

ONTARIO INFANT HEARING PROGRAM
PROTOCOL FOR THE PROVISION OF AMPLIFICATION

Version 3.1, October 2007

**Child Amplification Laboratory
National Centre for Audiology
University of Western Ontario
London, Ontario**

Contact: Marlene Bagatto, AuD

**Voice 519.661.2111 ext 88949
Fax 519.661.3805**

bagatto@nca.uwo.ca

CONTENTS

KEY ELEMENTS

1. PROGRAM CONTEXT
 - 1.1 Document Scope and Format
 - 1.2 IHP Core Principles (S)
 - 1.3 Amplification Goals
 - 1.4 Amplification Objectives (S)
 - 1.5 Target Impairments (S)
 - 1.6 Amplification Candidacy
 - 1.7 Amplification Personnel
 - 1.8 Non-IHP Amplification Services
 - 1.9 Second Opinions
 - 1.10 Instrumentation, Calibration & Supplies (S)
 - 1.11 IHP Protocols & CASLPO Guidelines
 - 1.12 Procedural Concerns
 - 1.13 Deviations from Protocol (S)
 - 1.14 Performance Audits (S)
 - 1.15 Types of Assessment
 - 1.16 Timing of Amplification (S)
 - 1.17 Infection Control Standards
 - 1.18 Calibration
 - 1.19 Otoscopy and Cerumen/Debris
 - 1.20 Amplification Components
 - 1.21 Clinical Records and Reports
 - 1.22 Personal Health Information

2. ASSESSMENT CONSIDERATIONS
 - 2.1 Auditory Characteristics (S)
 - 2.1 Consultation by an Otolaryngologist
 - 2.3 Acoustic Characteristics (S)
 - 2.4 RECD Measurement (S)
 - 2.5 Age-Appropriate Predicted RECD Values (S)

3. PRESCRIPTION OF AMPLIFICATION
 - 3.1 Ear Impressions
 - 3.2 Non-Electroacoustic Characteristics (S)
 - 3.3 Electroacoustic Characteristics (S)
 - 3.4 Device Selection (S)
 - 3.5 Other Assistive Technology (S)

4. VERIFICATION OF AMPLIFICATION

- 4.1 RECD Values**
- 4.2 Electroacoustic Analysis**
- 4.3 Electroacoustic Verification (S)**
- 4.4 Application of Advanced Technologies**
- 4.5 Simulated Real-Ear Measures**
- 4.6 Verification Stimuli**

5. INFORMATION AND INSTRUCTION

- 5.1 Orientation (S)**
- 5.2 Information**
- 5.3 Family Support**

6. OUTCOME EVALUATION

- 6.1 Follow-up Schedule**
- 6.2 Follow-up Visits**
- 6.3 Outcome Measures (S)**

7. TRAINING AND CLINICAL DECISION SUPPORT

- 7.1 Training Requirements and Support Mechanisms**
- 7.2 IHP Website**

APPENDICES

- A References**
- B IHP Instrumentation**
- C IHP Provision of Amplification Audit Process & Indicators**
- D Estimated Hearing Levels (EHLs) and Hearing Aid Fitting**
- E Coupling Insert Earphones to Personal Earmolds**
- F Comparing Audiograms for the Same Infant Over Time**
- G RECD Measurement Procedure**
- H Applying Age-Appropriate Predicted RECD Values**
- I Procedure for Obtaining an Earmold Impression**
- J Deriving 2cc Targets for the Purpose of Selecting a Hearing Instrument**
- K Electroacoustic Verification**
- L Protocol for Fitting FM Systems**
- M Instruction and Information**

1. PROGRAM CONTEXT

1.1 Document Scope and Format

This document addresses the provision of amplification ('Amplification') to infants and pre-school children registered in the Ontario Infant Hearing Program (IHP). Providing amplification includes the process of prescribing a hearing instrument based on appropriate assessment information, verification that the specified acoustical performance targets have been achieved, and evaluation of device effectiveness in daily life. Dispensing includes obtaining ear impressions for earmold fabrication, electroacoustic analysis of the prescribed hearing instruments (ANSI test), adjustment of the hearing instruments to the settings provided, and hearing instrument orientation. This document addresses the provision of amplification (hereafter: 'Amplification') to infants and pre-school children registered in the Ontario Infant Hearing Program (IHP). The document includes (i) Specifications of key contextual and procedural elements (bolded and italicized), (ii) Supplementary text for many elements that includes expanded descriptions of element context, rationale, and issues (denoted by 'S'), (iii) Technical appendices.

1.2 IHP Core Principles

Amplification shall be provided in accordance with the IHP core principles of informed family/caregiver choice and consent, timely provision of unbiased information based on the best available scientific evidence, and sensitivity to family culture and values.

1.3 Amplification Goals

The main goals of Amplification are (i) to provide an amplified speech signal that is consistently audible across levels, (ii) to avoid distortion of varying inputs at prescribed settings for the user, (iii) to ensure the signal is amplifying sounds in as broad a frequency range as possible, and (iv) to include sufficient electroacoustic flexibility to allow for changes in the required frequency/output characteristics related to ear growth or changes in the auditory characteristics of the infant.

1.4 Amplification Objectives

The specific objective of Amplification is to improve functional auditory capacity and participation in hearing- and communication-specific situations. Published reports suggest that early improvement in hearing can facilitate the development of sensory and perceptual skills, receptive and expressive language, speech production and literacy, academic performance and social-emotional growth (Carney & Moeller, 1998).

1.5 Target Impairments

The nominal target PCHI includes any hearing threshold equivalent to 30 dB HL or greater at any frequency in the range 0.5-4 kHz, in either ear. The target PCHI includes conductive impairment associated with structural anomalies of the ear but does NOT include impairment attributable to non-structural middle ear

conditions. The target PCHI also includes Auditory Dys-synchrony (AD, Auditory Neuropathy) and retrocochlear disorders affecting the auditory brainstem.

1.6 Amplification Candidacy

For an infant to be considered a candidate for amplification, PCHI will have been identified through IHP audiologic Assessment. The determination that amplification should be recommended on audiologic grounds is at the discretion of the IHP audiologist. If amplification is indicated audiometrically, is elected by the family after review of the options and information, and if absence of specific contraindications is confirmed by an otolaryngologist, the process of Amplification shall be undertaken in a timely manner.

1.7 Amplification Personnel

The prescription of a hearing instrument is a controlled act that audiologists are authorized to perform under the Audiology and Speech-Language Pathology Act, 1991. All services for Amplification funded by the IHP shall be conducted exclusively by an audiologist registered with the College of Audiologists and Speech-Language Pathologists of Ontario (CASLPO) who are also authorized by the IHP, having received approved training in this Amplification protocol. Audiologists who prescribe hearing instruments for infants in this program shall be registered prescribers with the Assistive Devices Program (ADP).

The dispensing of amplification within the IHP shall be completed by a dispensing audiologist who has been trained in this protocol. Individuals who are registered dispensers with the ADP shall dispense hearing instruments to infants in this program.

1.8 Non-IHP Amplification Services

Amplification services conducted by any person who is not an audiologist authorized by the IHP shall not be funded by the IHP and shall not be deemed to provide a sufficient basis for subsequent management within the IHP. Such services may be valid, but are not auditable by the IHP and therefore, full procedural compliance with this protocol cannot be verified.

1.9 Second Opinions

Review of Amplification for 'second opinion' purposes shall not qualify for IHP funding, except with prior approval of IHP management in individual cases. IHP audiologists may request, either from their regional IHP co-ordinator or from IHP Centres of Excellence, a review of Amplification services at an alternative, specific IHP facility, if they believe that such a review may materially improve the accuracy or effectiveness of the overall Amplification outcome. Also, IHP audiologists may at any time seek expert opinion from the designated provincial Centres of Excellence for this protocol, which are the Otologic Function unit at Mount Sinai Hospital, Toronto and the National Centre for Audiology at the University of Western Ontario, London.

1.10 Instrumentation, Calibration & Supplies

Amplification services shall be conducted only using equipment approved by the IHP maintained according to IHP specifications, and using operating supplies approved by the IHP.

1.11 IHP Protocols & CASLPO Guidelines

All IHP audiologists shall practice IHP Amplification procedures in full compliance with the requirements of both CASLPO and this protocol. IHP protocols may be more specific than CASLPO guidelines. Effort is made to ensure that IHP protocols do not conflict with CASLPO guidelines. Such conflicts may arise inadvertently and if any IHP audiologist perceives such a conflict, the CASLPO guideline shall apply. The audiologist shall notify Mount Sinai Hospital (Dr M Hyde) and/or The National Centre for Audiology at The University of Western Ontario (Dr M Bagatto) of the conflict promptly and the IHP will act to resolve the issue at a provincial level.

1.12 Procedural Concerns

IHP Protocols are evidence-based to the extent possible. Evidence is reviewed by the IHP on an ongoing basis. This may result in specification of procedures that differ from opinions in published journals. Every IHP audiologist shall bring significant procedural concerns to the attention of MSH and/or the NCA. Substantive issues will be addressed by new evidence review, re-examination of existing evidence, and/or provincial consensus development. Changes to IHP protocols are outside the mandate of regional management and shall be authorized ONLY by modification of the relevant IHP protocol document (such as this document), which shall govern IHP provision of amplification throughout Ontario.

1.13 Deviations from Protocol

Departures from this protocol may be appropriate in individual infants and under special circumstances. Their nature and rationale shall be documented in clinical IHP case records. The IHP reserves the right to review documentation and clinical records involving any such departures from this protocol, subject to consent from the individual family affected and to Ontario's personal health information and privacy legislation.

1.14 Performance Audits

Every IHP audiologist who provides Amplification services funded by the IHP shall be audited periodically by the IHP, selected at random. The Audit process and performance indicators are detailed in Appendix C. It is a condition of continued audiologist authorization by the IHP and continued procedural funding by the IHP that IHP Audiologists shall comply with the request to provide the specified procedural and outcomes documentation. The IHP also reserves the right to conduct event-driven audits of individual IHP audiologists' case records, as and when the need is determined by the IHP. All provision of audit materials shall conform to current provincial laws and standards relating to personal health information.

1.15 Types of Assessment

Assessments are ABR-based or Behaviour-based. The latter includes Visual Reinforcement Audiometry (VRA), Conditioned Play Audiometry (CPA), or conventional audiometry. The choice of approach is at the discretion of the IHP audiologist, taking account of the individual characteristics of the child and the context and purpose of the Assessment. Both types can provide ear- and frequency-specific information that shall be used for the provision of hearing instruments to infants within the IHP (see IHP Assessment Protocol).

1.16 Timing of Amplification

Where not medically contraindicated, the provision of Amplification to infants aged less than three months is at the discretion of the IHP prescribing audiologist, but is not generally recommended by the IHP. Many factors must be weighed when considering at what age to provide amplification. The IHP fully endorses the prescription and verification of amplification by six months of age, as recommended by the US Joint Committee on Infant Hearing (JCIH, 2000). Delay that will compromise that objective must be avoided wherever possible. However, there is negligible scientific evidence of relative benefit from fitting earlier than three months of age, and what evidence there is about intervention timing suggests that six months of age is sufficiently early to accrue full benefit.

1.17 Infection Control Standards

All Amplification services shall comply with all pertinent standards of the facility relating to infection control. In the absence of specific facility standards, generally accepted standards shall apply.

1.18 Calibration

The IHP audiologist shall perform at least weekly calibration of the Audioscan RM500SL and Verifit systems. These real-ear and hearing aid test instrumentation shall also be calibrated on an annual basis, as scheduled by the facility or the regional IHP.

1.19 Otoscopy & Cerumen/Debris

Cursory otoscopy shall be conducted at the start of any IHP Amplification appointment. Its main purpose is to detect foreign bodies, canal occlusion and any physical condition of the ear that indicates referral to physician.

