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Organization**

Newborn and infant hearing screening

CURRENT ISSUES AND GUIDING PRINCIPLES FOR ACTION

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List of abbreviations

| | |
|---------------|---|
| AABR | automated auditory brainstem response |
| ABR | auditory brainstem response |
| AOAE | automated otoacoustic emissions |
| ASSR | auditory steady-state response |
| BCG | Bacille de Calmette-Guérin (immunization) |
| DALY | disability-adjusted life year |
| dBnHL | decibel normal hearing level |
| DPOAE | distortion product otoacoustic emissions |
| EHDI | early hearing detection and intervention |
| ENT | Ear Nose and Throat |
| IALP | International Association of Logopedics and Phoniatics |
| IGCH | International Working Group on Childhood Hearing |
| JCIH | Joint Committee on Infant Hearing |
| NICU | neonatal intensive care unit |
| NGO | nongovernmental organization |
| OAE | otoacoustic emissions |
| OB-GYN | obstetrics and gynaecology |
| PDH | WHO Prevention of Deafness and Hearing Impairment programme |
| SCBU | special care baby unit ¹ |
| TEOAE | transient evoked otoacoustic emissions |
| USPSTF | United States Preventive Services Task Force |

¹ In some countries the term “SCBU” is equivalent to “NICU”. However in many developing countries, SCBU denotes a hospital facility that lacks the more-sophisticated equipment required in a NICU.

Preface

To progress its activities in reducing the global burden of hearing loss, the World Health Organization (WHO) convened an informal consultation on newborn and infant hearing screening. A group of leading experts were invited to share their broad range of experiences of national and multi-country newborn and infant hearing screening activities, and to identify and reach consensus on the key principles required to guide the development of WHO recommendations and technical guidance in this area.

By convening this consultation, WHO is responding to calls from Member States for improved guidance in the conducting of newborn and infant hearing screening to detect potential hearing impairment in full accordance with the overall aim of the WHO Prevention of Deafness and Hearing Impairment programme (PDH):

To assist Member States to reduce and eventually eliminate avoidable hearing impairments through appropriate preventive and rehabilitative measures.

During the course of the consultation, different national and multi-country approaches, methodologies and experiences were shared and reviewed; major related issues discussed; and a number of guiding principles for action formulated. It is intended that this process will help lead to a clear consensus emerging on the most effective, cost effective and appropriate approaches to newborn and infant hearing screening, especially in resource-limited countries.

All WHO strategies in the areas of hearing impairment and deafness are integrated into the overall chronic-diseases prevention and control strategy of the Department of Chronic Diseases and Health Promotion. The objectives of this strategy are to advocate for health promotion and the prevention and control of chronic disease; promote health (especially for poor and disadvantaged populations); slow and reverse the adverse trends in common chronic-disease risk factors; and prevent premature deaths and avoidable disability due to major chronic diseases. These objectives are based upon the guiding principles of comprehensive and integrated public health and intersectoral action, a life-course perspective, and stepwise implementation based on local considerations and needs.

Although the convening of this consultation represents only the beginning of the efforts that will be required to develop the policies and actions needed in this area, the level of commitment and enthusiasm shown by participants and others working in this field is highly encouraging.

WHO wishes to acknowledge the generous financial contribution made by CBM in support of this consultation.

1. Introduction – issues in newborn and infant hearing screening²

Hearing impairment in children across the world constitutes a particularly serious obstacle to their optimal development and education, including language acquisition. According to a range of studies and surveys conducted in different countries, around 0.5 to 5 in every 1000 neonates and infants have congenital or early childhood onset sensorineural deafness or severe-to-profound hearing impairment. Deaf and hearing-impaired children often experience delayed development of speech, language and cognitive skills, which may result in slow learning and difficulty progressing in school.

Congenital and early childhood onset deafness or severe-to-profound hearing impairment may affect the auditory neuropathway of children at a later developmental stage if appropriate and optimal interventions are not provided within the critical period of central auditory pathway development. Therefore, early detection is a vitally important element in providing appropriate support for deaf and hearing-impaired babies that will help them enjoy equal opportunities in society alongside all other children.

In May 1995, the World Health Assembly adopted Resolution WHA48.9: Prevention of hearing impairment (ANNEX A). This resolution sets out an agenda for action by WHO and Member States and creates a global mandate underlying the work of WHO technical units working in this area. Subsequently, a WHO Informal Consultation³ in 2000 produced a number of recommendations including:

5.1 Epidemiology of Deafness and Hearing Impairment

5.1.1 Epidemiological data

There is lack of epidemiological data in most countries. The prevalence of the problem should be assessed in various age groups (neonates if appropriate audiological services available...), in urban and rural communities, and in communities with special needs.

5.2 New Strategies for Prevention

5.2.1 Universal neonatal hearing screening:

*It is recommended that a policy of **universal neonatal screening** be adopted in all countries and communities with available rehabilitation services and that the policy be extended to other countries and communities as rehabilitation services are established.*

In 1999, the United States Preventive Services Task Force (USPSTF) concluded that there was insufficient evidence for or against the routine screening of neonates for hearing loss during postpartum hospitalization:

The USPSTF found good evidence that newborn hearing screening leads to earlier identification and treatment of infants with hearing loss. However, evidence to determine whether earlier treatment resulting from screening leads to clinically

² Based upon plenary discussion of the presentations given by: Dr Rajiv Bahl, WHO; Dr Ivo Kocur, WHO; Dr Young-Ah Ku, WHO; and Ms Alana Officer, WHO.

³ *Future programme developments for prevention of deafness and hearing impairment*. Report of the 4th Informal Consultation, WHO, Geneva, 17–18 February 2000 (WHO/PDH/02.1).

important improvement in speech and language skills at age 3 years or beyond is inconclusive because of the design limitations in existing studies.

However, in a recent update to this conclusion, the USPSTF recommended in 2008 that all neonates be screened for hearing loss.⁴ Other relevant declarations already made in this area include the 1993 National Institutes of Health Consensus Statement⁵ and the 1998 European Consensus Statement on Neonatal Hearing Screening.⁶

In some countries, newborn and infant hearing screening⁷ has become a widespread tool for the early detection of hearing impairment, while in other countries such screening is considered to be too costly and its value is questioned. Even when it is available, there is no consistent approach to newborn and infant hearing screening, and there is often great variation within individual countries. The reasons for this are not always financial – some wealthy countries have fragmented and ineffective programmes while a number of less-wealthy countries have very successful programmes.

Nor is it necessarily about technology either – equally, if not more, important is the building of capacity, and the creation of the required infrastructures, services and support for individuals, families and care providers. In some cases, for example, groups will culturally reject cochlear implants or other technologies – preferring instead to learn and use sign language. Before such choices can be properly made, information needs to be provided to parents. If there is to be a transition from the situation today (rather than an immediate move to technology), then a strong information and education element must be put in place alongside screening. Information and education are needed to inform parental choice, and to keep pace with any cultural shifts in perceptions and preferred choices. A focus will also be needed on the point of entry of hearing-impaired individuals into schools to ensure that they do not fall behind. Progress can also sometimes be as much about political will. In some countries, great progress has been made in a very short time, while in others 10–20 years have passed before intention has become reality.

In countries where newborn hearing screening is conducted it is assumed that the vast percentage of babies born deaf can be helped and their futures immeasurably improved. However, issues such as quality control, screening methods, follow-up and cost effectiveness need to be thoroughly discussed and reviewed. Quality assurance issues in particular are vital to successful newborn and infant hearing screening and related interventions – in some settings it is estimated that the poor training and performance of screeners renders up to 80% of screening useless.

For many countries, one major challenge is the lack of contact between the majority of mothers and their babies and the health system – with about half of all global births occurring at home without skilled care. In many settings there is no continuum of care from pregnancy

⁴ Nelson HD, Bougatsos C, Nygren P (2008). Universal newborn hearing screening: Systematic review to update the 2001 US Preventive Services Task Force Recommendation. *Pediatrics*, 122(1):e266–276. See: www.ahrq.gov/clinic/USpstf/uspsnbhr.htm#summary

⁵ Early Identification of Hearing Impairment in Infants and Young Children. *NIH Consensus Statement*, 1993, 01–03 March, 11(1):1–24. Available at: <http://consensus.nih.gov/1993/1993HearingInfantsChildren092html.htm>

⁶ Grandori F (1998). European Consensus Statement on Neonatal Hearing Screening. Finalised at the European Consensus Development Conference on Neonatal Hearing Screening 15–16 May 1998, Milan, Italy. *Scandinavian Audiology*, 27(4): 259–260. Available at: www.ecdcevents.biomed.polimi.it

⁷ For the purposes of the present report, “newborn” refers to the first 28 days of life and infancy is defined as the first year of life.

and birth to the neonatal period and childhood, and globally only a quarter of all neonates receive any postnatal care. Although efforts to increase the coverage of antenatal and postnatal services do provide opportunities to expand newborn and infant hearing screening, the global situation is complex. In urban Nigeria, for example, the typical delivery model has changed from “at-home” to private “maternity homes” but still not to a hospital-based system. Conversely, recent trends in Canada have seen increasing numbers of children born at home or during only very brief contact with health services. Any WHO guidance on newborn and infant hearing screening models must take into account variations in national, cultural and economic contexts.

