

**Report of a WHO Ad hoc consultation on hearing devices technology transfer in LMICs
held in WHO HQ, Geneva, Switzerland on 12 March, 2013**

Introduction:

Hearing loss is the most prevalent sensory disability globally. 360 million persons in the world are affected by disabling hearing loss. This represents approximately 5.3% of the world's population. The majority live in developing countries.¹ The management of hearing loss varies according to the cause and degree of loss. Some of the conditions are amenable to treatment through medical and surgical means, whereas others require amplification through hearing devices and other modalities, such as hearing and speech therapy, lip reading and sign language training.

A large number of persons with hearing loss can benefit from the use of well-fitted hearing aids of an appropriate quality. Great leaps have been made in refining the technology that goes into the device and a large variety of hearing aids are now available on the market, which include analogue and digital aids. Different models are available and fitted according to the patient's preference, needs, suitability and the cost. These include body worn, behind the ear, in the ear and in the canal types of aids. Despite this, the costs of hearing aids remain high across the world.

Overall lack of understanding about the need for, and benefit of, hearing aids and the prohibitive cost of the devices and batteries, as well as the non-availability of fitting and repair services, have made their use unattractive to policy-makers² as well as hearing aid manufacturers.

Currently, the majority of hearing aids are marketed by commercial organizations based in the developed world. Some countries, such as Brazil, China, Colombia, India and South Africa are involved in production of parts and assembly of hearing aids. Though this has lowered the cost of devices being provided within the countries, these are mostly restricted to the individual countries and overall costs of suitable devices remains high and their availability is low in most low-and-middle- income countries (LMICs) across the world.

¹ MBD, WHO: Estimates for disabling hearing loss, 2012.

² Hearing Aids Services: Needs and Technology Assessment for Developing Countries: report of a WHO/CBM workshop; WHO 1999.

Rationale for current consultation: despite the high need for hearing aid services, hearing aids still remain inaccessible to a large percentage of those requiring these devices especially in low- and middle-income countries. The role of this consultation was to initiate the process of identification of the most appropriate digital technology which permits a rapid fitting of the aid for use in the field and to facilitate access to this technology in resource-poor settings.

Goals of the consultation:

1. To discuss the current global situation with regard to hearing loss, hearing aid availability and fitting.
2. To review the current activities with respect to availability and access to hearing aids across the world.
3. To outline the challenges faced in accessing and fitting of hearing aids in LMICs.
4. To identify currently available technologies which can be appropriate for use in LMICs through technology transfer, including:
 - a. rapid fitting of hearing aids;
 - b. longer-lasting and cheaper batteries.
5. To start developing preferred product profiles for hearing aid technologies suitable for LMICs.
6. To identify potential partners.
7. To develop a roadmap with timelines and deliverables for making these devices accessible in LMICs.

Expected outcomes of the consultation:

1. Major challenges limiting accessibility to hearing aid services in LMICs identified.
2. Suitable technologies and mechanisms to promote access to hearing aid technologies in LMICs identified.
3. Strategy developed for adequate resource mobilization.
4. Key partners identified.
5. Roadmap developed.

6. Preferred product profiles for hearing aid technology suitable for technology transfer to LMICs that need to be developed identified. They will be developed following the consultation.

Proceedings

The session was opened by Dr Marie-Paul Kieny, ADG, WHO. In her opening address, Dr Marie-Paul Kieny spoke about the need for hearing aids and WHO's potential role in improving access to hearing devices in LMICs. Dr Francis Moussy outlined the objectives of the consultation and the expected outcomes.

Dr Oleg Chestnov, ADG, WHO and Dr Nicholas Banatvala, gave their points of view regarding the expected outcome of the consultation. They stressed the need to ensure that the discussions taking place would translate into action at the grass root level.

List of participants and agenda are annexed (Annexes 1 and 2)

Session I: Background

The following presentations were made:

1. Assistive devices including hearing aids, needs, challenges and opportunities, was presented by Mr Chapal Khasnabis. This, focused on the global need for assistive devices including hearing devices, high cost of assistive devices around the world and the possibility of using innovative technology to increase acceptability, accessibility, affordability and accessibility of quality assistive devices.
2. Barriers to hearing aids availability and access were outlined by Dr Andrew Smith. The barriers to hearing aids availability and access were identified as: magnitude of the problem, low production and limited distribution of hearing aids along with high costs. Lack of infrastructure and trained personnel required for hearing aid fitting and poor awareness regarding hearing loss, its impact and potential solutions was also a major roadblock in improving access to hearing devices.
3. Current landscape of activities and WHO guidelines for hearing aids were presented by Dr Shelly Chadha. The salient features of the WHO guidelines for improving access to hearing aids and services for developing countries (2004) were outlined. It was stressed that the

present consultation aimed to work with these minimum standards to develop the preferred product profiles for hearing aids.

