



ONTARIO

MINISTRY
of

Health and Long-Term Care

INFANT HEARING PROGRAM

Well-baby (DPOAE) Screening
Protocol and Training Manual

INFANT HEARING PROGRAM

INFANT HEARING SCREENING AND COMMUNICATION DEVELOPMENT PROGRAM: OVERVIEW

INTRODUCTION

The Infant Hearing Screening and Communication Development Program (Infant Hearing Program) was announced in the Ontario Government's 2000 Budget. This Program builds on the previously introduced government programs designed to give children a better start in life, including the Preschool Speech and Language Initiative.

This document provides an addendum to guidelines developed to assist in the local implementation of the Infant Hearing Program across Ontario. A province wide standard will ensure that infants born deaf or hard of hearing or at risk of developing hearing loss in early childhood will be identified and that access to the necessary services and supports will be available to these babies and their families.

CONTEXT

The importance of acquiring communication skills early in life is well understood. Research has shown that delay in language development can have significant impact on cognitive, emotional and psychosocial development and that language development is a prime indicator of future academic success. Children born with permanent hearing loss or who acquire permanent hearing loss during the early years of life are at risk for delay in language development, if identification and mediation are not initiated early. Further, it is well understood that the earlier the hearing loss is identified, and supports and services for communication development are provided, the better the acquisition of language skills.

Screening of newborns to detect permanent hearing loss has been advocated for many years. In Ontario screening of infants at high risk for hearing loss has been provided in some hospitals, but these services have reached only a small number of the 140,000 babies born in the province each year. The average age of identification of hearing loss in young children has remained about 2 ½ years of age in Ontario (Durieux-Smith & Whittingham, 2000), while the recommended maximum age is 6 months (JCIH, 2000).

VISION

Children who are born deaf or hard-of-hearing or at risk for developing hearing loss in early childhood will be identified and will be offered services and supports to assist them and their families in the development of communication. According to the choices made by the family, children identified as deaf or hard of hearing will be assisted in the acquisition of the communication skills needed for performance of daily activities and for personal and social sufficiency at home and at school.

GOALS OF THE PROGRAM

The goals of the program are to provide an integrated system of services in all parts of Ontario that will:

1. identify infants born deaf or hard of hearing or at risk for developing hearing loss in early childhood and
2. provide child and family centered services to support communication development.

PRINCIPLES

1. There will be access to the services of this program across Ontario
2. Every aspect of this program will be provided based on fully informed parent/guardian choice and consent, and will comply with confidentiality requirements.
3. All services will be child and family centered taking into consideration the cultural and ethnic diversity of the people of Ontario.
4. A seamless system of services will be developed that integrates this program with other existing children's programs and services.
5. The components of this program will be developed using the principles of evidence based practice.
6. The program will be monitored and evaluated on an ongoing basis.
7. The quality of the program will be continuously improved based on the evaluations.

THE PROGRAM

The Infant Hearing Screening and Communication Development Program (Infant Hearing Program) has three major components.

1. Universal Hearing Screening
2. Hearing Loss Confirmation and Audiologic Assessment
3. Follow up Support and Services

Training is provided for individuals who are involved in the delivery of all aspects of the program. Detailed protocols have been developed and will be followed for delivery of all components of the Program. These protocols will be reviewed and changed as required to reflect current evidence based practice.

The Program is administered through the infrastructure of the Preschool Speech and Language Initiative (PSL) using 12 Coordinating PSL Systems to coordinate local service delivery.

PROGRAM COMPONENTS

(1). Universal Newborn Hearing Screening

The hearing screening component of this program is designed, in keeping with the most current evidence, to achieve as low a false positive rate as possible, ideally less than 4%. It is expected that the model will constantly change over time as new evidence provides information of improved techniques and methodology.

As planned there are 4 approaches to the Universal Screening:

- 1) HOSPITAL PREDISCHARGE WELL BABY SCREENING

- 2) HOSPITAL PREDISCHARGE HIGH RISK BABY (NICU) SCREENING
- 3) WELL BABY SCREENING IN MIDWIFERY CARE
- 4) COMMUNITY SCREENING AND HIGH RISK MONITORING

1) HOSPITAL PREDISCHARGE WELL BABY SCREENING

The mothers of all newborns who do not have any known risk factors for congenital hearing loss will be offered a hearing screening for their baby prior to discharge from the hospital birth admission.

