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Protocol for the Provision of Amplification

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Ontario Infant Hearing Program

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EDITORS
Marlene Bagatto, AuD, PhD
Susan Scollie, PhD

CONTRIBUTORS
Susan Scollie, PhD
Marlene Bagatto, AuD, PhD
Sheila Moodie, PhD
Richard Seewald, PhD
Martyn Hyde, PhD
Stacey Weber, MSc
Vanessa Martin, MSc
Danielle Glista, PhD
Anne Marie Tharpe, PhD
Jeff Crukley, PhD
Marianne Hawkins, PhD
Charla Levy, MSc
Sahar Zimmo, MSc
Shane Moodie, MSc
Frances Richert, MSc
Vijay Parsa, PhD

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

CORRESPONDENCE
Marlene Bagatto, AuD, PhD
Room 2262J Elborn College
Child Amplification Laboratory
National Centre for Audiology
Western University
London, ON, CANADA
N6G 1H1
Voice: 519.661.2111 ext. 88949
Fax: 519.661.3805
Email: bagatto@nca.uwo.ca

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CONTENTS

SECTION 1: INTRODUCTION

This Protocol 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 specifies context and procedures for the provision of amplification, including specification of key procedures and equipment requirements. Furthermore, several IHP Protocol addenda have been included. These addenda provide updates to evidence and are intended to support current clinical practice within the IHP.

1.1 AMENDMENT HISTORY

This Protocol supersedes all previous provisions of amplification on subjects covered in this Document.

Date	Document Title	Amendment
October 2007	Ontario Infant Hearing Protocol for the Provision of Amplification Version 3.1	November 2014
May 2010	Ontarion Infant Hearing Program Outcome Measurement Protocol	Separate document (2010) www.dslio.com
April 2011	Ontario Infant Hearing Program Frequency-Lowering Hearing Aids Protocol Addendum and Support Document	November 2014
October 2013	American Academy of Audiology Pediatric Guidelines Summary and Support Document for the Ontario Infant Hearing Program	Minor changes. Included as Addendum 1 in this document

1.2 UPDATES TO THE PROTOCOL

With the recent amendments, several topics have been added or expanded based on current evidence and clinical practice.

Topic	Section
IHP Instrumentation	Appendix A
AAA Guidelines Summary and Q&A	Addendum 1
Frequency lowering technology	Addendum 2
Noise management	Addendum 3
Minimal/mild bilateral hearing loss	Addendum 4
Unilateral hearing loss	Addendum 5
Remote microphone hearing assistance technologies (FM)	Addendum 6

1.3 FORECAST CHANGES

We rely upon the accuracy of information contained in the Protocol. As such, any anticipated changes, omissions or additions may result in accordance with emerging research or recommendations.

Anticipated changes/additions:

a) Process and outcomes review
b) Bone conduction hearing aid verification
c) Updates to procedures to align with ANSI S3.46-2013

SECTION 2: SCOPE

2.1 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.

2.2 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.

2.3 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).

2.4 TARGET IMPAIRMENTS

The nominal target permanent childhood hearing impairment (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 Neuropathy Spectrum Disorder (ANSD) and retrocochlear disorders affecting the auditory brainstem.

2.5 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.

2.6 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.

2.7 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.

2.8 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. Second opinions may be requested by the IHP audiologist, the parents or another IHP service provider if they believe that such a review may materially improve the accuracy or effectiveness of the overall Amplification outcome. Specific procedures for intiating this request are outlined in a procedural document that is not within the scope of this protocol (REF). 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, the Children’s Hospital of Eastern Ontario (CHEO), Ottawa, and the National Centre for Audiology at the Western University, London.

2.9 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.

2.10 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 Hosptial (Dr M Hyde) and/or The National Centre for Audiology at Western University (Dr M Bagatto) of the conflict promptly and the IHP will act to resolve the issue at a provincial level.

2.11 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.

2.12 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.

2.13 PERFORMANCE AUDITS

Every IHP audiologist who provides Amplification services funded by the IHP shall undergo process and outcomes review periodically by the IHP, selected at random. 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 process and outcomes review of individual IHP audiologists' case records, as and when the need is determined by the IHP. All provision of process and outcomes review materials shall conform to current provincial laws and standards relating to personal health information.

2.14 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).

2.15 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, 2007). 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.

2.16 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.

2.17 CALIBRATION

The IHP audiologist shall perform at least weekly calibration of their hearing instrument test systems. These systems shall also be calibrated on an annual basis, as scheduled by the facility or the regional IHP.

2.18 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.

2.19 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) must be completed across test levels for speech and maximum output;
- 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 require

2.20 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 a performance review. They should also be sufficient to facilitate consultative, clinical review and case conferencing.

The audiologist shall complete the appropriate IHP Amplification summary report forms and send them 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.

2.21 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 unathorized access, theft or loss.

SECTION 3: ASSESSMENT CONSIDERATIONS

3.1 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.

3.2 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.

3.3 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.

3.4 RECD MEASUREMENT

Wherever feasible, IHP audiologists shall measure the individual infant's RECD as part of the Amplification process. RECD measurements should be obtained from each infant using an IHP approved real-ear hearing instrument test system (see Appendix A) 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.

3.5 AGE-APPROPRIATE PREDICTED RECD VALUES

In the event that the individual RECD measurement cannot be obtained, age-related predicted values shall be applied. 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).

SECTION 4: SELECTION AND FITTING OF AMPLIFICATION

4.1 EAR IMPRESSIONS

Ear impressions will be obtained from each ear for fabrication of personal earmolds (see Appendix D and CASLPO PPG, 2013) 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 D for details). The cost and need for frequent replacement of earmolds to prevent acoustic feedback should be explained to the parent/caregiver.

4.2 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.

4.3 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 IHP approved real-ear hearing instrument test systems (Appendix A). DSL v5 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). This change was based on evidence for 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 real-ear hearing instrument test system. Coupler targets for the amplified long term average speech spectrum and MPO across frequency for each ear requiring amplification shall be documented.

4.4 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.

4.5 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 remote microphone hearing system (e.g,. FM/DM 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. Further information about the selection and verification of remote microphone hearing assistance technologies can be found in Addendum 6.

SECTION 5: VERIFICATION OF AMPLIFCATION

5.1 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 S2.3 and S2.4 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.

5.2 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.

5.3 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 within approved real-ear hearing instrument test systems. For a detailed description of this procedure see Appendix E. 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.

5.4 APPLICATION OF ADVANCED TECHNOLOGIES

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.

Advanced signal processing, such as automatic noise reduction, automatic program switching, and frequency lowering processors, are continuously evolving. As new technologies and new evidence emerge, IHP clinicians are encouraged to use technologies that meet the listening needs of their patients. Specific evidence review and protocols have been developed for frequency lowering, noise management, and remote microphone hearing assistance technologies (Addendum 2, Addendum 3, Addendum 6).

5.5 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) shall be conducted for each ear requiring amplification through the use test box measurements within real-ear hearing instrument test systems. These procedures are outlined in Appendix E.

5.6 VERIFICATION STIMULI

Verification of hearing instrument performance across input levels in the range of 55 to 75 dB SPL shall be conducted to determine the audibility and compression characteristics of the instrument. Verification of speech

targets shall be completed using pre-recorded, calibrated speech test signals. Maximum output characteristics for most hearing instruments shall be verified using narrowband stimuli at a high test level (85 to 90 dB SPL).

SECTION 6: INFORMATION AND INSTRUCTION

6.1 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 care kit must be provided (see S5.1). 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.

6.2 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.

6.3 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.

SECTION 7: OUTCOME EVALUATION

7.1 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 neuropathy spectrum disorder, the regular

schedule is especially important. The schedule should be re-assessed on an ongoing, individual basis, with appropriate documentation.

7.2 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.

7.3 OUTCOME MEASURES

Validation of the fitting shall be done using procedures outlined in the IHP Outcome Measurement Protocol (2010) which is provided in a separate document (Bagatto et al, 2011).

SECTION 8: TRAINING AND CLINICAL DECISION SUPPORT

8.1 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 as well as the Children's Hospital of Eastern Ontario (CHEO), Ottawa for ABR-based and VRA-based Assessments and Western University, London for VRA-based Assessments and IHP Amplification protocols.

At any time, audiologists may fax records to Western University for a clinical or procedural opinion regarding Amplification. 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.

8.2 IHP WEBSITE

A website supporting the IHP has been developed at Mount Sinai Hospital. The URL is *http://www.mountsinai.on.ca/care/infant-hearing-program/health-professionals.* All IHP protocols and many related materials are available on the website.

SUPPLEMENT 1: PROGRAM CONTENT

S1.1 ONTARIO INFANT HEARING PROGRAM 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.

Audiologists will use equipment that meets the criteria established by the Ministry.

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 the reference section of this document.

S1.2 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, January 2008' 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).

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 discretional 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.

S1.3 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. Support for managing unilateral PCHI can be found in Addendum 5 of this document.

The IHP target also includes the cluster of disorders commonly termed 'Auditory Neuropathy' (AN). This is referred to within the IHP as Auditory Neuropathy Spectrum Disorder (ANSD) 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 Neuropathy Spectrum Disorder' is a legitimate, non-etiologic descriptor of an auditory system dysfunction that may include abnormal quantity and/or temporal distribution of afferent neural activity in varying degrees.

ANSD 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.

S1.4 INSTRUMENTATION, CALIBRATION & SUPPLIES

Audiologists will use the equipment that meets the criteria established by the IHP. Current IHP instrumentation requirements are listed in Appendix A.

Routine calibration checks of real-ear hearing instrument test systems are necessary for appropriate operation of the system and shall be completed by the audiologist. Yearly calibration services will be arranged by each lead agency and/or by the lead agency's subcontracted partners, with reasonable notice to the Amplification centres.

S1.5 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 discretional. 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.

S1.6 PROCESS AND OUTCOMES REVIEW

Protocol compliance will be evaluated routinely by several mechanisms, including chart review of IHP Audiologists, with random selection of who will be reviewed.

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).

S1.7 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). A decision support guide for managing infants with minimal/mild bilateral hearing loss can be found in Addendum 4. Infants identified with a unilateral PCHI may be candidates for amplification. Evidence suggests that amplification recommendations be based on the level of hearing loss in the affected ear. Further detail is described in Addendum 5. Infants who have been identified as having ANSD, 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 ANSD based on ABR findings should be evaluated behaviourally before amplification is considered. Individuals with ANSD 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.

SUPPLEMENT 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 ANSD 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 must be calculated using the eHL data obtained during the assessment (Bagatto et al, 2005). Further information about this application can be found in Appendix B.

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 ANSD 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 to improve the likelihood

that the phones will be retained in the child's ear (see Appendix C for practical description). Any changes to the infant's auditory thresholds should be applied to the hearing instrument prescription as needed.

S2.2 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 that the thresholds are represented in either real ear SPL or equivalent adult hearing level (sometimes called HLp), because both of these scales allow appraisal of threshold changes independent of ear canal acoustic changes. 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. These calculations are commonly automated in many commercial hearing aid analyzers.

S2.3 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). 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.

S2.4 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. An RECD measurement should therefore be attempted 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.

SUPPLEMENT 3: PRESCIPTION OF AMPLIFICATION

S3.1 NON-ELECTROACOUSTIC CHARACTERISTICS

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

1. 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
2. Custom products are more prone to feedback due to the close proximity of the receiver and microphone
3. BTEs allow for greater electroacoustic flexibility
4. Direct audio input capabilities are more compatible with the target population
5. 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 on a soft headband, bone anchored 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 typically 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. A bone anchored hearing instrument attached to a soft headband uses an adjustable elastic headband to house the bone conduction processor and hold it in place on the infant's head. It has been demonstrated that the direct contact force of the bone conduction 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 bone conduction instrument 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 a bone conduction hearing instrument on a headband, accompanied by validation via aided sound field thresholds and parent interviews/feedback.

S3.2 ELECTROACOUSTIC CHARACTERISTICS

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

1. Sufficient gain, level-dependent processing, and frequency shaping to allow the hearing aid to be adjusted to a child's individualized DSL v5 prescription using the procedures described in this document.
2. The hearing instrument(s) selected shall avoid unnecessary distortion.
3. The hearing instrument(s) selected shall provide electroacoustic flexibility to accommodate anticipated changes in ear canal growth, changes in hearing threshold level if known or suspected, and anticipated needs for coupling to external sound sources or for advanced signal processing.

S3.3 DEVICE SELECTION

Unless otherwise instructed, manufacturers may 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.

S3.4 OTHER ASSISTIVE TECHNOLOGY

It has been well documented that the use of remote microphone hearing assistance 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 (AAA, 2013). While a remote microphone technology (FM/DM) 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 remote microphone hearing assistance technologies be discussed with the family during amplification appointments and provided when appropriate. Further information on selecting and verifying remote microphone hearing assistance technologies can be found in Addendum 6.

SUPPLEMENT 4: INFORMATION AND INSTRUCTION

S4.1 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 F.

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.

SUPPLEMENT 5: OUTCOME EVALUATION

S5.1 OUTCOME MEASURES

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. Since 2010, the IHP has implemented a systematic, evidence-based Outcome Measurement Protocol for children who wear hearing aids. It consists of caregiver questionnaires that assess auditory development (i.e., LittlEARS Auditory Questionnaire) and auditory performance (i.e., Parents' Evaluation of Aural/Oral Performance of Children [PEACH]) as well as a parental satisfaction survey (i.e., IHP Amplification Benefit Questionnaire). In addition, tools to assess the quality of the hearing aid fitting (i.e., Speech Intelligibility Index) are provided in order to support interpretation of functional outcomes.

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SECTION 10: APPENDICES

APPENDIX A: IHP INSTRUMENTATION

In addition to hearing instrument programming software, sites providing Amplification Services for the IHP must have access to real-ear and hearing aid test systems that provide specific functions. The required functions are defined below.

1. **Desired Sensation Level (DSL) v5.0a Prescriptive Targets**

As indicated in the IHP Protocol for the Provision of Amplification, the DSL Method v5.0 (Scollie et al., 2005) shall be used to develop the appropriate electroacoustic characteristics for each infant requiring hearing aid amplification through the IHP. The hearing aid test system should provide DSL targets for every frequency at which audiometric data has been entered. Preferably, the system should also interpolate for targets in between frequencies at which audiometric data has been entered.

2**. Fitting Parameters**

(a) Age
The real-ear and hearing instrument test system must allow the end user to enter the age or birth-date of the patient, or read this information in from Noah or any other similar database. This variable will affect the calculation of predicted age-related transforms within DSL (the real-ear-to-coupler difference (RECD) and the real ear unaided response (REUR)).

(b) Client Type
The real-ear and hearing instrument test system must require the end user to choose whether the DSL prescription is based on pediatric hearing loss or hearing loss acquired in adulthood.

(c) Circuit Type
The real-ear and hearing instrument test system must define whether the targets are displayed for linear or wide dynamic range compression. Alternatively, if only one circuit type is used, the targets must be displayed for wide dynamic range compression.

(d) Prescription Type
The DSL Method v5.0 calculates different prescriptions for use in quiet or in noise environments. This variable creates two different prescriptions: the DSL-noise prescription uses less gain and output. It is recommended that the real-ear hearing instrument test system provides the DSL Quiet and Noise environment listening targets.

(e) Transducer Type
The real-ear and hearing instrument test system must require the end-user to define the transducer used for audiometry from the following list:
1) insert earphone + foam tip,
2) insert earphone + custom mold,
3) TDH phone,
4) Sound field, with specification of azimuth of 0, 45, or 90 degrees
5) frequency specific ABR in either nHL or eHL is preferred. If nHL is supported, the end user must be able to define program-specific corrections to convert nHL to eHL.

3. **Data Entry and Data Display**

(a) Acoustic Transforms
The real-ear and hearing instrument test system must prompt the end user to either enter values for, or measure directly the following transforms: RECD and REUG. For REUG measurements, the measurement azimuth (0, 45, 90 degrees) must be specified. For RECD measurements, the coupling type (foam tip, ear-mold) and coupler type (HA1 or HA2) must be specified. If the end user does not provide entered or measured data for any transform, the DSL age-predicted values should be used. The real-ear and hearing instrument test system must display onscreen the chosen RECD measurement option (from the list of 4 above) for the end user to see.

(b) Audiometric Data
The real-ear and hearing instrument test system must allow the end user to enter frequency-specific measures of the patient's air conduction thresholds and bone conduction thresholds.

(c) Verification Displays
The real-ear and hearing instrument test system must support hearing aid verification either when the hearing aid is coupled to the ear, or when the hearing aid is attached to a coupler. The system should provide appropriate corrections when coupler-based verification is used (accounting for both microphone location effects and the Real Ear to Coupler Difference). Testing with calibrated running speech must be provided in both the 2cc coupler and REAR displays, with analysis of the hearing aid in 1/3 octave bands both for percentile analysis and for the long term average speech spectrum. Running speech test signals may include the ISTS signal or any signal that provides equivalent test results. Percentile analysis should be offered for the 99^{th} and 30^{th} percentiles at a minimum. The speech test signals should be equivalent in spectral and dynamic range properties to the ISTS.

(d) SPL-ogram
The real-ear and hearing instrument test system must display and correctly label either the REAR90/OSPL-90 and/or the predicted or measured UCL values onscreen. The system must display and correctly label the patient's hearing thresholds, converted to SPL using the DSL transforms. These variables should be displayed together with the DSL targets and hearing aid verification curves. An analysis of the Speech Intelligibility Index should be displayed for each verification curve performed with running speech.

APPENDIX B: 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 their real-ear hearing instrument test system as well as hearing instrument programming software. The eHL option is often found in the 'Transducer' section of the system when DSL v5.0 Child Targets are chosen. Choosing eHL indicates that the ABR thresholds have been corrected as described above and no further correction will be applied by the system.

APPENDIX C: 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 may be coupled to them to improve retention in the child's 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.

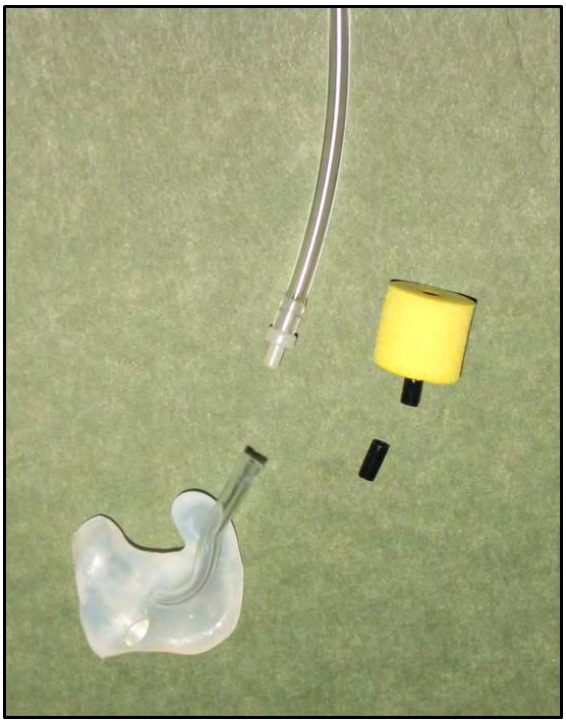


Figure 1

Figure 2

APPENDIX D: PROCEDURE FOR OBTAINING AN EAR 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).

3. 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.

4. 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 Syndrome, low birth weight, etc., insertion depth may need to be reduced.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. Inspect the impression for quality and completeness

14. Mark the canal for appropriate length.

15. Earmold Material and Style

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 E: ELECTROACOUSTIC VERIFICATION

1. Place selected hearing instrument in the test box coupled to the HA-2 coupler.
2. In the simulated real-ear section of the system, choose a calibrated speech stimulus. Select a level of 65 dB SPL and measure a simulated real ear aided response.
3. Adjust the instrument to provide a close match to the average speech targets for 65 dB SPL and store the curve.
4. Choose a high-level (85 – 90 dB SPL) narrowband stimulus and adjust the instrument so it approximates the DSL v5.0 MPO targets and does not exceed the UCL targets. Store the curve.

5. Choose the same standard speech stimulus as in Step 2 above. Select a level of 55 dB SPL to verify soft speech targets and a level of 75 dB SPL to verify loud speech targets.

6. Adjust the instrument to the soft and loud targets and store the curves.

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.

7. Repeat the verification procedure for average and MPO if you made adjustments in Step 6.

8. Save the final settings to the hearing instrument and print out the verification data from the real-ear and hearing instrument test system and the hearing aid fitting software for the patient's chart.

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.

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.

APPENDIX F: 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

- 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

SECTION 11: PROTOCOL ADDENDA

ADDENDUM 1: AMERICAN ACADEMY OF AUDIOLOGY PEDIATRIC AMPLIFICATION GUIDELINES

INTRODUCTION

Recently, the American Academy of Audiology (AAA) released an updated version of their clinical practice guidelines for pediatric amplification (AAA, 2013). Their previous guideline was published in 2003. Prior to the current version, The Ontario Infant Hearing Program's (IHP) protocol for the provision of amplification was updated in October 2007 (published in 2010; Bagatto, Scollie, Hyde & Seewald, 2010) with some protocol addenda that followed in more recent years. The IHP continues to develop protocol addenda as the need arises. Overall, the procedures described in the new AAA document are generally consistent with current IHP protocol. The updates we have made to the 2007 IHP protocol address specific issues of practice change, most recently by providing an outcome measures protocol (2010) and procedures for fitting frequency lowering hearing aids (2011; updated 2014: Addendum 2). These updates allow the main IHP Amplification protocol to remain consistent with current best practices knowledge. Further updates are expected as current knowledge continues to evolve.

This document includes a brief description of the purpose of the AAA Guideline and the process with which it was developed. In addition, highlights of guideline elements that are relevant to IHP Habilitation Audiologists will be addressed. This will be presented in a Question and Answer (Q & A) format to assist with quick referencing. It is recommended that this support document be read in conjunction with the AAA Guideline for Pediatric Amplification (AAA, 2013).

PURPOSE OF AAA GUIDELINE (2013)

The AAA Guideline provides systematically developed statements to assist audiologists in fitting hearing aids to the pediatric population. A summary and appraisal of the best available research evidence or expert consensus is provided along with a synopsis of the recommendations. It does not provide information about the exact clinical processes that would fulfill the Guideline. Specifics about how to execute a guideline are more characteristic of a protocol. The IHP Provision of Amplification and supporting addenda are examples of protocols. Protocols provide clinicians with details that support their adherence to a more general guideline.

