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Protocol for the Provision of Amplification

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Ontario Infant Hearing Program

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SECTION 1: INTRODUCTION

This Protocol addresses the provision of amplification (hereafter: 'Amplification') to infants and pre-school children who are receiving services from the Ontario Infant Hearing Program (IHP). Providing amplification includes the process of prescribing a hearing aid based on appropriate assessment information, verification that the specified acoustical performance targets have been achieved, fitting the device on the child, and evaluation of device effectiveness in daily life.

Dispensing includes obtaining ear impressions for earmold fabrication, electroacoustic analysis of the prescribed hearing aids, adjustment of the hearing aids to the settings provided by the IHP Prescribing Audiologist, and hearing aid orientation.

This 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 VERSION HISTORY

This version of the Amplification Protocol supersedes all previous versions of this document. Notable revisions/additional protocol elements and dates are listed below.

Version Date	Document Title	Previous Version
March 2019	Protocol for the Provision of Amplification 2019.01	Protocol for the Provision of Amplification 2014.01
March 2019	Outcome Measurement Protocol (included within 2019.01)	May 2010; separate document
November 2014	Protocol for the Provision of Amplification 2014.01	October 2007
2014.01 Addendum 1	American Academy of Audiology Pediatric Guidelines Summary and Support Document for the Ontario Infant Hearing Program	October 2013
2014.01 Addendum 2	Ontario Infant Hearing Program Frequency-Lowering Hearing Aids Protocol Addendum and Support Document	April 2011

1.2 REVISION SUMMARY FOR 2019.01

Recent amendments are largely minor housekeeping changes to include recent evidence, verification system software updates, and suggested record-keeping in preparation for continuous quality improvement.

Topic	Description	Section
Scope	Policy and procedural revisions as directed by the MCCSS. Corresponds to other IHP protocols so this can be a stand-alone document.	Various in Section 2: Scope
Consideration of College of Audiologists and Speech - Language Pathologists of Ontario (CASLPO) Practice Standards for Hearing Aid Provision (2016)	Align procedures with CASLPO <i>Practice Standards for the Provision of Hearing Aid Services by Audiologists</i> (2016) and provided further clarity for IHP Audiologists where necessary.	Throughout

Standard Practice Review for continuous quality improvement	Indicators have been developed and included in this document as a checklist in preparation for implementation of Standard Practice Review process. Implementation of the tracking form is discretionary at this time.	Section 2.15, 2.16; Appendix G
Dispensing	Clarification of the roles of IHP Prescribing Audiologists and IHP Dispensers	Section 2.6
Real-ear-to-coupler difference (RECD) procedures and their alignment with ANSI S3.46-2013	The RECD can now be measured using various couplers (HA-1, HA-2 or HA-4) and coupling type (foam or earmold) with some verification systems. Description of procedures and implications of updated RECD measurement.	Supplement 1.2
Infant Ear Impressions	Clinical tips for obtaining ear impressions with infants are now provided.	Appendix D
Outcome Measurement Protocol	No changes to 2010 protocol. A summarized version of the protocol is now included within this document. This incorporation of the Outcome Measurement Protocol means that we now have one document (amplification and outcomes) rather than two separate documents.	Section 7.3; Supplement 3.1; Appendix H
Frequency Lowering	Update to the protocol and corresponding case examples to include answers to commonly asked questions, references to the published source of the /s/ and /sh/ stimuli, and description of currently-available types of frequency lowering.	Addendum 2

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) Bone anchored and/or bone conduction hearing aid verification protocol
- b) Outcome measurement protocol update

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. Further details are provided in the *IHP Guidance Document*.

This document addresses the Provision of Amplification for infants and children who are receiving services from the IHP. The contents are based on: (i) numerous and ongoing reviews of scientific and clinical literature, (ii) ongoing protocol reviews and consultations with leading experts worldwide, (iii) extensive experience with infant hearing aid fitting, in Ontario, (iv) feedback from program professionals, and (v) policy and procedural developments initiated by the Ministry of Children, Community and Social Services (MCCSS).

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.

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 intervention with regularly-worn hearing aids can facilitate the development of speech sound recognition and spoken language (if spoken language is the modality used), particularly when used in a language-rich environment and when hearing aids are well-fitted to targets (McCreery, Brennan, Walker, & Spratford, 2017; www.OCHLstudy.org; Moeller & Tomblin, 2015).

For the purposes of this document, a ‘hearing aid’ is defined as any electronic device fitted to the ear or skull and designed to amplify and deliver sound to the ear in an individualized way for each person’s hearing loss. Hearing aids use signal processing to automatically adjust the level and bass/treble of the sound, and to limit the levels of loud sounds. They are available for most types, degrees, and configurations of permanent hearing loss.

Hearing aid styles include, but are not limited to, air conduction hearing aids that are worn behind-the-ear, in-the-ear, in-the-canal, completely in the canal, BICROS, CROS, and bone conduction hearing aids that deliver sound via bone vibrations in the skull. The vibrations may go through the skin or directly to the skull via an implanted abutment or magnet. The device is placed on the skin or snapped to the abutment for use. When placed on the skin, it can be used on a soft headband (non-surgical) or with a device implanted below the skin (surgical). These devices are recommended for children with conductive or mixed hearing losses who do not have space in the outer ear or ear canal to accommodate a BTE hearing aid.

Remote microphone hearing assistance technologies are an available device for mitigating the impact of distance, noise, and reverberation. They can be worn with or without hearing aids (air or bone) and shall be considered a viable option for children within the IHP, if appropriate.

2.4 TARGET DISORDERS

The IHP target disorder set includes permanent hearing loss (PHL) of 30 dB HL or more at 0.5, 1, 2 or 4 kHz in any ear, auditory neuropathy spectrum disorder (ANS), and auditory brainstem pathway disorders that may be detectable using auditory brainstem response (ABR) techniques (see IHP ABR Assessment Protocol [ABRA]). The target PHL includes conductive impairment associated with structural anomalies of the ear but does NOT include impairment attributable to minor, non-structural middle ear conditions. Discharge from the IHP to the Ontario Health Insurance Plan (OHIP) based system with caregiver counselling and discretionary referral to a physician is the norm.

2.5 AMPLIFICATION CANDIDACY

For an infant to be considered a candidate for amplification, PHL 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 via audiometry, 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 aid 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 trained and authorized by the IHP to conduct this protocol. With the exception of bone conduction hearing aids not listed, audiologists who prescribe hearing aids for infants in this program shall be registered prescribers with the Assistive Devices Program (ADP). The IHP Audiologist who prescribes the hearing device(s) is responsible for ensuring the device(s) are verified according to this protocol prior to being fitted to the IHP child.