1.20 Amplification Components

Wherever feasible, provision of Amplification shall include at least ALL of the following:

A complete description of the infant's auditory characteristics for both ears;

Consultation by an otolaryngologist;

A description of the acoustic characteristics of the infant's ear canal(s) in the form of a Real-Ear-to-Coupler Difference (RECD);

Accurate ear impression(s) for the purposes of fabricating an earmold;

An assessment of the non-electroacoustic needs of the infant;

Electroacoustic analysis of prescribed hearing instruments (ANSI test);

DSL m[i/o] v5 target ear canal sound pressure levels (SPL) for the amplified long-term average speech spectrum;

DSL m[i/o] v5 target ear canal SPLs for defining the maximum saturation response of the hearing instrument;

DSL m[i/o] v5 target ear canal SPLs for soft and loud speech;

Verification that the electroacoustic characteristics of the hearing instrument adequately match the auditory needs of the infant. For the target population, simulated measurements of the real-ear aided response (REAR) and the real-ear saturation response (RESR) must be completed;

Instruction and counseling sessions with the parent/caregiver when the hearing instrument is first fitted and at subsequent follow-up visits as needed;

An evaluation of the outcome of the intervention;

Appropriate follow-up schedule and adjustments to the amplification as required.

1.21 Clinical Records & Reports

All Amplification records shall be maintained in a manner satisfying both CASLPO and the IHP. The Amplification records shall be maintained in hardcopy and, for programmable hearing instrument settings, in data files. The infant's audiological record should include details of the procedure used to calculate prescriptive targets (i.e. RECD values, DSL targets), a summary of the prescribed amplification including the settings of the device, make and model, earmold specifications, and a synopsis of recommendations and information provided to the family/caregiver. It is also important to note progress that the infant is making with the amplification devices. The records must be fully sufficient to demonstrate compliance with the required elements of the IHP Amplification protocol, given an audit (See audit details in Appendix C for details for required record keeping). They should also be sufficient to facilitate consultative, clinical review and case conferencing.

The audiologist shall complete the appropriate IHP Amplification summary report form and send it to the local IHP coordinating agency in a timely manner. If completion of the provision of Amplification requires a further appointment that is feasible promptly, the report may be deferred to follow the ensuing appointment.

1.22 Personal Health Information

Management of all personal health information arising from the Amplification process shall comply with all current legislation of the Government of Ontario.

All transmission of personally-identifiable information shall be consented by the appropriate family member or authorized caregiver. All transmission of individual case information by fax, hardcopy or email, such as for IHP training follow-up, internal clinical decision support or IHP audit, shall be rendered non-identifiable.

Local computer storage of identifiable and interpretable health information must take account of current Ontario guidelines in relation to unauthorized access, theft or loss.

2. ASSESSMENT CONSIDERATIONS

2.1 Auditory Characteristics

Auditory characteristics shall be defined prior to providing amplification to infants within the IHP. Threshold estimates for at least 500 and 2000 Hz shall be obtained in each ear prior to initiating the provision of amplification. Threshold estimates at other frequencies (i.e. 1000 and 4000 Hz) are recommended, but not required for the provision of amplification. Strategies for determining hearing thresholds will vary depending on the age of the infant.

2.2 Consultation by an otolaryngologist

Where amplification is indicated and elected by the family, referral leading to review by an otolaryngologist is required in order to confirm that non-medical intervention is appropriate. This may occur during the same consult for the etiologic investigation of the PCHI. Provided the otolaryngologist establishes the absence of medical contraindications to amplification, the audiologist is free to proceed with the provision of amplification for the infant.

In the IHP context, an assessment by an otolaryngologist shall be recommended to the child's primary care physician whenever the IHP Audiologic Assessment reveals PCHI. That referral has the main goal of a broad review of the child's health status in light of the hearing impairment, and may include radiologic, serologic, and ophthalmologic tests, as well as genetic review and other cross-referrals.

2.3 Acoustic Characteristics

The Real-Ear-to-Coupler Difference (RECD) measurement procedure was developed to determine an individualized acoustic transform for use with the Desired Sensation Level (DSL[®]) Method (Moodie et al., 1994; Seewald, 1995; Scollie et al., 2005). The individual's RECD is used to obtain SPL thresholds, generate the appropriate gain and output response for a hearing instrument, and has been shown to be highly repeatable and valid (Munro & Hatton, 2000; Sinclair et al., 1996; Seewald et al., 1999). Therefore, it is a required element in the Amplification process for infants involved in the IHP.

2.4 RECD Measurement

Wherever feasible, IHP audiologists shall measure the individual infant's RECD as part of the Amplification process. RECD measurement procedures are outlined in Appendix G. RECD measurements should be obtained from each infant using SpeechMap DSL in the Audioscan RM500SL or Verifit hearing aid test system

following the procedure described by Moodie et al (1994). RECD values, tester, coupling type (earmold, foam tip, immittance tip), ear and test date shall be documented and retained on file.

2.5 Age-appropriate Predicted RECD values

In the event that the individual RECD measurement cannot be obtained, age-related predicted values shall be applied. A description of the use of these values within applications of DSL m[i/o] v5 is located in Appendix H. The predicted values used shall be specified (i.e. age, coupling type), documented, and retained on file. The current values are derived from data collected from infants and children of varying ages and are provided for foam tip and earmold coupling (Bagatto et al, 2002).

3. PRESCRIPTION OF AMPLIFICATION

3.1 Ear Impressions

Ear impressions will be obtained from each ear for fabrication of personal earmolds (see Appendix I) as per the earmold prescription. The prescription shall include length of canal and helix, material (silicone, etc.), tubing type, shell style, vent (if possible) and options. Some earmold modifications will be limited by the size of the infant's ear, and any difficulty meeting the requirements of the prescription should be referred back to the prescribing audiologist.

The infant's earmolds should be made of a soft material for comfort, safety and retention. Also, softer material reduces the possibility of acoustic feedback from the hearing instrument. The advantages and disadvantages of various earmold materials should be weighed for each individual infant (See Appendix I for details). The cost and need for frequent replacement of earmolds to prevent acoustic feedback should be explained to the parent/caregiver.

3.2 Non-electroacoustic Characteristics

The audiologists shall consider non-electroacoustic characteristics of the prescribed hearing aid. The style of the hearing aid, monaural vs binaural fitting, deactivation of advanced features, FM system compatibility, and tamper resistant battery doors are important considerations when providing hearing aids to infants and young children.

3.3 Electroacoustic Characteristics

The use of a systematic, objective approach to electroacoustic selection that incorporates age-dependent variables into the computations for selecting a hearing instrument is required. The formula that shall be used to develop the appropriate electroacoustic characteristics for each infant involved in the IHP is the Desired Sensation Level Method[®] m[i/o] v5 (Scollie, et al. 2005) included within the Audioscan RM500SL and Verifit. This version of the DSL Method provides targets that vary depending on the type of fitting. Specifically, targets for pediatric patients (i.e. congenital hearing loss) and for adult patients (i.e. acquired hearing loss) are now available. This change was implemented due to the numerous studies that have demonstrated adult-child differences in performance ceilings, loudness ratings, and preferences by listening level (see review in Scollie

et al, 2005). For the purposes of the IHP, clinicians shall use the DSL m[i/o] v5 'Child' targets within the Audioscan RM500SL or Verifit. Coupler targets for the amplified long term average speech spectrum and MPO across frequency for each ear requiring amplification shall be documented. A description of this application can be found in Appendix J.

3.4 Device Selection

Once the non-electroacoustic and electroacoustic characteristics of the potential hearing instrument have been identified, the audiologist shall select a hearing instrument that will meet the criteria. Earmolds and hearing instruments shall be ordered, with a request for pediatric filtered earhooks.

3.5 Other Assistive Technology

Some infants may be candidates for assistive listening technologies and devices other than personally-worn hearing instruments. If the IHP audiologist determines that the infant is a candidate for other assistive technology, such as a FM system, the audiologist shall explain the option to the family and facilitate careful consideration and informed choice. If the device option is elected by the family, the audiologist shall provide the appropriate prescription to the parents, and/or facilitate access to service provision, as soon as is appropriate.

4. VERIFICATION OF AMPLIFICATION

4.1 RECD Values

The acoustic properties of the infant's personal earmold shall be taken into account through the use of RECD measurements or age-appropriate predicted values (see sections 125 and 130 of this document). Whenever a new earmold is obtained, a new RECD measurement shall be collected and applied in the calculation of prescriptive targets. Thus, the prescriptive targets shall be updated with the new RECD measurement when a new earmold is obtained. The verification procedures described in this document shall be carried out every time the prescriptive targets have been updated.

4.2 Electroacoustic Analysis

Upon receipt of the hearing instruments from the manufacturer, the dispenser shall proceed with an electroacoustic analysis of the hearing instruments (ANSI 1996) to confirm that the hearing instruments are functioning according to the manufacturer specifications. Any departure from the specification of gain, output, or distortion at any frequency beyond acceptable tolerances should be reported back to the manufacturer and the hearing instrument returned for repair or replacement as appropriate. A biological listening check should also be performed to subjectively evaluate sound quality and physical function of components.

4.3 Electroacoustic Verification

The prescribed hearing instrument shall be adjusted to approximate the target electroacoustic values for gain and maximum output that were specified according to the section of this document dealing with Prescription. All verification curves, in SPL, and final hearing instrument settings shall be documented and dated for each

ear requiring amplification. Ideally, real ear measurements of gain and maximum output values should be performed on each ear (i.e., the RECD may have already been measured in the pre-selection phase) and the hearing instrument adjusted to provide the best match to targets. With the infant population, it is difficult to obtain valid and reliable measures of real-ear hearing instrument performance using this method. Therefore, predicting the real-ear performance of the hearing instrument using the infant's RECD is the preferred method for infants. This approach is fully implemented through the use of DSL in the Audioscan RM500SL and Verifit. For a detailed description of this procedure see Appendix K. One major advantage of this approach is that shaping the electroacoustic response of the hearing instrument can be performed in a highly controlled hearing instrument test box environment. Additionally, the infant does not need to be present for fine tuning adjustments made at this stage. It is, however, important for the clinician to check for feedback from the instrument once it has been placed on the infant's ear.

4.4 Application of Advanced Technologies

DSL targets are computed with the goal of listening to speech in quiet listening environments. As such, it is recommended that the prescribed hearing instruments be worn with this goal in mind. However, if technology that aims to improve the signal-to-noise ratio (i.e. directional microphones) is elected by the family, it should not be activated when verifying the hearing instrument for quiet listening environments. In addition, if these technologies are activated in the instrument, it is recommended that they not be used on a full-time basis until sufficient evidence exists regarding their impact on prelingually hearing impaired infants. Thus, multiple memories may be considered (i.e. quiet and noise programs) at the discretion of the audiologist and should be considered on an individual basis.

Automatic feedback suppression technologies should be employed if feedback is noted when the hearing instrument has been placed on the infant's ear following verification. Every attempt to reduce feedback (i.e. good earmold fit, use of lubricant) should be attempted prior to applying feedback suppression strategies. If applied, verification of the instrument shall be conducted following application of these technologies. The application of feedback reduction should be reassessed whenever new earmolds are obtained, and the feedback suppression technology should be deactivated when not required.

4.5 Simulated Real-Ear Measurements

With the infant population, it is difficult to obtain valid and reliable measures of real-ear hearing instrument performance using real-ear measurement procedures. Therefore, predicting the real-ear performance of the hearing instrument using the infant's RECD is the preferred method for infants and young children. Simulated measurements of the real-ear aided response (REAR) and real-ear saturation response (RESR) shall be conducted for each ear requiring amplification through the use of S-REM in the Audioscan RM500SL or Verifit. These procedures are outlined in Appendix K.

4.6 Verification Stimuli

Verification of hearing instrument performance at various input levels (i.e. soft, average, and loud speech) shall be conducted to determine audibility and

compression characteristics of the instrument. Verification of speech targets shall be completed using stimuli approximating speech as closely as possible. The Audioscan RM500SL and Verifit contain stimuli that meet these requirements. Maximum output characteristics for most hearing instruments shall be verified using narrowband stimuli. For aids that use multichannel broadband output limiting, use a loud speech stimulus (80 dB SPL) and ensure the peaks of speech fall at or below the Upper Limits of Comfort (Scollie and Seewald, 2000).

5. INFORMATION AND INSTRUCTION

5.1 Orientation

The dispensing and fitting of an instrument shall include explanations of use, care and maintenance of the devices provided in an understandable way and preferably supplemented by appropriate printed materials. Infants are unable to report if their hearing instruments are malfunctioning, so family vigilance is required and a kit is usually helpful. Supportive information and instruction for the family/caregiver shall be given at the time of the first fitting of the hearing instrument, and at follow-up visits.

5.1 Information

In any communication with families, the principles of the IHP should be reflected. Only evidence-based information should be imparted. Anecdotal information and personal opinions are not considered appropriate content for communication with parents. Service providers are encouraged to impart unbiased information in their area of expertise. Interdisciplinary referrals should be made when appropriate as questions arise which are outside of the prescriber's/dispenser's scope of practice such as prognosis, or medical issues.

