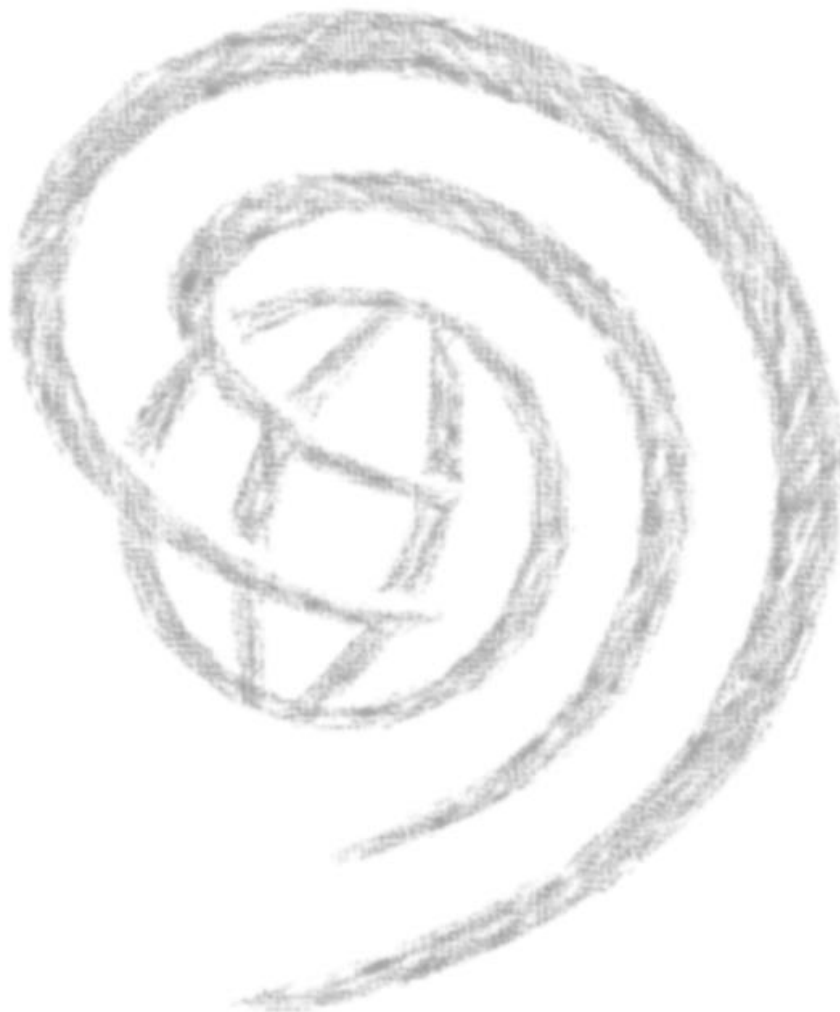


Preferred profile for hearing-aid technology suitable for low- and middle-income countries



**World Health
Organization**

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Executive summary

Hearing loss is the commonest sensory disability and the third greatest contributor to the global burden of disease. The majority of individuals with disabling hearing loss live in low- and middle-income countries (LMICs) and, for many of them, hearing aids are the key to rehabilitation. Currently, however, hearing-aid production meets only 10% of global need and most amplification devices are designed, manufactured and dispensed in industrialized economies.

Existing initiatives to improve access to hearing aids in many LMICs are often hindered by a lack of knowledge, among those responsible for their provision, of the most appropriate types of amplification device for use in such environments. Designers and manufacturers, too, are frequently unaware of the hearing-aid features that are most important in LMICs.

The purpose of this preferred profile is to summarize information on the features of hearing-aid technology that offer the greatest benefit in low-resource settings. The profile is the outcome of a 2013 World Health Organization meeting – Ad-hoc consultation on hearing devices technology transfer in LMICs – and of input from an advisory group working party and invited professionals and industry experts. It highlights aspects of design and distribution that are essential considerations for provision of hearing aids in LMICs. Hearing-aid type, acoustic performance and user controls, earmould and battery requirements, packaging and user information are among the issues that are reviewed and for which recommendations are given. Certain aspects that are desirable, although not essential, for successful provision of hearing aids in LMICs are also summarized and guidance is given on appropriate technology transfer.