4. The existing Intellectual Property (IP) landscape with respect to hearing aids was discussed by Dr Martin Friede. He outlined the international landscape with respect to patents for hearing aids and its various components. The countries and companies involved in patenting were discussed. It was concluded that there are a large number of innovations taking place in this field, most of which are patented by the hearing aid industry. Opportunities may exist to facilitate the production of generic devices in developing countries.

Session II: Technology and its use in Low- and Middle-Income Countries

5. Desirable features of a hearing aid for technology transfer were outlined by Dr Katherine Seelman. She stressed the need to involve persons with hearing loss in identifying the requirements in a hearing aid. She outlined the essential characteristics which must exist in a hearing device to make sure that it would be beneficial for, and acceptable to, persons with hearing loss.
6. Country projects for improving access to hearing aids: examples
 - Dr Jackie Clarke presented an array of projects in Africa, showcasing the different needs and strategies in different parts of the continent.
 - Dr N. Rao Gali showcased the types of devices currently manufactured by the Artificial Limbs Manufacturing Corporation of India (ALIMCO) and stated that they were on the lookout for suitable new and affordable technologies in this field.
 - Mr Christian Garms outlined the concept of WWHearing, the concept of PRETA (prevention, research, education, training and advocacy for hearing loss prevention) and the Hearing Express delivery model for hearing aid services, which WWHearing is field testing.
 - Mr Howard Weinstein spoke on behalf of 'Solarear' to outline the method for promoting access to affordable, rechargeable hearing aids through a sustainable franchise model and establishment of DREET (Detection, Research, Education, Equipment, Training) centres.
 - Ms Sian Tesni spoke about a CBM country project in Papua New Guinea, which stressed the need for building local capacities and training local resources.

- Ms Li Lu of China outlined the projects for fitting hearing aids in children and adults being undertaken at the China Rehabilitation and Research Centre for Deaf Children China.
7. A consumer perspective on hearing aids was presented by Dr Ruth Warick, President, International Federation for Hard of Hearing (IFHoH). She outlined the need for inclusion of technologies such as background noise reduction, comfortable ear mould, T switches, audio links for loops in the hearing aid. Taking care of other aspects such as colour blending and size helps to reduce the stigma attached with the use of hearing aids.
 8. Manufacturers' perspective on hearing aids was presented by Mr Soeren Hougaard, representing the European Hearing Instruments Manufacturers Association (EHIMA) and Hearing Industries Association (HIA). It brought out the fact that while technology is available, hearing aids must be seen as a part of a larger hearing health system and not in isolation.
 9. The American Association of Otolaryngologists (AAO)(Annex 3) was invited to the meeting, but could not attend. They sent a written statement which was not read at the meeting as it reached late. The idea of a purchasing consortium was adopted by the Mayflower Medical Organization (MMO) and is promoted/endorsed by Coalition for Global Hearing Health (CGHH), but this may be a short-term solution to a larger problem. "Self-fit" protocols for hearing aids promotes a "rapid-fit" model. The need and rationale for such a system is recognized, but it cannot replace clinical practice. AAO would advocate a two-tier system where some individuals would use a rapid-fit model and some (children, conductive hearing losses, profound hearing losses) would use a traditional medical model. AAO is concerned that developing an "ideal" product profile should not exclude other technologies and suggest that two or three ideal profiles would be more suitable.

Sessions III and IV: Discussion

The discussion in Sessions 3 and 4 centered around the desirable characteristics of the hearing aids and their accessories. The highlights of the discussion are as follows:

- Mechanism of technology transfer was outlined. Once the relevant technology profile has been developed and its various components identified, WHO would then work to identify the owners of the identified technologies. It would work to negotiate with the

companies to gain access to the relevant pieces, on a world-wide basis. Developing countries would be the first target for sharing this technology through technology transfer.

- Three aspects were identified to be the main focus of the preferred product profile:
 - hearing aids
 - ear moulds
 - batteries, including battery charger.

Hearing aids:

The discussions focused on the identification of those features which should be included in a hearing aid. It was agreed by all around the table that a wide variety of technology existed today and identification of a suitable device with the relevant features and appropriate price could be undertaken without much difficulty. The WHO hearing aid guidelines provides a suitable baseline for identification of such devices. Some features which were stated as being essential are listed below:

- digital (as compared to analogue)
- wide-range dynamic compression
- feedback reduction
- noise reduction
- humidity resistance (nano coating for dust and humidity resistance was suggested)
- robust and sturdy
- behind the ear type (as compared to body worn or in the ear types)
- appropriate size
- comfort and ease of wearing
- clarity of sound
- presence of T coil
- direct audio input feature
- on-off switch
- low-battery alert
- low price (US\$ 40-60 would be most appropriate)

The group was aware that adding features would add to the cost of the devices, but felt that these were essential aspects and must be included in a device for LMICs.

Pre-programmed hearing aids, such as the 'Clik' model or 'Erika' model of different companies are an option, which was identified as being worth exploring when developing the preferred product profile.