5.3 Family Support

Despite their decision to proceed with amplification, families may continue to need various supports to help them through the process of acceptance and adaptation. Psychological support is available through the local IHP Family Support Worker, but it is not the role of such personnel to provide information on audiological matters. A combination of timely and relevant information from the IHP Audiologist, written materials provided by the IHP, and psychological support from Family Support Personnel is the desired minimum.

6. OUTCOME EVALUATION

6.1 Follow-up Schedule

Follow up to the initial hearing instrument fitting should be accomplished on a regular schedule, with accommodation for individual needs. The Amplification Audiologist should see the infant and family for a minimum number of 2 follow up visits within the trial period which is recommended to be a minimum of 60 days. A schedule of follow-up visits thereafter shall include visits about every three months for one year after the fitting of amplification, about every six months for a second year, and annually thereafter until grade one entry. This follow-up schedule is typical but may vary from infant to infant. Some may require less frequent visits, but for infants identified as having a progressive or fluctuating

hearing loss or auditory dys-synchrony, the regular schedule is especially important. The schedule should be re-assessed on an ongoing, individual basis, with appropriate documentation.

6.2 Follow-up Visits

At each follow-up visit, an incremental history shall be obtained from the family. Use, care and maintenance of the hearing instruments should be discussed as parents' questions arise, or as re-instruction is required. Otoscopy, middle-ear analysis, and assessment of hearing levels (typically behaviour-based) shall be done (see IHP Assessment Protocol). Earmolds shall be assessed for appropriate fit and new earmolds obtained when required. An RECD should be re-measured to account for growth and development, as well as if the earmold has changed or if there has been a change in middle ear status. Subsequent adjustments should be made to the hearing instruments as needed.

6.3 Outcome Measures

Validation of the fitting may be done using behavioural reports from the family. Both informal and formal assessment methods may be used, and the IHP is currently evaluating systematic approaches which will be provided in a separate document.

7. TRAINING AND CLINICAL DECISION SUPPORT

7.1 Training Requirements and Support Mechanisms

All audiologists wishing to provide IHP Amplification services shall have received training in this protocol that is approved by IHP. The IHP training sites are Mount Sinai Hospital (MSH), Toronto, for ABR-based Assessments and the University of Western Ontario, for VRA-based Assessments and IHP Amplification protocols.

At any time, audiologists may fax records to The University of Western Ontario for a clinical or procedural opinion. An email to bagatto@nca.uwo.ca shall accompany the fax and all records shall be completely de-identified. Audiologists are encouraged to do this if significant difficulties arise in completing the IHP protocol. This is a funded part of IHP quality management.

Audiologists may receive additional training or procedural review, by application to the Ministry of Children and Youth Services.

7.1 IHP Website

A website supporting the IHP has been developed at Mount Sinai Hospital. The URL is <http://ihp.mtsinai.on.ca>. All IHP protocols and many related materials are available on the website. A password-protected area includes training and decision support materials. Every audiologist and regional coordinator will have a password that shall be treated confidentially.

SUPPLEMENTARY TEXT

1. PROGRAM CONTEXT

S1.2 IHP Core Principles

The IHP is a program of the Early Years Branch of Ontario's Ministry of Children and Youth Services (MCYS). It was implemented throughout the province in 2002 and is an example of an Early Hearing Detection and Intervention (EHDI) program. A better descriptor, recommended by the Public Health Agency of Canada's Canadian Working Group on Childhood Hearing (CWGCH, 2005), is an 'Early Hearing and Communication Development' (EHCD) program. The IHP includes UNHS (Ontario's birth rate ~ 130,000/y), surveillance of high-risk infants, comprehensive audiologic assessment, family support services, linkage to medical services, provision of assistive technologies, and a range of services and other linkages to enhance the development of language and early literacy.

The core values of the IHP are that service provision should be family-centered, with fully informed family/caregiver (hereafter 'family') choices based on unbiased information that is grounded in the best available scientific evidence. 'Family-centered' means that the family's choices are paramount and that their culture, values and preferences must be respected. The family should be the fullest possible partner in the development of an individualized pattern of required services. The family must be assisted in making choices among service options on the basis of information that is valid, timely, comprehensible, relevant, complete and unbiased. Interactions among IHP service providers and families must reflect these core program values and also must be consistent with documentary information for both families and professionals that is provided by the program.

During their path through the IHP, families will be provided with brochures and other information about program rationale, procedures, significance of outcomes, and options for actions. This is available in all the languages most frequently represented in Ontario. Families shall be encouraged to consider the evidence carefully in arriving at their choices. In all materials supplied by the IHP, both for families and for professionals, areas in which there is a lack of sound, scientific evidence will be identified. Standard, published methodologies of Evidence-Based Practice, including systematic and semi-systematic reviews will be used on an ongoing basis to evaluate and update scientific evidence.

The IHP funds ALL its core elements, including personnel training, instrumentation and supplies, protocol development, service provision, technical and clinical decision support, technology assessment, quality management, program development and program evaluation. Assistive technologies are funded wholly or in part by linked, complementary programs.

To justify the resource expenditure required by such a universal program, and also on ethical grounds, there is a need to achieve the highest possible service quality and consistency throughout Ontario. Accordingly, core program components such as audiologic assessment ('Assessment') must follow well-defined, evidence-based procedural standards. Many of the Assessment elements are mandatory and are required practice to qualify for IHP funding. Other procedures are recommended but not required, and in yet other areas there may be insufficient evidence even for a recommendation. The IHP acknowledges that individual infants and special circumstances of testing may require clinical judgment and adaptations of standard procedures. When the program standard of care is not followed, a documented rationale for the departures may be required by the IHP.

This document addresses Assessment of infants registered with the IHP. The contents are based on: (i) workshops for Ontario audiologists dating from December 2000 to the present (ii) numerous and ongoing reviews of scientific and clinical literature, (iii) ongoing protocol reviews and consultations with leading experts worldwide, (iv) extensive experience with tonepip ABR and other pediatric audiometric procedures, in Ontario, over a period of more than two decades, (v) feedback from program professionals, and (vi) policy and procedural developments initiated by the Ministry of Children & Youth Services.

The clinical protocol itself is based on current evidence about effectiveness and efficiency of specific procedures. Therefore, it will evolve. In some areas, current evidence is incomplete and interim decisions have been made. The IHP will continue to evaluate its operations and outcomes, as well as continue to assess new clinical technologies and published scientific data. Revisions or addenda to this document will be issued as required.

Key sources for some components of this protocol are listed in Appendix A.

S1.4 Amplification Objectives

This document addresses the Provision of Amplification for infants registered in the Ontario Infant Hearing Program (IHP). Most infants requiring amplification will have been identified with the IHP target permanent childhood hearing impairment (PCHI) through universal newborn hearing screening. These infants will typically have received Audiologic Assessment within the first three months. A minority will have been identified by repeat screening of at-risk infants or by other referral routes, and will have received Assessment in order to be eligible for IHP services prior to school entry at grade one. See the companion document 'Audiologic Assessment Protocol, version 3.1, October 2007' for the details and rationale of the IHP Assessment protocol.

The Provision of Amplification, as described in this document, is a process that includes the calculation of prescriptive targets based on assessment information, the selection of the physical and electroacoustic elements of a hearing instrument, verification that the specified acoustical performance targets have been achieved, and evaluation of device effectiveness in daily life. The prescription shall include a specification of the type of hearing instrument and earmold to be fitted, appropriate settings and applications that will result in an amplification system that addresses the needs of the individual infant and family.

For the purposes of this document, a 'hearing instrument' is defined as any electronic device fitted to the ear or skull and designed to amplify and deliver sound to the ear. These devices include, but are not limited to, hearing instruments that are body-worn, behind-the-ear, in-the-ear, in-the-canal, completely in the canal, BICROS, CROS, and bone conduction (including BAHA Softband) and that may employ analogue, programmable or digital technologies.

The goals of Amplification are to improve the ability to hear and thereby to facilitate the development of sensory and perceptual skills, receptive and expressive language, speech production and literacy, academic performance and social-emotional growth (Carney & Moeller, 1998).

This document defines the standard of care for Provision of Amplification within the IHP context, and provides a guiding framework for clinical practice. It defines key, mandatory and discretionary elements of the protocol and gives their underlying rationale. The procedures described are designed to provide audiologists with protocols for providing

hearing instruments to infants as part of a comprehensive plan for facilitating communication development.

S1.5 Target Impairments

The IHP target impairment set includes any PCHI for which there is satisfactory evidence that it will compromise auditory development and speech perception, in the absence of intervention. The target disorder includes puretone threshold elevation to a level equivalent in an adult to 30 dBHL or greater at any frequency in the range 0.5 to 4.0 kHz.

Currently, there is no compelling scientific evidence that lesser severities of impairment merit address by public health programming, but that issue is the subject of current research. Globally, some programs limit their targets to hearing levels that are 40 dBHL or greater in the better ear. Yet, from first principles of psychoacoustics it is clear that such a conservative criterion will fail to address many children with a substantive limitations of perceptual function.

Hearing impairment is considered 'permanent' by the IHP if it is irreversible by medication or surgery or if it is likely to sustain for a period of six months or more. This includes most impairment of sensory or neural origin, as well as conductive impairment with a 'structural' cause such as ear canal or middle-ear agenesis or dysgenesis.

It is appropriate to include in the IHP target definition children with unilateral PCHI because: (i) they are at risk for bilateral PCHI, (ii) they are at risk for increased disability should the normal ear acquire a conductive disorder, even if transient, and (iii) specific strategies are indicated to enhance hearing and/or communication development in such children.

The IHP target also includes the cluster of disorders commonly termed 'Auditory Neuropathy' (AN). This is referred to within the IHP as Auditory Dys-synchrony (AD) on the grounds that (i) many such cases may not have genuine neuropathy, as commonly defined neurologically, (ii) communication of an etiologically and pathophysiologically specific diagnosis such as 'neuropathy' is an act that is restricted in Ontario to physicians, and (iii) 'Auditory Dys-synchrony' is a legitimate, non-etiological descriptor of an auditory system dysfunction that may include abnormal quantity and/or temporal distribution of afferent neural activity.

AD is included in the target because it may be present in up to 10% of infants with pre-lingual PCHI and because even if there is negligible loss of hearing sensitivity, there is likely to be a significant disorder of speech perception, mediated by inadequate coding of rapid stimulus events.

Transient hearing disorders such as threshold elevations due to middle ear fluid and/or infection are NOT targeted by the IHP. Such disorders are the domain of the well-established, universal medical care system in Ontario (funded by the Ontario Health Insurance Plan, OHIP). The IHP is NOT an alternate system for audiometric services in the context of active medical or surgical management of conductive hearing disorders.

In practice, the 'effective' target disorder severity and frequency range for a UNHS program is dictated by the operating characteristics of the screening tests used. AABR screening is currently done using clicks. The click level is selected by IHP management and currently is equivalent to 35 dBnHL in an adult ear. That level may ultimately prove to be too high, given the target disorder definition. There are at least three factors that influence the severity of hearing impairment that will be detected by such a screen. First, the effective

SPL of any given click stimulus is greater on average in the infant ear canal than that in the adult ear canal, by an amount that depends on frequency of stimulus energy, anatomical characteristics of the individual child, and the age of the child. Second, the presence of a clear and reproducible ABR implies that the stimulus is substantially supra-threshold, probably by at least 10 dB with conventional ABR techniques at low stimulus levels. Third, the click ABR threshold will reflect most closely the best puretone sensitivity in the frequency range 1-4 kHz, so children with hearing losses at low, high or isolated frequencies may be missed.

Similarly, DPOAE screening typically addresses frequencies of 2 kHz and higher, so hearing losses below about 2 kHz may be missed. Current IHP settings for DPOAE screening are 1.5, 2, 3 and 4 kHz with a three out of four pass rule. Lower frequencies are impractical because of ambient noise levels. The IHP rule is designed to ensure that there must be detection of an OAE at an F2 of 2 kHz or below. OAE screening will not detect disorders that originate at a higher level in the auditory system than the outer hair cells; these disorders include AD and a range of retrocochlear lesions.

S1.10 Instrumentation, Calibration & Supplies

The IHP provides all the instrumentation and operating supplies necessary to conduct Amplification services according to this protocol. Current IHP instrumentation is listed in Appendix B.