The dispensing of amplification within the IHP shall be completed by a hearing aid dispenser or dispensing audiologist who has been trained in this protocol. Families should be guided to these individuals in their region, if the Prescriber is not dispensing the hearing aid(s). Individuals who are registered dispensers with the ADP shall dispense hearing aids to infants in this program according to the IHP Prescribing Audiologists' specifications. Non-audiologist dispensers must not apply active hearing aid(s) to infants or children registered with the IHP for the initial fitting or subsequent fittings (e.g., following repair, replacement of aid(s) and/or earmolds) without direct supervision by the IHP Prescribing Audiologist trained in this protocol. Direct supervision includes the IHP Prescribing Audiologist reviewing the verification graph (e.g., SLPogram, Speechmap) of the adjusted hearing aid(s) to be fitted, the fitting software file, and having knowledge of the type of RECD used (i.e., measured, predicted, other ear, previous). It is not required that the IHP Prescribing Audiologist perform the measures or adjustments, but they must approve them before the hearing aid(s) are used by the child for initial or subsequent fittings.

2.7 PROTOCOL ADHERENCE IS A REQUIREMENT

All IHP Amplification must be conducted in adherence to this protocol; such adherence is an expectation for continued authorization to provide IHP Amplification services.

2.8 LEGITIMATE DEPARTURE FROM PROTOCOL

It is acknowledged that case-specific situations that justify minor departure from protocol elements can arise. Such departures must be noted in the Amplification records with a brief explanation. All such notes must be accessible for IHP Standard Practice Review.

The IHP recognizes that special circumstances may indicate departures from some (but not all) of the procedures specified in this protocol. Such departures are at the discretion of the IHP audiologist. This does not mean that this protocol is generally discretionary. IHP funding for procedures is conditional upon specific activities 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 by the IHP Designated Training Centre (DTC) of their nature and the validity of their rationale.

2.9 CHANGES TO THE PROTOCOL

Prior approval by MCCSS is required in order to change substantively any element of this protocol. Program-wide changes can occur only through MCCSS directive or by a systematic process that may include survey of Audiologists' experiences or concerns, evidence review, and recommendation by a DTC.

2.10 NON-IHP AMPLIFICATION SERVICES

Amplification services conducted by any person who is not an audiologist or dispenser 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. Provision of Amplification done outside of the IHP must be reviewed by the DTC for validity, accuracy, and relevance, prior to provision of subsequent services funded by the IHP.

2.11 IHP DESIGNATED TRAINING CENTRES (DTC)

DTCs are authorized by the MCCSS to provide IHP support, including advanced training, consultative and Amplification referral services, protocol support, and clinical decision support to IHP Audiologists. DTCs also conduct standard practice review of services as directed by the MCCSS.

The DTCs are the Children's Hospital of Eastern Ontario (CHEO, Ottawa) and Humber River Hospital (Toronto) for ABRA, Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA), and the National Centre for Audiology (NCA; Western University, London) for Amplification and Outcome Measurement.

2.12 CLINICAL DECISION SUPPORT BY DTC

Audiologists who have any question or concern about any aspect of this Amplification protocol shall contact the Western University DTC. This is also a mechanism for protocol clarification and improvement.

2.13 SECOND OPINIONS

Second opinions may be initiated by the parent/caregiver of the IHP child or by a non-IHP service provider if they believe that such a review may materially improve the accuracy or effectiveness of the overall Amplification.

Specific procedures for initiating this request and the procedures that follow are outlined in a procedural document (*IHP Guidance Document*).

2.14 CONTINUOUS QUALITY IMPROVEMENT (CQI)

The IHP is required to implement quality assurance and quality management on an ongoing basis, for funding accountability as an Early Hearing Detection and Intervention Program. This is being done through a CQI program that targets all major program components, including Amplification. The CQI includes enhanced training and clinical decision support, as well as performance monitoring. This monitoring includes Standard Practice Reviews.

2.15 IHP STANDARD PRACTICE REVIEWS

Amplification providers must participate in document-based practice review (see section 2.27). A streamlined process specified by the MCCSS will be implemented through the Western DTC. Practice review is a routine, support-oriented procedure aimed at quality of care verification and improvement. IHP Audiologists are encouraged to use the checklist found in [Appendix G](#) to prepare and include it with each child's chart. This will serve as preparation for the implementation of the Standard Practice Review process for Amplification.

2.16 ADVERSE EVENT REVIEWS & STANDARD PRACTICE REVIEW

The IHP is obligated to review instances of possible shortfalls in quality of care for individual children and families. Irrespective of how such events come to light, if an adverse event is verified, case-specific clinical remedy will be sought and, depending on the nature of the event, the service involved may be subject to adverse event-triggered practice review by a DTC, where directed by MCCSS.

2.17 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. Audiologists will use the equipment that meets the criteria established by the IHP. Current IHP instrumentation requirements for this protocol are listed in [Appendix A](#).

Routine calibration checks of real-ear hearing aid 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 IHP lead agency and/or by the IHP lead agency's subcontracted partners, with reasonable notice to the Amplification centres.

2.18 IHP PROTOCOLS & CASLPO GUIDELINES

All IHP audiologists and dispensers shall practice Amplification procedures in full compliance with the requirements of both CASLPO and this protocol. IHP protocols are in compliance with, but 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 audiologist shall notify the DTC promptly and the IHP will act to resolve the issue at a provincial level.

2.19 PROCEDURAL CONCERNS

IHP Protocols are evidence-based to the extent possible. Evidence is reviewed by the Amplification DTC 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 the relevant DTC. 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 IHP Lead Agencies 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.

2.20 HEARING ASSESSMENT

Assessments are ABR-based or Behaviour-based. The latter includes Visual Reinforcement Audiometry (VRA), Conditioned Play Audiometry (CPA), Individualized Reinforcement Audiometry (IRA), or conventional audiometry. Hearing assessment can provide ear- and frequency-specific information that shall be used for the provision of hearing aids to infants within the IHP. Hearing assessment includes measurement of ear-specific thresholds and cross-check with physiological measures as specified by IHP protocols.

2.21 TIMING OF 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. Recent research indicates early hearing aid fitting (e.g., at three months of age) is associated with improved global language scores, especially for greater degrees of hearing loss (Ching et al, 2018). Furthermore, early hearing aid fitting increases the overall dosage of the treatment, reduces the length of time the PHL goes untreated, thereby maximizing critical brain development (Tomblin et al, 2015). As such, accounting for practical considerations of early hearing aid fitting (see below), it is reasonable to expect infants to be fitted with hearing aids between 3 and 6 months corrected age.

The process of prescribing, ordering, supplying, and verifying a hearing aid, and accounting for scheduling of appointments, mold and device 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 aid at six months but a completed process of prescription, verification and adjustment, if necessary, by six months. This timeline may require that the hearing aid evaluation appointment should typically occur by four months of age, which in turn may mean that the audiological 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 to 6 months corrected age. This is reasonably consistent with published data from large EHDl programs, but is itself an ambitious target in the population of Neonatal Intensive Care Unit (NICU) graduates. A minority of infants will arrive at amplification after six months of age; these represent infants identified by audiological assessment but for whom provision of amplification was delayed, as well as infants with confirmed hearing loss following at-risk audiological surveillance or referral.