The principles of newborn and infant hearing screening are no different from any screening, and activities must be placed in the broader screening context, which typically involves:

- an important health problem with a recognizable latent or early symptomatic stage;
- ensuring the availability of a suitable diagnostic test that is safe and acceptable to the population;
- ensuring that an accepted and established treatment or intervention is available to the population; and
- placing the cost of diagnosis and treatment in relation to expenditure on medical care as a whole.

Newborn and infant hearing screening is however procedurally distinct from screening based upon either physical examination or bloodspot testing. Currently there is almost global neonatal physical examination for congenital malformations, while bloodspot testing is conducted in most countries in Europe and Americas, is expanding in the Eastern Mediterranean and Western Pacific regions, and is almost non-existent in sub-Saharan Africa and South-East Asia. The current situation for newborn and infant hearing screening is outlined in **Part 2** of this report.

Screening activities must also be placed in the broader context of rehabilitation approaches. Early detection and the provision of rehabilitation and support services are crucial aspects in preventing disability or mitigating its impact. The United Nations Convention on the Rights of Persons with Disabilities⁸ was adopted in May 2008 with Article 7 of this convention specifically addressing the rights of children with disabilities, and Article 26 emphasizing that habilitation and rehabilitation should be provided at the earliest stage. All children have a right to treatment and to non-discrimination. A forthcoming WHO/UNICEF manual (*Let's Participate*) on improving the social, educational and other participation of children aged 0–6 years who may experience participation barriers represents another important initiative. This manual cuts across all impairment groups and is aimed at primary health care workers. The linkage between screening and rehabilitation is stressed, as is the vital importance of sectors other than health in making improvements.

There appears to be a growing consensus that linking screening with rehabilitation and support is key and should go beyond the health sector. However, it is unclear at present whether the provision of newborn and infant hearing screening without corresponding diagnostic, rehabilitation and other services and interventions already in place can be considered to be ethical or beneficial. On the one hand, it seems clear that screening alone is insufficient and potentially unethical, but it is also true that in some countries (for example,

⁸ www.un.org/disabilities/convention/conventionfull.shtml

the United States) setting up screening programmes acted as a spur to the subsequent expansion of service provision.

Because many children do not come into contact with health services, outreach efforts will also be needed (for example, in schools). This is particularly the case for children with other disabilities. Hearing testing among Special Olympics athletes has revealed high levels (up to 25%) of hearing disorders⁹ – clearly highlighting the need to set up hearing screening in the homes and schools of disabled individuals. At the same time, the awareness and rehabilitation capacity of health workers and others must be strengthened and expanded. In these and other key areas, it will be essential to work in partnership – for example with ministries of health and others – and to ensure the full participation of NGOs and other organizations representing disabled people.

When considering the implementation of any health care programme it is important to evaluate whether the benefits of the programme will outweigh the costs. For newborn hearing screening programmes, costs are incurred for all those screened, but the benefits are experienced by only a small percentage of all neonates. The most important variables to include in such an analysis are the actual cost of the screening, the effectiveness of the screening, the prevalence of hearing loss and the cost consequences associated with preventing, treating or managing hearing loss. Assessment of benefits must then include both the health and economic benefits associated with preventing, treating or managing hearing loss.

Nor should the cost analysis of newborn and infant hearing screening programmes be limited to evaluating “screening” versus “no screening”. Instead, evaluations should also be made of the different levels of costs and benefits associated with the timing of screening (for example, at 6 months, 12 months, 2 years, etc.); with targeted versus universal hearing screening; and with alternative methods for screening. Such analysis should evaluate the net cost to society of each approach as well as the cost benefits of each disability-adjusted life year (DALY) saved by the screening programme. There is now an increasing awareness of the significant personal and social benefits associated with the early detection of hearing impairment and the provision of prompt diagnostic and rehabilitation services. Similarly, the real burden and associated costs of undetected hearing impairment during infancy and childhood are also becoming clearer.

The current level of burden is already known to be high in some developed countries and is likely to be high everywhere. In the United States, for example, “diseases of communication”¹⁰ are estimated to cost the economy US\$ 154–186 billion per year. Though these figures are likely to be less in absolute monetary terms in developing countries, the burden will still be substantial. In all countries, a loss of potentially productive workforce members is a loss regardless of whether funds are being spent or not. Benefits here and elsewhere would include the benefits of having someone educated and in economically productive employment – and avoiding the above costs of not doing this. In addition, although

⁹ Neumann K et al. (2006). Auditory status of persons with intellectual disability at the German Special Olympics Games. *International Journal of Audiology*, 45:83–90.

¹⁰ “Diseases of communication” include hearing loss, voice and speech disorders, and language disorders. Although there are no precise figures on the prevalence of these disorders, one analysis indicated that the available data for North America are consistent with conservative estimates of 5% for hearing impairment, 3% for voice and speech disorders, and less than 7% for language disorders. Ruben RJ (2000). Redefining the Survival of the Fittest: Communication Disorders in the 21st Century. *The Laryngoscope*, 110:241.

cost-benefit is very difficult to determine when it involves “quality-of-life” issues, there is a pressing need to know how much health and other outcomes really improve when a hearing-impaired individual is identified in infancy rather than later in life. If such key concepts of benefit are used then they must be demonstrable, even where it is difficult to calculate their monetary value.

The whole issue of cost-effectiveness should be considered to be part of a larger picture of advocacy efforts. Although cost-effectiveness figures can be highly useful in some settings, in others the current cost of programmes is zero as there are none. Any expenditure is therefore an increase and doing nothing costs nothing if rehabilitation is simply not seen as a priority. The question then becomes political. National priorities will often be geared towards higher profile issues – especially those related to the Millennium Development Goals (MDGs) – and cost-effectiveness arguments in severely resource-constrained settings can therefore be ineffective. It was noted that in one country it took more than a decade to set up a cochlear-implant programme in the face of competing national health priorities. The allocation of funds relies upon functional governments committed to health spending, which is often not the case in many countries.

In other settings, cost-effectiveness and cost-benefit analyses are likely to be of great value. Many countries will be in a position where, despite other national priorities, cost-effectiveness, cost-benefit and hearing-loss burden data could become part of the efforts of dedicated individuals to set up services and advocate for government finance and support. Cost-effectiveness studies in these settings are likely to play a large part in advocacy efforts to expand the availability and coverage of required services. Costs need to include the opportunity costs of not doing something else and this overall cost may lead to a perception of high cost with only a relatively small number benefiting – especially if the hearing screening is not effective. In such settings, cost-effectiveness arguments might even become a “double-edged” sword. Evaluation is needed here to demonstrate that the costs do not outweigh the benefits.

Although WHO recommendations do not exclusively rely upon cost-effectiveness or cost-benefit ratios, they are intended to be “cost-sensitive” to reflect the reality of very low health spending in many countries. Newborn and infant hearing screening requires resources and any guidance must take into account the available data on its cost-effectiveness and affordability in developing countries. Many low-income countries will be unable to run national and/or sub-national programmes unless methods for their financing (including opportunities for public-private partnerships) are identified. In addition, the criteria for determining whether or not to initiate newborn hearing screening in a specific country should be identified – these are likely to include the level of development reached, and the availability of rehabilitation services, infrastructure and personnel. This raises the issue of how newborn hearing impairment should be measured and how best to organize screening given that most births in low-income countries occur at home.

Data in all these areas are still lacking and it is likely that this will severely hamper advocacy and other efforts in many countries. Unless a consensus backed up by evidence is developed on the best approaches to newborn and infant hearing screening, and its effectiveness and cost-effectiveness demonstrated, it would be difficult to justify its universal use in resource-poor countries. If however, a clear evidence-based consensus can be reached on the effectiveness and benefits of early detection and intervention then the implementation of such screening should be seen as a priority.

2. Current approaches to newborn and infant hearing screening

2.1 Multi-country approaches

A number of multi-country approaches to expanding and improving newborn and infant hearing screening programmes have been under way for several years. The presentations made on behalf of three of these initiatives are summarized below in the order in which they were presented.