Routine calibration checks of the Audioscan[®] RM500SL and Verifit are necessary for appropriate operation of the system and shall be completed by the audiologist. Yearly calibration services will be arranged by the IHP, with reasonable notice to the Amplification centres.

S1.13 Deviations from Protocol

The IHP recognizes that special circumstances may indicate departures from some (but not all) of the procedures specified in this protocol. Such departures are at the discretion of the IHP audiologist. This does not mean that this protocol is generally discretionary. IHP funding for procedures is conditional upon specific deliverables in terms of quantity, quality and effectiveness, as defined in this and other protocols. Every reasonable effort must be made to comply with IHP protocols, in the interest of quality of care, consistency of care (equity), and evaluability of overall program performance and outcomes. The evaluation requirement imposes a need for comprehensive and standardized documentation and clinical record-keeping. In addition, all significant deviations from this Protocol shall be documented so as to permit independent review of their nature and the validity of their rationale.

S1.14 Performance Audits

Protocol compliance will be evaluated routinely by several mechanisms, including chart audit of all IHP audiologists, targeted over a three-year cycle, with random selection of auditees.

It was established at the outset of IHP protocol development that periodic performance audit was necessary and appropriate. The agreed process is intended to enhance program quality and to facilitate Audiologists' understanding of, and compliance with, IHP mandatory procedures in a collaborative manner.

The audit includes detailed review by designated IHP expert assessors of clinical records and reports for a sample of case records, including records specified by IHP management and

records elected by the audiologist. Assessment performance is evaluated and assigned a rating of compliance. Compliance that is less than complete is addressed in confidence with the auditee by the expert assessor, by several support mechanisms including additional training as required. Continued entitlement to conduct IHP Assessments is conditional upon the evaluation by the designated expert assessor(s).

As well as the routine Audit schedule, event-driven Audits of specific audiologists may be initiated by the IHP when it is deemed necessary in the interests of children and families. If concerns arise about the performance of any IHP audiologist in reference to any child receiving services funded by the IHP, the concern shall be raised with the local coordinator, who shall request an event-driven quality Audit. This internal IHP process has no relationship to any peer review or disciplinary process specified by CASLPO. Any communication with CASLPO shall be at the discretion of the IHP auditor(s).

S1.16 Timing of Amplification

There are several concerns that must be taken into account when considering providing amplification to an infant less than three months of age. For example, the first three months of life is a period of plasticity and rapid change in the acoustical and physical properties of the external meatus. This can cause difficulty in achieving a satisfactory and stable earmold fit, and may necessitate many follow-up visits for adjustment. Rapid anatomical maturation coupled with small and diverse canal volumes in neonates affect real-ear SPLs and have implications for the accuracy of prescriptive parameters based on group norms as well as for the stability of real-ear measures over time. There is also rapid maturation of both the middle ear and the afferent auditory pathways, and these may cause changes in hearing as well as increase the possibility of audiometric error.

The process of prescribing, ordering, supplying, and verifying a hearing instrument, and accounting for scheduling of appointments, mold and instrument adjustments and various other possible delays, may take two months or more. The IHP interpretation of the JCIH recommendation is not prescription of a hearing instrument at six months but a completed process of prescription, verification and adjustment, if necessary, by six months. This timeline may require that the hearing instrument evaluation appointment should typically occur by four months of age, which in turn may mean that the Assessment and review by an otolaryngologist should be completed by about three months, wherever possible. This is reasonably consistent with initiating the Assessment process by about two months. Of course, factors such as illness, active middle ear disorders or audiometric uncertainty may cause significant delays in successful provision of amplification.

From these considerations, it is anticipated that the majority of IHP Amplification activities will occur in infants aged about 3-6 months. This is reasonably consistent with published data from large UNHS programs, but is itself an ambitious target in the population of NICU graduates. A minority of infants will arrive at Amplification after 6 months of age; these represent infants identified by UNHS but for whom provision of amplification was delayed, as well as infants with confirmed hearing impairment following at-risk repeat screening or referral.

Infants who have bilateral PCHI of moderate or greater degree are unequivocally candidates for binaural amplification, unless there is a clear, documented contraindication. It is emphasized that candidacy here means audiometric candidacy, and that the first outcome of candidacy determination by the audiologist is a recommendation that the family consider carefully the evidence for the amplification option, among other options that may be available locally. Should a delay in the provision of amplification occur due to the family's

participation, or lack thereof, in the process, and/or due to illness in the child, it should be fully documented by the IHP audiologist.

Within the IHP, infants with a PCHI of lesser severity but of at least 30 dBHL are also considered candidates for amplification and/or personal FM systems. Evidence suggests that infants with this degree of hearing impairment are at risk for experiencing academic difficulty (Bess, Dodd-Murphy, & Parker, 1998; Bess and Tharpe, 1984; Wake et al, 2004). Infants identified with a unilateral PCHI *may* be candidates for amplification, but the evidence of benefit is currently considered insufficient for the IHP to make a recommendation. Similarly, infants who have been identified as having AD, and where behavioural data exist, may be fitted with amplification at the discretion of the IHP audiologist, should the family elect it. Infants who have been identified as having AD based on ABR findings should be evaluated behaviourally before amplification is considered. Individuals with AD have been shown to have variable thresholds (i.e. range from normal to profound) which cannot be determined by ABR alone (see Assessment Protocol).

Infants in which no response by ABR is determined shall not exclude the individual from being considered a candidate for amplification. Residual hearing may exist at levels greater than the ABR system is capable of eliciting and the infant may still experience benefit from hearing instruments. Severe to profound hearing impairment is included as part of the candidacy criteria for cochlear implantation.

2. ASSESSMENT CONSIDERATIONS

S2.1 Auditory Characteristics

For infants under six months of age and for some older infants, Assessment is based on objective, physiologic measures, mainly but not exclusively on tonepip ABR. It is usually possible to obtain accurate, frequency-specific, ear-specific puretone threshold estimates by such measures. In most cases, tonepip ABR can provide audiometry that is sufficient to fully inform communication development services, including amplification. When the IHP Assessment protocol is followed, then unless there is a specific indication of unreliability of ABR findings (such as a finding of auditory dys-synchrony (AD) or fluctuating conductive impairment), it is not consistent with IHP goals and objectives to defer communication development options (where elected by the family) pending 'behavioural confirmation' of ABR-based threshold estimates. As described in the Assessment Protocol, the ABR-based threshold estimates are referenced in estimated hearing level (EHL). This represents a behavioural threshold derived from ABR-based estimates. The hearing instrument prescription can be calculated using the EHL data obtained during the assessment (Bagatto et al, 2005). A description of how to use EHL in DSL m[i/o] v5 can be found in Appendix D.

For children over the age of six months, visual reinforcement or play audiometry is appropriate and will provide ear- and frequency-specific information. Auditory characteristics for this age group must be defined following procedures outlined in the IHP Assessment protocol.

The availability of frequency-specific threshold data is important for the prescription of amplification. If the presence of PCHI has been confirmed, the process of amplification may proceed on the basis of ear-specific threshold estimations at 500 and 2000 Hz. Delay in the process pending the mandatory collection of thresholds at 1000 and 4000 Hz is not warranted at this stage. There will be cases where full audiometric information beyond 500 and 2000 Hz is not available. In these instances, the clinician must make a best estimate,

based on the thresholds provided as well as additional clinical and/or familial information, of the residual hearing across the frequency range important for speech.

For infants in whom no response is indicated on the ABR and AD is presumed absent, amplification should be provided cautiously. The following procedure is recommended:

- 1) If no response (NR) was indicated on the ISCIS Assessment form, consult with the Assessment Audiologist to determine the highest level (dB nHL) that was presented at each frequency in each ear during the ABR.
- 2) Apply the frequency-specific correction to that level (see Assessment Protocol) to obtain a corrected threshold in EHL.
- 3) Subtract 5 from the resulting EHL if the threshold search was conducted using 10 dB step sizes. If 5 dB step sizes were used, skip Step 3.

In such cases, continued observation and assessment of the infant are especially important.

Audiologic Assessment of an infant with PCHI is not an event, but a process. Even if complete and apparently accurate audiometry is obtained at three months, periodic follow-up audiometry is appropriate to confirm the early measurements, to refine threshold estimates and to detect and quantify possible changes in hearing. In older infants, the amplification audiologist will attempt VRA or CPA using insert earphones coupled to foam eartips. If the child has personal earmolds, the insert earphones should be coupled to the earmolds for a more accurate reading of hearing thresholds in both ears (see Appendix E for practical description). Any changes to the infant's auditory thresholds should be applied to the hearing instrument prescription as needed.

S2.3 Acoustic Characteristics

The acoustics of an infant's external ears significantly differ from those of the average adult (Kruger, 1987). In addition, RECD values are known to be highly variable among children of the same age (Feigin et al., 1989; Seewald & Scollie, 1999; Bagatto et al, 2002; Bagatto et al, 2006). For these reasons, it is strongly recommended that wherever feasible, IHP audiologists measure the individual infant's RECD as part of the provision of amplification. In the event that the individual measurement is unobtainable, age-related predicted values can be applied (Bagatto et al, 2002).

When comparing audiometric thresholds for the same infant over time, it is important to take into account the changes in individual ear-canal acoustics. RECD measurements shall be applied so the thresholds are represented accurately (i.e. in real-ear SPL or HLp). For example, when comparing VRA thresholds completed at 9 months of age to ABR threshold estimations collected at 3 months of age, the RECD must be applied to both sets of thresholds to obtain an individualized and more accurate threshold representation. If ear canal acoustics are not considered when making this comparison, what appears to be a change in hearing threshold sensitivity may be a result of changes in ear canal acoustics due to ear growth. See Appendix F for a description of this calculation.

S2.4 RECD Measurement

Briefly, the HA-2 coupler is connected to the coupler microphone of the unit and a transducer is coupled to the other end of the HA-2 coupler. A swept-frequency stimulus generated by the probe microphone system is delivered into the coupler and the coupler

response is measured by the microphone. A foam eartip or personal earmold is coupled to the transducer and inserted into the infant's ear. It may be helpful to couple the probe tube to an immittance or OAE tip with plastic wrap (i.e. moisture guard or soft surgical tape) for very small ear canals. Ensure the probe tube extends approximately 2-4 mm past the opening of the tip to obtain appropriate insertion depth (Bagatto et al, 2006; See Appendix G for details). This technique is helpful in coordinating insertion and ensuring a constant length of the probe tube remains at the tip edge. The same stimulus is presented via the probe microphone system and insert earphone coupling, and the real-ear response is measured. The difference between the real-ear response and the coupler response is obtained. This difference is the individual transfer function designated as the RECD and will be applied throughout several stages of the amplification process.

S2.5 Age-appropriate Predicted RECD values

Using an age-appropriate predicted RECD value is more desirable than using an average adult value for infants. However, age-appropriate average values in current use have some limitations. First, the average RECD values were derived from infants and children with normal middle ear status. Therefore, the predicted values will not reflect any acoustic changes that a fluid filled or perforated eardrum will display, in the individual ear. Second, individual real-ear SPL values may differ substantially from group average values, even in age-matched groups. When applying RECD predicted values for eartips, one can expect to fall within a range of ± 5.6 dB (at 500 Hz) as best and ± 10.9 dB (at 6000 Hz) at worst for children 24 months of age and younger. Predictions of earmold RECDs can span a range of accuracy from ± 6.7 dB (at 2000 Hz) to ± 12.4 dB (at 6000 Hz) for children 36 months of age and younger. For these reasons it is important to attempt an RECD measurement on an infant whenever possible. However, when these values cannot be obtained, age-appropriate predicted values found in applications of DSL *m[i/o]* v5 should be applied.

3. PRESCRIPTION OF AMPLIFICATION

S3.2 Non-electroacoustic Characteristics

Behind-the-ear (BTE) hearing instruments are most appropriate for infants for several reasons:

- i) rapid growth of the earmold causes frequent remakes which are less costly and more convenient than custom (i.e. in-the-ear, in-the-canal) hearing instruments
- ii) custom products are more prone to feedback due to the close proximity of the receiver and microphone
- iii) BTEs allow for greater electroacoustic flexibility
- iv) direct audio input capabilities are more compatible with the target population
- v) during out-of-office repairs of the BTE, a similar instrument can be coupled to the child's earmold so the child is not without amplification.