Some children with complex situations may take longer to receive their hearing aids, which is not unexpected. Reasons for delayed hearing aid fitting must be documented by the IHP Audiologist in the child's chart. Wherever possible, hearing aids should be provided to an IHP child no later than 45 days from hearing loss confirmation and caregiver election to pursue amplification (JCIH, 2007).

Where not medically contraindicated, the provision of Amplification to infants aged less than three months is at the discretion of the IHP prescribing audiologist. Many factors must be weighed when considering at what age to provide amplification.

There are several challenges 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 or repeat ear impressions to reduce acoustic feedback from the hearing aids. Rapid anatomical maturation coupled with small and diverse ear 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.

Infants who have bilateral PHL 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 PHL of lesser severity but of at least 30 dB HL are also considered candidates for amplification and/or personal FM systems. Evidence suggests that infants with this degree of hearing loss are at risk for experiencing academic difficulty (Bess and Tharpe, 1984; Lieu 2004; 2013). A decision support guide for managing infants with minimal/mild bilateral hearing loss can be found in [Addendum 4](#). Infants identified with a unilateral PHL 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 definite or probable ANSD based on ABR findings should be evaluated behaviourally before amplification is considered. Individuals with definite ANSD have been shown to have variable thresholds (i.e., range from normal to profound) which cannot be determined by ABR alone (see ABRA Protocol). Infants with probable ANSD require further study to understand their behavioural thresholds.

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 aids. Severe to profound hearing loss is included as part of the candidacy criteria for cochlear implantation.

Infants who have unilateral or bilateral microtia, atresia, and/or stenosis should be considered candidates for bone conduction hearing devices (BCHD). For these infants, supporting spoken language through BCHDs is a suitable option which can be offered as early as 3 months of age. Surgical candidacy is between 4 and 5 years of age and providing access to spoken language through non-surgical BCHDs in the early months of life stimulates auditory development.

2.22 INFECTION CONTROL STANDARDS

Infection control practices are typically governed by site-specific, institutional or IHP Lead Agency protocols and are outside the purview of this document. If local protocols are not available, generally accepted standards must be applied. Recent guidelines were issued by the Interorganizational Group for Speech-Language Pathology and Audiology (2010).

2.23 CALIBRATION

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

2.24 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/or any physical condition of the ear that indicates referral to a physician.

2.25 AMPLIFICATION COMPONENTS

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

- ☐ A complete description of the infant's audiometric thresholds for both ears as described in the IHP Assessment protocols;
- ☐ 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) if fitting an air conduction hearing aid;
- ☐ Accurate ear impression(s) for the purposes of fabricating an earmold if fitting an air conduction hearing aid;
- ☐ An assessment of the non-electroacoustic needs of the infant;
- ☐ DSL m[i/o] v5 target ear canal sound pressure levels (SPL) for the amplified long-term average speech spectrum for speech at soft, conversational, and loud levels;
- ☐ DSL m[i/o] v5 target ear canal SPLs for defining the maximum power output of the hearing aid;
- ☐ Verification that the electroacoustic characteristics of the hearing aid(s) 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 aid(s) are first fitted and at subsequent follow-up visits as needed;
- ☐ An evaluation of the outcome of the intervention;
- ☐ Appropriate follow-up schedule and adjustments to the amplification, as required.

2.26 CLINICAL RECORDS & REPORTS

All Amplification records shall be maintained in a manner satisfying both CASLPO and the IHP, which includes hard copy, soft copy or a combination of both. The infant's audiological record shall include a record of:

- ☐ All IHP summary reports (i.e., ISCIS forms for assessment, fitting, and questionnaires);
- ☐ Amplification prescription (make and model, earmold specifications);
- ☐ Hearing aid verification (including RECD values and fit-to-targets);
- ☐ Documentation of hours of use (e.g., data-logging and/or parent report);
- ☐ Verification of activated advanced features (e.g., noise reduction, frequency lowering, etc.);
- ☐ Hearing aid orientation with caregivers;
- ☐ Outcome measurement (e.g., SII, Amplification Benefit Questionnaire, LittleEARS, PEACH)

The records must be fully sufficient to demonstrate compliance with the required elements of the IHP Amplification protocol, given a Standard Practice Review. They should also be sufficient to facilitate consultative, clinical review and case conferencing. To ensure records are complete, the Hearing Aid Fitting and Verification Checklist found in [Appendix G](#) may be completed and kept on record at the clinician's discretion.

The audiologist shall complete the appropriate IHP Amplification summary report forms (ISCIS) 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.

2.27 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 (Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A). Hearing aid program files stored on computers and removable media must not be identifiable. Information communicated for approved monitoring and review procedures must be de-identified and code-referenced. All transmission of personally-identifiable information shall be consented by the appropriate family member or authorized caregiver.

SECTION 3: ASSESSMENT CONSIDERATIONS

3.1 AUDIOMETRIC THRESHOLDS (Minimum Requirements)

A minimum set of audiometric thresholds shall be defined prior to providing amplification to infants within the IHP. Before initiating the provision of amplification, threshold estimates for at least 500 and 2000 or 4000 Hz shall be obtained in each ear for air conducted stimuli and at least 2000 Hz in each ear for bone conducted stimuli. For infants with stenosis/atresia or other conditions that would preclude testing by air conduction, bone conducted stimuli at 500, 2000 and 4000 Hz for the affected ear(s) shall be obtained prior to initiating the provision of amplification. Threshold estimates at other frequencies (e.g., 1000 Hz) are recommended, but not required for the initial provision of amplification.

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 PHL. Provided the otolaryngologist establishes the absence of medical contraindications to amplification, the audiologist may 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 or by direct referral whenever the IHP Audiologic Assessment reveals PHL. That referral has the main goal of a broad review of the child's health status in light of the hearing loss, 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 (see reviews in Bagatto et al., 2005; Moodie et al., 2016; Seewald & Scollie, 1999). The individual's RECD is used to obtain SPL thresholds, generate the appropriate gain and output response for a hearing aid, and has been shown to be highly repeatable and valid, and is a required element in the Amplification process for infants involved in the IHP.

It is strongly recommended that wherever feasible, IHP audiologists measure the individual infant's RECD as part of the provision of amplification, because 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). 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, 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.

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 aid test system (see [Appendix A](#)) following the procedure described by Moodie et al (1994) and Moodie et al (2016). RECD values, tester, coupling type (earmold, foam tip, immittance tip), coupler type (HA-1, HA-2, HA-4), ear and test date shall be documented and retained on file.