Universal newborn hearing screening in the member states of the International Association of Logopedics and Phoniatrics (IALP)¹¹

Members of the IALP Audiology Committee recently reported on the activities of their newborn hearing screening programmes during 2008.¹² The data presented was either for the whole country (Australia; Brazil; China; Germany; Philippines; Serbia; and Sweden) or for specific regions (India: Maharashtra, and Mumbai; the United States: Colorado, and Washington DC). The detection threshold targeted by newborn hearing screening ranges from 20 dBnHL (Brazil) to 40 dBnHL (India) and is performed bilaterally in all replying countries. The screening methods used in all replying countries are transient evoked otoacoustic emissions (TEOAE) testing and automated auditory brainstem response (AABR), with distortion product otoacoustic emissions (DPOAE) testing also used in some countries. Most countries use AABR in neonatal intensive care units (NICUs) or for babies at risk of early infant hearing loss. The protocols used in the 1st stage are TEOAE alone (Brazil; India; and Serbia); TEOAE/DPOAE (China); TEOAE/AABR (some regions in Germany; Sweden; and the United States); or AABR alone (some regions in Germany). In the 2nd stage, TEOAE alone is used in India and Serbia; TEOAE/AABR in Sweden and the United States; and AABR alone in Germany. In India, AABR is also used for a 3rd stage. The 1st and 2nd stages of screening are performed mostly in hospitals (China; Germany; India; Serbia; and the United States), while the 3rd stage screenings are performed in hospitals (India), in Hearing Health Care Services (Brazil), or in paediatric-audiological or ENT departments and practices (Germany).

In some countries screening is performed on a national basis, and is either non-compulsory (China; and the United States) or mandatory (Germany; and the Philippines; pending in Australia). In other countries, screening is performed at the district or other sub-national level (Brazil; India; and Serbia). Screening is performed by nurses (China; Germany; Serbia; and the United States); by audiologists/technicians (Brazil; China; India; and the United States); by midwives (Germany); and by physicians (Germany; and Serbia). Financing for the newborn hearing screening programme comes from parents (China; and partially in Brazil and the United States); health insurance (Germany; and partially in Brazil and the United States); the government (Brazil for public hospitals; India; and Serbia); or hospitals (partially in the United States).

¹¹ Report of the IALP Audiology Committee presented by Professor Katrin Neumann, Chairperson.

¹² Data from Brazil is for 2007.

The reported prevalences of permanent hearing loss identified by newborn hearing screening programmes were: ~1/1000 (Brazil, bilateral; and Sweden); 1–3/1000 (China, bilateral) and ~5/1000 (China, unilateral); 1.6/1000 (Germany, bilateral) and 0.7/1000 (Germany, unilateral); 1.61/1000 of at-risk infants (India, bilateral); 1/1000 (Serbia, bilateral) and 0.3/1000 (Serbia, unilateral); 1.05/1000 (United States, Colorado, bilateral) and 0.45/1000 (United States, Colorado, unilateral); 1.83/1000 (United States, Washington DC); and 3/1000 (Philippines).

All countries reported that physiological hearing screening methods were preferred over screening based on questionnaires or behavioural methods. The reported prevalences from all member countries justify universal newborn hearing screening, and even developing countries are highly interested in such programmes.

Early hearing detection and intervention (EHDI) programmes in Europe¹³

The early detection of hearing impairment and provision of appropriate interventions has become the focus of health care programmes working in this area in the vast majority of European countries. However, the degree of implementation and coverage of EHDI programmes varies greatly from country to country, and may differ from one region to another within the same country. In about half of European countries, EHDI programmes are legislatively mandated. In the remaining half, EHDI programmes are not mandatory but are strongly recommended and conducted either on a voluntary basis or with the endorsement of national health authorities or a board of experts. The degree of implementation of EHDI programmes ranges from “very good implementation” with a coverage of more than 90% of births to “pilot programmes” where EHDI systems are under study in some of the birthing units of a given country and where coverage is less than 20% of births.

In about half of European countries, EHDI programmes are implemented nationwide. Region-based EHDI programmes are reported in about 30% of countries, while in the remaining 20% there are only local initiatives performing EHDI programmes. Countries where EHDI programmes are implemented on a national basis typically use standardized protocols where the same clinical protocol and the same equipment are used by all hospitals and other programme centres. “Benchmarking” is the evaluation of the programme against a set of quality standards which should include the minimum participation rate at screening; age at completion of the screening process; maximum referral rate; minimum participation rate and age at completion of diagnostic testing; and age at which infants receive first intervention. However, such benchmarking is conducted in only 60% of all European countries where EHDI programmes are implemented nationwide (corresponding to around one third of all countries). Moreover, most of these countries only use quality standards on the age and minimal participation rate at which hearing screening and diagnosis have to be performed. Only in one country do benchmarks include a quality indicator on the age and coverage rate of early intervention – as recommended by the 2007 Joint Committee on Infant Hearing (JCIH) Position Statement.

The percentage of neonates that receive hearing screening is typically greater in those countries that have implemented nationally based programmes than in those with regional

¹³ Presented by Dr Ferdinando Grandori. The data presented here are based upon a previous survey conducted by the International Working Group on Childhood Hearing (IGCH). An updated version of the survey is now being finalized and the results are scheduled for publication in the second half of 2010 on the IGCH web site: <http://childhearinggroup.isib.cnr.it/group.html>

programmes. In about 80% of the countries with nationwide programmes, screening is done for more than 80% of all births. However, in only half the countries with nationwide programmes do children receive proper audiological evaluation within 3 months of age. Of these, only four countries ensure that early intervention is provided to all those identified with hearing loss within 6 months of age – again as recommended by the JCIH.

Newborn and infant hearing screening in the South-East Asia Region – Sound Hearing 2030¹⁴

In almost all of the countries in this region, there has been no serious organized effort to set up newborn and infant hearing screening programmes.

- Bangladesh – there is no national policy regarding hearing screening. However, many institutions do conduct hearing screening activities. There are also many organizations providing hearing aid fittings and cochlear implants.
- Bhutan – has no newborn hearing screening programme, and is faced with a complete lack of audiological personnel, equipment and other material resources. It does however have a free hearing aid distribution programme.
- India – following the launch of the National Programme for Prevention and Control of Deafness, India has developed its own protocol for infant hearing screening, combining both institution-based and community-based modalities. It has now launched the programme in approximately 65 districts. The national government also provides support for hearing aid fitting and therapy, while many private centres provide cochlear implants.
- Indonesia – there is no national programme for hearing screening. However, many institutions do conduct hearing screening activities. There is no government support for hearing aid fitting, while cochlear implants are available in 5 centres.
- Maldives – has no newborn hearing screening programme, and is faced with a complete lack of audiological personnel, equipment and other material resources.
- Myanmar – has no newborn hearing screening programme and is faced with a severe lack of audiological personnel, equipment and other material resources, having only one centre with the required audiological equipment.
- Nepal – has no national policy regarding newborn hearing screening. There are three centres that offer suitable diagnostic services. There is no hearing aid distribution programme, but one centre offers cochlear implantation.
- Sri Lanka – has no national policy regarding newborn hearing screening, though most teaching hospitals offer suitable diagnostic services. There is no hearing aid distribution programme, but many centres offer cochlear implantation.
- Thailand – has no national policy regarding newborn hearing screening. A number of large hospitals do offer suitable diagnostic services. There is a hearing aid distribution programme, and a number of centres offer cochlear implantation.
- Democratic People's Republic of Korea; and Timor-Leste – no information available.

¹⁴ Presented by Professor Shelly K Chadha, Joint Secretary, Society for Sound Hearing.

The barriers to newborn hearing screening in the region can be summed up as:

- other pressing health priorities;
- poor audiological resources in countries, especially human resources;
- poor accessibility of infrastructure to the general population; and
- poor availability of rehabilitative services.

2.2 National programmes

Meeting participants involved in developing, implementing and operating national newborn and infant hearing screening programmes were invited to summarize the status of the programme in their country. A brief summary of each of the presentations is given below in the order in which they were presented.

Newborn hearing screening in the United States¹⁵

Approximately 4 million babies are born each year in the United States – 98% of which are born in hospitals. In March 1993, the National Institutes of Health recommended that all neonates be screened for hearing loss before leaving the hospital. At that time, less than 5% of all babies were screened. Since then, this percentage has increased each year and now more than 95% of all neonates are screened for hearing loss.

Each state has established an early hearing detection and intervention (EHDI) programme that is responsible for developing and operating a newborn hearing screening system, and for providing diagnosis, early intervention and family support. Since 2000, the federal government has provided a small amount of money each year to almost all states to assist in the development and operation of these EHDI programmes. The programmes are under the authority of the states, which establish their own protocols, standards and quality-assurance procedures.

The federal government has however established recommended benchmarks. These require that all neonates are screened for hearing loss before they are 1 month old; that those not passing the screening complete a diagnostic evaluation prior to 3 months of age; and that those identified with permanent hearing loss begin audiological, medical and educational interventions before they are 6 months old. Further recommendations on various aspects of the EHDI programme are given by the Joint Committee on Infant Hearing (JCIH), and most states are voluntarily working towards implementing these recommendations.