Addressing disparities in access to hearing health care in LMICs is challenging. Provision of effective amplification devices is an essential component of any rehabilitation programme in such regions. The aim of this preferred profile for hearing aid technology is to contribute to these programmes and improve outcomes for people with disabling hearing loss.

Background and purpose

Hearing health services in low- and middle-income countries

Overall, hearing loss is the twelfth most common contributor to the global burden of disease and the third commonest cause of years lived with disability (WHO, 2017). Two thirds of those with severe-to-profound hearing loss live in developing countries (Smith, 2008). Long-term, global demographic changes will accentuate this pattern, increasing the burden of hearing loss for those living in low- and middle-income countries (LMICs; Todaro & Smith, 2006). Communication disorders arising from untreated hearing loss are a significant contributor to poverty among many individuals in LMICs (Olusanya, Ruben & Parving, 2006). Of the projected 35 million hearing aids required each year in developing countries, only one million are actually provided (Smith, 2007¹); moreover, current hearing-aid production meets less than 10% of global needs (WHO, 2017). There are a number of reasons for this gap between demand and supply, principally: limited public awareness of the benefits of hearing devices; a scarcity of professional support for hearing-aid fitting; and cost, which is a barrier to purchase in many countries (Brouillette, 2008).

Hearing-aid market in LMICs

All major multinational hearing-aid manufacturers, whose combined share of global sales is almost 90% (Brouillette, 2008), are based in developed countries. Much of their manufacturing, however, is done in the developing world. China, together with Djibouti, Mexico, Thailand and Viet Nam, are among the key nations that sold the highest value of hearing aids to the United States of America in 2009 (Workman, 2010). Multinational manufacturers focus primarily on products that can be marketed in developed economies at a premium price (McPherson, 2012). In the USA, the average retail price for a hearing aid in 2009 was US\$ 1942, with advanced mini-BTE (behind the ear) hearing aids averaging US\$ 2957 each (Kirkwood, 2010). However, a range of hearing aids that meet the needs of less affluent consumers is also available in developed countries, including the USA, with prices starting at around US\$ 500 (Kirkwood, 2010).

¹ Smith AW (2007). Update on burden of hearing impairment, and progress of WHO/WWH hearing aids initiatives. Presentation at WHO/WWHearing Fifth Workshop on the Provision of Hearing Aids and Services for Developing Countries, 8–9 November 2007, Geneva.

In low-income developing nations – those with a GNP per capita of US\$ 1035 or less – price is a much greater barrier. The least expensive hearing aid in northern Nigeria, for instance, has been reported to cost US\$ 222 (Adoga, Nimkur & Silas, 2010), almost one month’s average salary. The cost barrier can be aggravated by high import duties and by the informal charges levied on medical appliances such as hearing aids in some developing countries (Bate, Tren & Urbach, 2006). In Ghana, for example, a 15% tax is imposed on imported hearing aids, adding to already substantial costs (Graphic Online, 2013), and import duty in Brazil is as high as 18%. The additional costs of earmoulds, maintenance expenses and regular purchase of batteries may also restrict hearing-aid use in many developing countries. Indeed, annual costs for batteries alone may exceed the total yearly income of an African subsistence farming family (Lasisi, Ayodele & Ijaduola, 2006).

Specific requirements for hearing aids for LMICs

There is an obvious need in LMICs for high-quality, affordable hearing aids and associated services. In addition, certain design features would be particularly advantageous in hearing aids marketed and distributed in LMICs. Hearing aids for developing countries need to be robust and low-maintenance, energy-efficient and able to cope with dust and humidity. Noise burdens can be high in LMIC environments (McPherson, 2012) and built-in noise-reduction features are important. The earmoulds provided in LMICs are often basic and of poor quality, making hearing aids with feedback suppression capabilities especially valuable (Brouillette, 2008). LMICs often lack the capital required for carrying a range of hearing aids, and devices that are adaptable to a wide range of hearing loss configurations are therefore desirable. The Hearing Aid Technology Advisory Group considered many design features – most of which originated at the 2013 WHO Ad hoc consultation on hearing devices technology transfer in LMICs – before listing them as either essential or desirable.