Many sources of information were used to develop the Guideline. These included systematic reviews of research, first principles (or facts) and expert consensus. The summaries of knowledge that were derived from these sources guided the development of the recommendations included in the document. The AAA Guideline follows the basic clinical processes of pediatric hearing aid fitting such as assessment (including candidacy and support), device selection and prescription, verification and validation. It also includes recommendations about ongoing audiological care, referrals and counseling and parent to parent support. A task force consisting of experts in the area of pediatric amplification participated in the development of the Guideline.

Q & A FOR AAA GUIDELINE (2013)

1) *What candidacy criteria are outlined?*

Rather than giving a specific age range, the AAA Guideline emphasizes that amplification is intended to minimize the negative impacts of childhood hearing loss on communication development and academic achievement. If a hearing aid alleviates the impact, then the child is considered a candidate. **These recommendations are similar to what is described in the current IHP protocol.**

2) What about borderline pediatric populations?

Several populations are emphasized in the AAA Guideline. Specifically, children with unilateral hearing loss, auditory neuropathy spectrum disorder (ANSD), permanent conductive hearing loss and severe or profound hearing loss. To summarize, children with unilateral hearing loss should be provided with a hearing aid on the affected ear if "aidable" hearing exists (see next question). The lack of evidence for the provision of CROS hearing aids for this population is noted in the Guideline, but they should be recommended if the child can control his/her environment. An IHP protocol addendum for the management of children with unilateral hearing loss can be found in Addendum 5.

Children with ANSD should have a trial with amplification when hearing sensitivity has been established through reliable behavioural audiometry. It is recommended that children with permanent conductive hearing loss should be fitted with either air or bone conduction amplification depending on candidacy. Lastly, children with severe or profound hearing loss in both ears who are considered to be candidates for a cochlear implant should complete a trial with amplification even for those children who have demonstrated no response from auditory brainstem response (ABR) testing and are negative for ANSD. This is because residual hearing may exist beyond the levels elicited by the ABR system and may benefit from amplification. **These recommendations are similar to what is described in the current IHP protocol.**

3) Is "aidable" hearing defined in the AAA Guideline?

No. However, there are specific statements that help with the interpretation of the term "aidable" hearing when it comes to the management of children with unilateral hearing loss. These statements are as follows:

"Audiologists are the single professional knowledgeable and competent to manage all aspects of amplification."

"An audiologist serves as case manager in the audiologic diagnostic and treatment processes."

"Regular, reliable and valid measures of a child's progress in meeting early intervention goals are necessary as part of the intervention process to ensure that amplification outcomes are being achieved."

Therefore, a child with "aidable" hearing on the affected side is one who *benefits* from using his or her hearing aid. Intervention with a hearing aid should not be pursued if there is a lack of benefit. As such, a trial with amplification may be necessary in some cases. **For the purposes of the IHP, accessing a loaner hearing aid would be appropriate for some children, such as when it is unclear whether or not the child is a candidate for amplification.**

4) What does the AAA Guideline state about hearing aid fitting formulae?

The Guideline outlines that manufacturer's fitting formulae (i.e., those that are included within hearing aid fitting software) are developed by hearing aid manufacturers for their proprietary use in adults. They are not standardized nor are they subject to external scrutiny or validation. The Guideline does not name a particular prescriptive formula to be used, but it recommends that audiologists use evidence-based prescriptive targets

employing pediatric features and normative data. **This recommendation supports the IHP's protocol for fitting hearing aids using the Desired Sensation Level Method (Scollie et al., 2005).**

5) What hearing aid technologies are recommended for children?

Similar to the IHP Protocol, behind-the-ear hearing aids with amplitude compression, flexible frequency response shaping and a broad frequency range are recommended for children. These have been stable recommendations over time given the evidence available to support their use. Feedback control can also be provided as needed as long as the hearing aid is verified following it's activation to ensure that it does not negatively affect speech audibility in the frequency response.

6) How are advanced hearing aid technologies addressed?

The AAA Guideline addresses advanced technologies such as directional microphones, digital noise reduction and frequency lowering. For these applications, it is recommended that candidacy be determined individually. This is similar to the overall goal of multimemory use in the IHP: "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." In addition, the AAA Guideline recommends that electroacoustic verification be performed to determine their function and impact on the audibility of speech. Specifics for each technology are described below:

1. Full-time use of directional microphones is not recommended for children because they may reduce audibility of off-axis talkers. Minimal advantages and no negative consequences of using adaptive directional microphones have been reported in adults. Adaptive microphones may be considered but the audiologist must understand how the switching works and ensure it is appropriate for the child. An FM system is supported as the technology that provides the best signal-to-noise ratio (SNR) and should be considered for all children with hearing aids. The Guideline points to the AAA clinical practice guidelines for remote microphone hearing assistance technology (AAA, 2011).
2. Research shows that digital noise reduction (DNR) supports ease of listening in noisy situations. DNR is not expected to negatively impact the child's speech recognition abilities. Clinicians are informed that the electroacoustic properties of the DNR vary among different hearing aids.
3. Frequency lowering should be used if audibility cannot be provided through the bandwidth of the hearing aid. If frequency lowering is provided, the least possible strength should be applied and an adaptation period may be necessary. This is consistent with the Addendum on fitting frequency lowering hearing aids initially issued for use in the IHP in 2011 and updated in this document in Addendum 2. Validation of the fitting is recommended to ensure benefit without negative side effects.

At this time, the IHP protocol deals with some advanced technologies by reminding the clinician that current prescriptive targets have been developed for listening to speech in quiet situations. Therefore, they should not be activated when verifying the hearing aid to targets for speech in quiet. Advanced hearing aid technologies that aim to improve the SNR may be elected by the family and should be applied by creating another listening program in the hearing aid (i.e., quiet and noise programs). These types of technologies are not recommended to be used on a full-time basis until further evidence about their impact is available. Overall, the application of these types of advanced technologies should be considered on a case-by-case basis. **A protocol addendum to provide specific guidance on verification and fitting of noise management technologies is provided in Addendum 3**.

7) *Has anything changed regarding electroacoustic verification?*

The importance of the verification of hearing aid performance is clearly supported, with the addition of the recommendation to verify advanced features if they are applied. Because the AAA document is a guideline, it does not include specific protocols for how to verify these advanced features. IHP clincians are therefore advised to consult this protocol and its Addenda for more specific protocols. .

Furthermore, the AAA Guideline describes other verification tools that can be implemented following primary verification procedures. Tools like the speech intelligibility index (SII) which can be used through verification software or computer programs (i.e., Situational Hearing Aid Response Profile [SHARP]). The IHP currently uses normative data to examine SII values through the Outcome Measures Protocol that was implemented in 2010.

Another topic addressed is the use of cortical auditory evoked potentials (CAEPs) to confirm that speech through the hearing aids is causing activity in the auditory cortex. They are valuable for children who provide limited behavioural feedback due to cognitive or developmental challenges. Currently there are some limitations to the clinical feasibility of these measures, and the Guideline provides a current statement about this strategy.

8) What about post-fitting validation measures?

The Guideline supports outcome measurement as an integral part of the pediatric hearing aid fitting process. A list of age-appropriate English speech tests as well as English questionnaires is provided. Although the IHP has a specific outcome measurement protocol that has been implemented since 2010, the list provided in the AAA Guideline offers other tools that may be useful for application when advanced technologies are applied, when the child or teacher are unable to complete a questionnaire, or when objective measures of speech sound detection or recognition are desired in addition to the IHP outcome measures battery.

SUMMARY

Current IHP procedures include the 2014 Provision of Amplification Protocol, as well as the following protocol addenda:

1. Outcome Measures
2. Frequency Lowering
3. Noise Management
4. Management of Minimal/Mild Bilateral Hearing Loss
5. Management of Unilateral Hearing Loss
6. Remote Microphone Assistance Technologies

Together, these documents generally fulfill most of the requirements of the 2013 AAA Pediatric Amplification Protocol. Updates to the current protocol will be offered in the future as new evidence arises.

LINK TO AAA 2013 PEDIATRIC AMPLIFICATION GUIDELINE:

https://audiology-web.s3.amazonaws.com/migrated/PediatricAmplificationGuidelines.pdf_539975b3e7e9f1.74471798.pdf

ADDENDUM 2: FREQUENCY LOWERING HEARING AIDS

SUMMARY

The rationale for using frequency lowering is equivalent to the rationale for using extended bandwidth in hearing aids: to provide access to the high-frequency sounds of speech.

This document is an update of verification procedures to improve audibility of these speech sounds from a previous IHP Protocol (2011). The sounds /s/ and /ʃ/ receive particular emphasis in this document because they have been studied extensively, because /s/ plays a strong grammatical role in the English language, and because frequency lowering can lead to spectral overlap and perceptual confusion of these two sounds.

Main content areas:

1. Overall, the IHP does not take a particular perspective on specific hearing aid selection decisions: this decision is the responsibility of the IHP prescribing audiologists. Selection decisions within the IHP should be made on a case-by-case basis, and should be informed by best available evidence. This document offers candidacy considerations to support IHP Audiologists' clinical decisions regarding the application of frequency lowering technology.

2. This document provides a summary of current evidence and rationale pertaining to frequency lowering technology.

3. The IHP requires that the audibility provided by each child's hearing aid be verified using speech signals. This document provides an introduction to new calibrated verification stimuli; calibrated /s/ and /ʃ/ are suggested for use in the frequency lowering verification protocol.

4. A specific verification and fitting procedure using the updated signals is provided, for use when the IHP audiologist elects to use a frequency lowering device. This procedure is consistent with the pediatric amplification guidelines suggested by the American Academy of Audiology Clinical Practice Guidelines (2013) and updates the 2011 IHP Frequency Lowering Protocol.

5. Specific cases are provided to illustrate decision-making, fitting protocol, and current challenges.

6. Frequently asked questions.

End of summary.

FREQUENCY LOWERING HEARING AIDS

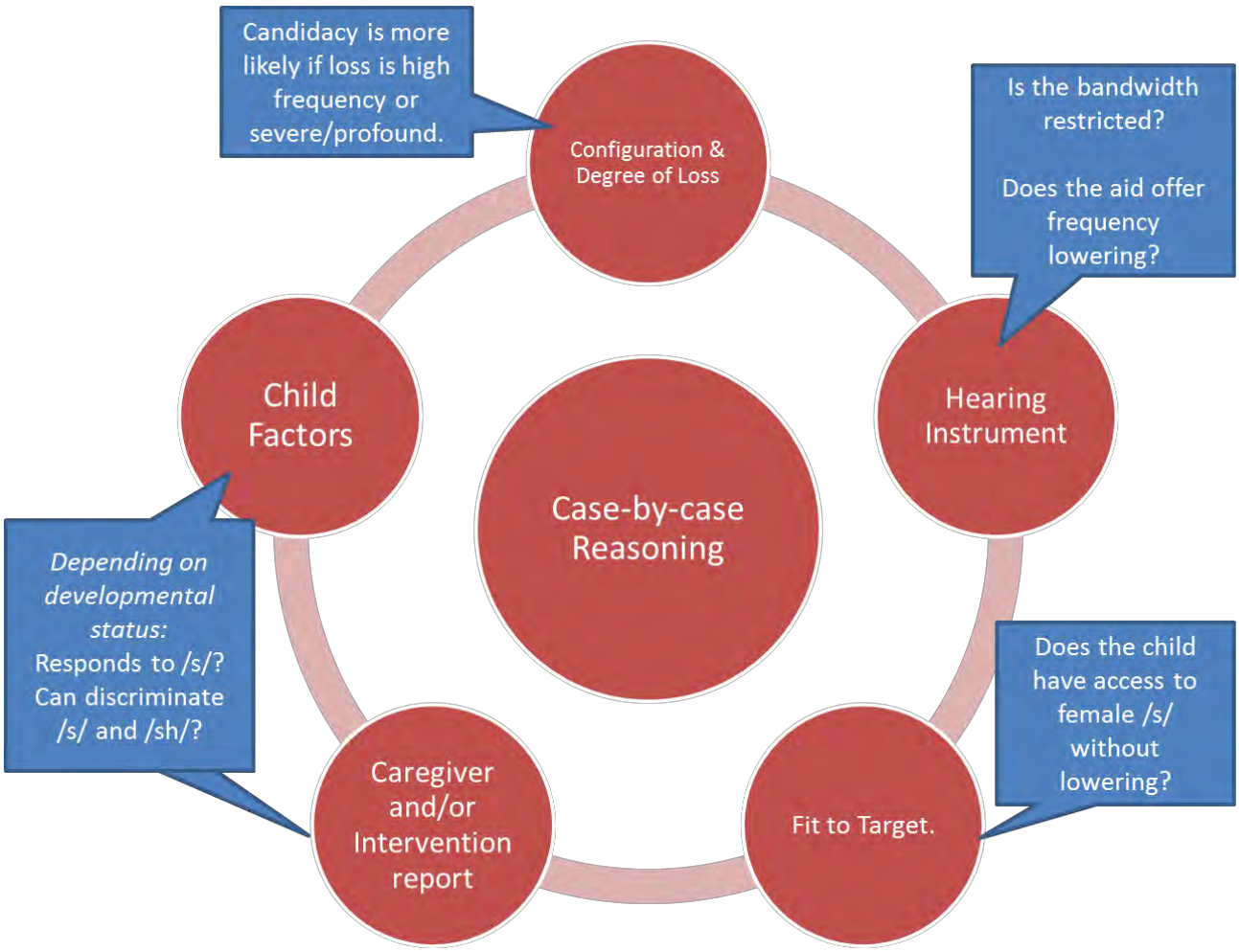
The IHP provides hearing aid services within early intervention in order to "facilitate the development" of hearing-related skills, such as receptive language and speech production (IHP Amplification Protocol). Specific recommendations of hearing aid technologies are not provided by the IHP, but unbiased and evidence-based review of information may assist clinicians in selecting technologies and/or communicating choices to caregivers. The purpose of this document is to review current evidence on frequency lowering technologies and illustrate preferred fitting methods for use in the IHP. All procedures in this document are intended to be applied together with other IHP protocols (Assessment, Amplification, and Dispensing).

CANDIDACY FOR FREQUENCY LOWERING

Children require audibility of a broad bandwidth of speech for optimal access to high-frequency speech cues (Stelmachowicz, Pittman, Hoover, Lewis, & Moeller, 2004). Audibility to 9000 Hz has been shown to improve word learning rates in children, when compared to audibility to only 4000 Hz (Pittman, 2008). Furthermore, speech production development is affected by hearing loss, particularly for affricate and fricative speech sounds (Moeller et al., 2007). Despite recent improved feedback management and extended bandwidth processing in current hearing aid technology, gain and/or feedback constraints limit our ability to provide audibility of high-frequency speech sounds. Clinically available hearing aids have begun to offer processing that lowers certain high-frequency sounds, presenting them to the listener at a lower frequency. Perceptually, this can be defined as high-pitched sounds that have been processed to be played at a lower pitch. If the original frequency is not audible, we might expect that frequency lowering may present the sound at a pitch where the listener has (a) better hearing thresholds; (b) more hearing aid gain and output; or (c) both. These effects may allow benefit for high-frequency sound detection or recognition.

A review of the rationale and evidence on frequency lowering devices for managing high-frequency hearing loss can be found in an article by Simpson (2009). Early evidence in older children suggests that frequency lowering hearing aid technology can increase the audibility of high-frequency speech sounds (e.g., /s/, /ʃ/) and can improve speech sound recognition ability for children with high-frequency hearing loss, when compared to conventional hearing aid fittings (Auriemmo et al., 2009; Glista et al., 2009; 2012; Wolfe et al., 2010). Studies of frequency lowering in children report benefit for listeners with hearing levels ranging from a moderate hearing loss by pure tone average (Wolfe et al., 2010; McCreery et al., 2014) to a severe to profound high-frequency hearing loss (Glista et al., 2009; 2012). In the study by Glista et al. (2009), children with a greater degree of hearing loss experienced greater benefit from frequency compression than did those with lesser degrees of impairment. Therefore, it is difficult to determine a strict candidacy criterion for frequency lowering in children based on current findings regarding degree of hearing loss presented in the literature. Recalling that children demonstrate greater need for audibility of high-frequency cues in speech (see review by Stelmachowicz et al, 2004), caution should be used when interpreting adult candidacy as a predictor of pediatric candidacy for either frequency lowering or extended bandwidth technologies. Within the IHP, one goal of amplification is to support oral development (when oral communication development is supported by the family). Therefore, it is reasonable to **consider frequency lowering as a means to provide access to high-frequency sounds, when these cannot be provided via conventional amplification**. As conventional amplification advances, it may be possible to provide a broader bandwidth without the use of frequency lowering. A summary of these factors is provided below.

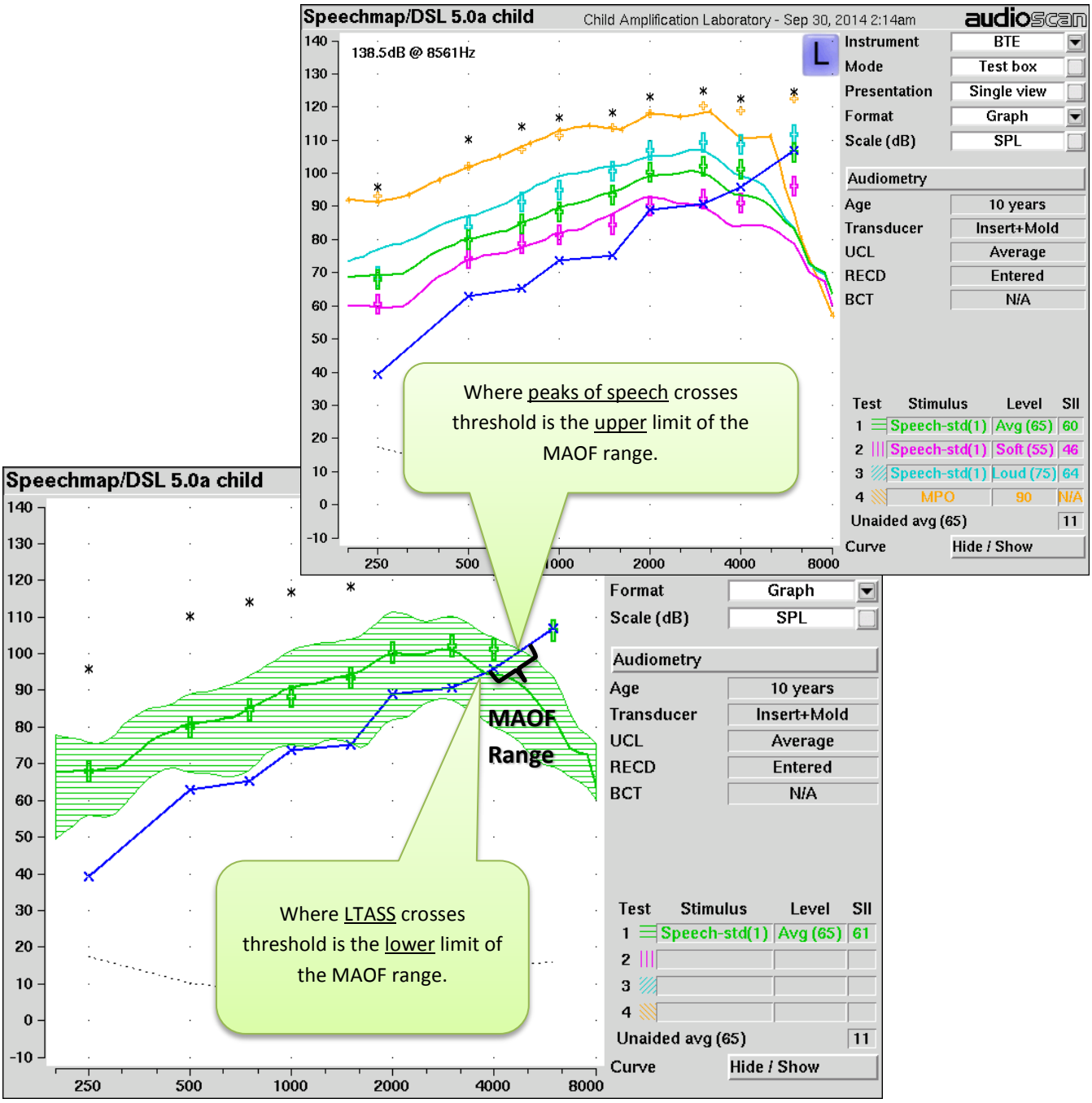
Candidacy Factors for Frequency Lowering:



OVERVIEW: THE MAXIMUM AUDIBLE OUTPUT FREQUENCY (MAOF) AND USE OF /S/ STIMULUS

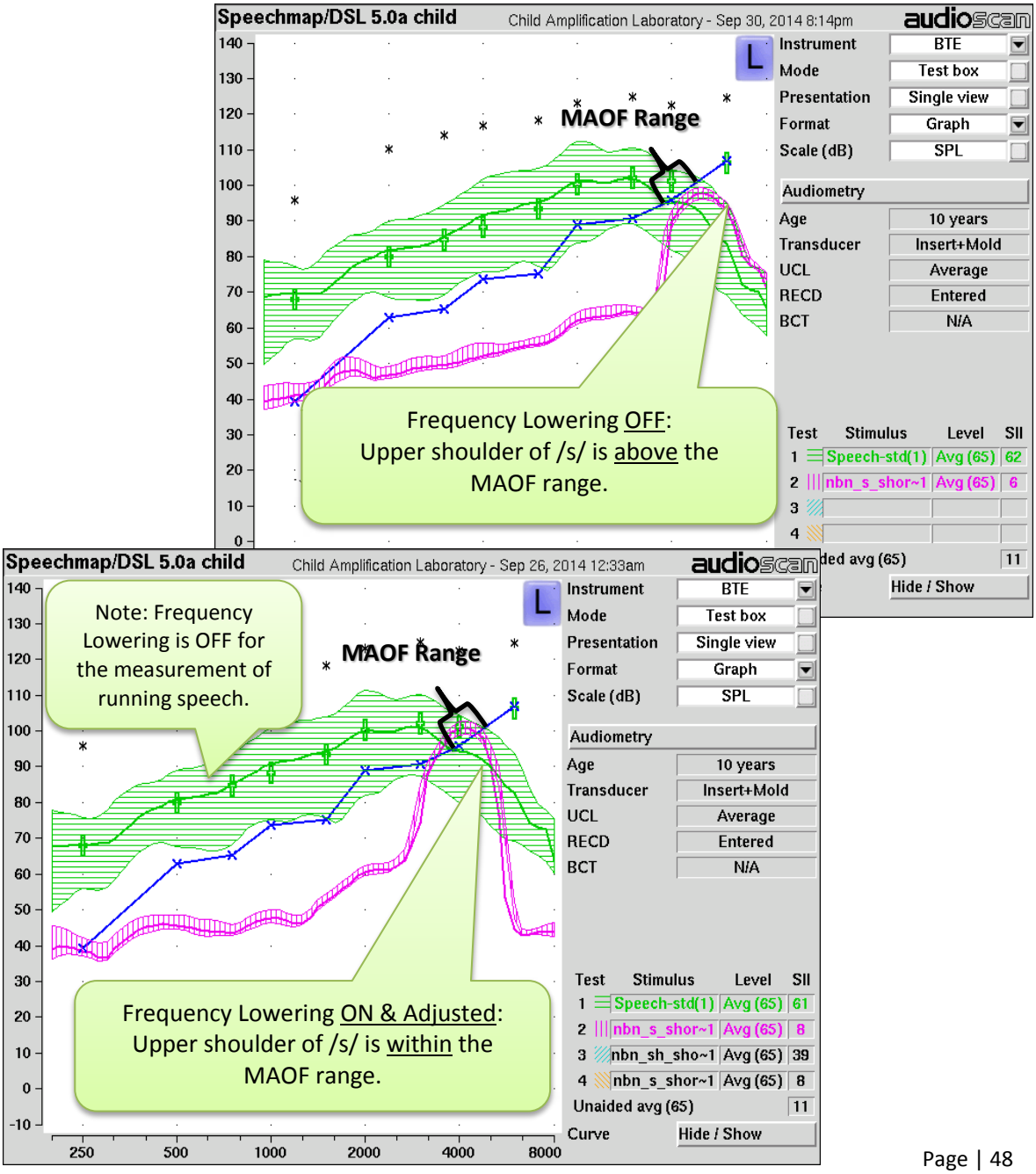
A study by McCreery et al (2014) suggests that increased audibility of speech due to frequency lowering improves speech recognition. In this study, high-frequency signals such as /s/were lowered below the maximum audible output frequency (MAOF) (McCreery et al., 2014). In doing so, compensation for constraints regarding output and bandwidth of the hearing instrument was achieved.