In keeping with the most recent evidence the "Well Baby Screening" will be a 2 stage process.

i) STAGE 1

The Stage 1 process consists of 2 parts, babies who receive a "refer" result from part 1 will have the second part of the screening. Part 1 of the Well Baby Screening will be done using Automated Distortion Product Otoacoustic Emissions (ADPOAE) technology. Babies with a "refer" result from the DPOAE, should have the second part of the Stage 1 process, which is a screening using Automated Auditory Brainstem Response (AABR). Ideally this will occur before the baby is discharged from hospital.

ii) STAGE 2

Every well baby with a "refer" result from the pre-discharge screening will receive another screen using the Automated Auditory Brainstem Response (AABR) technology. Ideally this Stage 2 screening will be arranged after 2 to 3 weeks to allow time for the resolution of any middle ear disease that may cause a false positive result. Babies with a "refer" result from Stage 2 screening will then receive an audiological assessment for confirmation of hearing loss.

2) HOSPITAL PREDISCHARGE HIGH RISK BABY (NICU) SCREENING

Any baby with risk factors for congenital hearing loss will be screened using Automated Auditory Brainstem Response (AABR) technology. This screening is a 1 Stage process. Babies with a "refer" result from this screening will go directly for audiological assessment.

Many babies who spend time in the NICU have risk factors for progressive or early-onset hearing loss. Therefore, even if these babies pass the Stage 1 screening procedure, they will be followed through repeat Stage 1 ADPOAE screenings until they are 3 years of age.

3) WELL BABY SCREENING IN MIDWIFERY CARE

The mothers of all newborns who do not have any known risk factors for congenital hearing loss who are under the care of a midwife will be offered a hearing screening for their baby at the first regularly scheduled office visit post partum. The midwife will screen the baby's hearing as part of routine well baby care using DPOAE technology (as described below).

Those babies who are admitted to NICU will be screened prior to hospital discharge using AABR technology by the hospital screening personnel.

In keeping with the most recent evidence the "Well Baby Screening" will be a 2 stage process.

- i) STAGE 1
The Stage 1 process for the Well Baby Screening will be done using Automated Distortion Product Otoacoustic Emissions (ADPOAE) technology. Babies with a “refer” result from the DPOAE, will have a STAGE 2 screening in the community.
 - ii) STAGE 2
Every well baby with a “refer” result from the STAGE 1 screening will receive another screen using the Automated Auditory Brainstem Response (AABR) technology. Ideally this Stage 2 screening will be arranged after 2 to 3 weeks to allow time for the resolution of any middle ear disease that may cause a false positive result. Babies with a “refer” result from Stage 2 screening will then receive an audiological assessment for confirmation of hearing loss.
- 4) COMMUNITY SCREENING
Regularly scheduled screening clinics will be offered in community locations throughout each of the 12 regions to provide screening to babies who missed the hospital predischarge screening.
These clinics will also be used to provide the Stage 2 screening for those babies who had a “refer” result from Stage 1.

(2). Hearing loss confirmation and audiologic assessment

All babies who receive a “refer” result from the screening will be sent to an audiologist for assessment. The system is designed so that a completed audiologic assessment is performed between 8 and 12 weeks of age. Evidence based protocol for audiologic assessment of infants has been developed through a consultation process with a representative group of provincial audiologists. The protocol will be reviewed and updated on a regular basis to ensure the procedures are consistent with current evidence based practice. The results of the audiologic assessment will be explained to parents by the audiologist and the appropriate referrals initiated, if indicated. All audiologists and agencies employing audiologists must agree to use the specified equipment, perform the assessment protocol as described, adhere to the Infant Hearing Program counseling principles, and provide the test results to the local coordinating PSL System.

Medical Referral and Management

All babies with a confirmed hearing loss must be referred to an otolaryngologist, preferably with pediatric experience, for assessment and medical management if it is indicated. For those babies who are candidates for amplification, it is a requirement of the Assistive Devices Program that an otolaryngologist assess the child, confirm the absence of contraindications to non-medical intervention and sign the forms.