Purpose of the preferred profile

The purpose of this preferred profile is to provide information on preferred technology and associated issues for high-quality, affordable hearing aids intended for use in LMICs. The profile is based on existing WHO guidelines (WHO, 2004) which set out minimum requirements and recommendations for hearing aids and related services in developing countries. A key recommendation from these guidelines was the priority for hearing aids and services that should be given to “children with an average hearing loss 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 loss in the range 41 to 80 dBHL in the better ear, in the same frequency range” (WHO, 2004; p. 6). The preferred profile, which is based partly on this

recommendation, is intended for use by governments and partners seeking to establish ear and hearing care intervention programmes, the hearing-aid industry, other rehabilitation device development groups, and hearing-aid providers.

It is important to note that the profile is based on knowledge of existing practices and technologies. As is the case with other WHO preferred product profiles (WHO, 2009), the requirements are not intended in any way to restrict efforts to innovate and should not be seen as discouraging new methods of improving the provision of hearing health services in LMICs.

Types and features of hearing aids

The initial requirements for hearing-aid type, features, cost and power supply and for earmould type and features are categorized as either essential or desirable. Essential requirements are key for high-quality hearing aids that are considered appropriate for fitting in LMICs. While each additional feature clearly adds to the cost of a device, these requirements are important for hearing aids targeting LMICs. The desirable features are those that have obvious applications in LMIC contexts but for which the evidence of benefit remains limited. A hearing aid comprising only the essential features would still be beneficial for users.

Types of hearing aids

Essential

Comfort and ease of wearing: A hearing aid needs to be of an appropriate size and shape for the user's ear. Attention must be paid to ensuring that the hearing-aid case does not cause skin abrasion or irritation with long-term usage and that the device can be securely fitted behind the ear.

Digital technology: Digital hearing-aid technology is now the standard in the developed world. Digital signal processing offers a range of advantages over analogue sound processing. It allows greater flexibility in shaping the output signal to accommodate a wide range of hearing loss configurations with a small range of devices; it also permits better use to be made of the individual's residual hearing (Kim & Barrs, 2006).

Hearing aid format: Behind-the-ear aids, with accompanying earmoulds, are preferred to body-worn or in-the-ear devices because they provide greater ease of fit. They are also less prone than in-the-ear aids to malfunctioning as a result of cerumen or debris in the ear canal. As the ear canal grows (which is a consideration in children), only the less expensive earmould, rather than the whole hearing aid, would need to be replaced.

Performance requirements: The ear and the ear canal are unique to the individual, and hearing-aid performance can be significantly influenced by both the shape and the size of an ear canal. To verify performance, the output of the hearing aid is measured either while the aid is being worn in the ear or when it is placed in a specially designed 2-cc coupler. Performance is measured through real-ear measurement, a hearing-aid analyser or functional gain aided sound-field measures. Unless hearing-aid performance is properly validated, there is a risk that the user will be receiving inadequate amplification or that the aid will over-amplify (especially in children, with small ear canals). Determining hearing-aid performance makes it possible to optimize the device for the individual user.

When determining absolute output (response) parameters, it is critical to determine the amount of amplification appropriate for the individual's hearing loss (i.e. “matching target”). There are many configurations of hearing loss, making a “one size fits all” solution impracticable. Table 1 summarizes a suggested range of electroacoustic performance requirement parameters for manufacturing hearing aids to meet preferred criteria, based on WHO guidelines (WHO, 2004), and updated to reflect current technical performance standards.

Table 1. Modified WHO performance requirements (WHO, 2004)^a

| Hearing aid parameter | Minimum requirement |
|--|--|
| Maximum OSPL (90) | 100–130 dB SPL +/- 4 dB |
| OSPL (90) at 1 kHz | 90–124 dB SPL +/- 4 dB |
| Maximum full-on acoustic gain | 45–67 dB SPL +5/-0 dB |
| Full-on acoustic gain at 1 kHz | 42–70 dB SPL +5/-0 dB |
| Basic frequency response | 200–4500 Hz 200–2000 Hz +/- 4 dB SPL 2000–4500 Hz +/- 6 dB SPL |
| Total harmonic distortion at 70 dB SPL input | 500 Hz <8% 800 Hz <8% 1500 Hz < 2% |
| Equivalent input noise @ 1 kHz | <30 dB SPL @ 1 kHz |
| Battery current drain | ≤1 mA |
| Battery life | 2–3 weeks |
| Telecoil sensitivity | ≥75 dB at 10 mA/m |

^a ANSI S3.22-2009/IEC 60118-7 measures; OSPL = output sound pressure level.