Other types of personal amplification such as bone conduction hearing instruments, BAHA[®] Softband, body worn hearing instruments, and cochlear implants should also be considered on an individual basis. It is the audiologist's responsibility to inform families of these options and to ensure their knowledge of current referral criteria.

Infants with confirmed PCHI in both ears shall be fitted with bilateral hearing instruments unless contraindicated. Many studies have demonstrated the benefits of bilateral hearing (Hawkins & Yacullo, 1984; Valente, 1982a, 1982b). Additionally, auditory deprivation in children with unilateral amplification has been reported (Boothroyd, 1992; Hattori, 1993).

Direct audio input (DAI) shall be included on the selected devices. This will enable coupling of assistive technology, such as FM systems, to the hearing instruments. Tamper resistant battery doors shall be included on hearing instruments for infants. A deactivation or locking system for the volume control and other automatic features shall be available on the hearing instruments.

While BTE hearing instruments may be the device of choice for infants with PCHI, some infants may have a conductive hearing impairment caused by a structural issue (i.e. atresia, middle ear malformation). Since children under the age of 5 years are not candidates for surgically implanted bone anchored hearing instruments, bone conduction hearing instruments shall be considered. Traditional bone conduction instruments are kept in place by a metal headband or two-sided tape. There are some disadvantages to this setup such as discomfort and difficulty keeping the instrument in place. The BAHA Softband uses an adjustable elastic headband to house the BAHA processor and hold it in place on the infant's head. It has been demonstrated that the direct contact force of the BAHA processor on the infant's head does not have a significant effect on audibility (Hodgetts et al, 2006). Therefore, a snug but comfortable setting of the headband should be sufficient to couple the BAHA Softband to the infant's head. Data from adults with normal hearing sensitivity indicate that a volume control setting of approximately three was closely associated with the preferred listening level. A volume control setting of at least 2.5 is therefore recommended for the BAHA Softband, accompanied by validation via aided sound field thresholds and parent interviews/feedback.

S3.3 Electroacoustic Characteristics

There are several other changes to the DSL Method that are important to note. In addition to targets for children and adults, DSL *m*[i/o] v5 provides targets for quiet and noisy listening environments. Targets for quiet listening environments aim to provide full, or nearly full, audibility of speech. For noisy environments, the targets aim to increase listening comfort without reducing intelligibility. Currently there is no evidence to support the use of noise targets in the pediatric population. Therefore, it is not a minimum implementation requirement for applications of DSL *m*[i/o] v5 and does not appear in the Audioscan RM500SL or Verifit. The changes that occur in applications of DSL *m*[i/o] v5 are a correction for binaural fittings and conductive losses. The application of the conductive correction is at the discretion of the clinician. The literature is not conclusive on whether a gain reduction is needed for binaural fittings in children. Until conclusive results are available, it is recommended that IHP clinicians do NOT apply the binaural correction, even for those children fit with binaural hearing instruments. A description of this application can be found in Appendix J.

Appropriate electroacoustic characteristics of the hearing instrument may include both linear (with output compression) and nonlinear processing in either an analog or digital format. Advanced signal processing schemes (expansion, multiple channels, frequency shifting, automatic feedback suppression) should be considered viable in pediatric hearing instrument fittings until such time as sufficient research data exists to exclude them. These advanced signal processing strategies should be assessed for each infant on an individual basis. Noise reduction and speech enhancement algorithms have not been evaluated for the infant population and cannot be recommended until relevant data regarding their effectiveness are provided. Directional microphones have been shown to provide benefit to older children and adults in noisy listening situations (Gravel et al, 1999; Ricketts & Tharpe, 2004). They may be considered useful for infants in certain settings and may be considered on an individual basis. See section 175 for more information. Signal processing schemes

that operate automatically (i.e. adaptive directional microphones) cannot be recommended at this time due to lack of evidence for their usefulness in the pediatric population.

When prescribing amplification for an infant, the selection of electroacoustic characteristics shall include the following:

- 1) A systematic, evidence-based prescriptive process that takes into account the unique acoustic properties of each infant's ear. The prescription should ensure speech audibility at a comfortable level over as broad a frequency range as possible, and should avoid tolerance problems. It should incorporate age-dependent variables, where necessary. The current IHP approach is the Desired Sensation Level (DSL) Method *m*[i/o] v5 (Scollie et al, 2005).
- 2) Individual ear characteristics (either measured or predicted) incorporated into the prescription.
- 3) Frequency-gain and output limiting characteristics of the hearing instrument determined using DSL calculations (see Appendix J for procedures).

Therefore, the hearing instruments selected shall avoid distortion, allow frequency/output shaping to provide audibility and avoid tolerance issues, apply wide dynamic range compression (Jenstad et al, 1999, 2000), compression output limiting, and electroacoustic flexibility.

S3.4 Device Selection

Unless otherwise instructed, manufacturers will send adult-sized unfiltered earhooks when BTE hearing instruments are ordered. A pediatric earhook will allow the BTE to stay situated on the infant's ear. In addition, unfiltered earhooks will add resonant peaks to the output response of the hearing instrument, possibly causing feedback and making adjustment to MPO targets difficult. A filtered earhook will smooth the response and allow for a better match to targets with less chance of feedback (Scollie & Seewald, 2002). Therefore, prescriptions should specify filtered pediatric earhooks unless contraindicated.

S3.5 Other Assistive Technology

It has been well documented that the use of FM technology by children in educational settings is an effective strategy for improving listening in environments with poor signal to noise ratios, great distance between listener and talker, and highly reverberant rooms (Crandell, 1993). While an FM system may not be used in the first few months of life, when the infant becomes a toddler, more difficult listening situations will develop. The child may be at a distance from the primary caregiver or talker and in highly reverberant environments. In addition, use of this technology may increase the rate of language acquisition (Moeller et al, 1996). For these reasons, it is recommended that FM systems be discussed with the family during amplification appointments and provided when appropriate. A summary of the steps involved in verifying an FM system is outlined in Appendix L.

4. VERIFICATION OF AMPLIFICATION

S4.3 Electroacoustic Verification

As the infant's external ear canal grows, the acoustic properties of the ear will change substantially, especially in the first year of life. This change in ear size will necessitate a new earmold. Whenever a new earmold is made, an RECD measurement should be obtained and applied in the calculation of prescriptive targets for the hearing instrument. Thus, the prescriptive targets must be updated with a new RECD measurement when a new earmold is obtained. The verification procedures described above must be carried out every time the prescriptive targets have been updated.

Aided soundfield measurements should not form the basis for the verification of the infant's hearing instruments for several reasons:

- 1) Prolonged cooperation from the infant is required
- 2) Frequency resolution is poor
- 3) Large critical differences for aided soundfield thresholds are not useful for comparing two gain control settings (Stuart et al., 1990)
- 4) Validity of results is poor, especially with severe to profound hearing losses, or when nonlinear signal processing is used

Aided soundfield threshold testing can be useful for hearing instrument validation, counseling and educational purposes, but is not the recommended procedure for verifying amplification for infants in the IHP.

5. INFORMATION AND INSTRUCTION

S5.1 Orientation

The dispenser will ensure that the following care and maintenance techniques are demonstrated to the parent or caregiver during the initial hearing instrument orientation:

- Demonstration of earmold insertion, including use of oto-ease and other practical fitting suggestions, such as putting the hearing instruments on, etc.
- Hands-on demonstration and practice of earmold insertion, tubing attachment to hearing instrument, insertion of batteries, etc.
- Demonstration of a daily inspection of ear canal, and daily listening check of the hearing instruments. The listening check should include adjustment of controls, Ling 6 Sounds Check, etc.
- Discussion and demonstration of troubleshooting techniques and solutions.
- Demonstration of equipment found in the care and maintenance kit – battery tester, earmold blower, stethoscope, dri-aid kit, etc.
- Discussion of retention techniques – demonstration of critter clips, double-sided tape, huggie-aids, etc.

A complete list of discussion topics for clinicians and families is included in Appendix M.

The dispenser will also provide written information from the manufacturer for parents to take home and refer to, and other appropriate Infant Hearing Program pamphlets and information.

6. OUTCOME EVALUATION

S6.3 Outcome Measures

If the initial prescription of amplification was based on ABR threshold estimates, if and when it is developmentally appropriate, the amplification audiologist should attempt VRA using insert earphones. If the child has personal earmolds, the insert earphones should be coupled to the earmolds for a more accurate reading of hearing thresholds in both ears (see Appendix E for practical suggestions). Any changes to the infant's auditory thresholds and acoustic properties of the ear canal (i.e. RECD) should be applied to the hearing instrument fitting as needed.

At the follow-up visits, the audiologist should meet with the parent/caregiver to discuss satisfaction with the fit of the hearing instruments and the infant's performance with them. Informally, specific questions on how the infant is or is not tolerating the hearing instruments can provide clues as to whether the amplification prescribed is excessive, for example if the infant cries or tries to pull the hearing instruments off particularly in response to high-level environmental sounds. Conversely, it is important to determine if the effects of the hearing impairment have been reduced. For example, if the infant is not making any verbal noises or developing speech sounds, this may indicate that the amplification prescribed is insufficient. While subjective reports from families can provide important information when validating an infant's outcome from amplification, caution is required when contemplating adjustments on the basis of such reports, because of the many sources of variation other than the appropriateness of the amplification. Repeated observations and more structured approaches to observation should be considered.

APPENDIX A: References

ANSI (1996). American National Standard Specification for Audiometers (ANSI S3.6-1996). New York, American National Standard Institute.

Bagatto, M., Moodie, S., Scollie, S., Seewald, R., Moodie, S., Pumford, J. & Liu, K.P. (2005). Clinical protocols for hearing instrument fitting in the Desired Sensation Level method, *Trends in Amplification*, 9(4), 199-226.

Bagatto, M.P., Scollie, S.D., Seewald, R.C. Moodie, K.S. & Hoover, B.M. (2002). Real-ear-to-coupler difference predictions as a function of age for two coupling procedures, *Journal of the American Academy of Audiology*, 13(8), 407-415.

Bagatto, M.P., Seewald, R.C., Scollie, S.D. & Tharpe, A.M. (2006). Evaluation of a probe-tube insertion technique for measuring the real-ear-to-coupler difference (RECD) in young infants, *Journal of the American Academy of Audiology*, 17(8), 573-581.

Bess, F.H., Dodd-Murphy, J. & Parker, R.A. (1998). Children with minimal sensorineural hearing loss: prevalence, educational performance, and functional status, *Ear and Hearing*, 19(5), 339-354.

Bess, F.H. & Tharpe, A.M (1984). Unilateral hearing impairment in children, *Pediatrics*, 74(2), 206-216.

Canadian Working Group on Childhood Hearing (2005). Early Hearing and Communication Development: Canadian Working Group on Childhood Hearing (CWGCH) Resource Document. Ottawa: Minister of Public Works and Government Services Canada.

Carney, A. & Moeller, M.P. (1998). Treatment efficacy: Hearing loss in children. *Journal of Speech, Language and Hearing Research*, 41, S61-S84.

Crandell, C.C. (1993). Speech recognition in noise by children with minimal degrees of sensorineural hearing loss, *Ear and Hearing*, 14(3), 210-216.

Elfenbein, Jill L. 2000. Batteries Required: Instructing Families on the Use of Hearing Instruments. In R.C. Seewald, (ed.), *A Sound Foundation Through Early Amplification: Proceedings of an International Conference* (pp.141-149 Table 1).

Feigin, J.A., Kopun, J.G., Stelmachowicz, P.G., & Gorga, M.P. (1989). Probe-tube microphone measures of ear canal sound pressure levels in infants and children, *Ear and Hearing*, 10 (4), 254-258.

Government of Ontario (1991). Audiology and Speech-Language Pathology Act, 1991. Retrieved May 14, 2007 from the World Wide Web: http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/91a19_e.htm

Gravel, J., Fausel, N, Liskow, C & Chobot, J. (1999). Children's speech recognition in noise using omni-directional and dual-microphone hearing aid technology, *Ear and Hearing*, 20(1), 1-11.

Hattori, H. (1993). Ear dominance for nonsense-syllable recognition ability in sensorineural hearing-impaired children: monaural versus binaural amplification, *Journal of the American Academy of Audiology*, 4(5), 319-330.

APPENDIX A continued

Hawkins, D.B. & Yacullo, W.S. (1984). Signal-to-noise ratio advantage of binaural hearing aids and directional microphones under different levels of reverberation, *Journal of Speech and Hearing Disorders*, 49(3), 278-286.