The United States Centers for Disease Control and Prevention has established a data-reporting system in which states are asked to submit information on the number of children screened, diagnosed and receiving early intervention. Because it is a voluntary system, there are some weaknesses in the data. The latest available data for 2007 indicate that:

- 94% of all babies were screened for hearing loss;
 - 1.8% of these babies did not pass the screening;
 - 55.2% of those needing a diagnostic evaluation were documented to have received one;
- and

¹⁵ Presented by Professor Karl R White.

- 64.3% of those identified with hearing loss were documented as being enrolled in an early intervention programme.

Loss to follow-up at all stages of the EHDI process continues to be a serious concern. States with the most well-developed EHDI programmes are reporting 2–3 children per thousand with permanent hearing loss but many states are reporting far fewer – presumably because of loss to follow-up.

Newborn hearing screening in Canada¹⁶

Canada is a nation of 10 provinces and 3 territories with an estimated population of 33 million, and is ranked globally between 30th and 35th for medical care. About 70% of the cost of health care is covered by the government through an expenditure of about 16.7% of its revenue. There is considerable variation across provinces in the extent to which health care costs are covered once the required basics are provided. Nevertheless, all Canadians enjoy excellent-quality health care.

In 2006–07, there were 352 848 births recorded. Universal hearing screening of those children could not be “mandated” by the Canadian government because such screening is beyond the basic coverage mandated by the health care system, and each province must decide whether to fund newborn hearing screening as an additional service. Even so, the federal government has provided a directive that “Universal newborn hearing screening shall be offered”. Four provinces are in compliance with full coverage and two are nearing compliance. This means that over two thirds of the country has implemented an early detection of hearing impairment programme which includes screening all neonates by 1 month, diagnosis of hearing loss by 3 months, and intervention by 6 months. The various programmes essentially mirror the United States Joint Committee on Infant Hearing recommendations.

Reported problems have focused on:

- the need to provide screening coverage 7 days a week because some babies leave the hospital over the weekend;
- the placing of universal newborn hearing screening into an overall programme which includes screening for phenylketonuria, congenital hypothyroidism, etc.; and
- the need for central oversight at the provincial level as opposed to fragmented control by local hospitals and clinics.

Programme success depends on consistency of procedures; rigorous evidence-based protocols; diagnostic and intervention training; outcome measures; family-centred services; and a sufficient, stable and dependable budget.

In Canada, newborn hearing screening is a health issue but not a medically controlled service. Most hearing-impaired children require educational, audiological and counselling services, and medical treatment as needed. As a result of all the above considerations, it should be emphasized that successful early hearing detection and intervention is a team process.

¹⁶ Presented by Dr George T Mencher.

Newborn hearing screening in England, United Kingdom¹⁷

Since 2006, newborn hearing screening has been offered to the parents of all babies in England. Since then, more than 3.5 million babies have been screened and 5200 cases of permanent childhood deafness detected in one or both ears. The test is optional but 99.8% of parents take up the opportunity. Across England, there are 118 local hearing screening services with over 2000 trained health care professionals carrying out the screening.

Two models are used:

- in hospital before discharge – if discharge takes place before the test is completed, a letter is sent asking the mother to attend an appointment for the screening test; and
- in some areas the test is done at home by a health visitor nurse.

The Newborn Hearing Screening Programme (NHSP) is guided by a comprehensive set of national standards which state that screening must be offered and completed for all well babies in hospital-based programmes by 4 weeks of age. For well babies in community-based programmes the standard is 5 weeks.

Two methods are used – automated otoacoustic emissions (AOAE) testing and automated auditory brainstem response (AABR). AOAE testing is carried out, and where there is no clear response in one or both ears then a second screening is conducted using AOAE and/or AABR. If there is no clear response on the second screening, the baby is referred to the local paediatric audiology department for follow-up. NHSP standards state that the family should receive a referral in 3 working days and that a baby should be seen in audiology no more than 4 weeks from the second screening.

NHSP quality assurance is underpinned by a national information and performance management system. Every local hearing screening programme in England uses this system to capture data from the screening tests. System functionality and analysis make it possible to assess local performance against national quality standards; to compare performance between different sites; and to track the progress of babies referred after screening through the early assessment care pathway. Standards also exist for the provision of support to parents and services for children following the identification of hearing loss.

Moving forward, the challenge for the NHSP is to maintain quality and drive its high standards through to audiological assessment and parental support. The NHSP must also continue to reduce health inequalities, and to work with health care and education professionals to ensure that babies who are diagnosed as deaf get the best outcomes from early interventions – including hearing aid services, cochlear implants and educational support. A major challenge at present is ensuring appropriate electrophysiological assessment after screening, as compliance with protocol has been found to be problematic in up to 10% of programmes.

Improving the health and well-being of children through prevention and early intervention – within the context of an integrated approach to supporting children and families – remains the key priority. In support of this, the NHSP will continue to work alongside other newborn and antenatal screening programmes to identify improvements and share best practice.

¹⁷ Presented by Professor Adrian Davis.

Newborn hearing screening in Germany and the State of Hesse¹⁸

In Germany, newborn hearing screening has been mandatory since 1 January 2009. Screening is designed to detect a permanent hearing loss of 35 dBHL or greater. The goal is to diagnose congenital hearing loss before the end of the 3rd month of life and begin therapy before the end of the 6th month of life. Screening is performed binaurally as a TEOAE-AABR two-stage screening or as a one-stage AABR screening. For babies with a risk factor for hearing loss, AABR is required. All parents receive written information on newborn hearing screening, and those who do not want to have their baby screened must sign a form indicating that screening has been refused in the booklet which documents the child's regular medical check-ups. For healthy babies, screening is recommended by the 3rd day of life and before discharge from the maternity ward (if the baby is born in a clinic), and must occur before the 10th day of life. For severely ill babies, screening should be done as soon as is practical considering the baby's medical condition, and before the end of the 3rd month of life. For pre-term babies screening should occur by the calculated birth date.

Tracking of screening is done by documenting in the child's booklet its first occurrence, the results, the occurrence of a second screening (if necessary), and the follow-up to final diagnosis and therapy. The home paediatrician is responsible for initiating any examinations that are lacking. However, the responsibility for the initiation, performance, documentation and quality assurance of the screening is clearly defined for hospitals and practices. Clinics have to provide annual hearing-screening reports, while nationwide evaluations of screening allow for the quality control of the overall newborn hearing screening programme.

In the German State of Hesse, a unique network exists where all 78 birth clinics involved in the newborn hearing screening programme send their data every day directly from the screening device via a telephone line to a central server in the screening centre. The data is then automatically fed into a database that indicates which babies failed the screening or did not receive a complete screen; creates reminder letters for the parents of babies who did not show up for a follow-up; and produces various reports and statistics. These reports include the proportion of invalid measurements to valid measurements, calibration errors, and the quality of the measurements made by the screening personnel. Based on data for 150 000 babies, median age at diagnosis of congenital hearing loss has decreased to 3.7 months, with a median age of 5.8 months at initiation of therapy.

Newborn hearing screening in the Russian Federation¹⁹

In 1996, the Russian Ministry of Public Health Care issued regulations on the hearing screening of neonates and first-year-of-life children. These regulations have the status of a legislative act, and determine all the steps and timing of screening and the follow-up stages. The system developed as a result of this legislation includes:

- activities aimed at educating community members and health care specialists;
- obligatory collection of information on the risk factors for hearing loss at all maternity hospitals;
- distribution of maternal questionnaires for evaluation of the child's reactions to sounds;

¹⁸ Presented by Professor Katrin Neumann.

¹⁹ Presented by Professor George Tavartkiladze.

- behavioural screening with the use of simple devices for audiological testing at paediatric outpatient departments;
- transient evoked otoacoustic emissions (TEOAE) recording at audiological centres;
- second-stage testing of children who have failed the first screening by means of additional TEOAE and auditory brainstem response (ABR) recordings; and
- rehabilitation of children with diagnosed hearing impairment.

In 2007–08, pilot projects were conducted in 4 regions of the Russian Federation as part of a federal programme (*Children of Russia*) in which universal newborn hearing screening was conducted based on TEOAE registration in maternity hospitals. The pilot projects included training programmes for audiologists, neonatologists, paediatricians and nurses.

In 2008, universal newborn hearing screening was included in the national programme *Health*, with federal financing available for 3 years. In 2008–09, 73% of the territory of the Russian Federation was equipped with the TEOAE units – 860 devices were placed in maternity hospitals and paediatric outpatient units. In addition, equipment for diagnostics and follow-up (including immittance meters, and diagnostic systems including ABR, ASSR, TEOAE and DPOAE) was placed in 152 audiological centres. Staff at each of these facilities were then trained in the use of this equipment. Training programmes for audiologists, neonatologists, paediatricians and nurses will now be continued permanently. In 2009, there were approximately 944 000 births in these regions (55% of all births in the Russian Federation). Around three quarters (73%) of these babies were screened. Of the 5.5% of babies who failed the screening, 55% completed diagnostic evaluations, and almost 4000 babies were identified with permanent hearing loss. It is projected that the newborn hearing screening programme will cover the whole country by the end of 2010.