Briefly, the HA-2 or HA-4 coupler is connected to the coupler microphone of the unit and a transducer is coupled to the other end of the 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. Once the coupler measurement has been obtained, a foam ear tip or personal earmold is coupled to the transducer and inserted into the infant's ear along with the probe tube. Coupling selection should be made in congruence with the coupling method used to obtain audiometric thresholds (see S1.2 below). For example, if VRA was conducted to obtain thresholds using an insert earphone coupled to the child's personal earmold, then RECD measurement should also be made using the

earmold. When this is not possible, some verification systems offer a correction factor in the event of a mismatch between audiometric thresholds and RECD transducer couplings (Glista, 2016; Moodie et al, 2016).

Consistent probe tube placement or prevention of venting can be difficult to obtain during RECD measurement in infants. 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 depth placement. The same stimulus is presented via the probe microphone system and insert earphone/custom earmold 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.

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, 2005) and may use software-assisted corrections to convert individual RECDs between foamtip and earmold formats when necessary (Moodie et al, 2016).

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. Second, individual real-ear SPL values may differ substantially from group average values, even in age-matched groups. When applying RECD predicted values for ear tips, one can expect to fall within a range of ± 5.6 dB (at 500 Hz) at 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.

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 Practice Standards, 2016) 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 IHP prescribing audiologist, if the impression is being obtained by an IHP dispenser.

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 aid. 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 caregiver.

The ear impression(s) and fitting of the earmold(s) shall be conducted by an IHP Prescribing Audiologist, IHP Dispensing Audiologist or IHP Dispenser.

4.2 NON-ELECTROACOUSTIC CHARACTERISTICS

The prescribing audiologist shall consider non-electroacoustic characteristics of the prescribed hearing aid. The style of the hearing aid and ear coupling for retention, monaural vs binaural fitting, ability to deactivate advanced features, remote microphone hearing assistance technology 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 aid 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 aid 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 feature 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 aid test system. The application of a conductive correction within the DSL formula for conductive or mixed losses is at the discretion of the IHP prescribing audiologist. Coupler targets for the amplified long term average speech spectrum, soft speech, and maximum power output (MPO) across frequency for each ear requiring amplification shall be documented.

For bone conducting hearing devices (BCHD), DSL Force Level targets for adults are available, however require further validation for use with children (Hodgetts & Scollie, 2017). Additionally, clinically-available skull simulators offer the capability of measuring the force level output of these devices for a descriptive comparison to the available targets. These strategies can be applied in addition to a listening check and aided testing for the verification and validation of these devices until a verification protocol is available.

4.4 DEVICE SELECTION

Once the non-electroacoustic and electroacoustic characteristics of the potential hearing aid(s) have been identified, the IHP prescribing audiologist shall select a hearing aid that will meet the criteria. Earmolds and hearing aids shall be ordered, with a request for pediatric filtered earhooks, tamper proof battery door, and pediatric care kit.

4.5 OTHER ASSISTIVE TECHNOLOGY

Some infants may be candidates for assistive listening technologies and devices other than personally-worn hearing aids. If the IHP audiologist determines that the infant is a candidate for other assistive technology, such as remote microphone hearing assistance technology (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 caregivers, 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 AMPLIFICATION

5.1 MAINTAINING APPROPRIATE RECD VALUES OVER TIME

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 using the earmold 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 dispenser shall notify the prescriber of the new earmold(s) so that these measures can be obtained and applied to the hearing aid programming as soon as possible. The verification procedures described in this document shall be carried out every time the prescriptive targets have been updated.

5.2 ELECTROACOUSTIC VERIFICATION

Prior to being fitted to the infant, the prescribed hearing aid shall be adjusted by the IHP audiologist who prescribed the device(s) to approximate the target electroacoustic values for gain and maximum output that were specified according to the section of this document dealing with Prescription (4.3). All verification curves, in SPL, and final hearing aid settings shall be documented and dated for each ear requiring amplification. Simulated real-ear measurements of the real-ear aided response (REAR) should be performed for each device and the hearing aid(s) adjusted to provide a match to targets (see Outcome Measures Protocol [Appendix H](#)) through the use of test box measurements within real-ear hearing aid test systems. For a detailed description of this procedure see [Appendix E](#). It is, however, important for the IHP service provider to check for feedback from the aid once it has been placed on the infant's ear. The prescribing audiologist is responsible for verifying the match to targets prior to the initial fitting of the devices to the child and following any returns from repair.

5.3 APPLICATION OF SIGNAL PROCESSING

Automatic feedback suppression technologies should be employed if feedback is noted when the hearing aid 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 aid shall be conducted following application of these technologies. The application of feedback suppression 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 emerges, 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](#)).

5.4 VERIFICATION STIMULI

Verification of hearing aid 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 device. Verification of speech targets shall be completed using pre-recorded, calibrated speech test signals. Maximum output characteristics for most hearing aids 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 provision of hearing aids 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 aids are malfunctioning, so family vigilance is required and a care kit must be provided. Supportive information and instruction for the family/caregiver shall be given at the time of the initial provision of the hearing aid(s), and at follow-up visits.

Non-audiologist dispensers may provide the initial hearing aid orientation but may not place active hearing aids on the child without direct supervision by the IHP Prescribing Audiologist. Direct supervision includes the IHP Prescribing Audiologist reviewing the verification graph (e.g., SLPogram, Speechmap) of the adjusted hearing aid(s) to be fitted, the fitting software file, and having knowledge of the type of RECD used (i.e., measured, predicted, other ear, previous). It is not required that the IHP Prescribing Audiologist perform the measures or adjustments, but they must approve them before the hearing aid(s) are used by the child for initial and subsequent fittings. If these cannot be provided, the hearing aid orientation can be conducted by the dispenser with the family but the Prescriber must fit the active hearing aid(s) to the child as soon as possible to avoid delays in the provision of amplification. It is important that the dispenser and the prescriber (if different providers) offer consistent messages to the family during this stage of the process.

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

- Demonstration of earmold insertion, including use of earmold lubricant and other practical fitting suggestions, such as putting the hearing aids on, etc.
- Hands-on demonstration and practice of earmold insertion and removal, tubing attachment to hearing aid, insertion and removal of batteries, etc.
- Demonstration of a daily inspection of ear canal, and daily listening check of the hearing aids. The listening check should include adjustment of controls (if active), 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, retention caps, 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 resources and information when appropriate.

6.2 INFORMATION

In any communication with families, the principles of the IHP should be reflected. Evidence-based information should be imparted whenever possible; anecdotal information and personal opinions should be avoided. Service providers are encouraged to impart unbiased information in their area of expertise and offer guidance to appropriate resources as necessary. 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, medical issues, or language development. Families should be provided with the necessary information to be supported in making informed decisions for their child.

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 to the device(s). The IHP Family Support Worker and other team members can provide support. Prescribing Audiologists shall attend regular team meetings that aim to facilitate information-sharing and a plan for supporting the family's goals for their child. If a family needs additional support such as connecting with available services, connecting with other parents of children who have PHL, helping with transitions to child care and school, etc., the Audiologist will arrange for the services that are needed. If necessary, they will make a referral to a social worker.