Hodgetts, W.E., Scollie, S.D. & Swain, R. (2006). Effects of applied contact force and volume control setting on output force levels of the BAHA Softband, *International Journal of Audiology*, 45(5), 301-308.

Jenstad, L., Seewald, R., Cornelisse, L., and Shantz, J. (1999). Comparison of linear gain and WDRC hearing aid circuits I: Aided speech perception measures, *Ear and Hearing*, 20(2), 117-126.

Jenstad, L., Pumford, J., Seewald, R., and Cornelisse, L. (2000). Comparison of linear gain and WDRC hearing aid circuits II: Aided loudness measures, *Ear and Hearing*, 21(1), 32-34.

Joint Committee on Infant Hearing. (2000). Year 2000 Position Statement: Principle and Guidelines for Early Hearing Detection and Intervention Programs, *Pediatrics*, 106(4), 798-817.

Kruger, B. (1987). An update on the external ear resonances in infants and young children, *Ear and Hearing*, 8(6), 333-336.

Moeller, M.P., Donaghy, K.F., Beauchaine, K.L., Lewis, D.E. & Stelmachowicz, P.G. (1996). Longitudinal study of FM system use in nonacademic settings: effects on language development, *Ear and Hearing*, 17(1), 28-41.

Moodie, K.S., Seewald, R.C., & Sinclair, S.T. (1994). Procedure for predicting real ear hearing aid performance in young children, *American Journal of Audiology*, 3, 23-31.

Munro, K.J., & Hatton, N. (2000). Customized acoustic transform functions and their accuracy at predicting real-ear hearing aid performance, *Ear and Hearing*, 21(1), 59-69.

Ricketts, T. & Tharpe, A.M. (2004). Potential for directivity-based benefit in actual classroom environments, pp. 143-153. In *A Sound Foundation Through Early Amplification: Proceedings from an International Conference*. Ed. R. Seewald & J. Bamford. Phonak AG: Chicago, IL

Scollie, S.D., Seewald, R.C., Cornelisse, L.C., & Jenstad, L.M. (1998). Validity and repeatability of level-independent HL to SPL transforms, *Ear and Hearing*, 19, 407-413.

Scollie, S., Seewald, R., Cornelisse, L., Moodie, S., Bagatto, M., Lournagaray, D., Beaulac, S. & Pumford, J. (2005). The Desired Sensation Level multistage input/output algorithm, *Trends in Amplification*, 9(4), 159-197.

Scollie, S.D., Seewald, R.C., Moodie, K.S., & Dekok, K. (2000). Preferred listening levels of children who use hearing aids: Comparison to prescriptive targets, *Journal of the American Academy of Audiology*, 11(4), 230-238.

Seewald, R.C. (1995). The Desired Sensation Level (DSL) Method for hearing aid fitting in infants and children, *Phonak Focus #20*, 1-19.

APPENDIX A continued

Seewald, R.C., Moodie, K.S., Sinclair, S.T., & Scollie, S.D. (1999). Predictive validity of a procedure for pediatric hearing instrument fitting, *American Journal of Audiology*, 8, 1-10.

Seewald, R.C. & Scollie, S.D. (1999). Infants are not average adults: Implications for audiometric testing, *The Hearing Journal*, 52 (10), 64-72.

Sinclair, S.T., Beauchaine, K.L., Moodie, K.S., Feigin, J.A., Seewald, R.C., & Stelmachowicz, P.G. (1996). Repeatability of a real-ear-to-coupler-difference measurement as a function of age, *American Journal of Audiology*, 5:52-56.

Stuart, A., Durieux-Smith, A., & Stenstrom, R. (1990). Critical differences in aided sound field thresholds in children, *Journal of Speech and Hearing Research*, 33 (9), 612-615.

Wake, M., Hughes, E.K., Poulakis, Z., Collins, C. & Rickards, F.W. (2004). Outcomes of children with mild-profound congenital hearing loss at 7 to 8 years: A population study, *Ear and Hearing*, 25(1), 1-8.

APPENDIX B: IHP Instrumentation

RECD	Audioscan RM500SL or Verifit
Prescriptive Targets	DSL m[i/o] v5 within Audioscan RM500SL or Verifit
Hearing Instrument Programming	Standalone module or within Noah
Verification	Audioscan RM500SL or Verifit
Outcome Evaluation	Discretionary

APPENDIX C: IHP Provision of Amplification Audit Process and Indicators

Key Elements

- **Random selection of site & audiologist**
- **Audit of every IHP audiologist (N=75) over a 3-year cycle**
- **Audiologist selects 5 illustrative cases**
- **IHP selects another 5 cases from ISGIS database**
- **IHP obtains family consent & release**
- **Audiologist assembles & submits materials**
- **IHP reviews materials (MSH and UWO)**
- **Two reviewers, independent ratings**
- **Categories: conform, equivocal, non-conform**
- **Discrepancy resolution, positive emphasis**
- **Confidential documented results to audiologist**
- **Agreement and implementation of remedies**
- **Follow-up audit where indicated**
- **Interview for continued equivocal and non-conforming auditees to discuss further remedies & continued IHP participation**

General Principles

The Audit seeks to show that IHP Amplification protocol has been followed. Amplification records will be evaluated for protocol conformity, overall consistency among all records and reports, and appropriateness of prescribed instruments. Records will be assessed based on the quality and appropriateness of content, including timeliness of procedures.

Protocol compliance will be assessed through the presence of each of the following elements in the audit file:

- Indication to the family of a discussion about candidacy for amplification for the child, with qualification per ear if required. This includes recommendations for binaural hearing instrument fitting unless contraindicated as well as information about warranty, cost and service.
- Documentation that medical clearance for amplification has been requested and/or obtained.
- RECD values for initial fitting and for subsequent earmold changes. This includes the date, ear, and type of coupling used for the measurement. If an RECD measurement could not be obtained, explanatory notes and which predicted values were used shall be included.
- Make, model, and style of recommended hearing instruments and earmolds. This includes documentation of DAI and pediatric filtered earhooks.
- Hard copy of verification graphs from RM500 or Verifit of each hearing instrument.
- Hard copy of final settings of each hearing instrument fitted.
- Date of initial fitting and orientation.
- Documentation of timely follow-up amplification services.

PLUS:

- IHP audiologic data tracking forms.
- Any textual reports (e.g., to physicians) arising from IHP services.

APPENDIX C continued

1. Evidence of compliance with required IHP Provision of Amplification Protocol through performance indicators as listed below:

The following amplification recommendations will have been clearly charted and communicated to the family. All amplification candidacy evaluation is consistent with IHP audiological assessment protocols.

- a. The specific candidacy for amplification for their child, with qualification per ear if required.
- b. The make, model, and style of hearing instruments and earmolds required.
- c. Warranty, cost, and service.
- d. Recommendations for binaural hearing instrument fitting unless contraindicated

Quality Indicator:

Documentation that discussion has occurred with family and/or caregivers related to the provision and candidacy of amplification for their child. This should include specification of the above items and opportunity for questions or concerns about amplification options.

2. Amplification will not be provided if contraindications are medically indicated by an otolaryngologist.

Quality Indicator:

Documentation that medical clearance has been requested and/or obtained.

3. Amplification provision will be consistent with the elements of a complete pediatric prescriptive fitting method required by the IHP protocol incorporating indicators below:

Quality Indicators:

1. The electroacoustic characteristics of the prescribed hearing instruments should be consistent with known effective signal processing strategies in children. FM compatibility is a requirement on any hearing instrument prescribed for a child.
2. The RECD is measured in the majority of infants fitted with amplification, specifically prior to the initial hearing instrument fitting and when the earmold changes. For visits after January, 2004 if entering/predicting RECDs appropriate normative data should be entered into the verification system.
 - a. If middle ear status is normal, one RECD may be used for both ears.
 - b. RECD data should be consistent with correct measurement procedures.
4. Provision of amplification will be consistent with the elements of a complete pediatric prescriptive fitting method required by the IHP protocol incorporating indicators below:

APPENDIX C continued

Quality Indicators:

The hearing instruments have been fitted to the DSL prescription:

- a. Records are on file for each child that show the thresholds, transducer type, age, and hearing instrument style were correctly entered into a DSL system, and that prescriptive targets were computed. Hearing instrument prescriptive targets should be computed with each RECD measurement.
 - b. Records are on file to show the hearing instrument settings, and the measured responses of the hearing instruments for speech-level inputs and maximum output, at user settings. The fit to prescribed targets should be documented and within an acceptable range of target (see DSL Requirements below). Maximum output levels should be exceeded by no greater than 5dB SPL at any given frequency. Clinicians who store this information electronically will be asked to provide hard copies for audit (most recent fitting(s) only).
 - c. Serial numbers, per ear, should be on file.
5. Amplification will be provided following the identification of permanent childhood hearing impairment and the appropriate steps in the IHP amplification protocol have been completed.

Quality Indicator:

Date of initial fitting with hearing instruments should be clearly documented. The overall goal of the IHP is to have hearing instruments fitted by 6 months of age, for families who choose an amplification option. In this context, amplification audiologists are expected to provide timely hearing instrument fitting services (i.e., first hearing instrument fitting within no more than 2 months of obtaining a clear diagnosis, medically stable condition, and parental decision to pursue amplification, or 6 months corrected age, whichever is later.)

Comment: There may be a difference in performance on this quality indicator for files from before vs. after the onset of the IHP loaner program in cases of lack of available funding for purchase of new instruments.

6. Documentation that follow-up amplification services have been supplied to the family. This includes regular appointments, at a minimum, of every 3-6 months for earmold impressions, hearing threshold reassessment, remeasurement of RECDs when earmolds have changed, and amplification adjustments as needed.

APPENDIX C continued

Requirements for fit to DSL targets

Part 1 : Speech-Level Inputs (Targets should be achieved within ∇ 5 dB)

RM500 SL test signal: Speech, shaped at 70 dB SPL
(midpoint of speech region, corresponding to LTASS)
Verifit test signal: Speech, shaped, at 70dB SPL
(midpoint of speech region, corresponding to LTASS)

<u>Degree of Hearing Loss</u>	<u>Target Bandwidth</u>
Mild to Moderately-Severe (65dB HL)	
Flat	500-4000 Hz
Sloping*	500-3000 Hz
Severe to Profound (90dB HL)	
Flat	500-4000 Hz
Sloping*	500-2000 Hz
Profound (>90dB HL)	
Flat	500-1500 Hz
Sloping**	500-1500 Hz

*Slope = >10dB/octave

** If the dynamic range is less than 10dB, fit-to-targets may not be reached.

Part 2 : Maximum-Level Inputs (Response should be \leq 5dB over UCL)

RM500: MPO
Verifit: MPO

<u>Degree of Hearing Loss</u>	<u>Target Frequency</u>
All degrees and slopes	Any frequency

APPENDIX D: Estimated Hearing Levels (EHLs) and Hearing Aid Fitting

Tonepip ABR thresholds in dBnHL are not directly equivalent to perceptual thresholds in dBHL, and both dBnHL and dBHL are defined with reference to adult norms. ABR thresholds are converted to bias-free estimates of true perceptual threshold in dB HL by applying adjustment factors based on empirical, longitudinal validation studies. This correction is applied by the IHP Assessment audiologist following completion of the protocol (see Assessment protocol for details). The resulting thresholds shall be referred to in the IHP context as 'Estimated Hearing Level' (EHL) thresholds, with units dB EHL. EHL values are entered as thresholds in the IHP report and data forms.

For the purposes of calculating the hearing aid prescription, the Prescribing audiologist shall use the EHL values directly in applications of DSL v5. In the Audioscan RM500SL and Verifit, the Prescribing audiologist shall follow these steps:

1. Enter *Speechmap* from the *Tests* menu.
2. Select *Audiometry* and set *Target* to **DSL Child** and *Age* to correspond to the infant's age in months.
3. In the *Transducer* section, select **ABR (eHL)**. This indicates that the ABR thresholds have been corrected as described above and no further correction will be applied by the system.

Audiometry	
Ear	Right
Targets	DSL child
Age	3 months
Transducer	ABR (eHL)
Threshold	Entered
Bone conduction	N/A
UCL	Average
RECD	Measure
Binaural	No
Cancel Continue	

APPENDIX E: Coupling Insert Earphones to Personal Earmolds

During follow-up appointments, the audiologist may conduct VRA or CPA using insert earphones. If the child has personal earmolds, the insert earphones should be coupled to them for an accurate assessment of hearing thresholds in both ears. For a more stable connection, a suggested modification is described below. It should be noted that the RECD should be measured with the child's personal earmolds if the hearing thresholds are measured with this coupling method. Any changes to the child's auditory thresholds and RECD values should be applied to the hearing instrument prescription as needed.