Candidacy for frequency lowering is determined by finding the limit of audibility of the fitting: the maximum audible output frequency (MAOF) range of the verified fitting (McCreery et al, 2014). The MAOF range begins where the long-term average speech spectrum (LTASS) and ends where the peaks of speech cross threshold (see below). Visual location of the MAOF is sufficient – exact measures with the cursor are not necessary.


Speechmap/DSL 5.0a child
Child Amplification Laboratory - Sep 30, 2014 2:14am
audioscan
138.5dB @ 8561Hz
L
Instrument BTE
Mode Test box
Presentation Single view
Format Graph
Scale (dB) SPL
Audiometry
Age 10 years
Transducer Insert+Mold
UCL Average
RECD Entered
BCT N/A
Test Stimulus Level SII
1 Speech-std(1) Avg (65) 60
2 Speech-std(1) Soft (55) 46
3 Speech-std(1) Loud (75) 64
4 MPO 90 N/A
Unaided avg (65) 11
Curve Hide / Show
Where peaks of speech crosses threshold is the upper limit of the MAOF range.
Speechmap/DSL 5.0a child
MAOF Range
Where LTASS crosses threshold is the lower limit of the MAOF range.
Format Graph
Scale (dB) SPL
Audiometry
Age 10 years
Transducer Insert+Mold
UCL Average
RECD Entered
BCT N/A
Test Stimulus Level SII
1 Speech-std(1) Avg (65) 61
2
3
4
Unaided avg (65) 11
Curve Hide / Show

CASE EXAMPLE A: OVERVIEW OF FITTING FREQUENCY LOWERING

This case illustrates a typical fitting for a child presenting with severe high-frequency hearing loss. With frequency lowering off (top), the response fits to target within 5 dB only to 3000 Hz. Audibility of average speech (green) is not available above 4000 Hz, and this bandwidth is further reduced for soft speech. Audibility for high-frequency speech sounds was assessed using the calibrated /s/ stimulus. Without frequency lowering, the /s/ was not audible (upper panel). With frequency lowering enabled (lower panel), the /s/ stimulus fell within the MAOF range. This fitting was set to the weakest amount of frequency lowering required, placing the /s/ near the upper limit of the MAOF range. A listening check revealed good sound quality and discrimination between /s/ and /ʃ/.

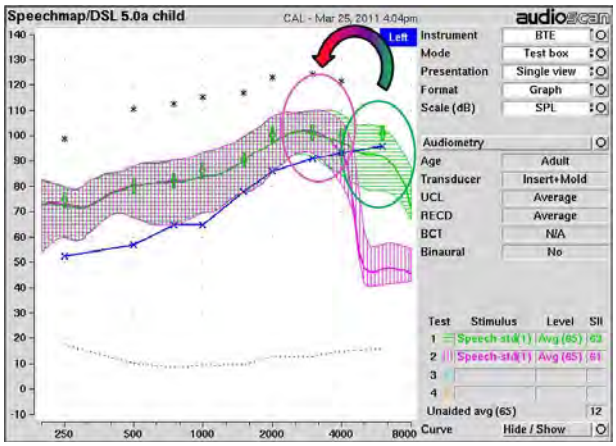


DETAILED DESCRIPTION: VERIFICATION OF FREQUENCY LOWERING

Within the IHP, we begin by fitting the hearing aid without frequency lowering. This allows us to optimize the fit to targets using level-dependent signal processing and frequency shaping. We then enable and fine-tune frequency lowering if necessary, using specific tests that evaluate the hearing aid in the frequency domain. The sections below will review the effects of frequency lowering on electroacoustic measures and present a protocol for verification and fine-tuning.

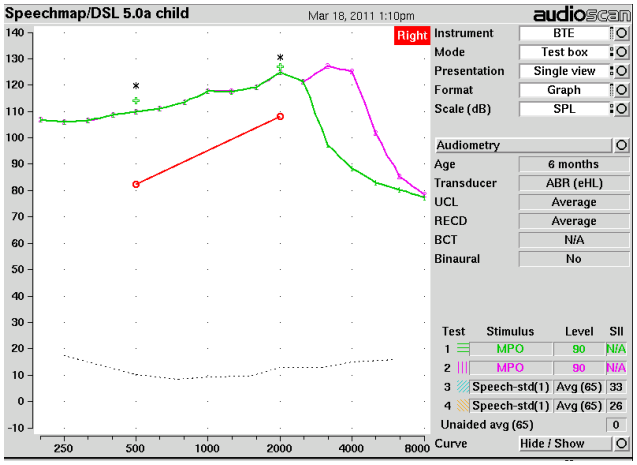
Electroacoustic measurements of hearing aid(s) with frequency lowering can appear unusual, especially in the high frequencies and when compared to measurements performed without frequency lowering. Three types of changes are usually noticeable.

1) It isn't a high cut, part one:



The response for broadband signals might seem as though a high-frequency cut has been applied when in fact the high-frequency energy has been lowered (e.g. Energy from about 5000-8000 Hz in Test 1 (green) has been lowered to about 2500 to 4000 Hz (pink) in the example in upper panel). Electroacoustically, this is not equivalent to a simple high cut:

2) It isn't a high cut, part two:



Tests using a narrowband sweep typically provide invalid results above the cutoff frequency. This is due to a limitation of the measurement systems, and does not reflect the true output of the hearing aid across frequencies. Specifically, if the analyzer uses a narrowband filterbank to measure the output at each frequency, it will measure at 4000 Hz when it is presenting a signal at 4000 Hz. If the hearing aid lowers the 4000 Hz signal to 2000 Hz, the analyzer does not capture the true aided levels of sound. This looks like a high cut, for example, during the measurement of the maximum output (lower panel). For this example, the measurements made above 2500 Hz are not valid. For this reason, the IHP protocol is to measure and set the MPO to targets with frequency lowering disabled.

3) It is possible to measure the effects of frequency lowering:

The solution to the problem above is simply to measure using a broadband analyzer. This is possible within any of the speech-based measures within the "Speechmap" function of the Verifit, but is not possible using the "MPO" test. Using a speech signal, the Verifit measures using all filters from very low to very high frequencies, and is able to capture aided energy that is lowered in frequency. In the next sections, we will discuss the use of calibrated speech sounds as a viable method for verifying frequency lowering.

Aided measures allow evaluation of (a) the frequency location (has it been lowered in frequency?) and (b) the audibility of a high-frequency stimulus (is it amplified enough to be heard?).

PREVIOUSLY RECOMMENDED SIGNALS

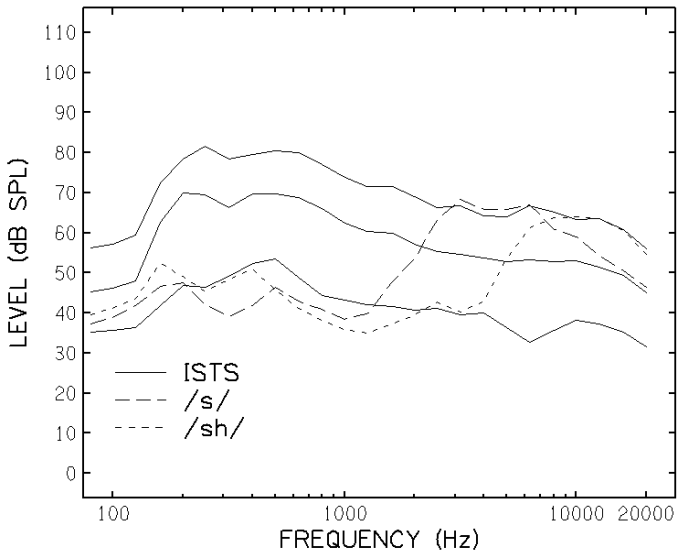
Previously, two types of frequency-specific speech sounds have been suggested (Scollie et al, 2011). First, live voice productions of isolated /s/ and /ʃ/ can be measured with the Verifit by using the "Speech-Live" option under "Stimulus Options", and using "Freeze Curve" to capture the fricative in isolation (Glista et al, 2009, Scollie et al, 2007). This allows estimation of the audibility and approximate bandwidth of the frication band to more accurately determine audibility and spectral separation between /s/ and /ʃ/. Alternatively, filtered speech signals have been used within the Audioscan Verifit system. These signals filter out all spectral energy, except for a specific 1/3 octave band that can be located at any of the following frequencies: 3150, 4000, 5000, or 6300 Hz. This allows the use of a calibrated level that is repeatable and reflects centre frequencies for /ʃ/ (4000 Hz) and /s/ (6300 Hz) (Stelmachowicz, 1993). As previously noted (Scollie et al, 2011), both of these frequency-specific stimuli have known limitations. In 2011, a protocol addendum for the IHP was issued that described these signals and their use. These signals are reviewed in brief, but will no longer be recommended:

1) *Live voice production of /s/ and /ʃ/:*
    a. Is not presented at a calibrated level. Live production cannot be calibrated for vocal effort, distance and azimuth from the hearing aid microphone(s) and room noise.
    b. Male and female talkers will produce /s/ at different frequencies. Male /s/ is typically about 5-6 kHz while female /s/ is 7 kHz or higher (Nittrouer, 1995; Pittman et al., 2003). Individual talkers will vary in their productions of /s/ (Munson, 2004).

2) *Filtered speech with high-frequency bands of energy:*
    a. The 1/3 octave band is narrower than the frication band of naturally produced speech sounds (e.g., /s/ or /ʃ/). This may lead to a conservative estimate of audibility.
    b. The 1/3 octave band is presented at the level of the Long Term Average Speech Spectrum at the test frequency. This presentation level is slightly lower than the level of /s/ or /ʃ/ would be in speech that is similar to the ISTS passage.
    c. This test allows evaluation only to 6300 Hz, while a female /s/ is typically higher in frequency.

CURRENTLY RECOMMENDED SIGNALS

To allow calibrated measures with fricatives, pre-recorded /s/ and /ʃ/ stimuli were created for use in the IHP. Calibration levels were obtained by extracting these phonemes from the International Speech Test Signal (ISTS; Holube et al., 2010) and measuring each fricative's average spectrum. Synthetic fricatives were then generated that match the observed spectra. These fricatives fall close to the peaks of speech, and represent average female production of the fricatives /s/ and /ʃ/.



ADVANTAGES AND DISADVANTAGES OF USING THE UPDATED CALIBRATED SPEECH SIGNALS

1) *Advantages:*
    a. The signal has been calibrated to a consistent level and frequency to improve replicability of measures. This improves test-retest reliability.
    b. Calibrated speech signals offer an accurate representation of the frication band. This allows the tester to estimate hearing aid output of the fricative.
    c. Measurement of the frication band of /s/ and /ʃ/ allows the fitter to assess the spectral separation (i.e., how far apart do /s/ and /ʃ/ lie in the frequency domain), which is correlated with the listeners' ability to discriminate between these two sounds (Seto, unpublished dissertation).

2) *Disadvantages:*
    a. The calibrated stimuli do not account for variability between speakers. This is especially evident in centre frequencies of /s/ produced by male vs female speakers. The test signals represent an /s/ from female speech, with energy from 4 to 10 kHz.
    b. For some processors, it would be more accurate to extract the /s/ and /ʃ/ phonemes from running speech than to measure them in isolation. However, this "gold standard" is not available in commercial hearing at analyzers at this time.

RECOMMENDED PROTOCOL

The following clinical protocol for verifying frequency lowering hearing aids is designed to assist clinicians in determining which setting is appropriate within the context of IHP protocols.

1) **Verify the shape and gain of the hearing aid fitting without frequency lowering.**
   Begin by verifying and fine-tuning the hearing aid to optimize the fitting without frequency lowering. Ensure that the aided speech spectra meet DSL prescriptive targets and provide a broad bandwidth of audibility.

2) **Determine candidacy for frequency lowering.**
   a. Check if a fit to target has been achieved across the high frequencies. If not, frequency lowering may be required to make high frequencies audible.
   b. With frequency lowering OFF and noise reduction OFF, measure the calibrated /s/ at 65 dB SPL. Determine if the calibrated /s/ is audible and falls within the MAOF range for an LTASS measured at 65 dB SPL. If it does not, the candidacy criterion for frequency lowering has been met.
   c. Consider measuring the calibrated /s/ at 55 dB SPL. This signal may not be audible for soft speech. Decisions regarding activation of frequency lowering in this case are at the discretion of the audiologist and should consider caregiver reports.

3) **Enable frequency lowering and adjust to optimize. Use the least amount of frequency lowering needed to obtain audibility of /s/ and /ʃ/.**
   a. Measure calibrated /s/ with frequency lowering at default settings and re-evaluate if it falls within the MAOF range at 65 dB SPL. Note that the upper edge frequency of the /s/ extends beyond 10 kHz.
   b. Fine-tune frequency lowering so the /s/ falls within the MAOF range while using the weakest possible setting. A tuned setting typically places the upper shoulder of /s/ close to the peaks of speech at the upper limit of the MAOF range or the upper bandwidth of the hearing aid, whichever is the limiting factor of the fitting's audibility.
   c. Optional: Measure the aided /ʃ/ to make a descriptive measure of the frequency separation between /s/ and /ʃ/. This measure may help with counselling or troubleshooting difficulty with discrimination between /s/ and /ʃ/. Because the fine-tuning steps above have already determined the weakest possible setting of the frequency lowering processor, the frequency separation between /s/ and /ʃ/ is likely already maximized. Listening checks are also useful for these purposes and should be completed after frequency lowering is verified and should be done at the user's frequency lowering setting.
   d. Re-enable noise reduction if this is a component of the fitting.

4) **Provide post-fitting supports.**
   a. Access counseling materials for caregivers, therapists, or anyone else that may do a listening check on the hearing aids. The sound quality will differ from conventional hearing aids, and these caregivers may require support materials. One approach is to alert caregivers or therapists that sound quality may differ from previous hearing aids, and that listening checks should focus on changes from baseline rather than on whether sound quality is similar to the child's previous hearing aids.
   b. As the infant or child embarks on a program of oral language development, incorporate feedback from therapists. For example, if the child cannot functionally detect /s/, should the fitting be adjusted to provide more gain or output (computer controls, new earmold), and/or adjusted frequency lowering settings? Some fitting cases can provide additional challenges in this regard, so feel free to request fitting support if needed.

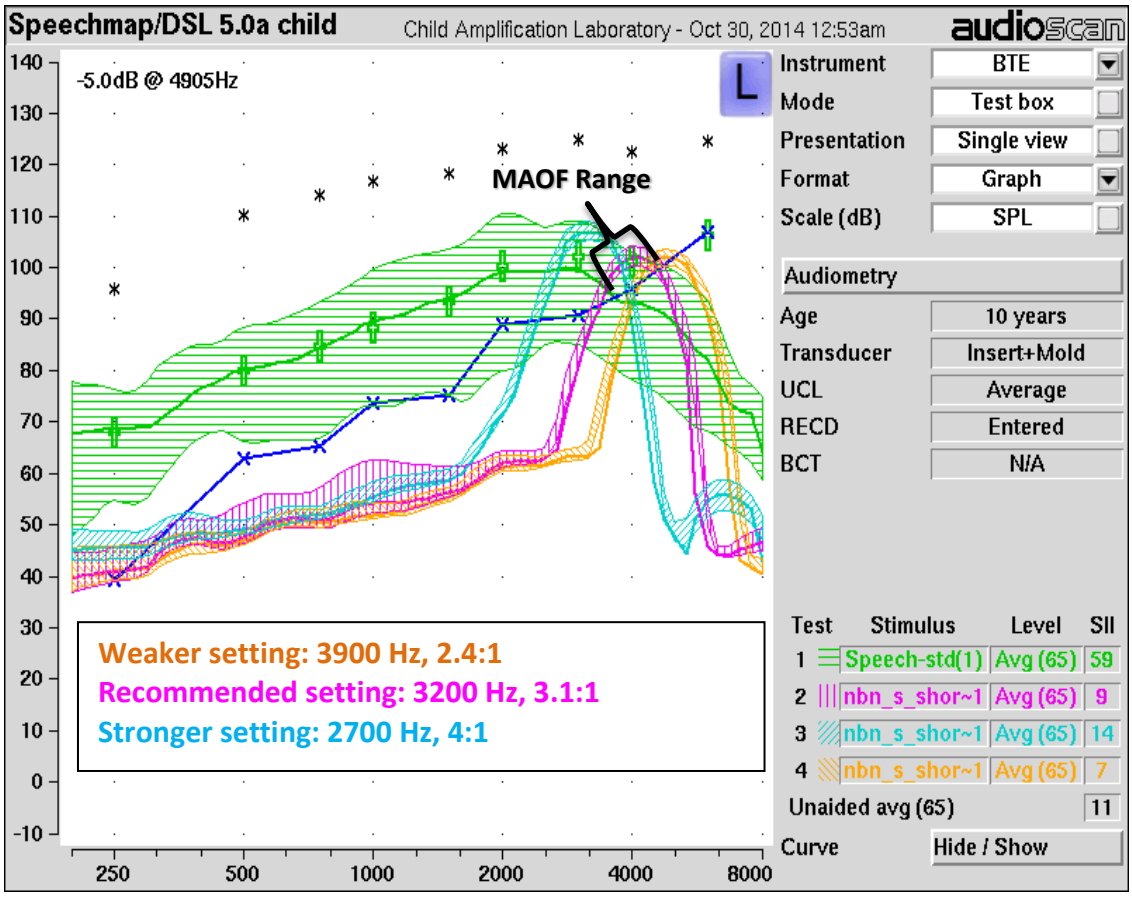
CASE EXAMPLE B: EFFECTS OF FINE TUNING ON /S/

To illustrate the effects of fine-tuning, Case A was verified with both stronger and weaker frequency lowering settings. This hearing aid uses frequency compression and settings have been selected using the combined slider tool to modify compression ratio and cut-off frequency together. The fine-tuned setting used a 3200 Hz cut-off and 3.1:1 compression ratio. The calibrated /s/ was measured and can be seen below in pink. The upper shoulder of /s/ falls within the MAOF range at the weakest possible frequency lowered setting.

The strength was increased by two steps from the fine-tuned setting and /s/ was re-measured (blue). The overall sensation level of the /s/ has increased, but the upper shoulder of /s/ is now at the lower edge of the MAOF range. This is not an optimal setting since a weaker frequency lowered setting is possible. We would postulate that a stronger setting such as this would cause increased /s-ʃ/ overlap which is undesirable.

The strength was decreased by two steps from the fine-tuned setting and /s/ was re-measured (orange). The signal is still audible (approximately 1 dB SL) and the lower shoulder of /s/ is within the MAOF range. This is not an optimal setting since the majority of the /s/ signal does not fall within the MAOF range, resulting in reduced audibility.

