

Equipment

°Audiometer with AC and BC, noise — excluding headsets, and access to calibration (special arrangements may need to be made for this at national or even regional levels)

°Tympanometer (impedance audiometer)

°Otoscope

°Ear mould manufacturing equipment and supplies

If a secondary level centre is not available, the equipment should be portable to enable these items to be done as outreach.

4.3 Tertiary Level

4.3.1 Audiologist

Training programme

The course should be located at a specialized centre in a teaching hospital or university department, preferably in the country of the trainee (if not available nationally, the trainee may have to obtain the training in regional countries or internationally, with in— built safeguards to encourage the graduates to return to work in their home countries).

The initial training course (modular if feasible) should be at least 1 year of mainly academic work followed by supervised practical training leading to a certificate of clinical competence.

A recognized qualification should be given and could

be a diploma, bachelor or masters degree depending on extent of development of the course and the situation in the country.

In some developing countries there are audiological physicians who are medically— qualified doctors who have received further training in audiological medicine.

Training objectives:

The person completing the course and passing the required examinations would be able to:

°Work independently

°Conduct assessments for all ages

°Provide hearing aids for all groups

°Provide support for all users

°Manage (including using quality assurance), monitor and evaluate programmes

°Train personnel at lower level

°Conduct research appropriate to the supervision available

Equipment

Training should be provided to enable the use of:

°Diagnostic audiometers with free field facilities

°OAE testers

°Evoked response audiometer

°Middle ear analyser

°Hearing aid analyser

°Vestibular test equipment

°Real— ear measurement equipment

Real— ear— measurement equipment is preferable to validate the acoustic frequency and amplification characteristics of the hearing aid and ear mould in the ear.

4.3.2 Earmould Technician

Trainee:

The trainee should have completed school education and have good manual dexterity and precision. It could be a possible job for a hearing impaired person. The applicant may already have other ' ear care' responsibilities (depending on demand for earmoulds).

Programme:

Currently there are no formal courses available for the training of earmould technicians and training needs are met by established laboratories giving in— service training.

The course should therefore be located in an established earmould laboratory. The initial training period should last about 4 to 6 weeks and consist of in— service, practical training followed by close supervision.

Training Topics:

- °Basic understanding of hearing aids and their use
- °Examination of the ear using an otoscope
- °Taking an ear impression
- °Earmould manufacture
- °Earmould fitting, modification and repair
- °Record keeping and administration

4.3.3 Hearing Aid Repair Technician

Trainee:

The trainee should if possible already have practical experience in electronics.

Programme:

Training should take place at an established hearing aid repair laboratory, and may initially have to be outside the country if not available nationally. The training course should last about 6—8 weeks followed by practical work under close supervision, and in—service practical training. Training is also partly the responsibility of the manufacturers of the hearing aids provided in a particular country.

Training Topics:

- °Basic acoustics
- °Acoustic measurements of hearing aids using hearing aid analyser
- °Hearing aid trouble—shooting
- °Replacement of faulty hearing aid parts
- °Calibration of acoustic measuring equipment
- °Quality control (i.e. checking new and repaired hearing aids)
- °Record keeping and administration

Equipment:

- °Hearing aid analyser (could be shared with audiology services)
- °Microscope
- °Soldering station
- °Digital multimeter
- °Hearing aid repair tools
- °Spare parts for all hearing aids issued

5 PILOT PROJECTS

In order to test the programme to be implemented, one or more pilot projects should be set up. These should be in rural communities and organized/ supervised by acceptably designated centres or units in various representative countries.

The pilot projects should be used to:

- °Evaluate the proposed services as a whole

- °Determine exact costs of setting up, running and maintaining these services.
- °Refine the model of service delivery.
- °Evaluate the effectiveness of the hearing aid(s) being used
- °Evaluate the impact of availability of hearing aids in a society

Pilot projects should be subject to appraisal within the methodology of a formal impact assessment or programme evaluation.

In addition to pilot projects, recognized methods of monitoring and evaluation should be built in to each project.

ANNEX 1: TERMS OF REFERENCE AND OUTPUTS FOR THE HEARING AIDS WORKING GROUP

Terms of Reference

With regard to hearing aids, earmoulds, batteries and their accessories for developing countries, the working group will carry out the following activities in the light of the recent WHO/CBM meeting.