Description of coupling the insert earphone to the earmold:

1. Trim approximately 5mm of tubing from a standard foam eartip, as shown in Figure 1.
2. Insert the trimmed tubing into the tubing of the earmold. Be sure the tubing of the earmold has been trimmed for use with the hearing instrument.
3. Insert the tip of the insert earphone transducer into the other end of the trimmed foam tip tubing, as shown in Figure 2.



Figure 1

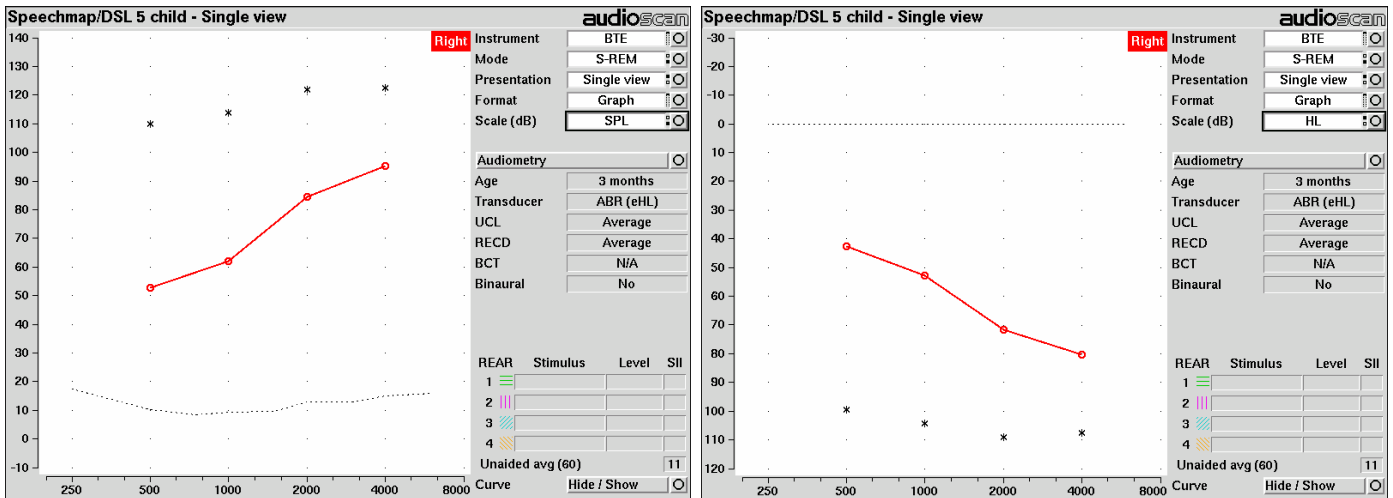


Figure 2

APPENDIX F: Comparing Audiograms for the Same Infant Over Time

When comparing audiometric thresholds for the same infant over time, it is important to take into account the changes in individual ear-canal acoustics. If ear canal acoustics are not considered, what appears to be a change in hearing threshold sensitivity may be a result of changes in ear canal acoustics due to ear growth. It is possible to apply RECD measurements to the hearing thresholds in EHL or HL for a more accurate representation in real-ear SPL or HLp. HLp represents an HL audiogram that has been corrected for ear canal acoustics (Bagatto et al, 2002; Feigin et al, 1989; Seewald & Scollie, 1999). When working in an SPLogram format on the Audioscan RM500SL or Verifit, the entered hearing thresholds will be converted to real-ear SPL.

To obtain HL thresholds that have RECDs accounted for (i.e. HLp), select *Scale* on the Speechmap screen and choose **HL**. To obtain the numerical HLp values, choose **Table** in the *Format* section.



APPENDIX G: RECD Measurement Procedure

Audioscan RM500SL and Verifit

System Setup: (assuming the system is on and both microphones are calibrated)

1. Select <TESTS> from the main menu.
2. In the test selection menu select <SPEECHMAP> and set the following menus:
Instrument: BTE
Mode: S-REM
Presentation: User preference
Format: User preference
Scale (dB): SPL
3. Select <AUDIOMETRY> and set the following menus:
Target: DSL Child
Age: Choose age in months
Transducer: insert + foam (for foam, immittance or OAE tip)
OR
insert + earmold
OR
ABR (eHL)
BONE CONDUCTION: User discretion
UCL: Average
RECD: Measure
BINAURAL: No
4. Press <CONTINUE> and follow prompt to enter audiometry. Press <CONTINUE>.

Coupler Measure

1. Carefully plug the coupler microphone into the test box and the RE-770 transducer into the front of the system.
2. Screw the HA-2 coupler onto the coupler microphone.
3. Couple the tip of the RE-770 transducer to the tubing of the HA-2 coupler.
4. Press <CONTINUE> to introduce the stimulus.
5. Press <CONTINUE> again to store the coupler measure. (TIP: once you have done this, it will be saved for up to one week. It saves time to do this in the morning right after calibrating the two microphones, so that it is completed when the infant arrives.)

Real-ear Measure

1. Perform an otoscopic examination on the infant.
2. Ensure the real-ear module is plugged into to the front of the system and that it corresponds to the ear that is activated on the screen.
3. Place the probe microphone module over the infant's ear and adjust for length.
4. To ensure the probe tube is positioned correctly, couple a probe tube alongside the eartip or earmold using plastic film or soft surgical tape. Ensure the tube extends approximately 2 to 4mm beyond the sound bore (see Figure 4).
5. Connect the RE-770 transducer to the tube/tip combination and insert the unit into the infant's ear. If you do not wish to couple the probe tube to the tip, inserting the probe

microphone approximately 11 mm from the *opening of the ear canal* will provide appropriate insertion depth for young infants (Bagatto et al, 2006).

6. Insert the tube/tip combination into the infant's ear canal and press <CONTINUE> to introduce the signal.
7. You will see four curves on the screen:
 - a. Top curve: real-ear response
 - b. 2nd curve: coupler response
 - c. 3rd curve: difference between a and b (this is the RECD)
 - d. 4th curve: a dashed line that represents an average RECD for comparison
8. The RECD will be saved in the system until you make another measurement.
9. Press <PRINT SCREEN> to print the curves. In the *Format* section, select **Table** to view and print the RECD values at each frequency. This is required for the patient's chart.



Figure 4

APPENDIX G continued

RECD Tips and Guidelines (Adapted from Bagatto, 2001)

Obtaining an accurate RECD measurement starts with learning what a typical RECD looks like. Typically, RECD values measured on an ear with normal middle ear status are positive across frequencies, and increase in the high frequency region:

- To convert from the real ear to the coupler, SUBTRACT the RECD
- To convert from the coupler to the real ear, ADD the RECD

By convention, positive RECD values indicate the extent to which levels measured in the real ear exceed levels measured in the coupler for the same test signal. Values in the low frequency region will generally be in the range of 0 dB to 10 dB and increase up to 20 dB in the high frequency region. In infants and small children, the size of the ear canal is much smaller than adults, therefore, the values will be larger. In other words, smaller volume, greater SPL, and thus greater RECDs. The general shape of the RECD is the same for both children and adults, but the values are different within and between these populations.

You can attempt to measure an RECD on an infant while the parent/caregiver cradles him/her or while the patient is still sedated from the ABR. The following steps outline some hints that will help you obtain an accurate RECD measurement.

1) Proper Probe Tube Placement

For infants, mark the probe tube approximately 11 mm from the medial tip. The mark should stop at the *opening of the ear* canal. Coupling the probe tube to the earmold or tip is also an appropriate strategy. For toddlers, mark the probe tube about 15 to 25 mm from the medial tip. When inserting the probe tube, the mark should stop at the *intertragal notch*. The insertion depth marks are to guide you in placing the probe tube to within 5 mm of the eardrum. This can also be done by measuring 5 mm from the medial tip of the infant's earmold.

Always use otoscopy before placing anything in the patient's ear canal. This helps you to determine the shape and length of the canal, and establish if there is any cerumen blockage. An otoscopic examination is helpful when placing the probe tube in order to ensure appropriate insertion depth.

2) Lubricate

Apply earmold lubricant (e.g. Otoease, Otoferm, etc.) to the portion of the tube that will be inserted into the ear canal. Be careful not to go right to the end, as the lubricant may plug the tube. The lubricant will help keep the probe tube resting on the floor of the ear canal. In addition, applying some lubricant to the foam tip or earmold will reduce friction when inserting the tip in the ear canal while the probe tube is in place. It will also help to insure that the tube does not move further into the ear canal.

3) Coordinate

When the probe tube is in place, insert a foam tip or earmold carefully without altering the position of the tube. When inserting the earmold or foam tip into the ear canal, stabilize the probe tube at the intertragal notch with your little finger. Use your thumb and index finger of the same hand to insert the mold/tip. Stabilize your hand against the infant's cheek and/or head when inserting the tube or insert/mold, so that sudden movements will not catch you by surprise. Also, make sure you are familiar with your equipment and the

procedure before trying to measure an RECD on an infant or young child. If you are confident, they will be less anxious.

5) Troubleshoot Your Measurement

Check the real ear portion of the RECD before you “accept” it as your measurement. Look for negative values in the low frequencies, and roll offs in the high frequencies. The next section will describe some possible causes of inappropriate RECD measurements, and some solutions.

When the probe tube and foam or impedance tip are situated in your patient’s ear, start the test signal and WAIT. Check the accuracy of your measurement while the signal is on. Before “accepting” the measurement, take note of the following:

a) *High frequency roll off at around 2 to 3kHz*

Possible Cause:

Earmold or Foam Tip Measurement
The probe tube may be too shallow.

Solution:

Reinsert the probe tube to within 5 mm of the tympanic membrane and remeasure.

b) *Negative values between -1 and -9 dB in the low frequency region*

Possible Cause:

Earmold Measurement: The probe tube may be causing some of the low frequency sound to escape from around the earmold. Also, the earmold may have a vent larger than 1 mm which will cause sound to leak out.

Foam Tip Measurement: The foam tip may not be fully expanded in the ear canal or the size of the foam tip is too small. Also, the foam tip may not be inserted deep enough into the ear canal. In all cases, low frequency sound will leak out.

Solution:

Use earmold lubricant (e.g. Otoease, Otoferm, etc.) on the foam tip or earmold to create a better seal around the ear canal. Plug the medial side of the earmold vent when doing the measurement. Also, if you have the appropriate size of foam tip, make sure the most lateral end of the tip is flush with the opening of the ear canal and the foam has completely expanded.

c) *Negative values between -10 and -15 dB in the low frequency region*

Possible Cause:

Earmold or Foam Tip Measurement
The patient may have a perforated eardrum or a myringotomy tube in place.

Solution:

Perform an otoscopic examination and check acoustic impedance results. It is normal to see extreme negative values in the low frequency region when a tube is in place or there is a perforation in the patient’s eardrum.

d) *Increased positive values in the low and mid frequency region*

Possible Cause:

The patient may have middle ear effusion. The increased mass and stiffness of a fluid-filled ear will cause increases in the RECD in the low and mid frequency regions, compared to a measurement obtained in an ear without middle ear effusion (Martin, et al., 1996). When a patient has middle ear effusion, the RECD results are more variable making it even more important to obtain this measurement.

Solution:

Check acoustic impedance results. It is normal to see increased positive values in the low and mid frequency regions when the patient has middle ear effusion.

Summary

The Real Ear to Coupler Difference measurement is used to capture an individual's occluded ear canal acoustics for the purposes of selecting and fitting amplification. Obtaining an accurate measurement is important for matching the appropriate electroacoustic characteristics of your patient's hearing instrument.

APPENDIX H: Applying Age-Appropriate Predicted RECD Values

The most recent version of the DSL Method (DSL *m*[i/o] v5) contains age-appropriate predicted RECD values for use with infants and young children when the RECD measurement cannot be obtained. These values differ from previous versions of DSL (i.e. DSL v4.1) in that they provide values for more discrete age ranges and different coupling methods (Bagatto et al, 2005; 2006). Audiologists within the IHP have been using these updated RECD values since 2001. Clinicians obtained the values from a table provided in a previous version of the Amplification protocol. The use of this table is *no longer required* since the predicted RECD values are available through the Audioscan RM500SL and Verifit's implementation of DSL v5. A description of how to access these values and apply them to the hearing aid fitting process is described below.