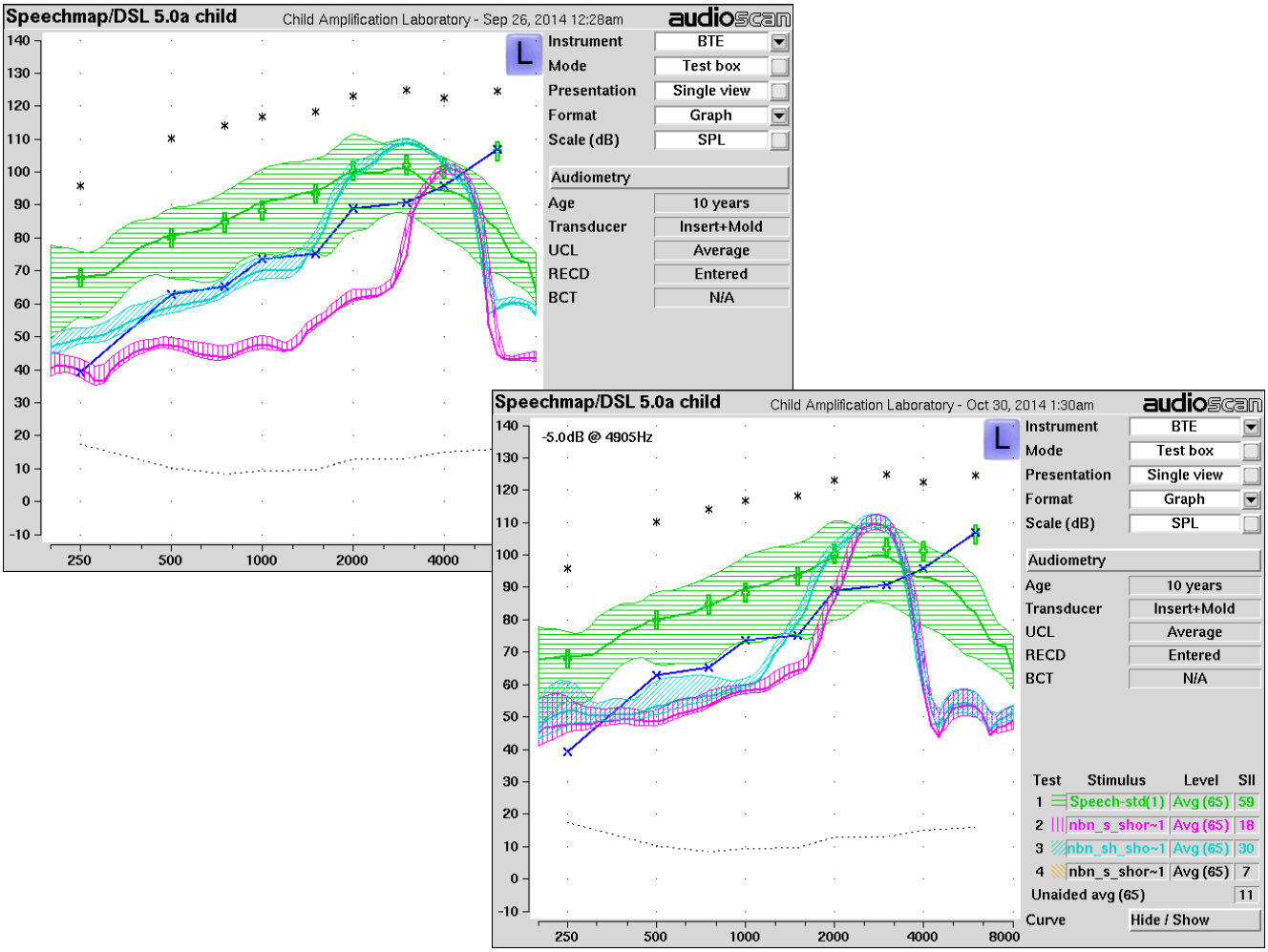
Overall, this exploration of settings illustrates the need for fine tuning to optimize the strength of frequency lowering on an individual basis.



CASE EXAMPLE C: OPTIONAL DESCRIPTIVE MEASURES OF /ʃ/

A calibrated /ʃ/stimulus is provided for optional use in description of fittings or troubleshooting. Because frequency lowering can superimpose /s/ and /ʃ/, it is possible that confusion between /s/ and /ʃ/ can occur. This is more likely when the frequency separation between these two sounds is very small.

To illustrate this, the response for /ʃ/was measured to describe spectral separation between /s/ and /ʃ/. The electroacoustic results depicted here (upper panel) matches with the listening check, in which the clinician could clearly discern the two fricatives. Both /s/ and /ʃ/ were also measured at the stronger frequency lowered setting (lower panel). We can see that, compared to the fine-tuned setting, that the /s-ʃ/ overlap has been increased. This may result in poorer sound quality and less ability of the listener to discriminate between the fricatives.

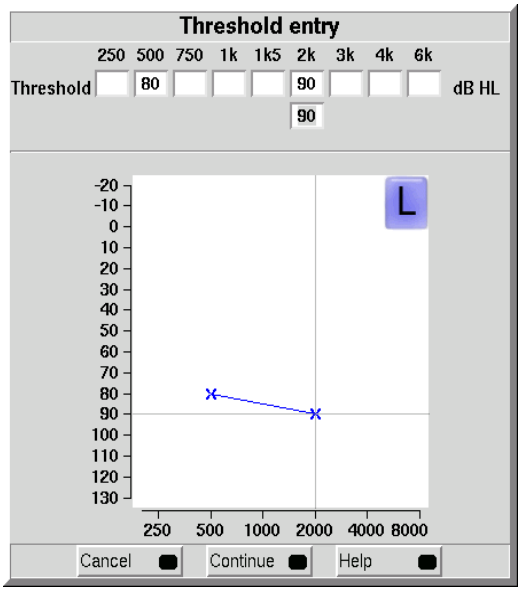


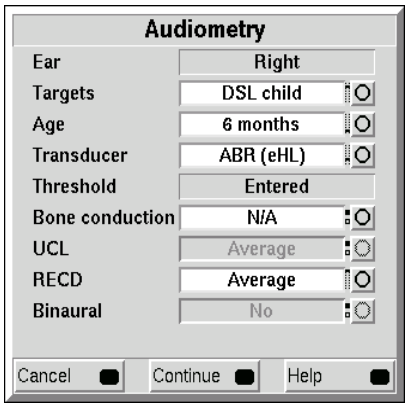
Unpublished studies indicate that providing more separation between the frequency locations of /s/ and /ʃ/ is better: this supports the listener's ability to hear the differences between them. A minimum of 200 Hz, and preferably more than 500 Hz is required for good discrimination between /s/ and /ʃ/ in adults. However, the IHP protocol recommends finding the weakest possible setting of a frequency lowering processor that makes /s/

audible. By following this protocol, maximal spectral separation is likely already achieved. For this reason, we do not recommend routine measurement of spectral separation of /s/ and /ʃ/. However, you can use the calibrated /ʃ/ signal to describe the separation when you wish to, as a descriptive measure, for counseling purposes, or for troubleshooting.

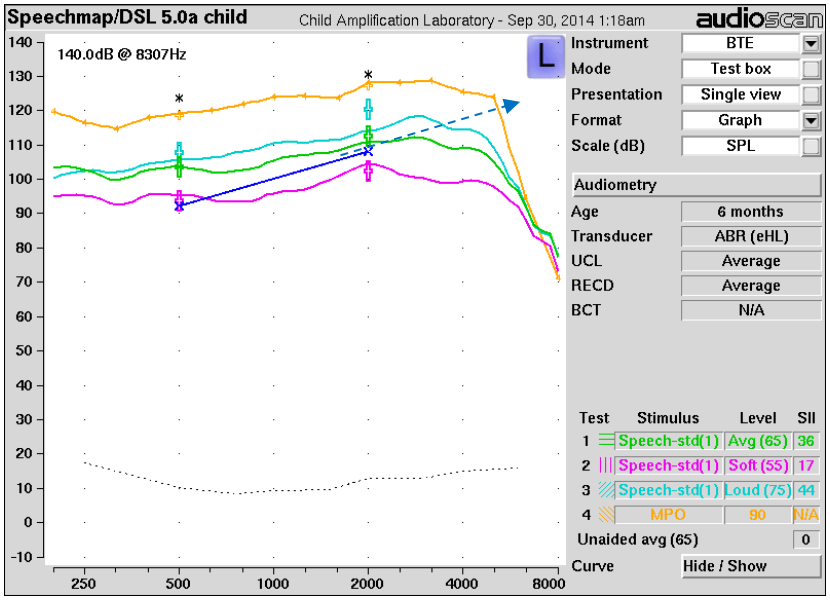
CASE EXAMPLE D: ILLUSTRATING THE CHALLENGES OF PARTIAL AUDIOMETRIC DATA

This six month old was assessed via frequency specific ABR. Results revealed a severe sensorineural hearing loss in both ears. Threshold estimates in the left ear were 80 and 90 dB eHL at 500 and 2000 Hz. Results were not obtained at other test frequencies. The infant's family elected to pursue hearing aid fitting, and measurement of this infant's thresholds is an ongoing goal for future appointments.

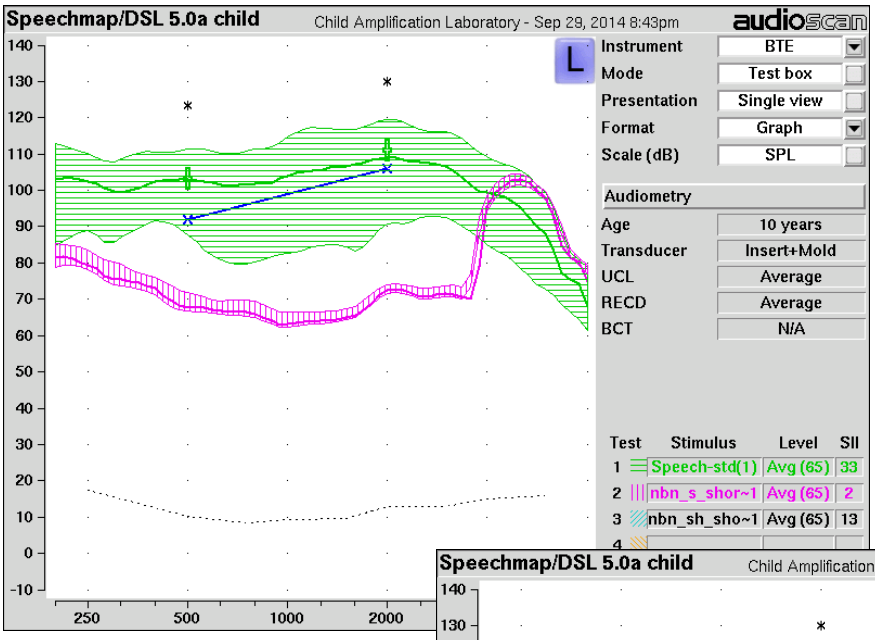


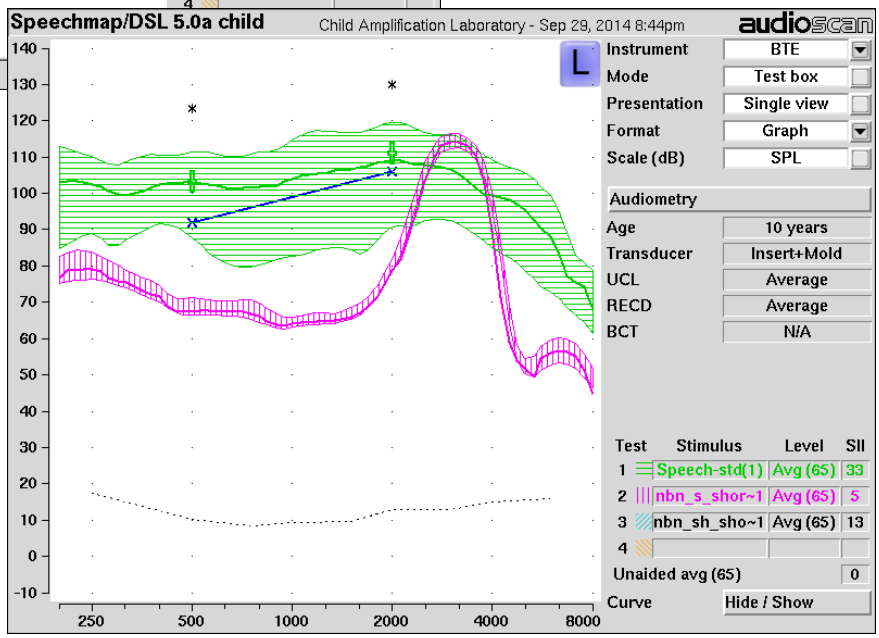


The initial fitting of the hearing instrument is shown below. The fit to target for soft and average speech is acceptable, though targets could not be reached for loud speech due to the limitations of the device. It is likely that the hearing loss will slope and therefore the loss above 2000 Hz is equal to or poorer than the loss at 2000 Hz as demonstrated by the dotted line extrapolating our estimation of the threshold. Using this estimation, we can speculate that average speech sounds above 2000 Hz are not audible and soft speech is not audible above 500 Hz.



Candidacy for frequency lowering was determined using the calibrated /s/ (pink) with frequency lowering off (below, left) and on (below, right). Using high-frequency threshold estimation, we can speculate that the /s/ is not audible without frequency lowering activated indicating that this infant is a candidate for frequency lowering. When activated, the /s/ is lowered to a region where the signal is likely audible based on our threshold estimation. A listening check was completed to note sound quality and phoneme discriminability. Further exploration using the calibrated /ʃ/ speech signal could be used for counselling purposes. Evaluation of efficacy of this setting can be determined at follow-up appointments with use of caregiver reports. Once a more detailed audiogram is available, these settings can be re-evaluated.



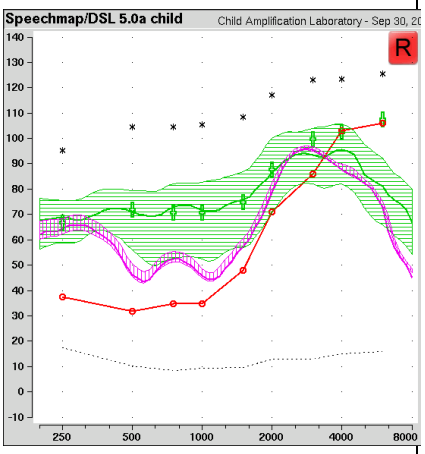
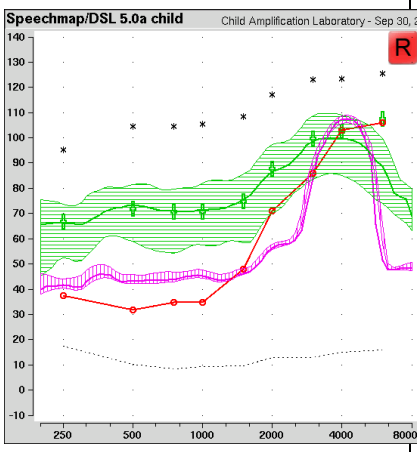
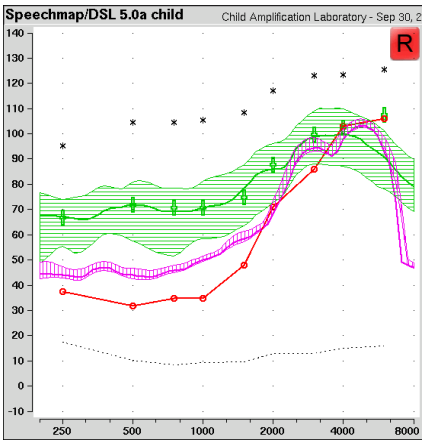


CASE EXAMPLE E: ILLUSTRATING DIFFERENCES IN FREQUENCY LOWERING TECHNOLOGIES

This case study presents three different types of frequency lowering fitted to the same hearing loss. Calibrated /s/ was not audible in any of the fittings without frequency lowering activated. Each frequency lowering technology was verified following the suggested frequency lowering protocol described above. Resulting settings are included below:

Frequency Transposition: *start frequency* = 6000 Hz
Non-linear frequency compression: *cut-off frequency* = 3200 Hz
Frequency Translation: *target region* = 2000-3000 Hz

The *start* and *cut-off* frequency values designate where frequency-lowering processing begins. The *target region* is the location where high-frequency information is being sent. Note that the final settings for each type of frequency lowering differ and yet yield acceptable results. This is due to the nature of the processing as discussed earlier.

Frequency Transposition	**Frequency Compression**	**Frequency Translation**
		
Start Frequency: 6000 Hz	Cut-off: 3200 Hz	Target: 2000-3000 Hz

Why do these settings look so different?

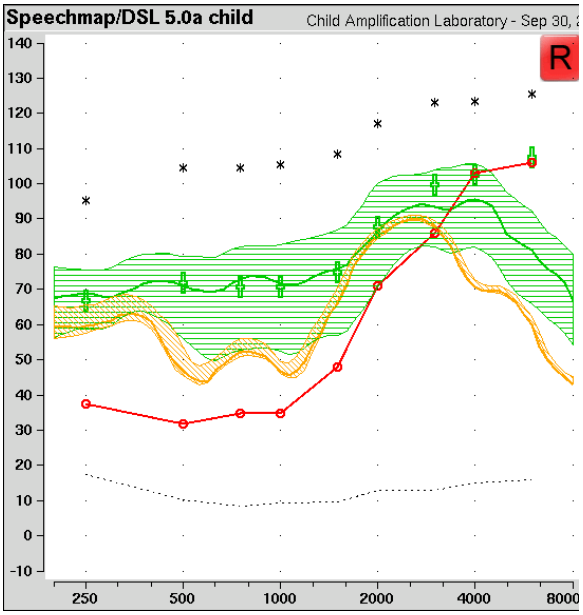
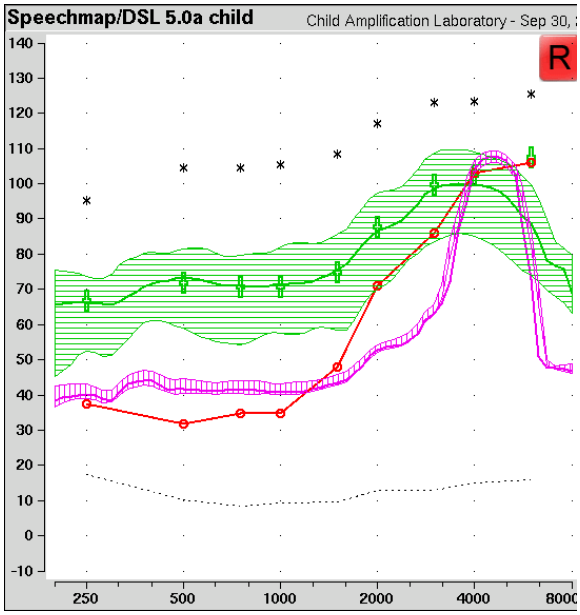
Transposition: This signal is very broad since high-frequency information is being lowered, but not compressed. The signal is falling at the lower limit of the MAOF range. This is because a weaker setting for this device resulted in inaudibility of the /s/ signal.

Compression: This signal is much narrower than the other types of frequency lowering since the high-frequency information of the signal is being compressed to a smaller bandwidth. This device is set to the weakest possible setting where the /s/ still falls within the MAOF range.

Translation: Use of the calibrated /s/ stimulus when frequency translation is activated creates a double peak. As previously discussed, this is because the original signal remains along with the frequency-lowered signal, thus both signals are being represented in the measurement. When verifying frequency translation, ensure that the lower peak of the signal falls within the MAOF range. In this case, the setting selected was the weakest available so the

lower peak could not be increased in frequency to fall within the MAOF range. However, activation of frequency translation at its weakest setting made the /s/ audible.

The nominal setting of each type of technology clearly differs greatly yet all provide an acceptable frequency lowered fitting. To demonstrate this further, the value of the start frequency for frequency transposition and the cut-off frequency for frequency compression were both set to 4000 Hz. Processing differences between technologies would suggest that a set value of 4000 Hz. The spectrum of the calibrated /s/ signal was measured, as shown below:

Frequency Transposition	**Frequency Compression**
	
Start Frequency: 4000 Hz	Cut-off: 4000 Hz

In this example, frequency transposition has lowered the peak of /s/ to approximately 3000 Hz whereas frequency compression is lowering to around 5000 Hz despite both using a setting of 4000 Hz. Due to the processing applied to the signal, frequency transposition appears to provide more lowering than frequency compression at the same setting.

The purpose of this case is to illustrate that these three types of frequency lowering technologies produce different effects on the aided response of the hearing aid. Summary points are:

1) All technologies provide measurable amounts of frequency lowering.

2) Choosing similar nominal settings for start/cutoff/target frequency does not result in similar amounts of frequency lowering between frequency transposition, compression and translation.

3) Frequency translation may create a double peaked /s/ stimulus. The lower peak is to be fine-tuned.

4) Frequency transposition appears to provide a stronger frequency lowering effect than other processors.

5) Processors should not be compared based on nominal software settings (e.g., “4000 Hz”) because these programming handles have different meanings for different processors.

For individual cases, choice of frequency lowering settings for frequency transposition, translation or compression should be based on electroacoustic evaluation of audibility as per this protocol, and should not be based on comparison of nominal settings across technology.

This case does not address whether one type of frequency lowering may be more beneficial for this hearing loss. Experimental studies comparing benefit in children are not available at this time.

FREQUENTLY ASKED QUESTIONS

1) When should I enable frequency lowering in a fitting?
   - Determine if the listener is receiving audibility across frequencies without frequency lowering activated by assessing the fit to target. If the fitting cannot meet all targets, they may be a candidate for frequency lowering.
   - If unsure if the fitting is providing sufficient audibility, measure the calibrated /s/ without frequency lowering activated. If the signal is either inaudible or not falling within the bandwidth of the device, complete further assessment with frequency lowering activated.

2) When should I turn frequency lowering off?
   - Child and caregiver reports should be monitored for any indication that frequency lowering may be hindering/disrupting performance. These indicators may include a change in speech production related to slurring of /s/ and /ʃ/, decreased use of the device, the child’s reluctance to wear the device, or reported complaint about sound quality.
   - In a case discussed by Scollie, Glista & Richert (2014), a child who was an experienced frequency lowering user, was refitted with new hearing instruments which had increased bandwidth. Objective and subjective tests suggested good and equal performance either with frequency lowering enabled or disabled. Since the child had no preference for either setting, frequency lowering was disabled (Scollie et al, 2014).

3) Should we be providing asymmetrical frequency lowering settings?
   - A study by John et al (2013) found that adults with asymmetric hearing loss received equal benefit from symmetrical and asymmetrical frequency lowering settings. This study spanned six weeks so acclimatization effects may be a factor. Similar studies have yet to be completed on a pediatric population.
   - In a case discussed in by Scollie et al. (2014), a child was fitted with asymmetrical frequency lowering settings. The child reported a remarkable increase in audibility of sounds suggesting an asymmetrical fitting did not diminish perceived benefit for this case (Scollie et al, 2014).

4) Can frequency lowering be enabled for mild to moderate hearing losses?
   - There is no reported evidence at this time that frequency lowering should or should not be used in cases of mild hearing loss across frequencies. Further research is needed on this topic. However, studies do show that individuals with a mild to moderate PTA and with more severe high-frequency hearing loss have received benefit from frequency compression.

- Wolfe et al. (2010) reported improved speech recognition when frequency compression was activated for individuals with moderate to moderately-severe hearing loss. As always, the use of frequency lowering is at the discretion of the audiologist and should be determined on a case-by-case basis following candidacy guidelines reported in this document (See question #1).

5) Is there a certain amount of audibility I should be achieving?
   - No. The goal of this protocol is to make /s/ audible at the weakest possible setting. By creating a fitting that falls within the MAOF range and/or within the band-pass of the device, the audibility of /s/ is maximized for that fitting.
   - If the hearing loss is too severe and the /s/ signal cannot be made audible within the MAOF range, increase the strength of frequency lowering to the weakest setting where audibility is achieved.