SECTION 7: OUTCOME EVALUATION

7.1 FOLLOW-UP SCHEDULE

Follow-up to the initial hearing aid fitting should be accomplished on a regular schedule, with accommodation for individual needs. The Prescribing Audiologist shall see the infant and family for at least one follow up visit within the hearing aid 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 discharge from the IHP. 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 (ANSO), 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 aids 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) using the child's earmolds connected to the transducer shall be done (see IHP Assessment Protocols). Earmolds shall be assessed for appropriate fit and new earmolds obtained when required. An RECD should be re-measured with the child's new earmolds to account for growth and development, or if there has been a change in middle ear status. A listening check of the hearing aids shall be conducted to evaluate sound quality and the need for further assessment or repair. Subsequent adjustments should be made to the hearing aids as needed and an evaluation of the need for additional technologies (e.g., remote microphones, noise reduction, frequency lowering) shall be conducted through counselling and outcome measures.

7.3 OUTCOME MEASURES

Validation of the fitting shall be done using procedures outlined in the IHP Outcome Measurement Protocol (2010) which has been summarized in [Appendix H](#) (Bagatto et al, 2011; 2016). In brief, the systematic, evidence-based protocol includes tools that assess the following dimensions: 1) subjective assessment of early auditory development; 2) subjective ratings of auditory performance in daily life; 3) acceptance and use of hearing aids; and 4) effectiveness of service delivery. The caregiver-report functional outcomes are supported by each child's hearing aid fitting information (i.e., real-ear-to-coupler difference (RECD), Speech Intelligibility Index [SII]). Caregiver-report functional outcome tools were targeted for the IHP population because objective measures of speech detection and recognition may be difficult to obtain in cases of children with complex factors (e.g., difficult

to test due to developmental level). Coincidentally, it is these same children who may also present assessment and/or management difficulties more generally.

Assessment of the quality of the hearing aid fitting and caregiver questionnaires is a routine part of the Provision of Amplification within the IHP. Hearing aid fitting is assessed by the reporting of RECD activities (measured or predicted) and comparing the Speech Intelligibility Index (SII; ANSI S3.5 – 1997 [R2012]) to normative values based on puretone average hearing loss in pediatric hearing aid fittings (Moodie et al, 2017). Caregiver questionnaires (LittleEARS, PEACH, and IHP Amplification Benefit Questionnaire) are administered and scored by the IHP Prescribing Audiologist at regular intervals. More comprehensive information in the form of a manual can be found at www.dslio.com. The application of the results of the Outcome Measurement tools shall be used to inform further management of the IHP child.

SECTION 8: TRAINING AND CLINICAL DECISION SUPPORT

8.1 TRAINING REQUIREMENTS AND SUPPORT MECHANISMS

All audiologists and dispensers wishing to provide IHP Amplification services shall have received approved training in this protocol. The DTC at Western University is responsible for Amplification training and the DTC at CHEO or Humber River Hospital is responsible for Behavioural Audiometry training.

Needs for Amplification training are identified to MCCSS by IHP Regional Coordinators as they arise. If approved, MCCSS will contact the Western DTC, determine the priority of the training and arrange its scheduling with the DTC. Details of the length and scope of training are found in the *IHP Guidance Document*.

If an IHP Audiologist or Dispenser authorized for Amplification does not carry out the provision of amplification for a period of one year or more, the IHP Regional Coordinator must advise the MCCSS of the lapse in practice. The MCCSS will contact the Western DTC for refresher training. Clinical decision support and performance monitoring may also be recommended. IHP Audiologists and Dispensers may seek such support, monitoring or refresher training on their own volition at any time. Authorization to provide amplification services may be withdrawn at the discretion of the MCCSS.

8.2 IHP INFORMATION SHARING

An information sharing and management application is available online for IHP service providers to access IHP protocols, documents, and relevant resources. Once authorized to provide services within the IHP, the service provider will be given access to the application. The Western DTC will manage access to the application.

SUPPLEMENT 1: ASSESSMENT CONSIDERATIONS

S1.1 AUDITORY ASSESSMENT FOR DETERMINING AMPLIFICATION CANDIDACY AND PRESCRIPTION

For infants under six months of age and for some older infants, assessment is based on objective, physiologic measures, mainly but not exclusively on frequency-specific ABR. It is usually possible to obtain accurate, frequency-specific, ear-specific pure-tone threshold estimates by such measures. In most cases, FS-ABR can provide audiometry that is sufficient to fully inform communication development services, including amplification. When the IHP ABRA protocol is followed, then unless there is a specific indication of unreliability of ABR findings (such as a finding of ANSD or fluctuating conductive loss), it is not consistent with IHP goals and objectives to defer language development services (where elected by the family) pending 'behavioural confirmation' of ABR-based threshold estimates. As described in the ABRA 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 aid 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 Protocol for Audiometric Assessment for Children Aged 6 to 60 Months*.

The availability of frequency-specific threshold data is important for the prescription of amplification. If the presence of PHL has been confirmed, the process of amplification may proceed on the basis of minimum ear-specific threshold estimations for air and bone conducted stimuli (see section 3.1 above). Delay in the process pending the collection of discretionary thresholds is not warranted at this stage. There will be cases where full audiometric information 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 these cases, the decision to begin the process of obtaining amplification is at the clinician's discretion in consultation with the family.

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

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 *IHP ABRA 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, measured RECDs, continued observation, and assessment of the infant are especially important.

The provision of amplification to an infant with PHL 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 and hearing aid settings. In older infants, the amplification audiologist will attempt VRA or CPA using insert earphones coupled to foam ear tips. 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 and better represent the amplified acoustic characteristics of the child's ear (see [Appendix C](#) for practical description). Any changes to the infant's auditory thresholds should be applied to the hearing aid prescription as needed.

S1.2 RECD MEASUREMENT EQUIPMENT

Many pieces of verification equipment meet the requirements outlined in section 2.26 Amplification Components and [Appendix A: IHP Instrumentation](#). This includes, but is not limited to, the Verifit and, more recently, the Verifit 2. The Verifit 2 has transitioned to the use of an 0.4cc coupler for the measurement of a wideband RECD (wRECD) up to 12,500 Hz. Since coupler type now differs between systems it is necessary to indicate which coupler type was used to measure the RECD/wRECD. This can be entered in the drop down menu shown in the Figure 1 below.

Please choose

Select ☐ HA-2 RECD or ☒ HA-1 RECD or ☐ 0.4cc WRECD

Select HA-1 if RECD measured on other Audioscan models with current software.

Measured Speechmap test box data will only be available to 8KHz when HA-1 RECD is entered.