It was strongly felt by all members of the group that identification of one profile of hearing aid to fit all was neither possible nor appropriate and it would be suitable to develop a variety of profiles (2-4), which could suit the needs of different types of hearing losses most commonly encountered and the variety of age groups being dealt with. Once these profiles were developed and adopted by WHO, they would be hosted on the WHO web site and used by individuals and governments. WHO may then identify one or more profiles for technology transfer, based on its mandate and situation.

Ear moulds:

Various options for ear moulds were discussed including:

- use of ear plugs
- custom-made ear moulds
- use of insta moulds
- standard ring open moulds in three sizes.

The importance of including ear moulds in the technology transfer aspect was stressed as suitable ear moulds are a necessity to ensure benefit from any hearing device.

Batteries:

Battery options available include:

- traditional hearing aid batteries
- traditional batteries used in watches may be an option which is more easily accessible
- rechargeable batteries
- solar-powered batteries.

The Solar ear solar and electricity-based chargers were discussed and considered a possible appropriate option for use in LMICs.

Other needs:

Besides the need for identification of appropriate technology, it was agreed that certain factors needed to be addressed:

- Sustainable hearing aid services: were essential to the success of any hearing aid programme, irrespective of the technology identified. It was strongly felt the sustainable interest and commitment from the government/programme managers is an essential prerequisite to starting a hearing aid programme or undertaking technology transfer.
- Training: As most LMICs have a shortage of adequately trained and qualified human resources for provision of hearing aids, it is important to train available local health/rehabilitation personnel in hearing aid fitting. The components of such a training must be outlined. The skills to be imparted should be identified and stated along with instructions regarding what not to do and identification of limitations.

Conclusion/Recommendations:

1. 360 million persons live with hearing loss in the world.
2. Majority of those can benefit with the use of a hearing device, such as a hearing aid.
3. Availability and accessibility of hearing aids are limited in LMICs.
4. Barriers to hearing aid fitting include:
 - a. size of the problem;
 - b. most hearing aids are manufactured in developed countries;
 - c. high cost of hearing aids;
 - d. lack of infrastructure and trained personnel for hearing aid fitting and maintenance;
 - e. general lack of awareness regarding hearing loss and hearing aids at all levels within the community as well as the policy-makers;
 - f. lack of information and research.
5. Any efforts to improve accessibility to hearing aids should be part of a larger health/rehabilitation intervention effort involving awareness creation, training, hearing aid provision and maintenance, including battery provision.

6. The WHO 2004 guidelines for improving access to hearing aids outline the overall requirements of programmes for fitting of hearing aids in developing countries needs to be reviewed.
7. Concept of purchase consortium was developed by WHO and WWHearing established in 2006 to improve access to hearing aid services in developing countries
8. A variety of technological innovations have been undertaken and are available in the market, including self-fitting hearing aids and pre-programmed hearing aids.
9. A variety of devices are available in the market, but cost remains high and accessibility low, mainly due to the barriers identified above.
10. In order to develop the preferred product profile (PPP), it would be appropriate to identify a spectrum of technologies/devices which can fit the needs of different types of hearing loss.
11. The PPP should also include the description of a suitable ear mould technology, which can be used in limited resource settings.
12. The PPP should also consider rechargeable battery options as a cost-effective measure for LMICs.
13. Once the PPP has been developed it should be shared with manufacturers to make them aware of the specific needs identified through this consultation and subsequent work on the PPP. The PPP will thus facilitate the development of suitable hearing aids for LMICs by providing details about the needed devices. The PPP will also be used to identify existing hearing aids (if any) that are suitable for LMICs. WHO will then discuss with companies that have suitable devices to explore approaches such as technology transfer, local production, tier pricing and other appropriate mechanisms to increase availability of hearing aids in LMICs. This will be done in collaboration with partnering organizations also working on hearing aid access.
14. Certain factors need to be considered when promoting use of hearing devices in LMICs:
 - a. It should be accompanied by a comprehensive hearing care programme, that includes awareness creation and screening.
 - b. An easy-to-fit technology (such as pre-programmed hearing aids) may provide a suitable option.

- c. It should be supplemented with a training package for local HR development. The philosophy adopted by SolarEar (deaf-deaf training) may be promoted in this regard and a partnership developed.
 - d. Suitable hearing aid parts should be locally available for repair.
15. Other devices, such as cochlear implants should be promoted, where possible and applicable.
 16. Research into the economic and social impact of hearing loss and hearing aids must be undertaken to gather greater evidence for advocacy.

Next steps:

1. Prepare and circulate report by 4 April 2013.
2. Setting up of a working group (3-4 members) to develop suitable Preferred Product Profiles (April to September 2013) for:
 - hearing aids;
 - ear moulds;
 - batteries/chargers.
3. Share the profiles with manufacturers through a call for interest and direct communications (October 2013).
4. Identify existing devices that meet the PPP (October to December 2013).
5. Discuss with companies that have suitable devices to explore approaches such as technology transfer, local production, tier pricing and other appropriate mechanisms to increase availability of hearing aids in LMICs (January to December 2014).
6. Continue similar activities to promote greater access to hearing aids.