(3). Follow up support and services

A. Family Support and Access to Information

It is the policy of the Infant Hearing Program that parents of babies identified as deaf or hard of hearing will have access to unbiased information on all approaches for communication available to their child. It will be the decision of

the parents as to what communication approach their child will use and it will be a fully informed choice.

Parents will be provided with counseling and support as they adjust to the knowledge that their child is deaf or hard of hearing and go through the decision making process to choose a communication approach. They will be provided with information on all communication approaches and on the various stakeholders that represent the different philosophies.

B. Technology

(a) Hearing Aid Selection and Verification

All babies with a confirmed permanent hearing loss, whose parents have chosen assistive technology, will be seen by an audiologist for hearing aid selection and verification. Evidence based protocol for hearing aid selection and fitting in infants has been developed through a consultation process with a representative group of provincial audiologists. Audiologists who are providing this service have completed training on the protocol. The protocol must be followed in choosing and fitting hearing aids for a baby as part of this program. The protocol will be reviewed and updated on a regular basis to ensure the procedures are based on current evidence based practice. All audiologists and agencies employing audiologists must agree to use the specified equipment, perform the selection and verification protocols as described, and provide appropriate documentation to the Coordinating PSL System.

Only audiologists who are registered prescribers with the Assistive Devices Program will be permitted to prescribe hearing aids for babies in this program.

(b) Hearing Aid Dispensing

A protocol for the dispensing of hearing aids for an infant has been developed through a consultation process with hearing aid dispensers, including dispensing audiologists, who have expertise in fitting infants. The protocol must be followed when fitting hearing aids on a baby. Dispensers who wish to provide this service will complete the training on the protocol. The protocol will be reviewed and updated on a regular basis to ensure the procedures are based on current evidence based practice.

Only individuals who are registered dispensers with the Assistive Devices Program will be permitted to dispense hearing aids to babies in this program.

(c) Other Assistive Technology

Some babies, whose parents have chosen the option, may be candidates for assistive listening devices other than personally worn hearing aids. If the audiologist determines that the infant would benefit from other assistive technology, such as FM systems, cochlear implant, or Bone Anchored Hearing Aid, the audiologist will provide the prescription to the parents or a referral to an agency that provides the service as soon as is appropriate.

C. Communication Development

As soon as the family has chosen an approach for communication with their baby, any support or services that may be required to assist the baby in learning language will be provided. Hearing parents who have chosen to communicate

with their baby using sign language as a first language will be given the opportunity to access sign language instruction. Those families who choose to use oral language with their baby will have access to auditory-verbal therapy or auditory/oral therapy. Services will be provided for the aforementioned approaches through the child's local PSL System or by other agencies or individuals as determined by each regional plan. The goal will be to provide access as close to the child's home as reasonably possible.

PROGRAM OBJECTIVES

- 1) A minimum of 95% of the target population will receive timely and appropriate screening
- 2) All babies accessed will have received a successful (two-stage) screening by 2 months corrected age or within 2 months of discharge from an NICU.
- 3) The referral rate for audiologic evaluation will be no more than 5% within 1 year and 4% or less within the 2nd year after program initiation.
- 4) At least 90% of babies who have a screening result of "refer" will receive an audiologic assessment.
- 5) The audiologic assessment will occur no earlier than 2 months corrected age, but no later than 4 months.
- 6) Infants with a confirmed hearing loss will begin use of amplification, when appropriate and chosen by the family, within 2 months of confirmation of the hearing loss, but no earlier than 3 months of age and no later than 6 months of age, wherever possible.
- 7) Infants with a confirmed hearing loss will access the services to support communication development chosen by the family within 2 months of confirmation of the hearing loss, but no later than 6 months of age.

PROGAM EVALUATION

The Infant Hearing Program will be evaluated on an ongoing annual basis. In the first 2 years the evaluation will focus on administrative objectives and process outcomes. Following complete implementation of the program, child performance outcomes will be developed and the program will be evaluated based on those indicators.