Special protocols for rural and community-based screening were developed and introduced. In addition, a protocol for combining audiological and genetic screening was developed in 2009. The expected advantages of such combined screening include:

- early intervention;
- reduced examination time;
- reduced test costs;
- revealing of hereditary deafness connected with the Cx26 gene;
- improved diagnosis of the presence or absence of other genetic mutations; and
- provision of genetic counselling.

Newborn hearing screening in the Republic of Korea²⁰

The population of the Republic of Korea is around 48 million, with about 480 000 births each year. Most women prefer to deliver their baby at a private clinic rather than a large hospital. As result, approximately 82% of babies are born at private clinics and 18% at larger hospitals. However, there are more than a thousand private OB-GYN clinics, and 37% of them have less than 100 births per year. In these locations, newborn hearing screening is not considered to be cost-efficient.

²⁰ Presented by Professor Seung-Ha Oh.

Newborn hearing screening began in the Republic of Korea in the mid-1990s when a number of private OB-GYN clinics began to follow the suggestions made by companies who imported and distributed the required devices. However, there were no guidance or quality-control systems put in place.

Meanwhile, the Association of Audiology and Otolaryngology introduced newborn hearing screening to large hospitals with most programmes initiated by ENT specialists or audiologists. Annual workshops and meetings provided education, and a series of papers reported on the data from various centres. However, there was no plan for a nationwide programme until 2004.

In order to launch a nationwide programme, a stepwise approach was used. First, the incidence of newborn hearing loss was investigated using a national survey. The incidence of bilateral hearing loss over 40dB was found to be about 0.3% with an incidence of 0.05% for hearing loss over 90dB (n = 44 066). Although the results were lower than expected, newborn hearing screening programmes had only been implemented for a short time and follow-up and data tracking were not satisfactory. Data-collection efforts are now ongoing and more accurate figures are expected to become available.

The referral rate from private OB-GYN clinics was found to be much lower than that of large hospitals. This significantly lower referral rate (0.36%) raised questions about the quality of newborn hearing screening programmes at OB-GYN clinics. An additional study found several cases of false negatives among the babies who had been classified as "PASS" by an AABR test. This clearly demonstrated a lack of education and quality control in the programmes of some OB-GYN clinics.

Since 2007, a top-down controlled programme has been tested in selected prefectures. Every year the results were analysed and the pilot-test area gradually expanded. Small private clinics without appropriate screening equipment were not allowed to be part of this programme. Tracking of the referred cases was found to be problematic.

Beginning in 2009, a coupon system was used to solve this problem. The free coupon consists of two parts (screening test and confirming test with the same ID number) and is issued to pregnant women at the public health centre. Babies born at a small clinic can be taken to any big hospital within 30 days for a screening test. Referred babies from any clinic can also be taken to any listed hospital where a confirming test is available within 90 days. Collected coupons from each institute were sent to the Ministry of Health for reimbursement. By analyzing the coupons, the tracking of babies should now be possible. The effectiveness of this system is yet to be determined.

The biggest challenges at the current time are educating participants and ensuring the application of quality-control measures in individual programmes, especially private clinics. Regular coursework with certificates is being developed. It is intended that pilot testing will be completed by 2010, and a nationwide mandatory programme launched by 2011.

Newborn hearing screening in China²¹

Approximately 20 million babies are born each year in China – of whom about 60 000 are expected to have congenital hearing loss. Recognizing the severe public health and social problems associated with hearing loss in infants and young children, the Chinese government has conducted pilot studies since 1999 and has strongly recommended that newborn hearing screening should be a routine procedure. Various regulations, national plans and technical criteria have been developed, and national and local training courses have been held every year since 2000. Newborn hearing screening practitioners must pass a government examination and be certified. Public-awareness activities and a National Ear Care Day, held every year on 03 March, are helping people to recognize the importance of such screening.

Because China has so many births, three different models are currently used to identify hearing loss in infants and young children. First, hospital-based universal newborn hearing screening is strongly recommended by the government and by health professionals. About 20 provinces and/or municipalities have newborn hearing screening programmes that are typically carried out in association with newborn screening for phenylketonuria and congenital hypothyroidism. Newborn hearing screening is conducted using OAE in the well-baby nurseries, and AABR in NICUs. The re-screening of infants who do not pass is done within 42 days. A diagnosis for those that do not pass the hearing screening is made in ENT/Audiology departments in the tertiary hospitals of each province when babies are 3–6 months of age. After diagnosis, rehabilitation is provided in dedicated centres. Parents currently pay for screening (US\$ 7 for OAE and US\$ 14 for AABR) but there is an expectation that public health insurance will soon cover these costs.

Second, targeted screening is recommended for infants living in rural and remote areas. Neonates who have high-risk factors are referred to the screening centre within one month of birth. Third, questionnaires and simple tests are recommended to monitor every child's hearing as part of a community screening approach.

Screening is designed to detect permanent bilateral or unilateral hearing loss of 30 dB or worse in the range 0.5–4 KHz. Because there is no national database, accurate incidence data are not yet available but reports indicate that 2.87–5.90 per 1000 neonates are identified with hearing loss. It is estimated that 20–25% of all babies in China are now screened for hearing loss but this is highly variable. In the capital and coastal cities, 95–98% of all neonates are screened. In terms of activities beyond newborn hearing screening, hearing screening is also conducted in some cities on 6-year-old children, while simultaneous screening for hearing and ocular diseases in neonates has been conducted in over 20 000 children in Jinan maternal and child hospital since 2002. In addition, a number of hospitals are conducting pilot studies evaluating newborn hearing screening plus screening for genetic mutations in mt12SrRNA 1555G; GJB2; and SLC26A4 genes.

The biggest challenges at the current time are the lack of human resources (especially audiological professionals), difficulty with follow-up of those who do not pass hearing screening, the lack of national and provincial databases, and the difficulties of programme implementation in remote and/or rural areas.

²¹ Presented by Professor Xingkuan Bu.

Newborn hearing screening in the Philippines²²

The Philippines is an archipelago of 7107 islands with a population of about 89 million people. It has an annual birth rate of 2 million, which equates to 4 babies born per minute. Based on an estimated incidence in developing countries of 6 per 1000 infants with permanent congenital and early-onset hearing loss, there would be 12 000 such infants born each year in the Philippines.

The Universal Newborn Hearing Screening and Intervention Act was signed into law in August 2009. This requires all health care practitioners to inform parents prior to delivery of the availability, procedures and benefits of hearing screening for neonates and infants 3 months of age and below. The law requires that all babies born in hospitals be screened for hearing loss before discharge, while those born outside hospitals must be screened within the first 3 months after birth. Newborn hearing screening centre or barangay health workers must refer all babies who do not pass the hearing screening for treatment at the provincial hospital of the local government unit concerned. If the treatment is beyond the clinical capability of the provincial hospital, the baby is referred to a Department of Health Tertiary Hospital. The Philippine Health Insurance Corporation includes the cost of hearing screening in its benefit package. Since only 40% of babies are born in hospitals, community-based hearing screening can also be done during routine immunization, which has a coverage rate of about 90%. There are however only about 50 items of OAE equipment and 40 items of ABR equipment all over the country in those facilities where babies who do not pass the first screening can be referred. Implementation rules and regulations for the newborn hearing screening programme are currently being drafted by the stakeholders.

Newborn hearing screening in India²³

India faces the challenge of a very large population and a high annual birth rate approaching 25 babies per 1000. Moreover, 75% of the population live in rural areas and over 50% of births occur at home and are frequently attended by a trained birth attendant. However, India also has a well-developed health care delivery system, right down to the grassroots/village level, and a well-established immunization programme.

In 2006, India launched the National Programme for Prevention and Control of Deafness. This programme is currently running in over 60 districts of the country and its aim is to identify babies with bilateral severe-profound hearing losses by 6 months of age and initiate rehabilitation by 9 months of age. Under this programme, the following two-part protocol for infant hearing screening is being implemented:

- **Institution-based screening** – to screen every baby born in a hospital or admitted there soon after birth using OAE. Those who fail the test are re-tested after 1 month. Those who fail the second screening are referred for ABR testing at the tertiary-level centres.
- **Community-based screening** – to screen babies who are not born in hospitals. Such screening is carried out using a brief questionnaire and behavioural testing. The screening is performed when the baby attends for immunization at 6 weeks of age and onwards. A trained health care worker at the subcentre administers immunization and conducts the hearing screening. The protocol is repeated at every immunization. Any baby failing the

²² Presented by Dr Norberto V Martinez.