6) What are the types of frequency lowering?

Frequency lowering hearing aid technology has evolved over the years to include different clinically available options: nonlinear frequency compression, frequency transposition and adaptive processors such as frequency translation. In general, frequency lowering hearing aids split the incoming hearing aid signal into two channels: low- and high-frequency sounds. Frequency compression compresses the high-frequency channel into a narrower bandwidth so that high-frequency information is lowered in frequency (Simpson, Hersbach, & McDermott, 2005). In contrast, frequency transposition does not compress the high-frequency region, but rather lowers it by adding it to the unprocessed low-frequency signal (Johansson, 1961). Frequency translation designates a *source region* (the high-frequency channel) which is copied and lowered into a *target region* (the low frequency region) when high-frequency signals are detected. As technologies are advancing, adaptive processors are becoming more common, and may use more complex signal processing than is fully described in this document. Both the low-frequency copy and the original high-frequency signal remain within the output of the device (Scollie, 2013).

7) Which type of frequency lowering should we use?

It is unknown whether the different types of frequency lowering technologies provide similar benefit, or if candidacy would interact with magnitude and configuration of hearing loss in a similar way across the different available technologies. To date, there are no studies that directly compare hearing aid performance across frequency lowering types.

8) What about acclimatization or training?

The studies summarized above provide evidence that some time may be needed to maximize benefit from frequency lowering technology. A study by Glista, Scollie and Sulkers (2012) looked at acclimatization effects associated with the use of frequency lowering in an older pediatric population. The study revealed that most subjects showed significant acclimatization trends after six to eight weeks without any auditory training. Changes over this time period were either gradual or sudden, and varied across children and outcome measures. Because children in the IHP are enrolled in communication development programs, interaction with therapists may be a rich source of information as to whether the child is learning to use the frequency-lowered sound and may provide some training to improve acclimatization to frequency lowering. Important items for inter-professional discussion could include whether the child responds to certain speech sounds, whether they can be discriminated, and whether speech sound confusions are encountered. Support for troubleshooting complex cases is provided within the IHP.

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ADDENDUM 3: NOISE MANAGEMENT IN HEARING AID FITTING

SUMMARY

The rationale for providing noise management in hearing aids is to reduce the occurrence of excessive loudness for a child who uses hearing aid(s). Routine outcome measures used within the IHP, and informal caregiver and/or child reports can be used to assess whether loudness is problematic and to monitor change following intervention.

Main content areas:

1. Overall, the IHP does not take a particular perspective on specific hearing aid selection decisions: this decision is the responsibility of the IHP prescribing audiologists. Selection decisions within the IHP should be made on a case by case basis, and should be informed by best available evidence. This document provides a summary of current evidence and rationale pertaining to noise management technologies.

2. The IHP supports evidence-based practice. Therefore, sections of a recent evidence-based guideline are endorsed by this protocol, and specific protocol steps have been developed that adhere to the guideline.

3. Specific cases are provided to illustrate decision-making, fitting protocol, and current challenges.

End of summary.

BACKGROUND

The IHP provides hearing aid services within early intervention in order to "ensure speech audibility at a comfortable level" (IHP Amplification protocol). Further, our goal is "to improve functional auditory capacity and participation in hearing- and communication-specific situations." Specific hearing aid technologies are not recommended by the IHP, but unbiased and evidence-based review of information may assist clinicians in selecting technologies and/or communicating choices to caregivers. The purpose of this document is to review current evidence on noise management technologies and illustrate preferred fitting methods for use in the IHP. All procedures in this document are intended to be applied together with other IHP protocols (Assessment, Amplification, and Dispensing).

Historically, pediatric audiology guidelines have varied in their recommendations for the use of noise programs (AAA, 2013; Bagatto et al., 2010; CASLPO, 2002; Foley, Cameron, & Hostler, 2009; King, 2010). This document reviews the background knowledge and evidence relevant to this type of fitting, and provides guidelines for practice within the IHP population.

WHAT IS THE RATIONALE FOR NOISE MANAGEMENT?

Children and infants experience a wide range of auditory environments in their daily lives. Many of these environments include high levels of speech, background noise, and/or reverberation (Crukley, Scollie, and Parsa, 2011) and may be louder than desired for children and infants who wear hearing aids even if loudness is normalized on formal loudness rating tasks (Ching et al, 2010; Crukley & Scollie, 2012; Scollie et al., 2010a;b). In addition, some children (and adults) experience significantly higher loudness perception than do others with similar hearing losses and similar amplification. Excessive loudness may be associated with fewer hours of daily hearing aid use in both adults and children, and may therefore limit benefit through inconsistent access to amplified sound (Humes, Wilson, & Humes, 2003; Ching et al., 2010).

Monitoring of outcomes post-fitting is part of the IHP Amplification Protocol. Information about loudness perception and hearing aid/instrument use are available from items within the IHP Amplification Benefit Questionnaire (IHP ABQ) and the Parents' Evaluation of Aural/Oral Performance of Children (PEACH). These may be supplemented with child and/or caregiver report and/or logging of hearing aid use time, environmental sound level information, and memory use.

DETERMINATION OF CANDIDACY FOR NOISE MANAGEMENT

Evidence-based rationales for providing noise management are to: (1) provide aided listening levels for the child that are comfortable across a wide range of environments, and (2) prevent excessive loudness percepts from limiting daily use of hearing aids. Trials with noise management are warranted on a case by case basis and at the clinician's discretion. Indicators of need for noise management include: (1) the child is regularly in noisy situations; (2) the child or caregiver reports limited hearing aid use attributable to noisy or loud environment limitations; (3) the child or caregiver reports loudness discomfort in any situation. Considerations for candidacy are summarized in Figure 1, along with device-specific considerations that dictate how noise management may be provided; these device considerations are discussed further below.

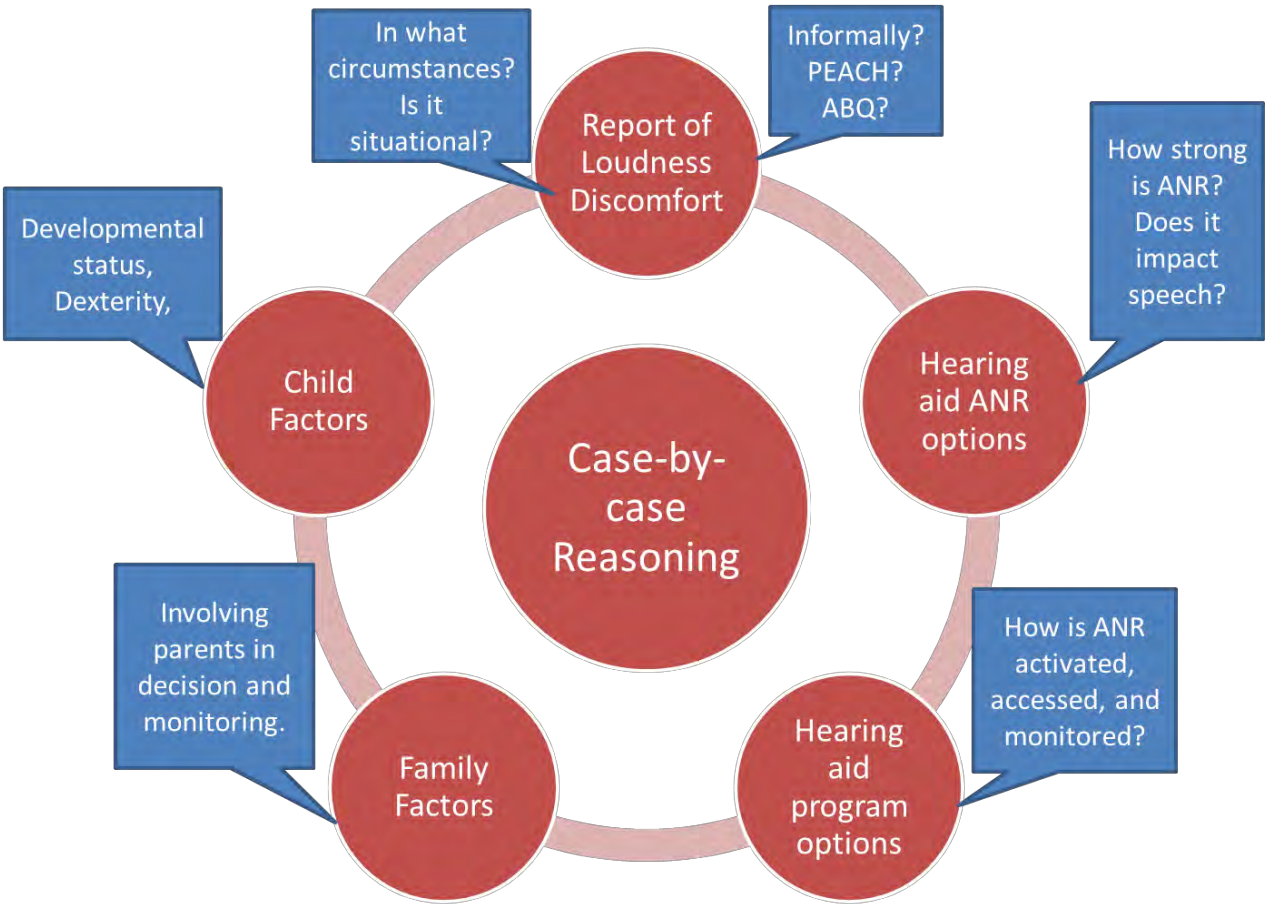


Figure 1. Candidacy and Device Considerations in Noise Management for Children who use Hearing Aids

WHAT ARE THE TYPES OF NOISE MANAGEMENT SIGNAL PROCESSING?

Modern hearing aids currently offer three main options for managing listening in noise. Directional microphone systems use more than one microphone to reduce the amplification of sounds coming from non-frontal locations. Adaptive noise reduction (ANR) involves digital signal processing to identify and minimize unwanted noise in the hearing aid's output. Frequency-gain shaping is the adjustment of the amount of amplification provided across the frequency and input range. Automatic switching between alternate programs within the hearing aid is also a common feature in modern hearing aids.

DIRECTIONAL MICROPHONES

Directional microphones can be beneficial for children or adults if the listener's head is pointed at the target talker, and the competing signals are from other directions (e.g., Crukley & Scollie, 2014). However, children have a low rate of accurate head orientation toward target talkers, and orientation away from a target talker can have

deleterious effects on speech recognition when directionality is used (Ching et al., 2009; Ricketts & Galster, 2007). Although there appears to be a directional advantage when the signal of interest is in front of the listener, there is also a clear directional disadvantage when the listener is not facing the sound source (Ching et al., 2009; Ricketts et al., 2007). Children rely on non-frontal listening and over-hearing for incidental language learning and for hearing the talker in home and daycare environments (Akhtar, 2005; Akhtar, Jipson, & Callanan, 2001).

Full time use of directional microphones is not recommended for infants and young children, because they are unlikely to orient to the target talker, and because reduction of sounds from the side and back may impair learning through overhearing (AAA, 2013). Part time use can be considered on a case by case basis, particularly if improvement of SNR is an aim of the directional strategy (AAA, 2013), with monitoring for benefit and appropriate use. Use of directional microphones may be less likely to impair overhearing if the directional profile is matched to that of a normal pinna, based on studies in adults (Keidser, et al., 2009). However, auditory localization continues to develop through childhood, with significant developmental trends to age 6 y and continued development through adolescence (Kuhnle et al., 2012). Evidence on directional microphone use, spatial hearing, and benefit in real world environments is lacking at this time. Use of directional microphones in children older than the IHP age range may have a different use and benefit profile than described here. Training on correct directional microphone use may be needed to ensure appropriate use of these systems (Pittman & Hiipakka, 2013).

ADAPTIVE NOISE REDUCTION (ANR)

Research with adults has shown no improvement in speech recognition performance with the use of ANR (e.g., Bentler & Chiou, 2006; Bentler et al., 2008). The use of ANR in children's hearing aids does not affect speech recognition (Crukley & Scollie, 2014; McCreery et al., 2012; Pittman, 2011b; Stelmachowicz et al., 2010). One study found that medium-strength ANR provides some loudness reduction when speech is presented in babble, but also that this effect varies across children (Crukley & Scollie, 2014). Stelmachowicz et al. (2010) evaluated ANR in children across a range of speech recognition tasks in noise. Overall, this study found no significant effect of ANR. However, individual results with 5 to 7 year old children indicated more variability in this group, with some children showing benefit or decrement with ANR. The authors interpreted the results, overall, as indicating a neutral effect for the ANR system tested, and suggested that fitting practices that preserve speech audibility may help to avoid negative impacts of ANR use. Another recent study found increased rates of novel word learning with ANR in older children, but not with younger children (Pittman, 2011a). Pittman speculated that this was due to improved ease of listening, which is consistent with a recent study in adults (Sarampalis et al., 2009), and that older children were better able to take advantage of this versus younger children. More recently, children's performance and preference with directional-ANR systems was assessed, and in general children preferred systems that helped them perform well, including those with ANR activated (Pittman & Hiipakka, 2013). These children were 8 and older, and were able to indicate which memory they preferred in a lab demonstration of multiple memories in a hearing aid.

ANR systems differ, providing more or less noise reduction across devices and settings (AAA, 2013). Provided that a given hearing aid's ANR does not reduce audibility for speech in quiet, it may be activated in hearing aids for infants and young children. Counselling around expectations should reflect whether the child's specific DNR strategy can reduce steady state noises and/or multi-talker speech.

FREQUENCY-GAIN SHAPING

Another option for providing improved loudness comfort in noisy environments is the use of less gain and output, either in the hearing aid's main program or in a second program, or by means of a volume control.

The most recent version of the Desired Sensation Level Method (v5.0; Scollie et al., 2005) includes an alternate prescription for use in noisy situations (Scollie et al., 2005). The noise prescription was designed to maintain audibility of the frequency regions of speech believed to contain acoustic cues most important for speech intelligibility based on the Speech Intelligibility Index (SII, ANSI S3.5, 1997). This prescription was designed to manage loudness comfort in noisy environments without degrading speech recognition abilities (Scollie et al., 2005). Evaluations in children have found that an alternative hearing aid program using either NAL-NL1 or the DSL v5 noise program can alleviate excessive loudness for noisy environments or for high-level signals (Crukley & Scollie, 2012; 2014; Ching et al., 2010; Quar et al., 2013).

On average, using less gain in a noise program does not affect speech recognition in quiet, although some individual children may experience some decrement in speech recognition (Crukley & Scollie, 2012; Scollie et al., 2010b). Children appear to prefer using higher gains for quiet, communication intensive situations, particularly for children who have greater degrees of hearing loss (Quar et al., 2013; Scollie et al., 2010a). Use of a validated lower-gain prescription can alleviate noise tolerance issues in children who are more susceptible to loudness tolerance problems (Ching et al., 2010; Crukley & Scollie, 2012; 2014; Quar et al, 2013). Older children may actively switch between memories, although this has not been tested in younger children or in a broad clinical population that includes children with medical or developmental challenges. Validated prescriptions that have been evaluated in children include the DSL5-Child Noise target and the NAL-NL1 target. These options are available in some hearing aid verification systems.

AUTOMATIC PROGRAM SWITCHING

Some hearing aids provide automatic switching between programs, allowing the audiologist to configure environment-specific programs for different listening scenarios (e.g., quiet, noise, remote mic, phone). These hearing aids monitor the ongoing acoustic environment, classify it by acoustic features, and switch to the program that is associated with that environment. Although little research is available on the use of these features in infants and young children, it stands to reason that manual switching is not feasible in this population. Trials of automatic program switching should be explored at the clinician's discretion, if this feature assists in the development of a monitored noise management strategy.

ARE THERE ELECTROACOUSTIC MEASUREMENTS OF ADAPTIVE NOISE REDUCTION (ANR) PROCESSING?

There are many different signal processing strategies for adaptive noise reduction (ANR) and these may vary in strength, defined as amount of noise decreased (dB), and time to activation/deactivation(s). ANR creates a reduction in gain when ongoing noises are present in the environment. This reduction may act quickly or take up to 20 seconds to activate fully. It may act over all frequencies or be shaped in frequency.

Currently, noise reduction technologies in hearing aids can be verified in the test box using three different 'noisy' signals (Air Conditioner, On the bus, and Vacuum within the Audioscan Verifit system and Speech Noise, Vacuum, and Babble within the Aurical system). For testing to be reliable, the noise signal must play for 30 seconds to allow all manufacturer's ANR strategies to activate to full strength and to produce replicable results. Therefore, it is necessary to **use a timer** to ensure accurate recording time for accurate data collection. A test level of **85 dB is recommended**. In the example below, the hearing aid provides an overall attenuation between 0 and 17 dB, depending on the setting:

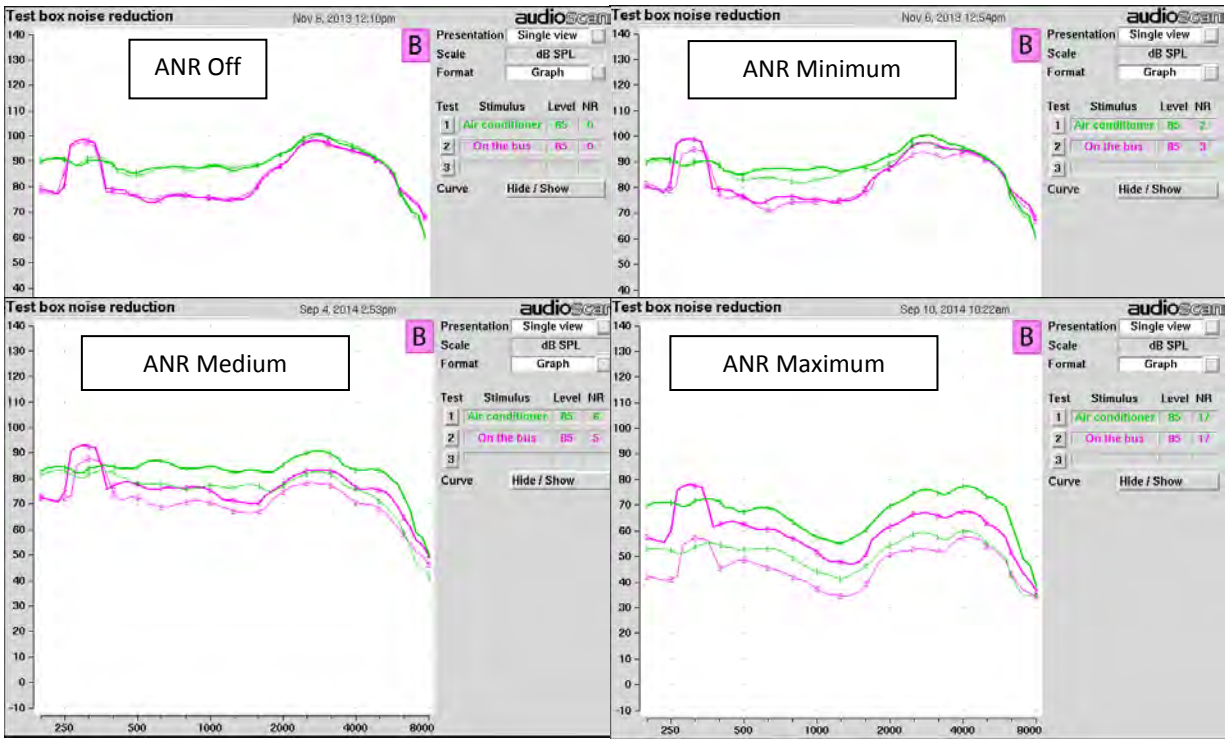


Figure 2. Test results for ANR strength testing across processor settings.

TYPICAL PERFORMANCE RANGES FOR ANR PROCESSING

As shown in the case above, ANR processing varies with the nominal strength of the processor chosen in the software. It also varies across brands. A representative sample of hearing aids was tested at all possible settings, and the results of the "Noise Reduction" tests at 85 dB were noted, for the amount of attenuation (dB) provided over 30 seconds.

The results indicated that some brands of hearing aids have stronger or weaker ANR systems. The nominal settings in software are correlated with these performance categories, but brand variation also exists. Software settings that are labelled as "Off" have 0-4 dB attenuation, in contrast to software settings that are labelled as "On" or "Medium" or similar, which offer 0-8 dB attenuation (mean 4 – 6 dB), and software settings that are labelled as "Maximum" or "Strong" or similar, which offer 3-16 dB of attenuation (mean 8-9 dB).

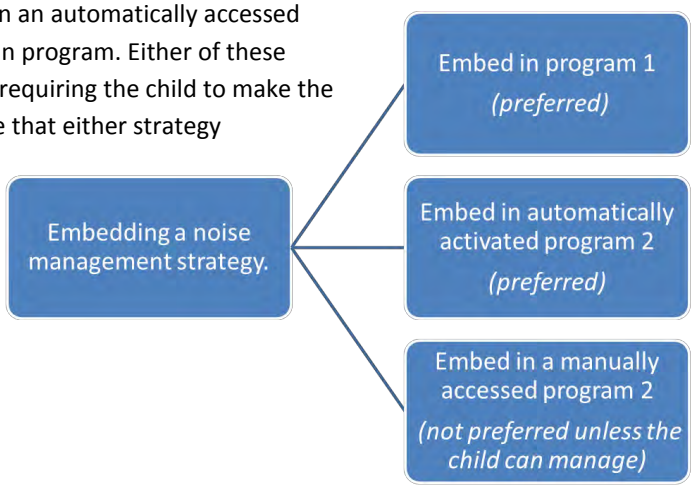
IHP clinicians are advised to consider the objectively measured strength of ANR systems when interpreting whether a noise management strategy has or has not been effective for an individual child.

PRACTICAL CONSIDERATIONS IN BUILDING A NOISE MANAGEMENT STRATEGY

Because different brands of hearing aids provide noise management options in different ways, having flexibility in how to build a noise management program is important. The considerations below summarize these choices in current products:

1) Embedding the strategy in a program.