A quality assurance process is under development for service providers and several mechanisms of ongoing operational support are under consideration. These may include web-based information and educational resources, case-conferencing, internet, fax or phone consultations for discussion of results and outcomes and for other clinical support issues. Seminars, updates and other traditional avenues for continuing education are also under consideration.

The clinical support mechanisms will complement other aspects of program quality management which may include client satisfaction survey, case review, random audits of clinical records and/or site visits. These procedures are now widely recognized as appropriate in the quality management of medical and allied health services delivery. Regional and provincial procedures to ensure service quality will be implemented on an ongoing basis.

SYSTEM DESIGN

The Infant Hearing Program is developed across the province based on 12 service delivery regions. One PSL System from each region has been designated as the Coordinating System for the region. These service delivery regions have been determined based on a number of criteria including: the presence of at least one audiologist with experience in assessment of infants or young children; linkages or possible linkages between the audiologist(s) and local neonatal intensive care units; population size; geographic distribution; and a local Preschool Speech and Language System (PSL) that is using the Ministry of Health and Long- Term Care PSL database (PSL ISCIS) to record and report statistics.

In each region, one local Preschool Speech and Language System has been designated as the lead with responsibility to co-ordinate the planning and implementation of this program. Partners involved in various aspects of the planning include Ministry of Health and Long Term Care Regional Managers, Provincial Infant Hearing Program staff, other local PSL systems, hospitals and audiology departments, local audiologists with expertise in assessment, hearing aid selection and dispensing for infants, hearing aid dispensers with experience with infants, the education sector, stakeholder/parent organizations and any other individuals or organizations that provide service to deaf or hard of hearing children.

DATA MANAGEMENT AND COMPLETION OF FORMS

Data for the Infant Hearing Program (IHP) is captured in the Preschool Speech and Language (PSL) version of ISCIS (Integrated Services for Children Information System). Each IH Regional Co-ordinating Agency will enter the data for babies who reside in their region.

Type of data being collected includes:

- Demographic data (name, address, date of birth, etc. for the child and for the family). Note that the health card number is not required.
- Service delivery data
- Dates of screenings/assessments/interventions
- Service status (e.g., waiting, accessing service, etc.)
- Whether the child is High Risk or not (of being born deaf or hard of hearing or of developing a hearing loss in early childhood)
- Location where service was provided
- Names of screening and other personnel
- Results of screenings/assessments

PURPOSE OF DATA COLLECTION

1. Service delivery

These data are being used to track babies and their families as they pass through the various stages of the IHP; to make sure no baby gets missed; to track wait times between service delivery points and to schedule appointments. Capturing these data is an essential part of service delivery. Parents should be encouraged to consent to sharing the above demographic and service delivery data within their regional IH System to enable services to be provided.

2. Monitoring of the Program

The Ministry of Health and Long-Term Care will receive aggregate data (no individualized or personally identifiable data) on a quarterly and annual basis from each regional IHP agency. Individualized data will only be shared at the local level.

CONSENT

The hearing screening is a quick, easy, non-invasive screening test, which does not involve the performance of any of the controlled acts under the *Regulated Health Professions Act, 1991*. However, provision of parental consent is required. The importance of hearing screening and the procedure itself should be explained to the parent prior to doing the screen. This includes preparing the parent for both pass and refer outcomes of the screen and explaining the results in more detail afterwards.

RELEASE OF INFORMATION

It is important that parents give consent to share information between specified agencies within the local/regional IHP System. As mentioned above, the IHP coordinating agency must have information on the babies who have received the screening (and any other services) in order to track that baby/family and make sure they receive appropriate follow-up care. The provision of this kind of consent is essential in order to provide service. It is understood that local procedures for authorization for release of information between one agency and another will be followed.

PERFORMING THE SCREENING

STAGE 1 Screening with Distortion Product Otoacoustic Emissions (DPOAE)

Screening of hearing with DPOAE is usually quick, easy to do and reliable. It is completely objective. No behavioral response is needed from the baby, who ideally is tested asleep. Under good conditions, it takes less than two minutes to screen a baby, less than one minute per ear. The testing is done using a hand-held, automatic screening unit.