²³ Presented by Professor Shelly K Chadha,

screening is referred for formal OAE screening to the district hospital, and if they fail OAE they are then sent for ABR testing.

The programme includes:

- training of existing human resources using standardized training programmes and other materials;
- provision of the equipment required for behavioural testing and for OAE at the respective centres;
- provision of suitable audiological personnel for diagnosis and for rehabilitation at the district hospitals;
- creating awareness of the importance of detecting childhood hearing loss amongst parents and the general population through the use of posters, flipcharts, fliers, handouts and other suitable materials; and
- provision of a referral slip to aid patient compliance and simplify the visiting process.

Once an individual is identified as hearing impaired, they are referred for hearing aid fitting and for suitable therapy at the district hospital.

Identified problems include the need for patients/parents to make repeated visits and to visit different centres. In addition, even though OAE is provided at all centres, there is a shortage of centres where ABR is done. There is also a shortage of audiological personnel and a heavy burden placed on health care workers.

At present, the programme has been initiated in more than 60 districts of India, training has been undertaken in most districts, and awareness material developed and provided to all centres. OAE machines have been made available and human resource development and deployment efforts are under way. A cost-benefit analysis of the programme, and an assessment of its validity and workability, will be available in 2011 once the protocol has been completely field-tested.

Newborn hearing screening in Brazil²⁴

The Brazilian Public Health Care System implemented a National Policy for Attention to Hearing Health Care in 2004. This policy specifies the procedures and actions to be taken for all people in Brazil based on levels of complexity. It ranges from prevention and identification (including newborn hearing screening) to diagnosis and intervention (including hearing aids and cochlear implants). Brazil has approximately 3.1 million babies born per year and less than 10% currently receive hearing screening. The challenge is to develop a high-quality newborn hearing screening and intervention programme for the entire country. There is agreement that the newborn hearing screening programme should be part of the larger Public Health Care System, and should represent only the beginning of a process from identification to diagnosis and intervention. Such a programme will require complex procedures and qualified professionals, governmental quality assurance and database tracking.

In organizing the newborn hearing screening programme, it will be important to take advantage of other related programmes already in existence in the country – such as phenylketonuria screening. This is a very well-organized programme in Brazil with good

²⁴ Presented by Dr Maria Cecilia Bevilacqua.

results. By linking newborn hearing screening and phenylketonuria screening, information can be coordinated for those babies who did not have one of the tests prior to hospital discharge, or who need a second-stage test. Another programme being implemented in Brazil that will be coordinated with newborn hearing screening is the Kangaroo Mother Care Programme that organizes the follow-up for low-birth-weight infants. In this approach, the infant health booklet is used to report newborn hearing screening results. This is potentially very helpful for hearing follow-up because other professionals can access the results and motivate and support families to take part in diagnosis and intervention activities.

The results of exploratory studies in Brazil have shown that hospital-based hearing screening using an “at-risk” protocol can be very successful as a starting point for universal newborn hearing screening. This approach can be useful in organizing follow-up, maintaining an integrated database, and training community health workers to follow up on hearing and speech development. These studies have also demonstrated that although there is no significant cost difference between OAE and AABR, the false-positive and referral rates are significantly lower for AABR.

Newborn hearing screening in Oman²⁵

Located in the southern part of the Persian Gulf, Oman has approximately 2.4 million inhabitants and 41 000 annual births. As a result of the emphasis on easily accessible primary health care, optimum utilization of health services and community participation, Oman was ranked 5th among WHO Member States in health service utilization in 2000. More than 95% of births are in hospitals. Hearing loss has been targeted as a priority health problem since 1995, and was identified as one of the leading causes of disease burden in Oman in 2000. In 2001, Oman incorporated the establishment of universal newborn hearing screening into its 6th National 5 Year Health Plan.

In 2008, approximately 72% of all neonates were screened using a two-stage protocol. First-stage OAE testing is usually performed by a nurse in the maternity or paediatric department when the baby is 24–48 hours old. Babies who fail this test are tested again before the mother leaves the maternity ward. If hearing impairment is suspected, the baby is referred to ENT staff at the birth hospital who carry out the second-stage screening at about 6 weeks of age. At that time, the infant receives a physical examination and a repeat of the screening test using OAE. Infants who fail this second-stage screening are referred to the audiology unit at Al-Nahdha hospital in Muscat. At this tertiary care centre, infants are evaluated using OAE and ABR. If they are found to have sensorineural hearing impairment, an appropriate hearing aid or cochlear implant is prescribed. Monthly screening progress and other tracking data for infants suspected of having hearing impairment are reported through the health information system coordinated by Al-Nahdha hospital.

Technical and other obstacles identified so far have included:

- frequent breakdown of machines;
- unavailability of probes in good time;
- uneven distribution of machines; and
- problems associated with multiple stakeholders.

²⁵ Presented by Dr Mazin Al-Khabori.

Despite these obstacles, the goal of screening all neonates for hearing loss is expected to be achieved during the course of the coming 7th National 5 Year Health Plan.

Newborn hearing screening in Nigeria²⁶

The secondary prevention strategy of screening infants for the early detection of conditions that cannot be addressed by primary prevention is rare in Nigeria – as it is in many developing countries. The high prevalence of hearing loss (about 14%) documented by one 1995 study conducted among school-age children in regular schools, as well as a 2002 national population survey, culminated in the first early childhood hearing detection and intervention policy for Nigeria in 2004.

In 2005, a local nongovernmental organization (Hearing International Nigeria) in partnership with the Federal and Lagos State Ministries of Health initiated the first pilot infant hearing screening programmes. Between May 2005 and April 2006, a total of 3333 infants were screened either in the hospital at birth (n = 1330) or in 4 community clinics when they received Bacille de Calmette-Guérin (BCG) immunization (n = 2003). About 99% of eligible neonates were successfully screened at a mean age of 1.3 days in the hospital compared to 88% of infants at a mean age of 17.7 days in the community – where the majority were born outside hospital facilities. First-stage referrals were 32.2% in the hospital compared with 14.3% in the community-based programme, while second-stage referrals were 3.3% and 4.2% respectively. However, only 50 out of 82 infants (61%) referred in the community returned for diagnostic evaluation. Of these, 45 (90%) were confirmed with hearing loss. Additionally, 11 infants who had previously passed the first-stage screening were also confirmed with hearing loss resulting in a yield of 28 per 1000 (56 out of 2003).

The mean age at diagnosis in the hospital-based and community-based programmes was 233 and 51 days respectively. Sensitivity, specificity and positive predictive values for the community-based programme were 80.4%, 99.7% and 90.0% respectively. Corresponding values for the hospital-based programme were not available due to a very poor follow-up return rate. In the community-based programme, positive and negative likelihood ratios were 268 and 0.2 respectively, whilst the screening cost per infant and the cost per infant detected with sensorineural hearing loss were US\$ 7.62 and US\$ 602.49 respectively. Risk factors for sensorineural hearing loss were hyperbilirubinaemia requiring exchange blood transfusion, birth asphyxia (indexed by low Apgar scores), admission into a special care baby unit (SCBU), absence of a skilled attendant at birth, maternal hypertension and undernourished physical state.

The routine screening of infants attending BCG immunization clinics by community health workers without prior audiological experience is feasible and effective in the early detection of permanent congenital or early-onset hearing loss in Nigeria. It also appears to be more cost effective in this setting where non-hospital deliveries are predominant, a situation typical of many resource-poor countries. However, an efficient tracking and follow-up system is needed to improve the return rates for screening completion and diagnostic evaluation.

²⁶ Presented by Dr Bolajoko O Olusanya.

3. Guiding principles for action

As shown by the presentations outlined in **Part 2** of this report, countries representing different health care systems, and different economic and social circumstances have implemented successful newborn and infant hearing screening programmes. However, in many other countries such programmes have not been implemented due to a number of obstacles including the lack of evidence-based local guidance, lack of financial and/or human resources, and the absence of political will. Even in countries where early hearing screening is available, it is clear that many challenges and questions remain regarding issues such as the best screening methods, loss to follow-up, family support, cost effectiveness, and quality control.

Although good data on the prevalence of congenital hearing loss is not available in many parts of the world, more and more studies are indicating that at least 2–3 children per thousand have some level of permanent congenital hearing loss. In some developing countries, the figure may be much higher. Infants and young children with permanent hearing loss almost always experience delayed development of speech, language and cognitive skills, which results in slow learning and difficulty progressing in school. If hearing-impaired babies are identified early and provided with appropriate support and interventions, many of them will reach levels of achievement similar or equal to their fully hearing peers.

Based upon the presentations given on the status of newborn and infant hearing screening and intervention programmes in various countries, meeting participants discussed and formulated a number of guiding principles that could be used by countries to improve the early detection of hearing loss. The considerations and guiding principles which follow set out the current thinking on how best to implement newborn and infant hearing screening programmes in a range of economic settings and in the context of different health care systems.