Prescription-based amplification: The fitting of hearing aids should follow an evidence-based prescription formula method that calculates the amount of amplification appropriate for the degree of hearing loss for both adults (Humes & Krull, 2012) and children (Ching, 2012). The National Acoustic Laboratories (Dillon et al., 2011), Desired Sensation Level (Scollie et al., 2005) and the CAM2 (Moore & Füllgrabe, 2010) are examples of such fitting formula methods. In view of their relative ease of use, hearing threshold-based prescription procedures are preferred. Hearing aids should permit objective measurement to verify benefit within the context of the region where fitting takes place.

Robust design: Given that access to hearing care professionals and repair technicians in LMICs is often limited, hearing aids should be designed to withstand mild impact shocks, light rain showers and dust, and should provide at least five years’ continuous usage.

Desirable

Open-source fitting software and interface: Free, open-source fitting software that is compatible with an affordable hearing aid – or range of aids – is preferred. Standard fitting interface hardware that can transfer across a range of different devices and manufacturers is also encouraged.

Hearing aid features

Essential

Compression: Hearing loss results in a restriction of the audible frequency range. Compression systems reduce the range of sound levels in the environment to better match this restricted hearing range (Dillon, 2012). Compression makes higher-intensity sounds more comfortable, with less distortion in listening experience, and can improve the intelligibility of quiet speech. Without proper management of compression, there is a danger that intense sounds received by a hearing aid may cause amplification-induced hearing loss. Amplitude compression may be implemented as the signal enters the hearing aid (input) and/or after the hearing aid amplifies the signal (output). A variety of compression methods, including both single-channel and multichannel, are available.

- Automatic gain control – output. The output compression detector identifies and controls output from the hearing aid. This specific feature is the most common method of controlling the maximum power output (signal) entering the ear from the hearing aid, typically through compression with a high activation and compression ratio. Together with volume control, it is especially important for comfort when the individual wearing a hearing aid finds themselves in a louder environment.
- Automatic gain control – input. The input compression detector identifies and controls signals being received by the hearing aid before the volume control. Once the input exceeds the allowable level, compression is activated and gain is reduced at the pre-amplifier.

Some form of compression is required for wearer comfort and optimal intelligibility.

Feedback management: An acoustic feedback loop degrades the hearing-aid listening experience, adversely affects the quality of the input signal, limits the effective output of the hearing aid and causes excessive battery drain. Feedback is most often the result of loose, ill-fitting custom earmoulds or of non-custom earmoulds; both types of mould are common in LMICs. Feedback is also experienced by new users, who may have difficulty inserting the earmould into the ear canal, and frequently by elderly wearers who have dexterity problems and find insertion difficult. The amount of additional amplification that is available when a feedback management technique is activated, compared with when it is

disabled, is termed added stable gain (ASG) and is an index of the effectiveness of feedback management (Valente, Valente & Czarniak, 2012). It varies widely among hearing aids. An ASG of 10 dB or more is recommended (Merks, Banerjee & Trine, 2006).

On-off switch: A dedicated on-off switch or simple alternative means of powering down is required to facilitate user management of the hearing aid and battery conservation.

Volume control: A volume control is one of the most common user-directed controls and can be especially important for the wearer's comfort when the amplified signal is too intense.

Desirable

Adaptive noise reduction: Adaptive noise reduction systems improve ease of listening in situations where significant background noise is present (Dillon, 2012). Since background noise levels can be excessive in environments such as school classrooms (McPherson, 2012), adaptive noise reduction is a desirable feature for any hearing aid.

Climate resistance: Hearing aid breakdown is a frequent user complaint, particularly in regions of high heat and humidity (Brouillette, 2008). Technicians who can repair hearing aids are often unavailable, particularly in rural areas. The potential for humidity-related damage can be reduced by "tropicalizing" hearing aids during manufacture, using spray- or dip-applied coatings of water-repellent materials (McPherson, 2012). Recently, several reports have described liquid-repellent nano-coatings that can be applied to all hearing-aid components (Coulson, 2010; ReSound, 2011). Nano-coatings bond with components at the molecular level, resulting in high resistance to water (and oil and wax); protection of this kind is worthy of consideration. Use of water-repellent fabric for the microphone inlet port and of waterproof membranes for receivers and battery compartments (Dillon, 2012) is also desirable. Adequate protection of the metal components used in hearing-aid switches, battery contacts and volume controls can be achieved in a number of ways, such as: protecting exposed metal parts by ensuring good solder joints and removing any flux after soldering; coating metal parts with a silicon or lacquer compound; and advising the user to store the hearing aid, when not in use, in a bag or box containing silica-gel.