1. consider the needs and requirements for these items at all ages and all aidable levels of severity in these countries now and in the future.
2. draw up requirements for these items so that they are appropriate and affordable for developing countries and so that manufacturers could produce them at low — cost and in bulk with currently available technology.
3. consider and make recommendations on method and location of manufacture and assembly, costing, bulk purchase, tendering, importation, distribution, warranty, and maintenance & repair services.
4. consider and make recommendations on the most likely needs for research and development in the future
5. use these specifications and recommendations so developed to convene or encourage others to convene a meeting with interested manufacturers to determine possibilities for future production.

Outputs

- 1 A document containing detailed specifications and recommendations as listed under Terms of Reference.
- 2 Convening of, or agreement to convene by an appropriate non — governmental development organization (NGDO) in cooperation with WHO, a meeting with hearing aid manufacturers to discuss production of hearing aids according to the recommendations made in the document



described in paragraph 3. 1.

## ANNEX 2: MEMBERS OF HEARING AIDS WORKING GROUP

Professor Agnete Parving (coordinator)  
Professor of Clinical Audiology  
Head, Department of Audiology  
H.S. Bispebjerg Hospital  
Bispebjerg Bakke 23,  
DK-2400 Copenhagen NV, Denmark  
Tel: +45 35 31 27 17  
Fax: +45 35 31 39 51  
e-mail: AP03@BBH.hosp.dk

Professor Xingkuan Bu,  
ORL Dept, Jiangsu Province Hospital  
Nanjing Medical University  
300 Guangzhou Rd. Nanjing 210029  
China.  
Tel / Fax: +86 25 8661 1637  
E-mail: bxkjbjq@jlonline.com

Brother Andrew de Carpentier  
Director, Holyland Institute for the Deaf  
P.O. Box 15, Salt 191-10, Jordan  
Tel: +962-555-4953  
Fax: +962-555-4951  
Email: hlid@go.com.jo

Ms Clare Litzke  
Audiological Scientist,  
Gilborn 13  
30900 Wedemark/Mellendorf  
Germany  
Tel: +49 (5130) 928601  
clarelitzke@hotmail.com

Mr Mike Martin, OBE  
Wildwood, Plaistow Road  
Ifold, Loxwood  
RH14 0TY West Sussex, U.K.  
Tel/fax: +44 1403 75 34 89  
Email: mikemartin@haslemere.com

Professor Valerie Newton,  
Human Communication and Deafness

Group,  
University of Manchester, Oxford  
Road, Manchester M13 9PL, UK  
Tel: +44 161 275 3370  
Fax: +44 161 275 3373  
email: valerie.newton@man.ac.uk

Professor Suchitra Prasansuk  
Director, Bangkok Otological Centre and  
WHO Collaborating Centre for  
Prevention of deafness and hearing  
impairment,  
Department of Otolaryngology  
Faculty of Medicine, Siriraj Hospital  
Mahidol University  
Bangkok 10700, Thailand  
Tel: +66 2 419 8043  
Fax: +66 2 465 4050 or 66 2 411 3254  
e-mail: sispa@ksc.th.com

Professor C.A.J. Prescott  
ENT Department  
Red Cross War Memorial Children's  
Hospital, Klipfontein Road, Rondebosch,  
7700, South Africa  
Tel: +27 (0)21 406-6420  
Fax: +27 (0)21 448 8865  
Email: cprescot@uctgsh1.uct.ac.za

Mr Padman Ratnesar  
66 Camden Park Road  
Chislehurst, Kent, BR7 5HF U.K.  
Tel: +44 282 467 0493  
Fax: +44 181 295 0352  
e-mail: ratnesar@aol.com

Mr Christopher Shaw  
Former General Secretary, International  
Federation of Hard of Hearing People,  
6 Rue de Nièvre,  
58700 Prémy,  
France  
Tel: +33 386 37 94 92  
Fax: +33 386 68 02 17

Dr A. W. Smith

Prevention of Blindness & Deafness  
(PBD)

World Health Organization, Geneva,  
Switzerland

Tel: +41-22-791-4322

Fax: +41-22-791-4772

Email: smitha@who.int

Dr J. Verschuure (Hans),

Secretary-General, International

Society of Audiology (ISA),

Audiological Centre, ENT Department

Erasmus Medical Center — Dijkzigt

Hospital Dr. Molewaterplein 40

NL-3015 GD Rotterdam

The Netherlands

E-mail: j.verschuure@erasmusmc.nl

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