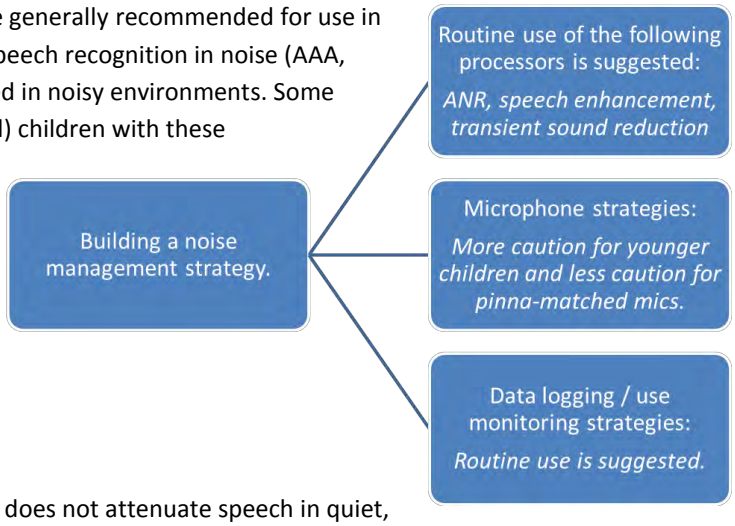
Some hearing aids provide environmental classification and switching between programs, while others do not. For this reason, the noise management strategy may be embedded in an automatically accessed second program, or it may be embedded in the hearing aid's main program. Either of these options allow access to the noise management strategy without requiring the child to make the switch. Pilot evaluations of a broad range of hearing aids indicate that either strategy provides both activation and de-activation of the noise management processing when the hearing aids are exposed to high- and mid-level speech in quiet and in a variety of background noises (work in progress).



2) Adding signal processing to the program. (see Appendix 3-1 for trade names)

Adaptive processors that act to reduce noisy signals, attenuate transient signals, and enhance speech-only signals are all versions of Adaptive Noise Reduction (ANR). These are generally recommended for use in children, although they should not be expected to improve speech recognition in noise (AAA, 2013). They are recommended to improve comfort when used in noisy environments. Some evidence exists that loudness is reduced for many (but not all) children with these processors (Crukley & Scollie, 2014). Therefore, trials with processors at known strengths can determine if a child is receiving benefit from the processors.

Directional programs may be trialed with young children, but caution is suggested for younger infants and children especially with full-band directionality (AAA, 2013).



3) Verification considerations

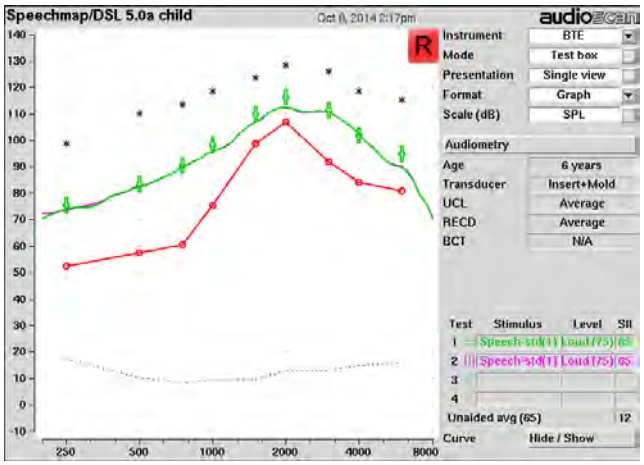
Verification of noise management is needed to ensure that it does not attenuate speech in quiet, and to verify that the noise management processing actually reduces noise. In the protocol below, a baseline measurement will allow the audiologist to know the strength of the noise reduction, so that this information is available for ongoing monitoring. For example, if the initial noise reduction strength is mild, and insufficient benefit is achieved, a stronger noise management strategy could be added to the hearing aids.

RECOMMENDED PROTOCOL

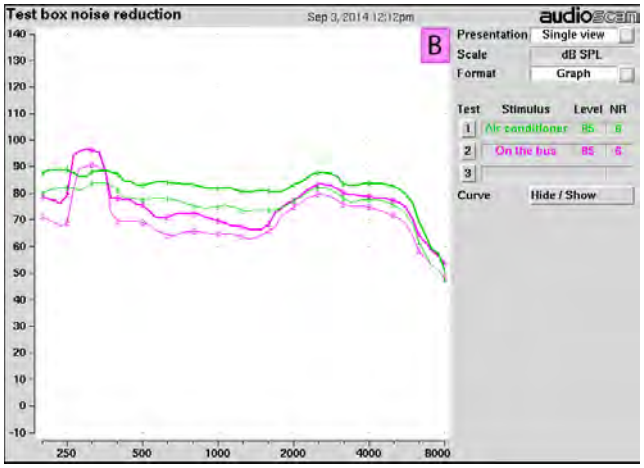
1) **Consider the candidacy factors for noise management.**
    - **a.** Does the child or caregiver report any loudness discomfort, either informally or formally (on the PEACH or IHP- ABQ). Under what circumstances does loudness discomfort occur?
    - **b.** Is the hearing aid use time per day limited, and if so, is it limited because of loudness and/or noise issues? Under what circumstances does loudness discomfort occur?
2) **Consider practical factors in planning a noise management strategy.**
    - **a.** Child Factors: Does the child have the cognitive/developmental/dexterity abilities to monitor his or her own environment and manually choose between hearing aid programs?
    - **b.** Family Factors: Involve the caregivers in choosing to provide noise management in order to facilitate their awareness, engagement, and monitoring.
    - **c.** Hearing Aid Options: What noise management features does the hearing aid offer? How strong is the noise reduction, and how can it be accessed (via automatic or manual programs?) and monitored (via data or use monitoring?).
3) **Verify the shape and gain of the hearing aid fitting without ANR.**
    - **a.** Begin by verifying and tuning hearing aid to optimize the fitting without ANR. Ensure that the aided speech spectra meet DSL prescriptive targets and provide a broad bandwidth of audibility.
    - **b.** Check whether the Loud response is on target. If the hearing aid is over target, this may be impacting the child's loudness comfort in daily use.
4) **Enable the noise management program. How will the child access the noise management strategy?**
    - **a.** Can you embed it within the hearing aid's only program?
    - **b.** Can you embed it in an automatically accessed second program?
    - **c.** Can you embed it in a manually accessed program?
5) **Program the noise management strategy, by adding features to the noise management program.**
6) **Verify the noise management strategy: Does it attenuate speech in quiet?**
    - **a.** Run a 75 dB SPL speech signal to the hearing aid, with and without the noise management strategy enabled.
    - **b.** The two curves should be highly similar.
    - **c.** *Because this step rarely produces any concern, it is sufficient to run this when learning a new make/model/processing scheme, and does not need to be performed on a case by case basis unless there are concerns.*
7) **Verify the noise management strategy: Does it attenuate high-level noise?**
    - **a.** Measure the "Air Conditioner" or "On the bus" signal in the Noise Reduction tests for 30 seconds. Note the overall amount of attenuation provided as a measure of strength of processing.
    - **b.** Consider strengthening the processor if the tests provide fewer than 3 dB of attenuation.
8) **Counsel on appropriate use and monitor outcomes at the next visit.**
    - **a.** Does hearing aid use increase, including in situations of concern?
    - **b.** Does loudness discomfort decrease, including in situations of concern?
    - **c.** **Steps to consider if problems are not resolved:**
        - **i.** Consider a stronger noise management setting or an automatically accessed gain-reduced noise program fitted either to DSL5-noise or NAL-NL2-child.
        - **ii.** Consider a trial with a loaner instrument that offers stronger noise management.
        - **iii.** Request further support from the IHP.

CASE EXAMPLE A: ILLUSTRATING THE FITTING PROTOCOL

The following case illustrates a fitting for a child who is a full time user, and for whom a noise management strategy was created. The hearing aid's adaptive noise management feature was enabled in the main program of the hearing aid together with an omnidirectional microphone. Verification indicates that the noise management strategy reduces the level of noises by 6 dB, while leaving speech in quiet unaffected. Monitoring plans include software-supported hearing aid use logging, evaluation of use on the IHP-ABQ, and continued monitoring of reports of loudness comfort in loud environments on the IHP-ABQ and by caregiver report. Any changes in these outcomes may inform the clinician about the real-world effectiveness of the strategy.



When a loud speech input is delivered to the hearing aid with noise management, the hearing aid maintains a good fit to DSL targets. Therefore, the noise management strategy does not impact the audibility of speech in quiet:



When the noise management strategy is enabled, an average of 6 dB noise reduction is noted when 'Air Conditioner' and 'On the bus' signals are delivered to the hearing aid.

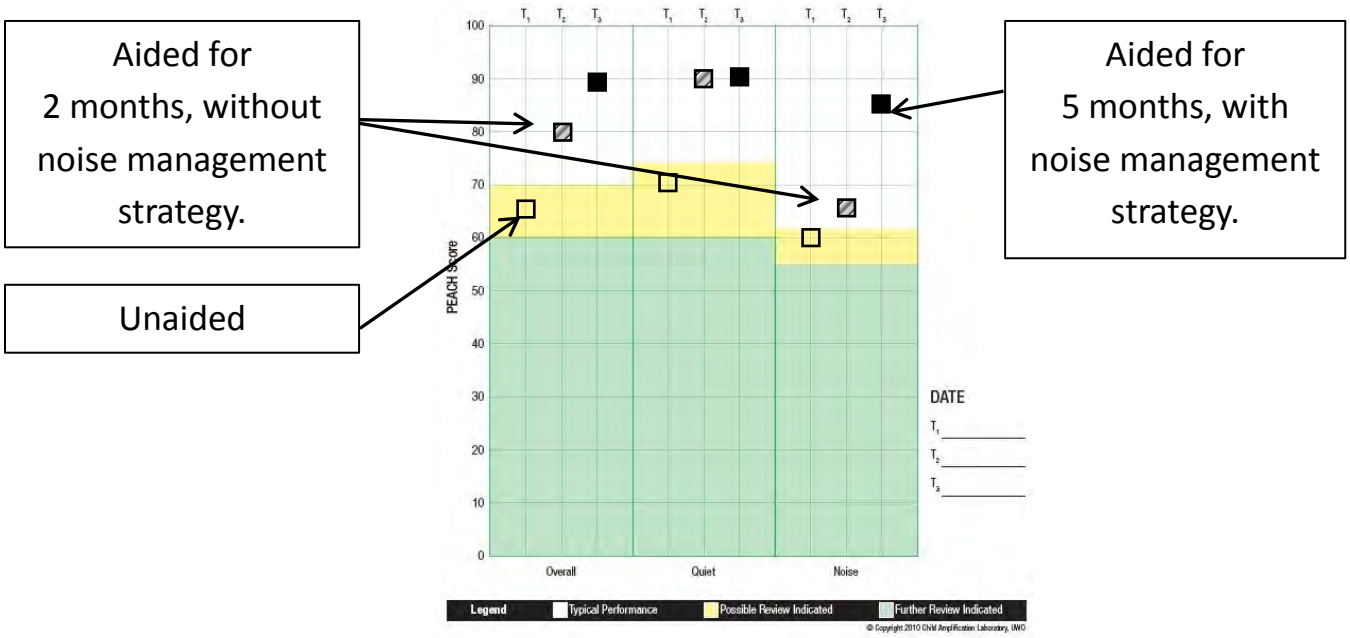
Test 1: ANR Off
Test 2: ANR On

Thick line: at onset of signal.
Thin line: after 30 seconds.

CASE EXAMPLE B: ILLUSTRATING THE ROLE OF MONITORING AND FOLLOW UP

In this example, a child with normal developmental status was fitted with hearing aids at 4.5 years of age. She has a bilateral moderately-severe hearing loss and was fitted late due to lack of parental follow-up. Noise management strategies were not initially activated in the hearing aids. Prior to being fitted with hearing aids, the mother completed the PEACH, as recommended by the IHP Outcome Measurement Protocol (2010). Scores ranged from 65%, 70%, and 60% for the Overall, Quiet and Noise subscales respectively for the unaided condition. After two months of experience with the hearing aids, the child's scores on the PEACH increased to 80%, 91%, and 65% for the same subscales. Items in the noise subscale were discussed with the family and the need for a noise management strategy for certain situations was identified. Therefore, a noise management strategy in a second manually-accessible program was applied in consultation with the parents and child. This included adaptive noise reduction and omni-directional microphones. At the follow-up appointment, scores improved to 88%, 91%, and 85% on the Overall, Quiet and Noise subscales respectively. An improvement in the noise score likely coincided with the introduction of the noise management strategy.

This demonstrates that the PEACH is sensitive to auditory performance in the unaided and aided condition and shows progression in scores with more experience with hearing aids as well as the application of noise management strategies. In this case, a positive outcome with intervention was documented by systematically tracking the child's auditory performance over time.



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APPENDIX 3-1: GENERIC AND BRAND-SPECIFIC NAMES OF NOISE REDUCTION FEATURES (2014 MODELS)

Brand	Generic Name	Proprietary Name	Strength Settings:
Bernafon	Transient Manager	Transient Noise Reduction	Off, Medium, High
	Noise Reduction	Adaptive Noise Reduction Plus	Off, Minimum, Medium, Maximum -Adaptively (slow, fast)
	Repetitive Noise Manager	Soft Noise Management	0, 1, 2
Oticon (adult)	Noise Reduction	Noise Management	OFF→Max (0-7) depending on rationale; but can choose ON or OFF
	Transient Manager	Transient management	Min→Max (0-3) depending on rationale
Oticon (pediatric)	Noise Reduction	Noise Management	OFF, ON
Phonak	Noise Reduction	NoiseBlock	Off, weak, moderate, Strong
	Wind Noise Reduction	WindBlock	Off, weak, moderate, Strong
	Reverberation Manager	EchoBlock	Off, weak, moderate, Strong
	Transient Manager	SoundRelax	Off, weak, moderate, Strong
Resound	Noise Reduction	NoiseTracker II	Off, Mild, Moderate, Considerable, Strong -Per environment (quiet, speech, speech in noise, noise)
	Wind Noise Reduction	WindGuard	Off, Mild, Moderate, Strong
Siemens	Noise Reduction	Speech and Noise Management	-Broadband or Multichannel adjustment; Speech in noise only option -Min – Max (1-24; 7 steps)
	Transient Manager	Sound Smoothing	Min – Max (-20 to -40; 3 steps)
	Wind Noise Reduction	eWindScreen	Min, Med, Max
Starkey	Wind Noise Reduction	Wind	0-20 db (4 options 1-4)
	Repetitive Noise Manager	Machine Noise	0-20 db (4 options 1-4)
	Noise Reduction	Voice iQ 2	0-20 db (4 options 1-4)
Unitron	Transient Manager	AntiShock	Off, Mild, Moderate, Max
	Noise Reduction	SmartFocus Configuration	Comfort (max), Neutral, Clarity (min)
	Wind Noise Reduction	Wind Noise Manager	Off, Mild, Moderate, Max
Widex	Noise Reduction	Speech and Noise Modes	Off, Noise Reduction, Noise Reduction Minimal, Noise Reduction Enhanced, Noise Reduction Comfort (max), Speech Enhancer
	Transient Manager	Impulse Sound Modes	TruSound Softener on, TruSound Softener Plus on, TruSound Softener off

ADDENDUM 4: DECISION SUPPORT GUIDE FOR HEARING AID USE IN INFANTS AND CHILDREN WITH MINIMAL/MILD BILATERAL HEARING LOSS[1]

SUMMARY

Evidence suggests that the majority of children with minimal/mild, permanent, bilateral hearing loss (MBHL) are at greater risk for academic, speech-language and social-emotional difficulties than their normal hearing peers. It is reasonable to assume that appropriate and timely hearing technology could mitigate the negative impact of such losses. However, there currently is no way to predict which children will experience difficulties and which will follow a typical course of development. This makes early intervention recommendations unclear, leading to several pediatric amplification guidelines recommending hearing aids to these children on a case-by-case basis. The absence of more specific management guidelines presents a challenge to pediatric audiologists who work with families of infants and children with MBHL as they lack the evidence to support clear amplification recommendations. Although comprehensive management of infants and children with MBHL is multifaceted, this addendum will focus on the consideration of hearing aids. Specifically, a process is described that is intended to facilitate appropriate case-by-case reasoning when considering amplification for infants and children identified with MBHL.

The contents of this document include:

1. Definition of MBHL and the potential impact on development.
2. Factors to consider when working with families of infants and young children with MBHL.
3. A decision support guide in the form of a flow chart to assist with hearing aid management decisions.

End of summary.

[1]This addendum is based on the following publication: Bagatto, M.P. & Tharpe, A.M.T. (2014). Decision Support Guide for Hearing Aid Use in Infants and Children with Minimal/Mild Bilateral Hearing Loss, In Ed. J. Northern, A Sound Foundation Through Early Amplification 6th International Conference Proceedings, Phonak AG: Stafa, page 145-151.

BACKGROUND

For the past several decades, evidence has accrued suggesting that a large percentage of children with minimal and mild degrees of bilateral permanent hearing loss (MBHL) have psychoeducational and behavioral difficulties (Bess, Dodd-Murphy & Parker, 1998; Bess & Tharpe, 1984; Most, 2004; Wake, Hughes, Poulakis, Collins & Rickards, 2004). It is reasonable to assume that appropriate and timely hearing technology could assuage the negative impact of such losses. Toward that end, several hearing technology options have been recommended for these children (Tharpe, Ricketts & Sladen, 2003; Tharpe, Eiten & Gabbard, 2008) but evidence-based guidance regarding these fitting practices has been lacking. Extant consensus-based and evidence-based protocols and guidelines have consistently recommended the selection of amplification for children with MBHL on a case-by-case basis (e.g., Bagatto, Scollie, Hyde & Seewald, 2010) with consideration for whether the degree of loss could interfere with normal development (e.g., American Academy of Audiology [AAA], 2013). However, additional guidance has not been forthcoming. This lack of guidance has resulted in uncertainty about hearing aid recommendations with this group of children (Fitzpatrick, Whittingham & Durieux-Smith, 2013).

A decision support guide is provided herein that is designed to help Ontario Infant Hearing Program (IHP) clinicians compile information that will assist them in deciding whether an infant or child with MBHL is a good candidate for hearing aids. The rationale for this work is to reduce clinician uncertainty when making hearing aid recommendations for these children. It is intended to facilitate appropriate case-by-case reasoning when selecting amplification for infants and children with MBHL identified through Ontario's Infant Hearing Program. As indicated in the IHP Protocol for the Provision of Amplification (2007, Version 3.1; 2014 Version 4.0), "the determination that amplification should be recommended on audiologic grounds is at the discretion of the IHP Audiologist". This remains a guiding principle in the management of infants and children with MBHL within the IHP and this addendum provides support for clinical decisions with this population.

The proposed decision guide is based on several assumptions. First, it is assumed that audiologic certainty has been obtained. That is, there has been reliable determination of degree, configuration and type of hearing loss for at least two frequencies in each ear (AAA, 2013; IHP Assessment Protocol, 2008). Another assumption is that all infants and children with MBHL who are provided with personal hearing aids are also considered candidates for remote microphone hearing assistance technologies (e.g., FM/DM). Such technology is known to improve listening in environments where distance, noise and reverberation are an issue (e.g., Lewis & Eiten, 2011). Guidelines for remote microphone hearing assistance technologies for children and youth are provided in a recent document from the American Academy of Audiology (2011) and has been endorsed by the IHP (Addendum 6) so will not be discussed herein. Third, the family must be well-informed of the potential benefits and limitations of hearing aids for their infant or child with MBHL. A family-centred approach to decision making is central to the IHP's intervention process. Finally, the decision support guide provided in this document is not intended to be comprehensive, but rather provide guidance to audiologists when considering hearing aids for infants and children with MBHL. Selection of hearing aids is but one part of comprehensive and fluid management of childhood hearing loss, which should also include periodic, comprehensive monitoring of hearing, speech, language and family-focused counseling (Joint Committee on Infant Hearing [JCIH], 2007).

Several elements have been included for consideration in the proposed guide to support clinical decision making (Figure 1). These factors include: 1) configuration and degree of hearing loss; 2) ear canal and earmold acoustics; 3) hearing aid gain/output and noise floor; 4) child factors; and 5) family factors. Details about each of these factors are described in the following sections.

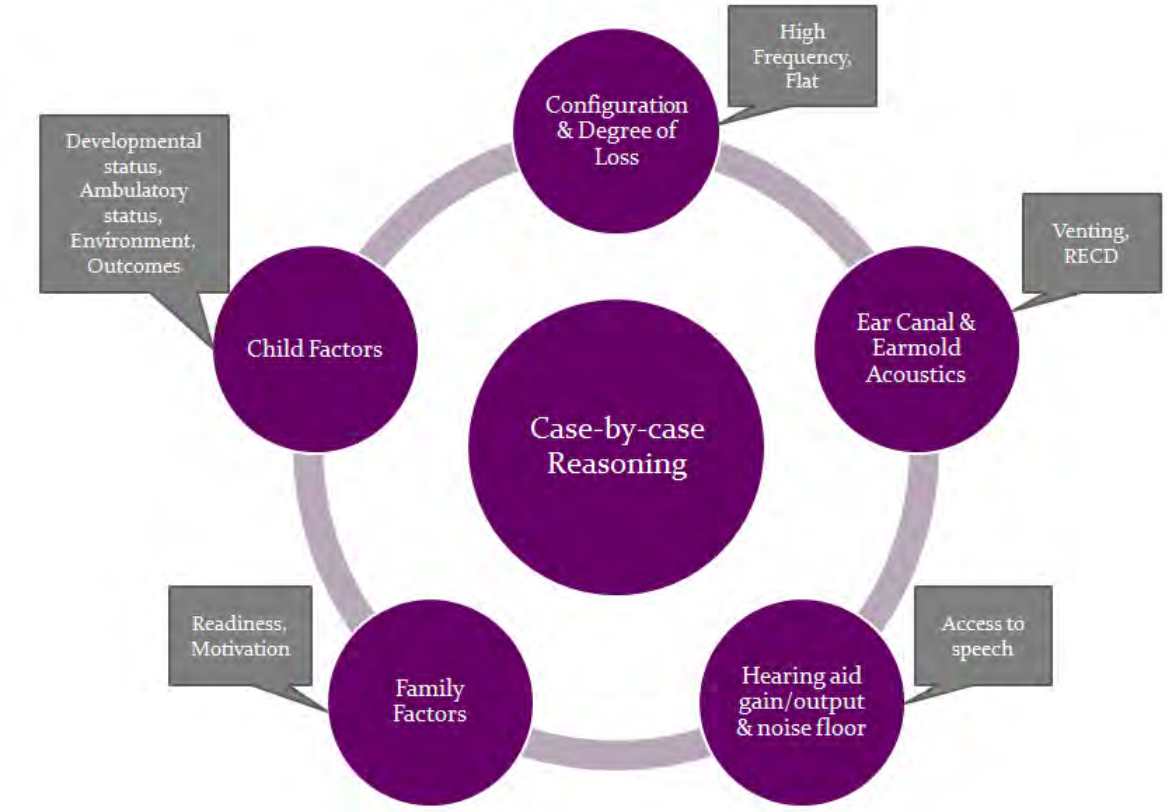

Figure 3. Factors to consider when determining the appropriateness of a hearing aid for an infant or child with MBHL.