Figure 1: RECD coupler selection screen on the Audioscan Verifit 2

In determining which coupler was used for measuring an RECD, the Audioscan® software version should be considered. HA-2 RECD should be selected when the RECD was measured with software versions prior to 3.12, HA-1 RECD for versions 3.12 and above, and 0.4cc WRECD for Verifit2. Further information on this topic visit <http://canadianaudiologist.ca/issue/volume-2-issue-6-2015/column/science-matters/>. Instructional videos on RECD measurement can be found on the Audioscan website or at <https://youtu.be/p57vcjTUGYA>.

SUPPLEMENT 2: PRESCRIPTION OF AMPLIFICATION

S2.1 NON-ELECTROACOUSTIC CHARACTERISTICS

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

1. Many infants are born with well-developed pinna and ear canals to accommodate the signal processor connected to a personal earmold;
2. Rapid growth of the outer ear requires frequent earmold remakes which are less costly and more convenient than custom (i.e., in-the-ear, in-the-canal) hearing aids;
3. Custom products are more prone to feedback due to the close proximity of the receiver and microphone;
4. BTEs allow for greater electroacoustic flexibility;
5. Direct audio input capabilities are more compatible with the target population;
6. During out-of-office repairs of the BTE, a similar device can be coupled to the child's earmold so the child is not without amplification.

Bone conduction hearing aids on a soft headband, bone anchored hearing aids, 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. Children who receive cochlear implants are no longer eligible for IHP amplification services.

Infants with confirmed PHL in both ears shall be fitted with bilateral air conduction hearing aids 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 remote microphone hearing assistance technologies, to the hearing aids. Tamper resistant battery doors shall be included on hearing aids for infants. A deactivation or locking system for the volume control and advanced signal processing (e.g., noise management, frequency lowering, datalogging) features shall be available on the hearing aids.

Some infants may have a conductive hearing loss 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 aids, bone conduction hearing aids on a soft headband shall be considered.

Traditional bone conduction aids 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 device in place, though they may be a suitable option for families due to their lower cost.

A bone conduction hearing aid 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 device to the infant's head. Bone conduction processors may also be attached using a small adhesive patch. For each device option, validation measures via aided sound field thresholds and parent interviews/feedback are necessary to ensure the fitting is at an appropriate level for the infant. At the time of this writing, the outcomes of the different styles of BCHDs are unknown. An in depth protocol for pediatric bone conduction hearing aid fittings is currently in development. Audiologists are encouraged to provide bone conduction services when indicated, and to monitor outcomes with fittings through aided audiograms and IHP outcome measures. Consultation with a DTC for support is available, as are loaner bone conduction hearing aids.

S2.2 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 aid(s) selected shall avoid unnecessary distortion.
3. The hearing aid(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.

S2.3 PEDIATRIC-SIZED FILTERED EARHOOKS

Manufacturers routinely send pediatric-sized filtered earhooks when BTE hearing aids are ordered for a child. A pediatric-sized 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 aid, 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).

S2.4 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 3: OUTCOME EVALUATION

S3.1 OUTCOME MEASURES

At the follow-up visits, the audiologist should meet with the parent/caregiver to discuss satisfaction with the fit of the hearing aids 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., LittleEARS Auditory Questionnaire; Tsakpini et al., 2004) and auditory performance (i.e., Parents' Evaluation of Aural/Oral Performance of Children [PEACH]; Ching & Hill, 2005) as well as a parental satisfaction survey (i.e., IHP Amplification Benefit Questionnaire, 2010). In addition, tools to assess the quality of the hearing aid fitting (i.e., Speech Intelligibility Index; ANSI S3.5, 1997 [R2012]) are provided in order to support interpretation of functional outcomes.

Caregiver-report functional outcome tools are targeted for IHP children because objective measures of speech detection and recognition may be difficult to obtain in cases of children with complex factors (e.g., difficult to test due to developmental level). Coincidentally, it is these same children who may also present assessment and/or management difficulties more generally. Focusing on objective strategies as the primary strategy for outcome evaluation, therefore, is not likely to be successful on those very cases in which outcome measures are needed the most. Caregiver reports (i.e., subjective outcome measures) can be completed by the parent regardless of the child's developmental level and provide rich and important real-life information that can support the more objective tests that clinicians may perform as well as being more applicable to children with complex needs. Therefore, this protocol focuses on the evaluation of subjective outcome evaluation tools that assess auditory-related behaviors in infants and children. The IHP Outcome Measurement Protocol (aka: UWO PedAMP) has been implemented with children of varying ages, developmental abilities and degrees of hearing loss and the impact of these variables on outcome have been presented elsewhere (Bagatto et al, 2011; 2016).

DEVELOPMENT OF THE IHP OUTCOME MEASUREMENT PROTOCOL (UWO PEDAMP)

Using a knowledge-to-action (KTA) approach (Graham, Logan, Harrison, Strauss, Tetro, Caswell & Robinson, 2006) a critical review of available outcome evaluation tools for infants and children aged birth to six years within the category of caregiver-report questionnaires was conducted (Bagatto, Moodie, Seewald, Bartlett & Scollie, 2011). This allowed for an appraisal of the current tools to eliminate the need for developing new tools. Through the critical review process, there was an attempt to include tools with good statistical properties and available norms and avoid tools that were too lengthy or complicated in favor of those that had good clinical feasibility and utility (Andresen, 2000).

Following the critical review, the Outcome Measurement protocol was developed and members of the Network of Pediatric Audiologists of Canada were invited to review the proposed outcome evaluation tools and provide objective and subjective feedback regarding the components of the guideline (Moodie, Bagatto, Seewald, Kothari, Miller & Scollie, 2011). Their feedback was also requested regarding barriers and facilitators to implementing outcome evaluation tools within the contexts in which they worked. This provided an opportunity to use an engaged community of practice with a shared understanding of the knowledge and clinical needs. It also allowed the authors of the Outcome Measurement protocol to strike a balance between creating an evidence-based guideline, which can be rigid and complex, with a more actionable, flexible guideline through the development of clear and specific tools (Bhattacharyya, Reeves & Zwarenstein 2009).

CONTENT AND CLINICAL APPLICATION OF THE OUTCOME MEASURES

The IHP Outcome Measurement tools consist of the following:

Tool	Purpose	Description
Amplification Benefit Questionnaire	<ul style="list-style-type: none">- Acceptance & use of hearing aids- Satisfaction with services	11 items 5 point rating scale
Hearing Aid Fitting Details	<ul style="list-style-type: none">- Quality of hearing aid fitting	RECD, MPO, Speech Intelligibility Index (SII)
LittleEARS Auditory Questionnaire <i>(Tsiakpini et al, 2004)</i>	<ul style="list-style-type: none">- Receptive & semantic auditory behaviour- Expressive vocal behaviour	35 items Yes/no response
Parents' Evaluation of Aural/Oral Performance of Children (PEACH) <i>(Ching & Hill, 2005)</i>	<ul style="list-style-type: none">- Communication in quiet & noise- Responsiveness to environment	13 items 5 point rating scale

The IHP Outcome Measurement protocol is intended to be used with IHP children who wear hearing aids. Monitoring children with PHL who do not wear hearing aids is also considered an important use of the protocol, but is not currently required in the IHP context. Further information about accessing each tool and the clinical administration of the protocol can be found in [Appendix H](#).