The test involves presenting sounds to the baby through a special probe that is gently inserted into the entrance of the ear canal. The normal inner ear actually generates tiny sounds in response to the stimulus, and these sounds are the otoacoustic emissions (OAE). A computer inside the screening unit distinguishes the OAE from ambient sound, which is always present in the baby's ear canal. Some ambient sound comes from the room where the test is done. Other sounds are generated if the baby or the probe moves during the test. The computer decides whether a real OAE is present, or just ambient sound, and then displays a 'pass' or 'refer' result.

The important ingredients of a successful screening test are a quiet room, a quiet baby and correct positioning of the probe in the ear. By a quiet room is meant a room in which it would be possible to have a conversation by whispering. There should be no talking during the test, which will not last more than about a minute. If the environment is obviously too noisy, and cannot be made more quiet, it may be a good idea to go into another area for few minutes, if available.

The ideal subject is a sleeping baby, although it is possible to test a baby who is awake but laying still and quietly. If the baby is fussing, wriggling, fretting or crying, a successful test is unlikely. However, most neonates spend most of their time sleeping, and they can be fussing one minute and sleeping the next, so there are usually going to be plenty of opportunity to test. If the baby is not asleep or at least laying quietly, it may be necessary to wait a few minutes. Babies can be tested in their mothers' arms, if necessary but cannot usually be tested while actually feeding, because the act of sucking moves the walls of the ear canal.

If the environment is less than satisfactory but the screener has done what she or he can within reason to create a good test situation, the test can be tried on one ear, and if a pass is obtained then the other ear should be tested. It does not matter which ear is done first. If any ear produces a "refer" result the test should be tried again on that ear. If there is an obvious cause of failure the test should be re-tried after an attempt to solve the problem. There is no need to retest an ear that has passed.

The screening unit is light, portable, and easy to use and powered by a rechargeable battery. Simple operating instructions are displayed when necessary. Screening is totally automatic, and the device will check to see if the probe has been properly fitted to the ear canal; if not, a message is displayed. Test results are stored automatically, and may be printed out on a custom mini-printer, when convenient.

Parents usually want to know the results of the test right away. If there is a pass in both ears, there is usually no problem. If one or both ears give a refer result, then it is important to reassure the parent(s) that all this means is that a more detailed hearing check-up would be a good idea, preferably within a few weeks. The word

'fail' is never used in connection with a screening result, because it alarms parents unnecessarily and because it does not capture the true significance of not recording an OAE. If the test is done properly, less than about 5% of well babies will fail it. If the baby does indeed fail, what it means is that there is an increased *risk* of a hearing problem, but not that there *is* a hearing problem. The odds are that a baby who fails the screen will have normal hearing, but virtually ALL babies who DO have hearing loss will fail. Leading authorities on hearing health consider the false-positive rate for this test to be a perfectly acceptable price to pay for the ability to detect all babies with hearing problems. This test is much more reliable than any possible test based on observing the baby's behavior. Behavioral screening tests are no longer recommended.

The fact that the screening test is obviously not behavioral means that in the event of a refer result it can be emphasized that this initial screening test does not actually measure true hearing. It measures 'echoes that come out of the baby's ear, and is a good test but certainly not perfect'.

The most likely reasons for not getting a pass result are that the conditions in the ear canal were not quiet enough. The OAE are very, very faint sounds and can be hard to detect. Another possibility is that there was debris in the ear canal, blocking the OAE probe. Also, the baby might have a cold, which may cause a small hearing loss. There are many reasons not to get a pass result, so the parents can be reassured. However, it is certainly desirable, and in the baby's best interests, that they attend for a follow-up check.

The follow-up check is a stage 2 screen using a more advanced test, the AABR (automated auditory brainstem response), that measures the baby's brainwaves (EEG). The AABR test is also quick, painless and automatic, and is best done on a sleeping baby. It is more accurate than the DPOAE test, and the equipment is MUCH more expensive. It usually takes about 15 minutes, in a quiet baby. Most babies will pass this Stage 2 screen.