3.1 Etiology of hearing loss in infants and young children

Although the etiology of congenital or early-onset hearing loss most likely varies from country to country, there is widespread agreement that at least half of such hearing loss is due to genetic mutations. Infections (such as cytomegalovirus, rubella, and meningitis); diseases (such as measles, mumps and chronic otitis media); adverse perinatal conditions (such as birth asphyxia, low birth weight and hyperbilirubinaemia); and head trauma can also cause hearing loss. Regardless of its cause, unidentified hearing loss at birth or during the first few years of life adversely affects speech and language development, as well as success in school and social-emotional development. In the absence of universal hearing screening programmes for neonates and infants, a significant number of children with hearing loss are not detected until well beyond the neonatal period. In fact, it is not unusual for the diagnosis of milder hearing loss and unilateral hearing loss to be delayed until children are six years of age or older. When identification and intervention occur during the first few months of life, infants and young children with hearing loss perform dramatically better on school-related measures such as vocabulary development, articulation, social adjustment and behaviour.

3.2 Use of case definition in newborn and infant hearing screening

Most existing newborn and infant hearing screening programmes target permanent sensory or conductive hearing loss, averaging 30–40 dB or more in the frequency region important for speech recognition (approximately 500–4000 Hertz). There is growing agreement that milder hearing loss (20–30 dB) is also important and needs to be detected and treated early because of the negative consequences of such losses on the later development of children. Some programmes are designed to identify only bilateral hearing loss, but there is growing agreement that the identification of unilateral hearing loss is also important and valuable. Similarly, fluctuating conductive hearing losses caused by otitis media are generally not targeted by newborn hearing screening programmes – even though chronic otitis media has serious negative consequences. In all cases, the use of an appropriate and consistent case definition will help to determine the focus of newborn and infant hearing screening programmes and greatly facilitate assessment of their impact.

3.3 Approaches and methods used in newborn and infant hearing screening

As shown in **Table 1**, a number of different approaches can be used to identify hearing loss in neonates and infants. There is widespread agreement that the best approach is universal physiological screening using otoacoustic emissions (OAE) testing or auditory brainstem response (ABR). However, where such programmes are not possible because of financial considerations or because appropriate equipment and personnel are unavailable (or because of a need to start in a more limited way and work towards universal physiological screening) other approaches can be valuable interim measures.

Table 1: Newborn and Infant Hearing Screening Methods

| | | Screening methods | | |
|------------------------------------|-----------------------------|----------------------|-------------|---------------|
| | | Family questionnaire | Behavioural | Physiological |
| Neonates or infants to be screened | Geographical subset | | | |
| | SCBU/NICU babies | | | |
| | Babies with risk factors | | | |
| | Universal hearing screening | | | |

Screening methods

Depending on the circumstances – and based on evidence from well-conducted pilot studies – different methods can be used to decide which neonates and infants should be referred for a complete diagnostic audiological evaluation. Although physiological screening is the most accurate, it may not be feasible in all circumstances.

- **Family questionnaires** – parents or other caregivers may be asked about the response of their neonate or infant to sounds and their use of language, including early indicators of language such as babbling and other vocalizations. Babies performing poorly on such measures can then be referred for more-comprehensive audiological assessment. Ideally, such questionnaires should be validated before widespread application.
- **Behavioural measures** – the responses of babies to behavioural measuring devices (ranging from simple noisemakers to more sophisticated audiological equipment and procedures) can also be used to identify hearing loss. However, such methods produce high levels of both false negatives and false positives with babies less than 12 months old.
- **Physiological measures** – measures of OAE or ABR have been shown to be effective methods of screening for hearing loss in neonates and infants. OAE measures are obtained from the ear canal by using a sensitive microphone within a probe assembly that records cochlear responses to acoustic stimuli. OAEs measure the status of the peripheral auditory system extending to the cochlear outer hair cells. ABR measurements are obtained from surface electrodes that record neural activity generated in the auditory nerve and brainstem in response to acoustic stimuli delivered via an earphone. Screening ABR measurements are usually automated (AABR) and reflect the status of the peripheral auditory system, the eighth nerve, and the brainstem auditory pathway.

Neonates or infants to be screened

In order to identify all neonates and infants with permanent hearing loss in a particular area, all babies in that area need to be screened. In **Table 1** and elsewhere in this report this is referred to as “universal hearing screening”. Where this is not feasible, especially in the early stages of implementation, some programmes may instead focus on a subset of babies in that area.

- **Geographical subset** – when newborn hearing screening programmes are starting up, it is not unusual for them to focus first on babies in a particular geographical region because of issues of accessibility and the availability of equipment and personnel. Alternatively, some programmes use this approach to pilot-test their procedures and the benefits associated with hearing screening activities.
- **SCBU/NICU babies** – because the incidence of permanent hearing loss is 10–20 times higher among neonates who require intensive medical care during the first few days of life, hearing screening programmes that are unable to screen all babies often focus on those admitted to a SCBU/NICU.
- **Babies with risk factors** – many studies have shown that babies who exhibit recognized hearing-loss risk factors have a much higher rate of hearing loss than those who do not. Such factors include (but are not limited to) a family history of permanent childhood hearing loss; infections such as cytomegalovirus, herpes, rubella, syphilis, or toxoplasmosis; cranial-facial anomalies; syndromes associated with hearing loss; adverse perinatal conditions such as birth asphyxia, low birth weight and hyperbilirubinaemia; and neurodegenerative disorders such as Friedreich-Ataxia. Consequently, when universal

hearing screening is not possible, programmes sometimes focus on babies exhibiting risk factors. This approach is similar to screening only babies in the SCBU/NICU – however, a significant number of babies with risk factors (such as those who have a family history of permanent childhood hearing loss) will not be in a SCBU/NICU. Conversely, approximately half of babies with congenital hearing loss will not exhibit any risk factors. The risk factors that are most predictive of hearing loss in babies will vary from country to country. It is therefore important that the risk factors used are good predictors of hearing loss in that particular geographical area.

- **Universal hearing screening** – to identify all neonates and infants with permanent hearing loss it is necessary to screen all babies in the targeted area. Universal hearing screening using physiological measures (either OAE or AABR) should therefore be the goal wherever feasible.

Approaches

Where universal hearing screening using physiological measures is not possible, the other screening approaches shown in **Table 1** can be used to identify a significant number of babies with hearing loss. It should be remembered that each of the methods shown could be applied in locations other than a hospital (such as well-child care or immunization clinics, or other settings where infants and young children are likely to be present in large numbers). When conducting physiological screening, it is crucially important to make sure that there is local evidence that the equipment is functioning correctly.

It is also important for programme organizers to specify the type of hearing loss being targeted by the screening programme. If unilateral hearing loss is targeted, the procedures will be different than if only bilateral hearing loss is being targeted. Additionally, although it is best to identify permanent hearing loss as early as possible (preferably within the first month of life) it is still valuable to identify it in infants who are a few months older. This will be very relevant in settings where the only places where screening can be feasibly performed are not available until babies are 6–12 months of age.

Programmes should ideally aim to screen all neonates in a given area before **1 month** of age. A diagnostic audiological evaluation should be completed for those who do not pass the screening as soon as possible and by no later than **3 months** of age. Audiological, medical and educational services should then be provided to infants diagnosed with hearing loss as soon as possible and by no later than **6 months** of age. There is increasing evidence that infants and young children with permanent hearing loss have better outcomes the sooner they begin early-intervention programmes.

The specific population to be targeted will depend on circumstances within the country. For example, lack of equipment and screening personnel in parts of the country may make it advisable to use a questionnaire or behavioural method in some locations. Risk factors may also differ between and even within countries. For example, if some areas of a country have high rates of consanguinity, the incidence of hearing loss is likely to be much higher compared to areas where consanguinity rates are low. In areas with a higher incidence of rubella or measles, hearing loss will again be much higher.

The ideal is for all countries to work towards the universal physiological hearing screening of all neonates. In cases where that is not possible, physiological screening of a targeted population – with either a questionnaire or behavioural method used for the remainder of the

population – will still be a valuable approach. In areas where the collecting of risk-factor information is difficult, screening all neonates and infants who have been in a SCBU/NICU can be highly valuable as this is a relatively good proxy measure of risk factors. It should be remembered, however, that half of all children with hearing loss do not exhibit any risk factors, so the eventual goal should remain the universal physiological hearing screening of all neonates.