System Setup: (assuming the system is on and both microphones are calibrated)

1. Select <TESTS> from the main menu.
2. In the test selection menu select <SPEECHMAP> and set the following menus:
 - Instrument: BTE
 - Mode: S-REM
 - Presentation: User preference
 - Format: User preference
 - Scale (dB): SPL
3. Select <AUDIOMETRY> and set the following menus:
 - Target: DSL Child
 - Age: Choose age in months
 - Transducer: insert + foam (for foam, immittance or OAE tip)
 - OR
 - insert + earmold
 - OR
 - ABR (eHL)
 - BONE CONDUCTION: User discretion
 - UCL: Average
 - RECD: Average**
 - BINAURAL: No
4. Press <CONTINUE> and follow prompt to enter audiometry. Press <CONTINUE>.

APPENDIX I: Procedure for Obtaining an Earmold Impression

Recommended Materials

- silicone-based earmold impression material
- 2 measuring scoops
- impression syringe – pediatric tip
- oto-blocks
- earlight
- otoscope with pediatric specula
- mixing spatula
- non-stick mixing pad
- non-latex plastic gloves

Procedure

- 1) Instruct parent re: positioning, and child control
- 2) Wear a clean pair of non-latex plastic gloves throughout the entire procedure (or follow your clinic's specified infection control guidelines).
- 2) Perform an otoscopic examination to ensure that there are no conditions that would preclude taking an earmold impression (e.g. discharge from the ear, excessive cerumen). Make an estimate of ear canal size and length.
- 3) Measure and mark earlight using the following general guidelines:
 - <6 months – mark earlight for approximately 10 mm from ear canal entrance
 - >6 months – mark earlight for 10-15 mm from ear canal entrance, depending on ear size and age.

Note: If infant is premature, has Down's syndrome, low birth weight, etc., insertion depth may need to be reduced.
- 4) Using the earlight, insert the oto-block gently into the ear canal so that the marked position on the earlight is at the ear canal entrance (see #3 above). Examine the depth and position of the oto-block with the otoscope. When satisfied with the placement, wrap the string from the block over and around the infant's ear.
- 5) Measure the appropriate amount of earmold impression material as indicated on the container. Mix the material together as directed. Place the material in the syringe and insert the plunger forcing the material down the syringe.
- 6) Place the tip of the syringe down the ear canal as close to the otoblock as possible. Do not pull on the patient's ear, as this will change the shape of the ear canal.
- 7) Depress the plunger slowly and move the syringe out as the canal fills. Keep the tip of the syringe in the impression material at all times. Once the canal is full, move out into the concha, filling in as much as possible without removing the syringe from the impression material. Next, fill in the helix area and then the rest of the concha. Gently press on the tragus to ensure that this area is not overfilled.
- 8) Employ techniques to encourage jaw movement while filling the canal e.g. sucking or other mouth movement. Movement need not continue throughout the hardening process.

- 9) Allow the impression material to harden; approximately 5 to 10 minutes. If you push your fingernail on the material without leaving an indentation, then the material is set.
- 10) To remove the impression, pull gently on the pinna to loosen the impression in the infant's ear. Then, carefully peel out the concha portion without bending the canal; at the same time remove the helix portion. When the concha portion is about a third of the way out, gently rotate the impression forward (towards the patient's nose) and remove the canal portion of the impression.
- 11) Perform an otoscopic inspection of the ear canal to ensure removal of the oto-block and earmold material, and to evaluate the status of the ear canal.
- 12) Inspect the impression for quality and completeness
- 13) Mark the canal for appropriate length.

Earmold Material and Style

Although earmold labs have a variety of brand names for their products, 2 main choices of pliable earmold material should be considered for children: PVC (vinyl) or Silicone.

For very young children (<12 months), the size of the ear canal may limit the diameter of the sound bore and how completely the earmold can be tubed. If the earmold material is too pliable, a small ear canal could constrict or close off the un-tubed portion of the sound bore.

Silicone materials do not accept glue and usually require the use of a tube lock or tubing retention ring to hold tubing in place. This can distort the shape of the earmold in small ear canals, causing irritation or even feedback. PVC (vinyl) material accepts tubing glue and is somewhat stiffer in shape than silicone; therefore it is preferable for children under 6 months of age, or for children with unusually small ear canals.

Earmold venting should be considered with caution. The primary fitting problem with infants and young children is feedback. A vented earmold can be an additional source of feedback. The size of an infant's ear canal will often limit the ability to add a vent. If venting is possible, it is diagonal, rather than parallel venting and tubing retention again will be affected.

Shell-style earmolds are the standard style recommended for children, because of retention and feedback-prevention. Helix locks may improve earmold retention, but parents should be carefully instructed on inserting them correctly to prevent irritation or feedback from a helix lock that is not placed properly.

APPENDIX J: Deriving 2cc Targets for Purposes of Selecting a Hearing Instrument

Much of the work in DSL *m[i/o]* v5 has been aimed at preserving most of the prescriptive characteristics for infants and children applied in previous versions of the DSL Method (i.e. v4.1). However, there have been some target modifications that clinicians can apply at their discretion. A detailed description of these changes can be found in Scollie et al, 2005. A Conductive Correction is available to compensate for mixed and conductive losses. This can be applied at the discretion of the clinician by choosing it in the *Bone Conduction* menu described below. A binaural correction is available, however, it is recommended that IHP audiologists do not apply this correction for their pediatric patients fitted with binaural amplification. The literature is not conclusive whether a gain reduction is required for binaural fittings in children. Therefore, this item needs further investigation and future revision.

A description of deriving 2cc targets for selecting a hearing instrument using DSL *m[i/o]* v5 within the Audioscan RM500SL and Verifit is described below.

System Setup: (assuming the system is on and both microphones are calibrated)

1. Select <TESTS> from the main menu.
2. In the test selection menu select <SPEECHMAP> and set the following menus:
Instrument: BTE
Mode: S-REM
Presentation: User preference
Format: 2cc Targets
Scale (dB): SPL
3. Select <AUDIOMETRY> and set the following menus:
Target: DSL Child
Age: Choose age in months
Transducer: insert + foam (for foam, immittance or OAE tip)
OR
insert + earmold
OR
ABR (eHL)
BONE CONDUCTION: User discretion
UCL: Average
RECD: Measured or Average or Enter
BINAURAL: No
4. Press <CONTINUE> and follow prompt to enter audiometry. Press <CONTINUE>.
5. Print out, or write down the Full On Gain (FOG), User Gain and Maximum Power Output (MPO) targets.
6. Using manufacturer's specification books, Noah Modules or real measures on consignment hearing instruments, select a hearing instrument that can provide this amount of gain, slope, and output limiting.

APPENDIX K: Electroacoustic Verification

1. Follow steps 1 through 4 in Appendix J.
2. Place selected hearing instrument in the test box coupled to the HA-2 coupler.
3. In the *REAR 1* section of Speechmap, choose the <Speech-std(1)> or <Speech-std(2)> stimulus type. Select a level of *70 dB SPL* to verify average speech targets. NOTE: the DSL targets will not appear on the screen until a stimulus has been selected.
4. Adjust the instrument to the average speech targets (+) for 70 dB SPL.
5. Press <CONTINUE> to store the curve. This curve will be saved as *REAR 1*.
6. In the *REAR 2* section, choose the <MPO> stimulus. Adjust the instrument so it approximates the small (+) targets and does not exceed the (*) targets. Press <CONTINUE> to store the curve.

NOTE: The ULC target (*) is intended to be matched by fully saturated hearing aid responses, therefore a slightly lower target may be more appropriate for use with the MPO test signal. For this reason, the target input/output function within DSL v5 can be used to compute a level-dependent target for either 85 dB SPL (in the real ear) or 90 dB SPL (in the coupler, using simulated real ear measurement). This new target will be somewhat lower than ULC for most hearing losses.

7. In the *REAR 3* section, choose the <Speech-std(1)> or <Speech-std(2)> stimulus type. Select a level of *55 dB SPL* to verify soft speech targets and a level of *75 dB SPL* to verify loud speech targets.
8. Adjust the instrument to the soft and loud targets and press <CONTINUE> to store the curve.

NOTE: Do not compromise your fit to targets for average speech or MPO to obtain a better match for soft and loud. A close match to average conversational speech and maximum output targets of the hearing instrument are to be given priority when verifying hearing instruments for infants and young children.

9. Repeat the verification procedure for average and MPO if you made adjustments in Step 8.
10. Save the final settings to the hearing instrument and print out the verification data from the Audioscan and Noah module for the patient's chart.

APPENDIX L: Protocol for Fitting FM Systems

Goal for Fitting FM Systems

The goal is to maintain approximately 10 dB difference between the FM and environmental microphone (EM) signals when both are activated *simultaneously*. The extent to which this goal can be achieved will be affected by the degree of hearing loss, maximum output of the system, hearing instrument processing and AGC in the microphone (transmitter).

General Steps for Fitting FMs

*always make measurements in output

- 1) Confirm that the hearing aid is set for optimal audibility and maximum output for the individual
- 2) Connect instrument to FM and turn on. Run instrument again to ensure instrument still functions with this setup. Run MPO first and then speech.
- 3) Place FM microphone in test box and evaluate with a 65 dB SPL speech input
- 4) If the difference between the hearing aid response and the FM response is greater than ± 2 dB, adjust the FM setting appropriately and re-evaluate.
- 5) Evaluate the system using an 85 dB SPL speech signal into the FM. The FM response should be at least 5 dB higher, on average, than the hearing aid.
- 6) Perform a listening check with simultaneous inputs to the FM and the hearing aid microphone. Adjust the relationship as needed.

APPENDIX M: Instruction and Information

Orientation Checklist

Below is a suggested Orientation Checklist or a set of discussion topics for clinicians and families. Audiologists and dispensers will need to ensure that all of the following are covered in discussion and related questions are answered.

- Amplification and the speech signal, e.g. explanation of aided audibility and its implications for speech and language development
- Impact of noise and distance
- Coping with noise and distance (e.g. at home, in the car)
- Equipment needed to care for hearing instruments
- Techniques for cleaning earmolds and hearing instruments
- Procedures for battery checks and insertion
- Procedures for listening checks of hearing instruments
- Putting hearing instruments on the child and securing them – retention and loss-prevention
- Setting user controls
- Incorporating use of hearing instruments into the child's routine
- Plans for documenting experiences with hearing instruments – hearing instrument diaries could be provided or recommended
- Safety issues (e.g. battery ingestion)
- Understanding and combating feedback
- Protecting the hearing instruments from potential hazards (e.g. moisture, pets)
- Troubleshooting techniques
- Trial periods, warranty and insurance information
- Financial Assistance information (e.g. Assistive Devices Program)
- Plans for repair of malfunctioning hearing instruments
- Discussion of earmold life expectancy and hearing instrument life expectancy
- Plans for follow-up contact between the family and clinician
- Options to be used at a later date (e.g. T-coil)

Adapted from: Elfenbein, Jill L. 2000. Batteries Required: Instructing Families on the Use of Hearing Instruments. In R.C. Seewald, (ed.), *A Sound Foundation Through Early Amplification: Proceedings of an International Conference* (pp.141-149 Table 1).

Pediatric Considerations

The unique needs of the infant must be considered when selecting non-acoustic features of the hearing instruments. Tamper resistant battery doors should be implemented, because hearing instrument batteries are toxic if ingested. Applying a volume control cover or lock will ensure that the infant is wearing the hearing instruments at the prescribed volume setting at all times. Pediatric earhooks should also be utilized as a loss retention device as well as for filtering for appropriate acoustic outcomes. Non-acoustic features of hearing instruments should ideally be selected as part of the amplification prescription, but may be discussed between the prescriber and dispenser prior to ordering and fitting the devices.

Care and Maintenance "Kit"

Dry Aid Kit for removing moisture from the hearing instrument and earmold
Stethoscope for daily listening check

APPENDIX M continued

Battery Tester

Earmold Blower for removing moisture and debris

Hearing instrument 'Clips' or Huggie Aids to prevent loss and protect from damage

Care and maintenance kits are available upon request from the hearing instrument manufacturers for pediatric fittings, as are *special pediatric extended warranties*.

In addition to the above list, manufacturers' kits may also include:

Other cleaning tools

Informational brochures, videos, books, stickers

Carrying case

End of document /mpb