Telecoil facility: A telecoil is a small copper coil that allows the hearing aid to detect an electromagnetic induction signal. It permits hearing-aid wearers to listen directly to landline telephones and some cellular telephones, bypassing the normal microphone of the hearing aid. Telecoils can also be of benefit for listening to other induction field signals, such as in auditoriums and school classrooms or for television viewing, provided that a telecoil "loop" system is installed.

Direct audio input: Direct audio input allows a hearing aid to be attached to other audio equipment, such as a cellular or landline telephone, MP3 player, television, microphone or FM wireless receiver. This greatly extends the range of rehabilitative options available to users, particularly children in educational settings.

Low-battery alert: As the output of hearing-aid batteries diminishes, sound volume will be reduced and distortion increased (Dillon, 2012). An audio signal to alert the user to the need to replace a battery is a desirable feature.

Hearing-aid cost

Essential

Affordability: Cost is a key barrier to hearing-aid uptake in developing countries; hearing aids should be affordable for the majority of those in each community. Affordability needs to be determined on a country-by-country basis and in a transparent manner, based on economic data. Efforts should be made to ensure that bulk purchases can be made at favourable prices from manufacturers and that government policy does not inflate consumer costs.

Desirable

Financial support: Even if a retail price can be established that meets the needs of the country in which the hearing aid is distributed, consideration should be given to the possibility – and means – of subsidizing hearing-aid purchases (by the distributor, the user, or both).

Hearing-aid labelling

Essential

Each hearing aid should be permanently marked with the name of the manufacturer or distributor, the model name, serial number and year of manufacture. Unless it is physically impossible to insert the battery the wrong way round, a “+” symbol should be used to indicate the location of the positive terminal.

Hearing-aid packaging

Essential

Robust packaging: Packaging, and the associated labelling, should be able to withstand exposure to excessive moisture and other impacts associated with the long distribution chain often found in LMICs. Packaging should also ensure that the hearing aid is stored safely.

Technical data: Technical specifications concerned with electronic and acoustic performance expectations for the hearing aid should be included with the device; as a minimum, these specifications should include the parameters summarized in Table 1.

Contraindications: Package covers should contain an advisory statement addressed to hearing-aid dispensers. The statement should advise dispensers, before fitting a hearing aid, to encourage the prospective recipient to seek clearance from appropriate health-care personnel if any of the following conditions exist:

- visible congenital or traumatic deformity of the ear,
- aural discharge,
- acute or chronic dizziness,
- pain or discomfort in the ear,
- history of sudden or progressive hearing loss,
- unilateral hearing loss of sudden or recent onset,
- severe tinnitus,
- hyperacusis.

User guide: Clear instructions on use should be enclosed with every hearing aid. The information should include the following:

- an illustration of the hearing aid, indicating operating controls, user adjustments and battery compartment;
- information on the function of all controls intended for user adjustments;
- a description of any accessories that accompany the hearing aid;
- instructions for maintenance and care of the hearing aid, including the procedure to be followed in cleaning an earmould, replacing the sound tube and storing the hearing aid.

The contents of the guide should be written in the national language(s) of the purchase country, supported by simple diagram/picture material, and the text checked to ensure appropriate reader comprehension levels (Caposecco et al., 2016). Maintenance and care advice should include information appropriate to the local community, such as cost-effective dehumidification (e.g. Nelson et al., 2016).

Hearing-aid power supply

Essential

Obtainable power cells: Hearing aids should be designed to accept a battery type that is readily obtainable in the local region. Possible battery types include conventional hearing-aid batteries, watch batteries (which may be more readily available in some LMICs; Brouillette, 2008) and rechargeable cells.

Safe packaging: Hearing aid batteries can be dangerous as ingestion may lead to death (Litovitz, Whitaker & Clark, 2010). Battery packaging must be clearly labelled that batteries are to be kept out of reach of children and small animals; it must be designed in such a way that it should be difficult for a young child to open.

Desirable

Rust resistance: Hearing-aid batteries are prone to rust (Valente et al., 2007), particularly in the challenging climatic conditions found in many LMICs. Those intended for use in excessively humid environments should be manufactured with rust resistance in mind.