3.4 Programme implementation

Differences between countries in terms of health care systems and the availability of resources and personnel to implement hearing screening programmes will result in very different approaches to implementation. Evidence from successful newborn and infant hearing screening programmes indicates that the following factors are associated with better outcomes:

- Programmes need to have clearly stated goals with well-specified roles and responsibilities for all those involved.
- Each hearing screening programme needs to have a clearly designated person who is responsible for the programme.
- A clearly defined screening protocol based on local circumstances should be documented and made available to all stakeholders.
- Regular monitoring should be carried out to ensure that the protocol is being correctly implemented.
- Staff conducting the screening need to be specifically trained in what they are expected to do, and such training needs to include the hands-on use of whatever equipment, behavioural method or questionnaire is being used.
- Training needs to cover not only the implementation of the screening protocol but also how to inform parents of the results; how to record and report screening information; and on the procedures that need to be followed in the hospital or other screening setting.
- Quality-assurance procedures should be implemented to document results and show when these are not consistent with expectations; track what happens to all those who do not pass the screening; and document any failures of follow-up procedures with families.

In all cases, documenting screening results and tracking what happens to individuals following screening is absolutely essential. It is important to remember that screening is only the first step in the process of helping those with hearing loss achieve good outcomes. For screening to be effective, it must be linked to an early hearing detection and intervention (EHDI) system which includes timely and appropriate diagnosis, early intervention and family-support programmes.

In most cases, it makes sense to coordinate hearing screening with other screening activities – such as screening for inborn errors of metabolism or haemoglobinopathies based on the dried bloodspot test. Consideration should also be given to coordinating the EHDI system with existing programmes such as those for immunization or well-child care in community settings. The follow-up procedures from such programmes may be very useful in supporting the follow-up of hearing screening programmes.

If a health record already exists for each infant, the results of hearing screening should be recorded there to ensure that they receive the follow-up services they need. In all cases,

screening and recording should be done in a way that adheres to local regulations related to privacy and the confidentiality of medical information.

It is also important to link family-support activities to screening, diagnosis and early intervention programmes. Families need guidance and support at various stages, including:

- information prior to screening on why the early identification of hearing loss is so important, and on how the screening will be done;
- information for those whose babies do not pass the screening on specifically what needs to be done, and what resources are available to help – including answers to any questions the family may have; and
- information as part of the provision of support and assistance during the diagnostic and treatment process.

An important component of support is the opportunity for the families of those newly identified with hearing loss to have contact with other families who have had similar experiences and come from similar cultural and socioeconomic backgrounds. Parent associations and other support groups can be an important part of the infrastructure put in place to assist families. Creating registries of people who have children with hearing loss can be valuable if it is done in a way that provides adequate protection to fully meet privacy and confidentiality concerns.

Ensuring high levels of awareness among stakeholders of the vital importance of early identification of hearing loss is crucial. Systematic and comprehensive information should therefore be provided to parents, physicians, audiologists, policy-makers, educators and all other stakeholders on the importance of hearing, the consequences of not identifying hearing loss early, and the benefits of identifying and treating hearing loss. Achieving such levels of awareness will generally require a variety of approaches (such as printed materials, web sites, newspapers, training of health care providers, radio and television announcements, and use of social media). It is important that all public-awareness information be culturally appropriate and sensitive to differences in language and customs within a particular area. Many examples of materials that have been used in countries that have already implemented successful newborn and infant hearing screening programmes are available, but these materials will often have to be modified appropriately for use in a new area.

It is particularly important to make sure that those who provide health care to very young children are educated on the importance of early identification of hearing loss, as well as on the newborn and infant hearing screening procedures being implemented in their area. Parents often turn to health care providers for advice and assistance. Health care providers will only be able to provide appropriate support and assistance if they have been well educated. Primary health care providers are often in a good position to help the family access all the various services they need, such as ophthalmological examinations, genetic evaluations and counselling, speech-language therapy and enrolment in educational programmes.

The regular monitoring of screening programmes and outcomes is also important to ensure that they are functioning as intended. Some type of certification process for those involved in screening, diagnosis and early intervention services should be considered to maintain quality and continually improve the programme. In the absence of ongoing monitoring and support, programmes can drift and become less efficient.

3.5 Cost-effectiveness

Although there is widespread agreement that identifying permanent hearing loss and providing treatment to infants and support to families has long-term beneficial effects, there is relatively little data on the cost-effectiveness of various approaches, or on the cost-benefit of newborn and infant hearing screening. Several studies have demonstrated that universal hearing screening using physiological measures is more cost effective than either targeted screening using physiological measures or the use of questionnaires or behavioural approaches. However, in areas where screening is just getting under way, universal newborn and infant hearing screening may not be feasible. Furthermore, the conditions and variables involved in evaluating the cost-effectiveness of various approaches will vary from country to country – and even between locations within the same country. Therefore, it is important that each newborn and infant hearing screening programme documents its procedures, outcomes and costs.

3.6 Policy and legislative issues

Legislation and regulation function very differently in different countries. It is important to ensure that those providing services related to the early identification of hearing loss meet the standards of care determined by local and national professional associations. In some cases, legislation can be very useful in ensuring that hearing screening is available to all, and that standards are being met. Locally relevant legislative, regulatory and professional standards should all be used to ensure that individuals receive the best possible services and the most timely care.

It is important that screening programmes be set up in such a way that local governments are responsible for the ongoing financing and quality of all components of the early hearing detection and intervention system – from screening through to intervention. Legislation or regulatory standards and professional associations can be used to help achieve this goal – and this will require ongoing work. Involving key governmental agencies and policy-makers can also help to lay the foundation for ongoing data collection that can be used in cost-benefit analyses, and in determining how the programme can continue to be refined and improved. In line with Resolution WHA48.9, opportunities for public-private partnership and the active engagement of nongovernmental organizations in the design and implementation of hearing screening programmes should also be considered.

Summary

The benefits of early hearing detection and intervention (EHDI) programmes through which permanent hearing loss is identified during the first few months of life and linked to medical, audiological and educational interventions for affected babies and their families have been frequently demonstrated.

Successful newborn and infant hearing screening programmes have been implemented in many different countries using a variety of screening methods, protocols, and linkages to existing health care, social and educational systems.

The consensus of meeting participants is that the aims of such programmes are widely accepted as both highly worthwhile and attainable, and that they should be expanded to include all neonates and infants. Although universal newborn hearing screening using OAE or AABR should be the goal for all countries, interim approaches using targeted screening based on questionnaires, behavioural methods and/or physiological methods guided by evidence from well-conducted pilot studies will also be beneficial. Whatever approach is used, it is important that the EHDI programme is linked to existing health care, social and educational systems, and that the procedures and outcomes of the programme be documented so that ongoing quality-assurance activities can be implemented and experiences shared.

Annex I: Resolution WHA48.9

The Forty-eighth World Health Assembly

Recalling resolution WHA38.19 on prevention of hearing impairment and deafness, and WHA42.28 on disability prevention and rehabilitation;

Concerned at the growing problem of largely preventable hearing impairment in the world, where at present 120 million people are estimated to have disabling hearing difficulties;

Recognizing that severe hearing impairment in children constitutes a particularly serious obstacle to optimal development and education, including language acquisition, and that hearing difficulties leading to communication problems are a major subject of concern in the elderly and thus one of growing worldwide importance in view of the aging of populations;

Aware of the significant public health aspects of avoidable hearing loss, related to causes such as congenital disorders and infectious diseases, as well as use of ototoxic drugs and exposure to excessive noise;

Noting the persistent inadequacy of resources for hearing impairment prevention, despite the increasing commitment of international nongovernmental organizations,

1. URGES Member States:

- (1) to prepare national plans for the prevention and control of major causes of avoidable hearing loss, and for early detection in babies, toddlers, and children, as well as in the elderly, within the framework of primary health care;
- (2) to take advantage of existing guidelines and regulations or to introduce appropriate legislation for the proper management of particularly important causes of deafness and hearing impairment, such as otitis media, use of ototoxic drugs and harmful exposure to noise, including noise in the work environment and loud music;
- (3) to ensure the highest possible coverage of childhood immunization against the target diseases of the Expanded Programme on Immunization and against mumps, rubella and (meningococcal) meningitis whenever possible;
- (4) to consider the setting-up of mechanisms for collaboration with nongovernmental or other organizations for support to, and coordination of, action to prevent hearing impairment at country level, including the detection of hereditary factors, by genetic counselling;
- (5) to ensure appropriate public information and education for hearing protection and conservation in particularly vulnerable or exposed population groups;

2. REQUESTS the Director-General:

- (1) to further technical cooperation in the prevention of hearing impairments, including the development of appropriate technical guidelines;
- (2) to cooperate with countries in the assessment of hearing loss as a public health problem;
- (3) to support, to the extent that resources are available, the planning, implementation, monitoring and evaluation of measures in countries to prevent hearing impairment;
- (4) to develop further collaboration and coordination with nongovernmental and other interested organizations and institutions;
- (5) to promote and support, to the extent feasible, applied and operations research for the optimal prevention and treatment of major causes of hearing impairment;
- (6) to mobilize extrabudgetary resources to strengthen technical cooperation in hearing impairment prevention, including possible support from organizations concerned;
- (7) to keep the Executive Board and the Health Assembly informed of progress, as appropriate.

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