CONFIGURATION AND DEGREE OF HEARING LOSS

Minimal/mild bilateral hearing loss in children is defined as (Bess et al., 1998):

a) Permanent Mild Bilateral: pure tone average (500, 1000, 2000 Hz) between 20 and 40 dB HL

b) Permanent High Frequency: pure tone thresholds > 25 dB HL at two or more frequencies above 2000 Hz

These definitions are supported by the National Workshop on Mild and Unilateral Hearing Loss (2005) and are used to categorize different configurations of MBHL: flat and high frequency. It should be noted that these criteria do not consider minimum response level (MRL) concepts for audiologic assessment in very young children, which are included in the IHP Assessment Protocol (2008). A study examining hearing levels in infants and young children in relation to test technique and age group suggests responses to threshold rather than MRL by around three years of age (Sabo, Paradise, Kurs-Lasky & Smith, 2003). Given these factors, the definitions cited should be interpreted accordingly. The degree of hearing loss in the high frequencies can range from mild to profound for the purposes of this guide. With both configurations, the hearing losses should be defined in each ear by at least one low and

one high frequency threshold, as is required by several pediatric hearing aid fitting protocols (e.g., AAA, 2013; Bagatto et al., 2010).

The target IHP impairment includes “any hearing threshold equivalent to 30 dB HL or greater at any frequency in the range of 0.5-4 kHz, in either ear….not including impairment attributable to non-structural middle ear conditions” (IHP Amplification Protocol, 2007; 2014). IHP assessment procedures often elicit an estimated or minimum response from the infant or child at 30 dB nHL or HL. This value is further corrected to 25 dB eHL or true HL depending on whether the assessment procedure was electrophysiological or behavioural. This is considered to be “IHP normal” within our program. It is possible that a child may have a 25 dB threshold at one frequency and a 30 dB threshold at another in the same ear, in which case, the decision algorithms provided in this document may provide some guidance.

EAR CANAL AND EARMOLD ACOUSTICS

The external ears of infants and young children are significantly smaller than those of adults (Bagatto, Scollie, Seewald, Moodie & Hoover, 2002; Feigin, Kopun, Stelmachowicz, & Gorga, 1989; Kruger, 1987) and the size changes as the child grows. This growth has substantial implications when defining accurate hearing levels as well as when measuring hearing aid output in devices that are calibrated with reference to an average adult ear canal. It is therefore essential to measure the real-ear-to-coupler difference (RECD) in infants with MBHL and use this measurement to convert the audiogram (referenced in dB HL) to sound pressure level (SPL; Seewald & Scollie, 1999). This will provide a more accurate description of the infant’s hearing levels that can be directly compared to hearing aid output on an SPL scale. As the infant grows, the ear canal changes thus changing the SPL delivered to the ear. Therefore, the RECD must be measured on a regular basis over time for a given infant so that changes to the ear canal acoustics can be applied when comparing sequential audiograms and defining the amount of output provided by a hearing aid.

Small infant ears can also impact the earmold acoustics of a potential hearing aid fitting for a child with MBHL. In many instances, the ear canals of infants and young children are too small to accommodate a vent in the earmold. An earmold vent provides an outlet for sound up to about 1000 Hz, depending on vent diameter (Dillon, 2012). The ability to provide venting has implications for some degrees and configurations of MBHL where amplification may not be required (see Figure 2).

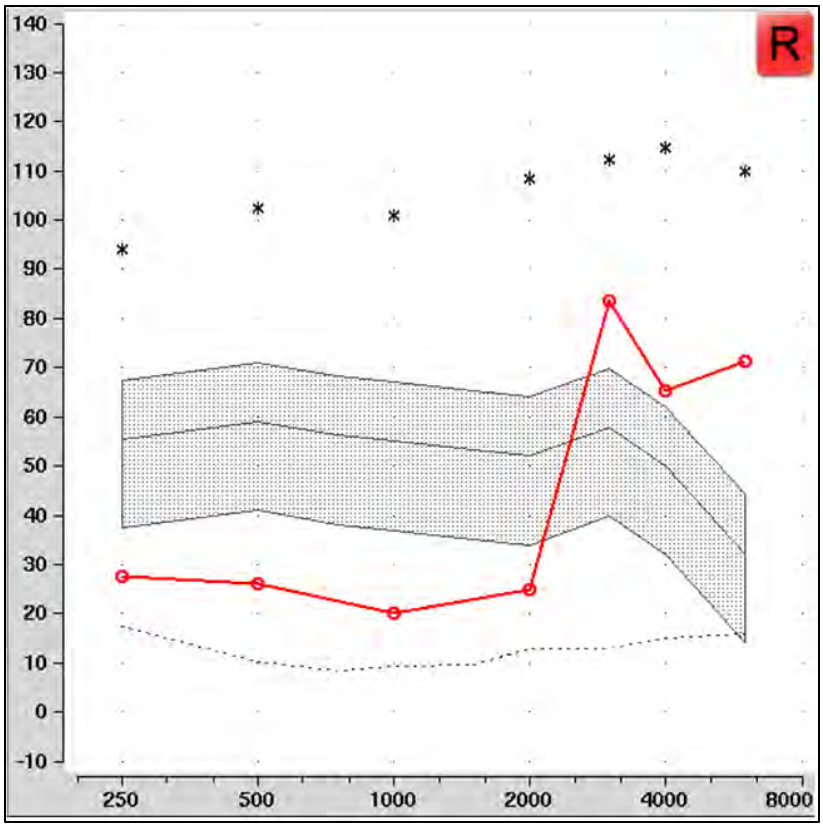

Figure 4. An example of unaided speech (shaded region) audibility for a child with a mild high frequency hearing loss (open circles). The x-axis is frequency (Hz) and the y-axis is sound pressure level (SPL) at the eardrum. Note that no amplification is required in the low frequency region, but is needed in the high frequency region. A vented earmold will help reduce the impact of upward spread of masking.

An occluding earmold will not allow sound to escape in the low-frequency region thus providing amplification in an area where little or no hearing aid gain is needed. This may interfere with the hearing aid benefit necessary in the high frequency region because of upward spread of masking. When considering a hearing aid recommendation for infants and children with MBHL, it is important to weigh the implications of potentially masked high frequency speech cues resulting from an unvented earmold compared to the potential high frequency benefit provided with the same fitting. The small ear canals of infants impact the assessment of hearing sensitivity in this population as well as the ability to provide a vented earmold in the hearing aid fitting. As such, ear canal size and earmold acoustics are important factors when considering whether to pursue a hearing aid fitting with an infant or child with MBHL.

HEARING AID GAIN/OUTPUT AND NOISE FLOOR

Confirmation that a broad frequency range of speech is audible at various input levels and ensuring loud inputs to the hearing aids are comfortable for the infant are explicit goals of a pediatric hearing aid fitting, regardless of degree of hearing loss. Easy and safe access to speech supports a child's development of language. This is achieved by employing coupler-based verification techniques and RECD measures to assess the output of the hearing aid to be provided. In the case of MBHL, minimal hearing aid gain may be required and could interact with the low-level

hearing aid noise floor (Figure 3). Consequently, the noise could be heard by the child and mask speech sounds amplified by the hearing aid. With venting, an improvement in performance may result. However, careful consideration of hearing aid benefit compared to the unaided condition is necessary when considering a hearing aid for an infant or child with MBHL.

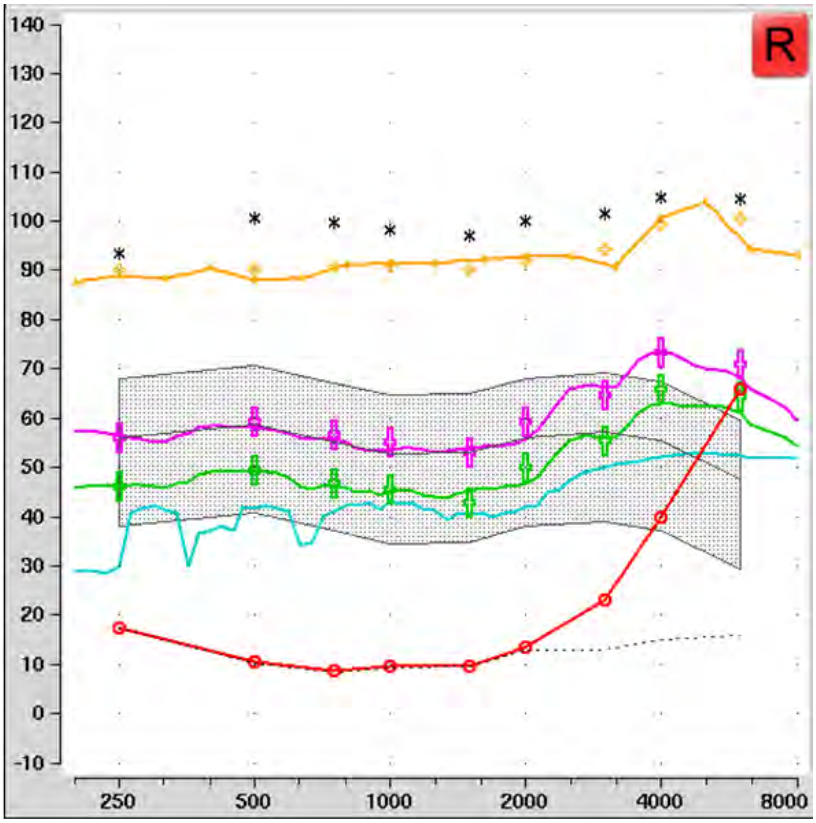

Figure 5. An example of a low-gain hearing aid fitting. The x-axis is frequency (Hz) and the y-axis is sound pressure level (SPL) at the eardrum. The blue line is the hearing aid's noise floor which may be heard by the listener. Note that soft aided speech (green line) is not much better than the noise floor. The SII values for average aided speech (pink line) is 94% and the SII values for soft aided speech are 89%.

Considering the Speech Intelligibility Index (SII; ANSI S3.5-1997) values during verification of hearing aids offers support on whether providing a hearing aid will result in benefit compared to the unaided condition. The SII values shown in Figure 3 for both the unaided and aided conditions are high (89% and 94% respectively). At these levels, ease of listening is more prominently impacted than performance (Scollie, 2008). Speech audibility may be improved for some children with MBHL without hearing aids by increasing the vocal effort of the talker, decreasing speaker-listener distance, and reducing background noise. Conducting appropriate outcome measurements that evaluate access to speech in various conditions (e.g., Ling 6(HL) Detection Task; Scollie, Glista, Tenhaaf, Quelenec, Dunn, Malandrino, Keene & Folkeard, 2012) might provide important information when considering providing

hearing aids to an infant or child with MBHL. The outcome measures mentioned are not currently part of the IHP Outcome Measurement Protocol (2010), but clinicians may use them at their discretion.

CHILD FACTORS

The individual characteristics of a child with MBHL and his or her listening environment are an integral part of hearing aid management decisions. Evidence suggests that 25 to 40% of children with hearing loss have additional handicapping conditions that might further impact their capacity to develop normally (Tharpe, Fino-Szumski & Bess, 2001). The presence of comorbidity can result in poorer functional auditory outcomes when compared to typically-developing children who have been fitted with hearing aids (Bagatto, Moodie, Malandrino, Richert, Clench & Scollie, 2011). For example, as seen in Figure 4, the auditory development of children with MBHL who have not been provided with hearing aids was assessed using the LittlEARS Auditory Questionnaire (Tsiakpini, Weichbold, Kuehn-Inacker, Coninx, D'Haese & Almadin, 2004). Those children who did not meet auditory development milestones (represented by the encircled scores) were noted to have disabilities in addition to hearing loss that impacted their auditory development. It is therefore important to conduct outcome measures in the aided as well as unaided conditions to inform the decision to recommend hearing aids for infants and children with MBHL. The current IHP Outcome Measurement Protocol (2010) can be used for this purpose.

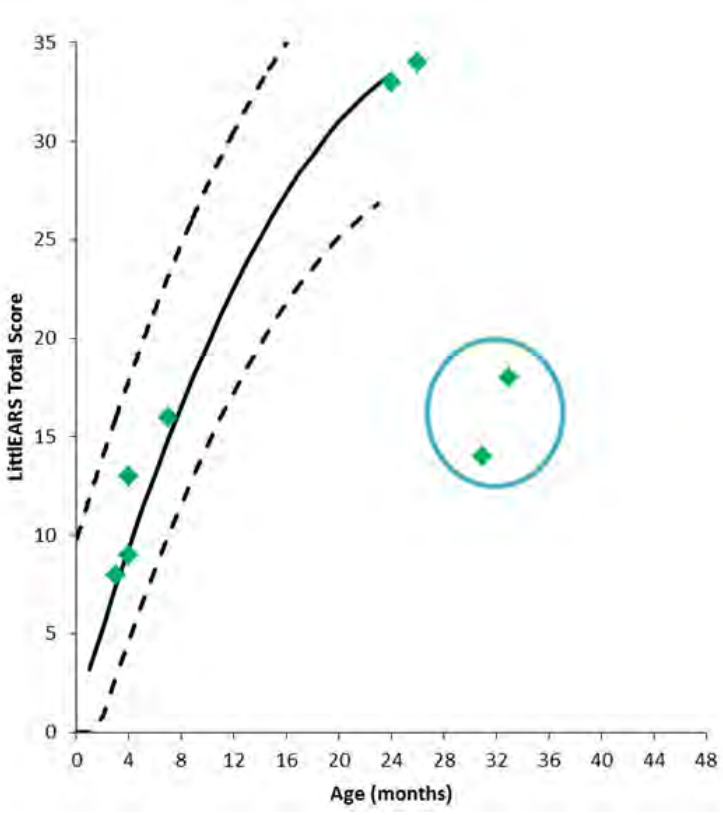

Figure 6. An example of LittlEARS scores (y-axis) by age (x-axis) for children with unaided MBHL. The solid line represents the average LittlEARS scores for normal hearing children and the dashed lines are the upper and lower 95% confidence intervals. The diamonds represent individual child's LittlEARS scores. The diamonds that are circled are children with comorbidities.

Another factor to consider is the ambulatory status of the child, as opposed to just the age of a child, when contemplating hearing aids for an infant or child with MBHL. Whether a child is crawling, walking, or otherwise able to distance him/herself from the talker of interest is a relevant consideration because distance will directly impact the SII as well as signal-to-noise ratio. A tool that takes speaker-listener-distance into consideration is the Situational Hearing Aid Response Profile (SHARP; Brennan, Lewis, McCreery, Creutz & Stelmachowicz, 2013). The SHARP is a software application used to characterize the audibility of speech signals across a wide range of realistic listening situations with varying acoustic environments. Applying this tool to a hearing aid selection procedure can provide useful information to guide case-by-case reasoning when managing MBHL in children. Figure 5 provides SHARP examples of the audibility of speech for a given hearing loss in SPL at various levels and distances and provides SII values to inform the amount of speech audibility.

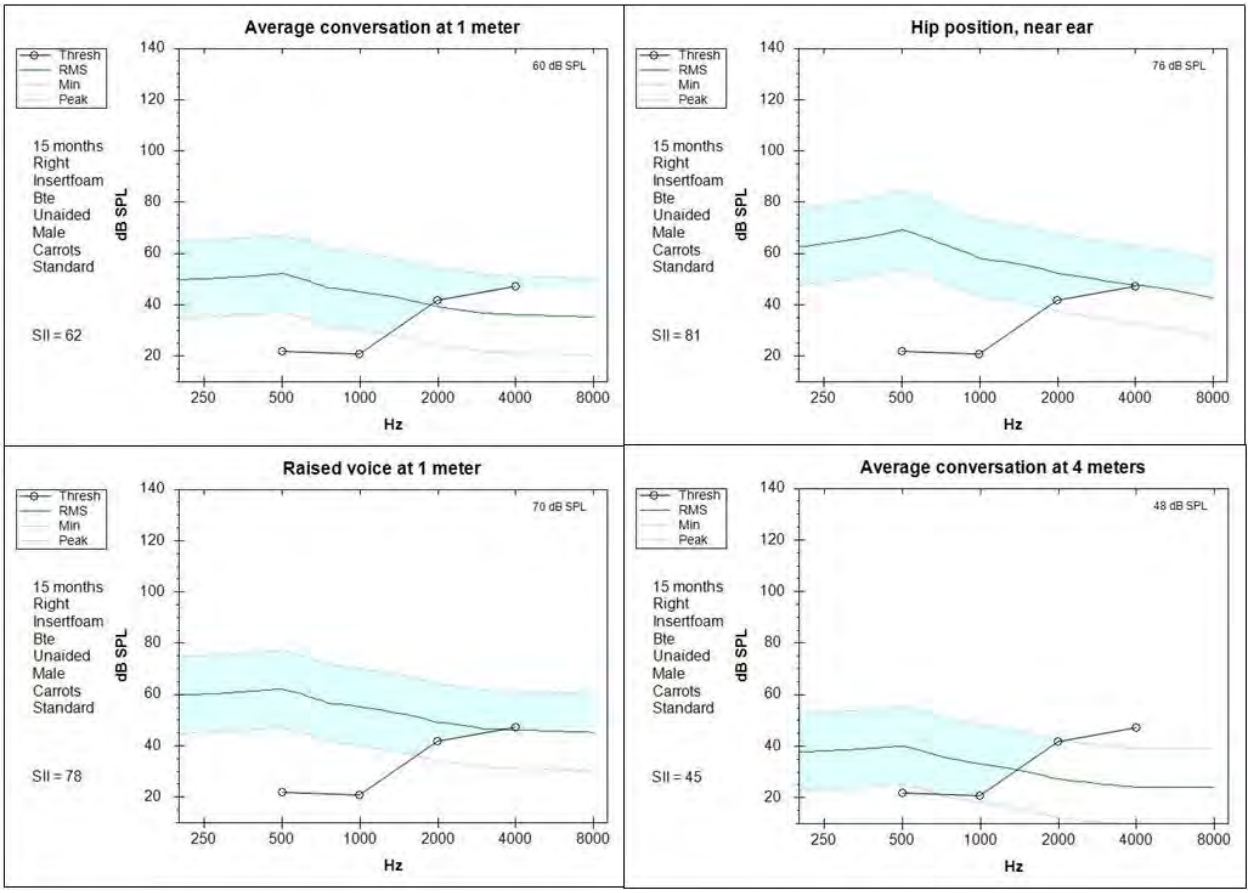

Figure 7. Examples of the audibility of speech for a given hearing loss in SPL at various levels and distances for a child with MBHL. SII values are provided to inform the index of speech audibility.

As demonstrated, if the source of speech is close to the child (e.g., hip position), a hearing aid may not be required due to the high SII value. However, for distant sounds (e.g., average conversation at four meters) the ambulatory abilities of the child matters.

One final child factor for consideration is the child's listening environment. This can be described as the acoustics of a room (noisy versus quiet) or a group or a non-group situation. The environment in which the child spends

most of his/her waking hours should be considered when managing infants and children with MBHL. For example, some infants will be in a quiet home setting throughout the day while others may be in a daycare or school setting where signal-to-noise ratios are not ideal. The presence of distance, noise and reverberation in the child's listening environment impacts development and performance in several areas. Listening in the presence of background noise can affect the development of speech and language skills, social-emotional functioning and educational performance in children with and without hearing loss (Lewis & Eiten, 2012). It has been demonstrated that children with MBHL have better speech perception ability in noise when wearing an FM system compared to the unaided condition (Tharpe et al., 2003). Remote microphone hearing assistance technologies can provide a clear, audible input signal and reduce the impact of noise and reverberation. They are available in a variety of configurations (e.g., ear-level FM only, sound field) regardless of whether the child with MBHL uses hearing aids (AAA, 2011; Addendum 6). The child's listening environment is an important consideration when selecting hearing technology for children with MBHL.

FAMILY FACTORS

Another important aspect to the management of children with MBHL is their family. Their readiness and motivation to proceed with the exploration of hearing aids are essential to this process. A family-centred approach is a guiding principle underlying the management of children with hearing loss and should be applied when considering hearing aids for infants and children with MBHL. Caregivers should be apprised of the benefits and limitations of a hearing aid fitting for their child and, where possible, these should be illustrated through the use of outcome measures (e.g., LittlEARS, Ling 6(HL) Detection Task). Providing hearing aids on loan to the family for a trial period provides a real-world demonstration that can be invaluable in this process. A supportive and fluid approach to case management will facilitate careful case-by-case reasoning when combined with the previous factors discussed.

DECISION SUPPORT GUIDE

With the above factors in mind, a decision support guide in the form of a flow chart has been created to assist IHP clinicians in determining the appropriateness of a hearing aid recommendation for individual children with MBHL (Figure 6). This guidance is based on the definitions of MBHL for both flat and high frequency configurations (Bess et al, 1998) as well as the IHP target population and associated assessment procedures. Whether a hearing aid recommendation is pursued or not, caregiver counseling and close monitoring of the child's hearing levels, development and auditory performance is recommended as changing circumstances could support fitting at a later time in the child's life.