Rechargeable battery systems: Hearing aids that accept batteries recharged via a low-cost solar-powered unit (McPherson & Brouillette, 2004) or by other means will reduce replacement battery costs substantially and be of benefit in many LMIC localities. It should be possible for an unskilled individual to accomplish the recharging quickly and simply and the extra cost of the recharging unit should be as low as possible.

Mercury cells: Mercury cells and devices based on mercury cells are to be avoided.

Earmould types and features

Essential

Appropriate earmoulds: Earmoulds should be compatible with the type of hearing aid, device gain/output, and user requirements. Various options may be satisfactory, including stock earmoulds (pre-configured), custom earmoulds, instant earmould products, and disposable standard flexible dome moulds.

Sustainable production facilities: Custom earmoulds are known to be a better long-term option; if established, earmould production facilities should be sustainable within a local or regional context.

Desirable

Disposable standard flexible dome earmoulds: Facilities for earmould production are rare in developing countries. Moreover, custom earmoulds are often unaffordable for most individuals with hearing loss (Basavaraj, 2008), and there are issues of substandard product quality (Brouillette, 2008). Non-custom earmoulds are thus preferred in LMICs where feasible.

Hearing-aid repair

Essential

Hearing-aid housing: The hearing aid should be designed so that the housing can be opened for maintenance purposes and to allow preset controls (if provided) to be adjusted without risk of damage to the housing or internal components.

Post-fitting service: All hearing aids are susceptible to malfunction, for a variety of reasons. Service support by hearing-aid suppliers in LMICs is therefore essential; the nature and extent of service activities will depend on the type of hearing aid used. Facilities must be available for minor repairs such as device cleaning, replacement of earhooks, adjustments of battery contacts, changing of switches, and trimmer and volume controls.

Desirable

Post-fitting service: A facility for major hearing-aid repairs, staffed by appropriate technical personnel, is desirable.

Other factors to be considered for suitable provision of hearing aids

Besides identification of appropriate technology, certain other factors should be addressed in the provision of hearing-aid technology in LMICs.

Essential

Sustainable hearing-aid services: Sustainable hearing-aid services are essential to the success of any hearing-aid programme, irrespective of the technology identified. The interest and commitment of government/programme managers are essential prerequisites for establishing a hearing-aid programme and for technology transfer. Suitable spare parts should be locally available for hearing-aid repair.

Training: In most LMICs there is a shortage of personnel adequately trained and qualified in the provision of hearing aids; it is thus critical that local health/rehabilitation personnel be trained to an appropriate standard in hearing-aid fitting. The components of training and the skills to be imparted need to be identified and clearly stated, together with the scope of activities that can be undertaken by the personnel after training. Guidance on training can be found in *Guidelines for hearing aids and services for developing countries* (WHO, 2004), *Primary ear and hearing care training resource* (WHO, 2006), and *Curriculum in audiology* (International Society of Audiology, 2004).

Outcomes evaluation: The hearing-aid fitting programme should make provision for continuing evaluation of the fitting process through client questionnaires or similar forms of outcome assessment; client feedback should then be used for purposes of quality improvement and quality assurance.

Desirable

Preprogrammed or user-programmed hearing aids: Preprogrammed or user-programmed hearing aids are an emerging option, worth exploring for efficacy in some LMICs in view of the scarcity of professional support. Preprogrammed hearing aids may enable rapid fitting for individuals with selected types of hearing loss. In theory, user-programmed hearing aids allow for even wider application since they “learn” the wearer’s unique amplification preferences (Convery et al., 2011). However, user-programmed devices should be submitted to validity and evidence-based studies before being widely used for adults in LMICs, since the evidence base is currently very limited (Wong, 2011).

Alternative devices: Other devices, such as cochlear implants, should be promoted where feasible and applicable.

Comprehensive hearing care programme: Hearing-aid provision should be accompanied by a comprehensive hearing health care programme that includes awareness-raising, screening

and follow-up. It is essential that follow-up services are developed within an integrated community process, ensuring that the care of individuals with hearing loss is integrated into the overall medical/rehabilitation services provided within the country.

Research: Research into the economic and social impact of hearing loss and of the provision of hearing aids is needed to gather greater evidence for advocacy and for improvements in future hearing health care programmes.

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