SECTION 9: APPENDICES

APPENDIX A: IHP INSTRUMENTATION

In addition to hearing aid programming software, sites providing Amplification Services for the IHP must have access to real-ear and hearing aid test systems that provide specific functions that support the entirety of hearing aid evaluations and verification procedures described in this protocol. These include the required functions 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 aid 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 aid 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 aid 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 aid test system provides the DSL Quiet and Noise environment listening targets.

(e) Transducer Type

The real-ear and hearing aid 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 aid 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 (HA-1, HA-2 or HA-4) 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 aid 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 aid test system must allow the end user to enter frequency-specific measures of the patient's air conduction thresholds and bone conduction thresholds for each ear requiring a hearing aid.

(c) Verification Displays

The real-ear and hearing aid 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 RECD). 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 99th and 30th 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 aid 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 (SII) should be displayed for each verification curve performed with running speech.

(e) Evaluations of accessories and signal processing

The system should provide support for assessment of external microphone systems (e.g., FM systems and similar) as well as assessment of noise reduction, frequency lowering, noise floor, and any other test abilities required by this protocol.

APPENDIX B: ESTIMATED HEARING LEVEL (eHL) & HEARING AID FITTING

Frequency-specific ABR thresholds in dB nHL are not directly equivalent to perceptual thresholds in dB HL, and both dB nHL and dB HL 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 ABR Audiologist following completion of the IHP ABRA protocol in which PHL has been confirmed. 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 ISCIS data forms by the ABRA audiologist.

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 aid test system as well as hearing aid 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 must conduct VRA or CPA using insert earphones. If the child has personal earmolds, the insert earphones must be coupled to them to improve retention in the child's ears and provide more accuracy with the hearing aid fitting. 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. If this is not the case, verification systems including the Verifit 1 version 3.12+, Verifit 2 version 4.2+ and the Axiom version 1.8+ will apply a correction factor when a coupling mismatch is entered (Figure 2). Any changes to the child's auditory thresholds and RECD values should be applied to the hearing aid prescription as needed.

Audiometry	
Ear	Left
Targets	DSL child
Age	6 years
HL transducer	Insert + mold
Threshold	Entered
Bone conduction	N/A
UCL	Average
RECD	Enter
RECD coupling	Earmold

Transducer coupling for Audiogram

Transducer coupling for RECD

Figure 2: Menu for entry of audiometric information using current Audioscan software.

Description of coupling the insert earphone to the earmold:

1. Trim approximately 5mm (maximum) of tubing from a standard foam ear tip, as shown in Figure 3a.
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 aid.
3. Insert the tip of the insert earphone transducer into the other end of the trimmed foam tip tubing, as shown in Figure 3b. Note: Please ensure that the earmold and tubing are not damaged or occluded with cerumen.

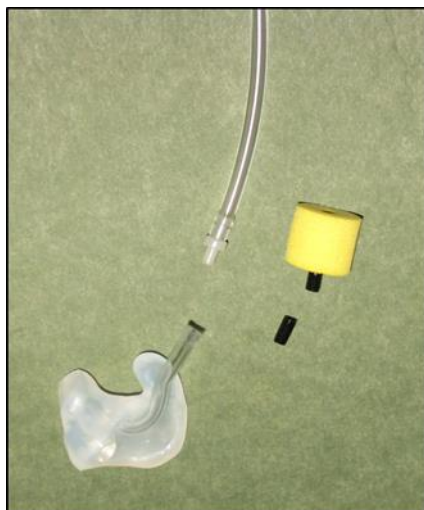


Figure 3a



Figure 3b

APPENDIX D: PEDIATRIC EAR IMPRESSIONS AND EARMOLDS

RECOMMENDED EAR IMPRESSION MATERIALS

- silicone-based earmold impression material
- measuring scoops
- impression syringe – pediatric tip
- small otoblocks – trim for size as needed
- earlight
- otoscope with pediatric specula
- mixing spatula
- non-stick mixing pad
- non-latex plastic gloves (optional)

PROCEDURE FOR OBTAINING EAR IMPRESSIONS

1. Instruct parent regarding the procedure, including positioning and child control. Some bracing of the head and torso may be necessary during insertion of impression material.
2. Wear a clean pair of non-latex plastic gloves throughout the entire procedure (optional; 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.

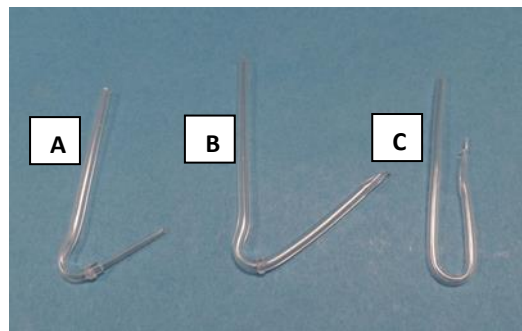
5. Using the earlight, insert the oto-block gently into the ear canal so that the marked position on the earlight is at the ear canal entrance (see #3 above). Examine the depth and position of the oto-block with the otoscope. When satisfied with the placement, wrap the string from the block over and 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. With the child still, place the tip of the syringe down the ear canal as close to the oto-block 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. Time will vary depending on the material and proportions used. Quick drying material is desirable for active children. It is desirable to protect the impression in the ear with a cupped hand to prevent it from being misshapen with movement. When your fingernail can be pushed 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 and complete the earmold order form.

EARMOLD MATERIAL AND STYLE

1. Although earmold labs have a variety of brand names for their products, 2 main choices of pliable earmold material should be considered for children: Silicone or vinyl/formaseal.
2. For very young children (<12 months corrected), 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. For this reason, it is possible to connect a smaller diameter of tubing (#16) to the standard tubing diameter (#13). Hard wall tubing should be used (see Figure 4).

Figure 4: Earmold tubing styles
A: #13 to #16 with tube lock
B: #13 with tube lock
C: #13 without tube lock



3. 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. Vinyl or formaseal material accepts tubing glue and is somewhat stiffer in shape than silicone; therefore it may be a better option for children under 6 months of age, or for children with unusually small ear canals.
4. Earmold venting should be considered when possible, being cautious that it does not cause acoustic feedback with the fitting. The size of an infant's ear canal will often limit the ability to add a vent, but it can provide important acoustic modifications for the fitting.
5. 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 aid in the test box coupled to the HA-2 or HA-4 coupler.
2. In the simulated (test box) 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 aid 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 hearing aid 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 hearing aid 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 or loud speech. A close match to average conversational speech and maximum output targets of the hearing aids are to be given priority when verifying hearing aids for infants and young children.