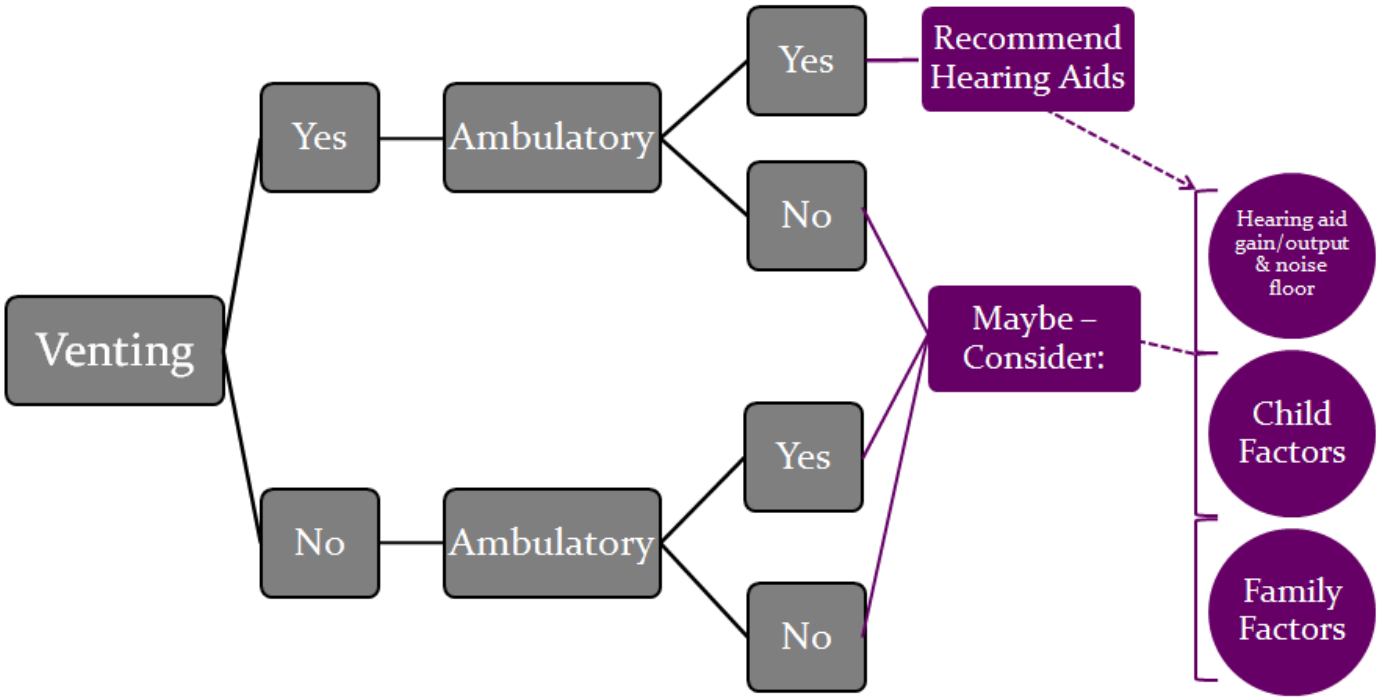

Figure 8. Decision support guide for clinicians considering hearing aids for infants and children with MBHL.

CONCLUSION

A significant number of children with MBHL experience difficulties with language, academic, and psychosocial development (Bess et al, 1998; Hicks & Tharpe, 2002; Most, 2004; Wake et al., 2004). Hearing aid management decisions for these children are not well-established, which results in clinical uncertainty (Fitzpatrick et al., 2013). A decision support guide in the form of a flow chart to support clinical decision making when dealing with individual infants and children with MBHL and their families has been provided in this addendum. It describes many factors to consider when making case-by-base decisions with this population. Regardless of whether a hearing aid has been recommended for a specific child, it is important to continue to monitor that child's auditory as well as functional development. As the child's ear canal grows and changes, the acoustic properties change which impact hearing thresholds and the gain requirements of the hearing aids to be fitted. In addition, children in the first three years of life often experience otitis media with effusion that can impact hearing thresholds. Therefore, including immittance measures in audiological monitoring protocols is vital. Finally, audiologists should monitor the child's functional auditory abilities, their speech-language skills and educational progress as part of routine evaluation, whether or not hearing aids are provided. Intervention strategies should be adjusted as required, in consultation with the family, as new evidence is gathered.

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ADDENDUM 5: MANAGEMENT OF INFANTS AND CHILDREN WITH UNILATERAL HEARING LOSS

SUMMARY

Infants and young children identified with unilateral hearing loss (UHL) comprise approximately 15% of children seen within the Ontario Infant Hearing Program (IHP). The IHP Provision of Amplification Protocol (2007) and other guidelines (American Academy of Audiology, 2013) advises providing hearing aids to these children on a case-by-case basis. The lack of clearer recommendations imposes a challenge for IHP Audiologists and the families of infants and young children with UHL with whom they work.

This document aims to:

1. Describe current research on the impact of UHL in the pediatric population.

2. Introduce and endorse management recommendations from the Cincinnati Children's Hospital Medical Center (2009).

3. Hearing aid recommendation and outcomes data from OIHP infants and young children who have UHL.

End of summary.

BACKGROUND

Permanent unilateral hearing loss (UHL) is identified in infancy through Ontario's Infant Hearing Program (IHP). Evidence suggests that the majority of these children are at greater risk for academic, speech-language, and social-emotional difficulties than their normal hearing peers (Bess, Dodd-Murphy & Parker, 1998; Bess & Tharpe, 1986 and 1988; Lieu, 2004). Currently, there is no way to predict which children will experience difficulties (McKay, Gravel & Tharpe, 2008). This makes intervention recommendations unclear, leading to many pediatric amplification guidelines recommending hearing aids to these children on a case-by-case basis (Bagatto et al., 2010; McKay, Gravel & Tharpe, 2008). The absence of specific management guidelines presents a challenge to pediatric audiologists who work with families of infants, toddlers, and preschool children with UHL as they lack the evidence to support clear amplification recommendations.

Outcomes of children with UHL who wear hearing aids have been examined for decades. Recent speech perception scores of children aged 7 through 12 years of age with UHL showed no significant aided benefit or detriment in the conditions assessed (Briggs, Davidson & Lieu, 2011). On the other hand, subjective assessment of aided benefit was noted at home and at school by the children as well as their parents (Briggs et al., 2011). These and other similar findings make it difficult to provide clear management recommendations for this population.

Additionally, the topics of auditory deprivation in the affected ear and whether there is a critical period for auditory reorganization are important considerations for the UHL population. It has been demonstrated that younger patients with UHL who received a hearing aid by 5 years of age had significantly improved localization acuity (Johnstone, Nabelek & Robertson, 2010). In contrast, children with UHL who were aided at 9 years of age or older had significantly impaired localization acuity (Johnstone et al., 2010). It is speculated that the localization abilities of the older children are not likely to improve with amplification because they learned how to localize monaurally (Johnstone et al., 2010). This notion is supported by recent work with deaf children who wear cochlear implants. When studying children with unilateral and bilateral cochlear implants, it was noted that early unilateral cochlear implant use disrupts bilateral auditory pathways and this reorganization can be avoided by providing minimal exposure to the unilateral cochlear implant condition (<1.5 years) before moving to bilateral implants (Gordon, Wong & Papsin, 2013). This work provides support for a critical period for bilateral auditory input in children.

EVIDENCE-BASED STATEMENT

Recently, the American Academy of Audiology (AAA) updated their pediatric amplification clinical practice guidelines and indicated that children with aidable unilateral hearing loss should be considered candidates for amplification (AAA, 2013; Addendum 1). Specific parameters regarding what is considered aidable were not provided in the guideline. Other information has been offered in an evidence-based statement about the audiological management of children with permanent UHL. The statement became available in 2009 and has provided pediatric audiologists with some guidance for intervention (Cincinnati Children's Hospital, 2009). The best evidence statement is based on a technique used in evidence-based medicine that frames and answers a clinical question (i.e., PICO process: Problem, Intervention, Comparison, Outcome). The statement offers a guideline for amplification in school-age children based on degree of sensorineural hearing loss (SNHL) in the affected ear. It deals with both personal hearing aids and frequency-modulated (FM) systems. Specific recommendations for children with either severe to profound or mild to moderately-severe unilateral SNHL are provided and

summarized in Figure 1. Detailed information about the recommendations is provided in the document (Cincinnati Children's Hospital, 2009).

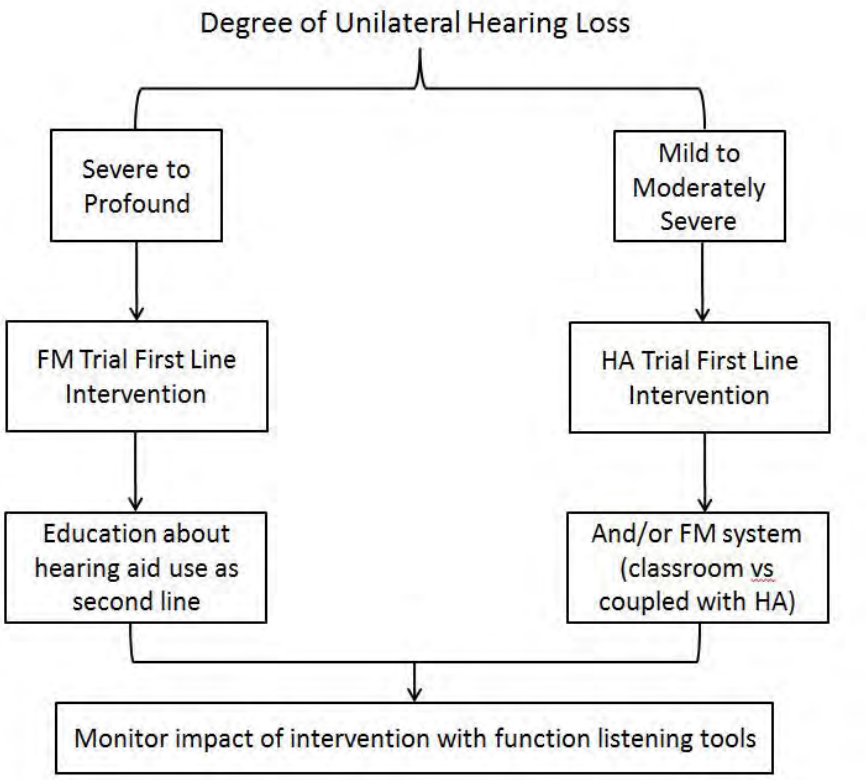

Figure 1. Summary of management recommendations for children with permanent sensorineural unilateral hearing loss. Copyright 2009 Cincinnati Children's Hospital Medical Center.

Although the document specifies application for school-age children, the recommendations should be considered by IHP Audiologists for infants and toddlers as long as attention is given to patient, caregiver, environment, and medical factors. Utilizing the IHP loaner hearing aids may provide important evidence to inform more permanent management decisions for infants with UHL. Loaner hearing aids have been acquired by the IHP and distributed to each region. They can be obtained from the regional coordinator to be used by a child for up to three months.

The Cincinnati Children's Hospital document also includes a recommendation to monitor both the effectiveness and potential problems associated with children with UHL who wear a device as well as those who do not. The IHP currently has an Outcome Measurement Protocol in place (Bagatto, Moodie & Scollie, 2010) that can be used for this purpose. Age-appropriate aided testing can also be conducted to provide further assessment of outcomes. This can be conducted by plugging the normal hearing ear and assessing detection for children < 3 years of age (e.g., aided audiogram using Ling 6 sounds), word discrimination for children 3 to 6 years of age (e.g., NU-CHIPS) and speech in noise for children > 6 years of age (e.g., BKB-SIN). See the 2013 AAA Pediatric Amplification Guideline for more information.

IHP DATA FROM CHILDREN WITH UNILATERAL HEARING LOSS

In conjunction with the clinical implementation of the IHP Outcome Measurement Guideline (2010), data from these tools have been collected provincially in order to examine outcomes of the program in more detail. From a total of 977 children that were included in the data set up to March 2011, 155 were identified as having UHL. Therefore, approximately 15% of children identified within the IHP as having a permanent hearing loss have a UHL configuration. Of the children with UHL, 44% were provided with a hearing aid and 56% were not provided with a hearing aid for the affected ear at the time of the data extraction. Further, when examining the breakdown by degree of hearing loss, it was noted that a higher percentage of children with moderately-severe hearing loss or better in the affected ear were provided with a hearing aid (up to 68%) and a smaller percentage of children with severe (16%) or profound (0%) hearing loss were provided with a hearing aid. This demonstrates that the recommendations of IHP Audiologists for children with UHL have been consistent with the recommendations in the Cincinnati Children's Hospital document. These results validate the appropriateness of the Cincinnati Children's Hospital document for use within the IHP.

The outcomes of the IHP children with UHL were also examined. The results for the LittlEARS Auditory Questionnaire generally demonstrate typical auditory development for children with UHL who were aided or unaided. Similar findings are exhibited with the PEACH data which indicate typical auditory performance for the majority of children with UHL who may or may not have a hearing aid on the affected ear. The good outcomes for the children with unaided UHL, regardless of degree of hearing loss in the affected ear, may be the impact of the normal hearing ear's contribution to real-world listening situations identified with the questionnaires. Further examination using localization or speech testing may reveal a positive impact of a hearing aid for children with UHL.

CONCLUSION

Children with UHL loss are identified by the IHP screening and assessment protocols and as a result audiological management decisions for this population arise often. Approximately 15% of children on the IHP provincial caseload have UHL. Recent work has offered preliminary evidence of a critical period for auditory reorganization in children with cochlear implants which provides support to deliver amplification to children with UHL at an early age. The Cincinnati Children's Hospital best evidence statement for the management of children with UHL has already been applied by some IHP Audiologists who have found it to be helpful to support the management of their patients with sensorineural UHL. This is reflected in the provincial data that was examined. In addition, the IHP's loaner hearing aids and current Outcome Measurement Protocol support management decisions for infants with UHL based on the Cincinnati statement.

We therefore endorse the statement as good evidence to support management recommendations for infants and children identified with permanent UHL within the IHP. Children with permanent unilateral conductive hearing loss or single sided deafness shall be considered for a surgically implanted bone conduction hearing device (if older than age 5 years; Christensen, Greshem & Dornhoffer, 2010) or a bone conduction hearing aid with a soft headband. Non-surgical bone conduction hearing aids may be a viable option for children under the age of 5 years (see IHP Amplification Protocol, 2014). CROS hearing aids are a consideration for some children with a profound hearing loss in the affected ear. However, both the American Academy of Audiology and the American Speech-Language-Hearing Association (ASHA) site the lack of evidence for the provision of CROS hearing aids for children

and should be recommended if the child can control his/her environment. This is because noise entering on the impaired side could interfere with the non-impaired side and have detrimental effects (Updike, 1994).

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ADDENDUM 6: REMOTE MICROPHONE HEARING ASSISTANCE TECHNOLOGIES

SUMMARY

It has been well documented that the use of remote microphone hearing assistance technology (e.g., frequency- and digital-modulated (FM and DM) systems) by children 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 (Lewis & Eiten, 2011). In addition, use of this technology may increase the rate of language acquisition (Moeller, Donaghy, Beauchaine, Lewis & Stelmachowicz, 1996). Guidelines for the selection and verification of remote microphone hearing assistance technologies (HAT) are necessary to support their use with children involved with the Ontario Infant Hearing Program (IHP).

This document aims to:

1. Introduce and endorse remote microphone HAT selection and verification procedures from the American Academy of Audiology (2011).

2. Highlight sections of the Guideline that are relevant to IHP Audiologists.

3. Provide considerations for this technology for infants and young children.

End of summary.

BACKGROUND

Infants and children within the IHP may be candidates for remote microphone hearing assistive technologies (HAT) in addition to or instead of personally-worn hearing aids. Provision of these devices is at the discretion of the IHP Amplification Audiologist in consultation with the family. For this reason, direct audio input (DAI) shall be included on hearing aid(s) provided to children within the HIP. This will enable coupling of remote microphone HAT to the hearing aid(s) when deemed appropriate.

If the IHP audiologist determines that the infant or young child is a candidate for remote microphone HAT, 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.

CLINICAL PRACTICE GUIDELINES

The American Academy of Audiology (AAA) developed clinical practice guidelines for remote microphone HAT for children and youth from birth to 21 years (2011). The document, which is based on peer-reviewed and non-peer-reviewed evidence as well as consensus practice, provides a comprehensive guide to the application of remote microphone HAT for children and youth with specific listening needs. It offers specific procedures for fitting and verifying the various types (e.g., ear-level, sound field) of these technologies. The Guideline also addresses the listening needs of three groups of children: 1) children and youth with hearing loss who are actual or potential hearing aid users; 2) children and youth with cochlear implants; and 3) children and youth with normal hearing sensitivity who have special listening requirements. For the purposes of this protocol addendum, sections of the Guideline pertaining to Group 1 are relevant to most children eligible for services within the IHP. For children with unilateral hearing loss where remote microphone HAT is desired for the unaffected ear, verification procedures for Group 3 are appropriate.

Although the AAA Guideline aims to span a large age range (i.e., birth to 21 years), much of the research and clinical application related to the use of remote microphone HAT is conducted with school-age children in educational settings. For infants and young children, specific listening situations may introduce a source of noise that may impinge on the child's clear access to speech and language (e.g., car, daycare). In addition, when the child becomes mobile, increasing distance from the primary talker may be a situation requiring management. For these reasons, identifying challenging listening situations through outcome measures or caregiver reports is essential when considering providing remote microphone HAT to infants and children within the IHP. It is also important that the introduction of the HAT is appropriately timed in the early stages of hearing aid use so that the family has sufficient time to establish a consistent hearing aid use routine with their child (McCreery, 2014).

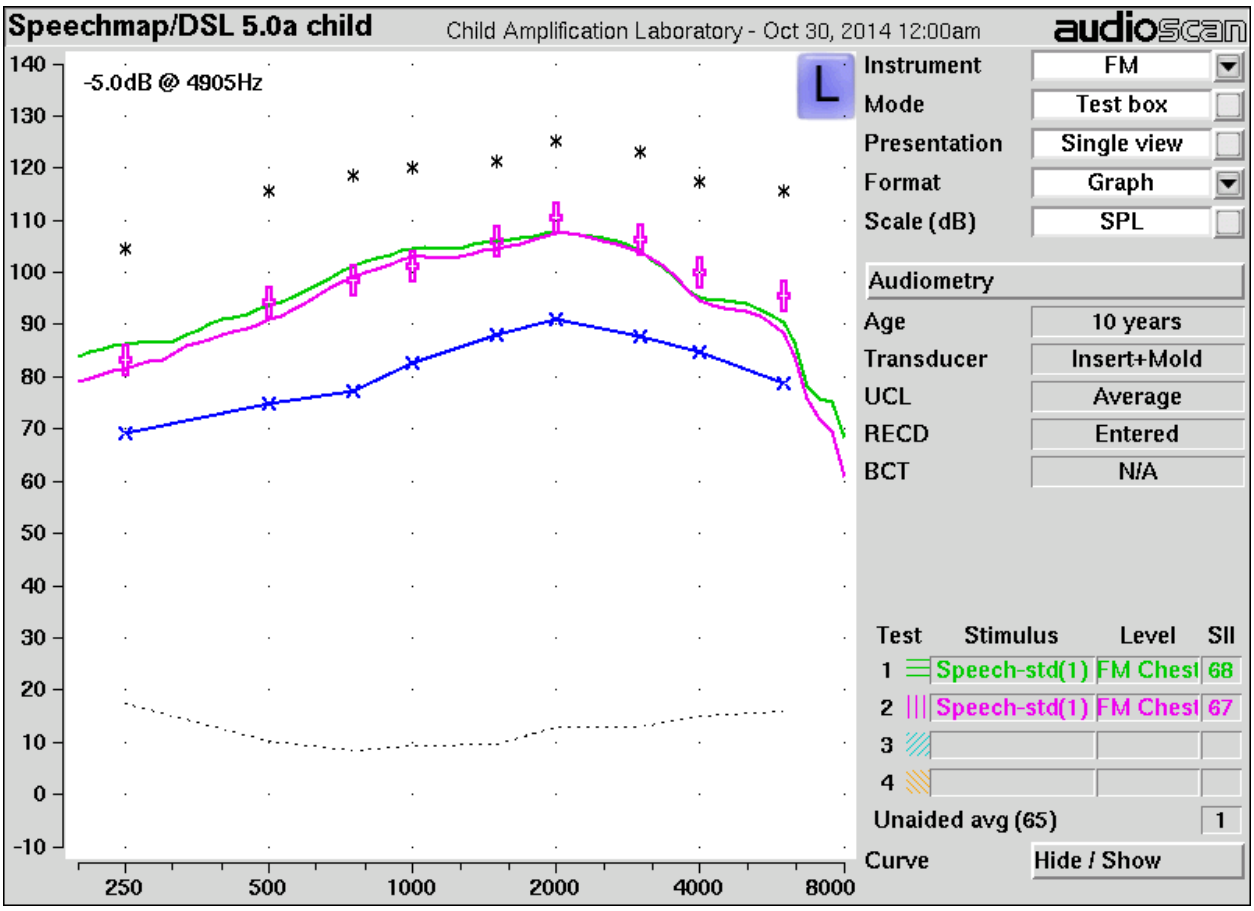
A GUIDE TO THE GUIDELINE

The AAA Clinical Practice Guideline for Remote Microphone HAT for Children and Youth (2011) is a comprehensive, evidence-based document. Although the complete Guideline is a rich source of information for pediatric audiologists, particular sections are of relevance to Audiologists managing children within the IHP. These sections are outlined in the table below:

Guideline Section	Page Reference	Scope
5. Remote Microphone HAT Candidacy, Implementation and Device Selection Considerations	7 through 18	Group 1 is relevant to the IHP in the majority of cases. Group 3 would be relevant for unilateral hearing losses.
6. Fitting and Verification Procedures	18 and 19	Further detail in Supplement A
10. Supplement A: Fitting and Verification Procedures for Ear-Level FM	48 and 49	General verification information and terminology.
10. Supplement A1: Fitting and Verification Procedures for Group 1	50 through 64	Behavioural verification procedures may not be compatible with the IHP population and are considered optional.
10. Supplement A3: Fitting and Verification Procedures for Group 3	71 through 75	Applicable for children with unilateral hearing loss when an ear-level FM is desired for the normal hearing ear.
10. Supplement A: Quick reference summary of verification steps	76 and 77	Verification protocols.
Supplement B: Classroom Audio Distribution Systems – Selection and Verification	All	Section 5.2 on page 10 relates to children with hearing loss.

FM/DM VERIFICATION

For personal FM/DM systems coupled to hearing aids, the AAA Guideline recommends a “transparency protocol” in which the output of the FM/DM/Hearing aid combined system is matched to the output of the hearing aid alone. These measures are performed with a moderate input signal, such as speech at 65 dB SPL. This “transparency protocol” has been endorsed by training programs and major manufacturers of FM/DM systems for several years, and is likely not new to most IHP sites. An example of this protocol is shown below for a system that meets the fitting requirements outlined in the Guideline.



Example of the Ear-level FM Transparency Verification Protocol

CONCLUSION

For many children within the IHP, remote microphone HATs are indicated in addition to their hearing aids. The AAA Guideline (2011) for selecting and fitting these devices on children and youth provides evidence-based support for pediatric audiologists who work with this population. We therefore endorse the Guideline as an appropriate document to provide candidacy and device selection and verification support for IHP Audiologists considering remote microphone HATs for their young patients.

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