APPENDIX 1

DEFINITIONS

At Risk/High Risk – There are several factors that indicate if an infant is at risk of having been born deaf or hard of hearing or at risk of developing permanent hearing loss during early childhood. Of these factors, residence in a Level 3, Modified Level 3 or Advanced Level 2 NICU of longer than 48 hours; family history of permanent childhood hearing loss and craniofacial abnormalities associated with certain syndromes which may be related to congenital deafness or hearing loss) will be used by the Infant Hearing Program to indicate “risk”.

Automated Auditory Brainstem Response technology - AABR screening evaluates the function of the auditory pathways through use of electrodes placed on the baby’s scalp and connected to the AABR machine. The machine records electrical responses to sounds as travelling from the inner ear to the brain. A wave with five peaks is produced, which provides information about the baby’s hearing sensitivity by analyzing the size of the peaks. The automated ABR machine allows for computerized interpretation and pass-fail-no result reporting.

Distortion Product Otoacoustic Emissions technology – Evoked otoacoustic emissions occur during or after external acoustic stimulation. This “echo” occurs in almost all ears with normal hearing. DPOAE screening measures the otoacoustic emissions using a two-tone stimulus, which is delivered using a probe tip inserted into the baby’s ear canal (similar to an in-the-ear thermometer). The procedure is non-invasive and does not require sedation if the infant is calm. The test takes approximately 30 seconds to 2 minutes for each ear. DPOAE is used rather than Transient Evoked OAE because these can be recorded in babies with a greater degree of hearing loss, at higher frequencies and with finer frequency resolution.

Progressive Hearing Loss – a hearing loss that is not present at birth but develops during early childhood

APPENDIX 2

CONGENITAL AND NEONATAL RISK FACTORS FOR PERMANENT CHILDHOOD HEARING IMPAIRMENT (PCHI)

Congenital and neonatal risk factors for permanent hearing loss may include:

- birthweight < 1500 g
- APGAR (5 minute) 0-6
- perinatal TORCHES infection – toxoplasmosis, rubella, cytomegalovirus, herpes, syphilis (CMV is especially important)
- postnatal infections associated with hearing impairment, including bacterial meningitis, viral encephalitis or labyrinthitis
- hyperbilirubinemia at serum levels indicating exchange
- Ototoxic medication dosage risk (e.g., double dose error – standard courses of aminoglycoside antibiotics with normal trough levels are no longer considered a significant risk indicator)
- any condition requiring ECMO (extracorporeal membrane oxygenation)
- mechanical ventilation > 5 days
- PPHN (persistent pulmonary hypertension) associated with mechanical ventilation
- indicators of syndromes associated with hearing loss (e.g. Down, Goldenhar, CHARGE)
- craniofacial anomalies (including dysmorphic pinna/canal, ear tags)
- significant head trauma associated with loss of consciousness or skull fracture
- family history of childhood permanent hearing impairment

All newborns with risk indicators for hearing impairment should be screened before discharge from the hospital (if admitted to a special care nursery), using AABR instrumentation. Babies with any of the above indicators are at risk for progressive early childhood hearing loss and will be monitored by the Infant Hearing Program until they are three years old.

A refer result at any point indicates the baby should have a comprehensive hearing assessment. Because these babies have risk indicators, they will go directly to an audiology assessment with only one AABR refer result.

NEONATAL RISK FACTORS

Babies who were successfully screened at birth may be referred to the Infant Hearing Program up to the age of 24 months if they exhibit an acquired, late-onset or progressive risk factor for permanent hearing loss. Hearing screening and assessment services will be provided for these infants as soon as possible upon referral.

Referral must be based on evidence of a valid risk indicator for permanent hearing loss. The indicators include, but should not be limited to:

- postnatal infections associated with hearing impairment, including bacterial meningitis, viral encephalitis or labyrinthitis
- stigmata or other findings associated with a syndrome known to include a sensorineural and/or conductive hearing loss (e.g. neurofibromatosis, osteopetrosis, Usher's syndrome)

- neurodegenerative disorders, such as Hunter syndrome, or sensory motor neuropathies such as Friedreich's ataxia and Charcot-Marie-Tooth syndrome
- significant head trauma associated with loss of consciousness or skull fracture that required neurological consultation
- family history of childhood permanent hearing impairment