7. Repeat the verification procedure for average and MPO if you made adjustments in Step 6.
8. Repeat steps 1 through 7 with the other hearing aid for binaural hearing aid fittings.
9. Save the final settings to the hearing aid(s) and record the verification data from the real-ear and hearing aid 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 aid(s). 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 aid(s).

Aided soundfield threshold testing can be useful for hearing aid 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 aids
- ☐ Techniques for cleaning earmolds and hearing aids
- ☐ Procedures for battery checks and insertion
- ☐ Procedures for listening checks of hearing aids
- ☐ Putting hearing aids on the child and securing them – retention and loss-prevention
- ☐ Setting user controls
- ☐ Incorporating use of hearing aids into the child's routine
- ☐ Plans for documenting experiences with hearing aids – hearing aid diaries could be provided or recommended
- ☐ Safety issues (e.g., battery ingestion)
- ☐ Understanding and combating feedback
- ☐ Protecting the hearing aids 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 aids
- ☐ Discussion of earmold life expectancy and hearing aid 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 aids. Tamper resistant battery doors should be implemented, because hearing aid batteries are toxic if ingested. Applying a volume control cover or lock will ensure that the infant is wearing the hearing aids 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 output. Non-acoustic features of hearing aids 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 aid(s) and earmold(s)
- Stethoscope for daily listening check

- Battery tester
- Earmold blower for removing moisture and debris
- Hearing aid clips to prevent loss and protect from damage
- Battery door opener tool, where applicable
- Instruction manual

Care and maintenance kits are provided by hearing aid 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

APPENDIX G: HEARING AID FITTING AND VERIFICATION CHECKLIST

This form provides a list of amplification details to consider when performing a new hearing aid fitting or an adjustment. Check all that apply and provide comments on bottom/reverse if necessary. The use of this form is discretionary at this time. If used, please maintain a copy of this form in the patient file. The checklist is a guide for key performance indicators in preparation for routine Standard Practice Reviews in Amplification.

DESCRIPTION OF EAR CANAL ACOUSTICS

Transducer used to assess hearing thresholds:	<input type="checkbox"/> insert earphones + personal earmold	
	<input type="checkbox"/> insert earphones + foam-tip	
	<input type="checkbox"/> Other: _____	
RECD for verification:	<input type="checkbox"/> new	<input type="checkbox"/> previously measured
RECD Coupler:	<input type="checkbox"/> HA-1	<input type="checkbox"/> HA-2 <input type="checkbox"/> 0.4cc WRECD
RECD Coupling type:	<input type="checkbox"/> foam-tip	<input type="checkbox"/> personal earmold
If predicted RECD used, provide reason: _____		

ELECTROACOUSTIC VERIFICATION OF FIT-TO-TARGETS AND SII VALUES

Soft level speech (55 dB SPL)	R ear	<input type="checkbox"/> within ± 5 dB of DSL targets	<input type="checkbox"/> over targets	<input type="checkbox"/> under targets
	L ear	<input type="checkbox"/> within ± 5 dB of DSL targets	<input type="checkbox"/> over targets	<input type="checkbox"/> under targets
Average level speech (65 dB SPL)	R ear	<input type="checkbox"/> within ± 5 dB of DSL targets	<input type="checkbox"/> over targets	<input type="checkbox"/> under targets
	L ear	<input type="checkbox"/> within ± 5 dB of DSL targets	<input type="checkbox"/> over targets	<input type="checkbox"/> under targets
Maximum power output (MPO)	R ear	<input type="checkbox"/> within ± 5 dB of DSL targets	<input type="checkbox"/> over targets	<input type="checkbox"/> under targets
	L ear	<input type="checkbox"/> within ± 5 dB of DSL targets	<input type="checkbox"/> over targets	<input type="checkbox"/> under targets

CONSIDERATION OF ADVANCED AMPLIFICATION TECHNOLOGIES

Noise management	Candidate?: <input type="checkbox"/> yes <input type="checkbox"/> no	Feature Enabled?: <input type="checkbox"/> yes <input type="checkbox"/> no
	Verification documented? <input type="checkbox"/> yes <input type="checkbox"/> no	_____ dB of noise reduction
Frequency lowering	Candidate?: <input type="checkbox"/> yes <input type="checkbox"/> no	Feature Enabled?: <input type="checkbox"/> yes <input type="checkbox"/> no
	Verification documented? <input type="checkbox"/> yes <input type="checkbox"/> no	
Remote microphone	Candidate?: <input type="checkbox"/> yes <input type="checkbox"/> no	Feature Enabled?: <input type="checkbox"/> yes <input type="checkbox"/> no
	Verification documented? <input type="checkbox"/> yes <input type="checkbox"/> no	
Feedback suppression	Candidate?: <input type="checkbox"/> yes <input type="checkbox"/> no	Feature Enabled?: <input type="checkbox"/> yes <input type="checkbox"/> no
	<input type="checkbox"/> considered status of earmold(s)	New earmold(s) required? <input type="checkbox"/> yes <input type="checkbox"/> no
Directional microphone	Microphone mode selected:	<input type="checkbox"/> pinna matched <input type="checkbox"/> fixed <input type="checkbox"/> adaptive
Data-logging	Feature Enabled?: <input type="checkbox"/> yes <input type="checkbox"/> no	hrs/day of use: _____
Comments: _____		

APPENDIX H: OUTCOME MEASUREMENT PROTOCOL APPLICATION

Clinical application of the IHP Outcome Measurement Protocol will be explained through the use of a case example: Cyrus was identified with a moderate rising to mild bilateral sensorineural hearing loss and fitted with hearing aids binaurally when he was eleven months old. The reason for the delay in hearing aid fitting was due to parental indecision in the early stages. Cyrus was born full term and does not have any other medical issues besides hearing loss. The following sections describe each outcome measurement tool in the protocol and provide results for the case example. The administration of each tool is based on the following administration guidelines. Check marks indicate when a particular tool should be administered (first column) at an IHP visit (first row).

	Initial Assessment	Prefitting	Initial Fitting	30 Day Recheck	3 month Recheck	6 month Recheck	Yearly Rechecks	Event Driven
Hearing Aid Fitting Details	✗	✗	✓	✗	✓	✓	✓	✓
IHP Hearing Aid Benefit	✗	✗	✗	✗	✓	✓	✓	✓
LittEARS	✓ Establish Unaided Baseline: Administer at one of these appointments			✓ If score ≥27 & ≥ 24 mos, stop LittEARS, use PEACH.	✓ If score ≥27 & ≥ 24 mos, stop LittEARS, use PEACH.	✓ If score ≥27 & ≥ 24 mos, stop LittEARS, use PEACH.	✓ If score ≥27 & ≥ 24 mos, stop LittEARS, use PEACH.	✓
PEACH	✗	✗	✗	↓	↓	↓	↓	✓

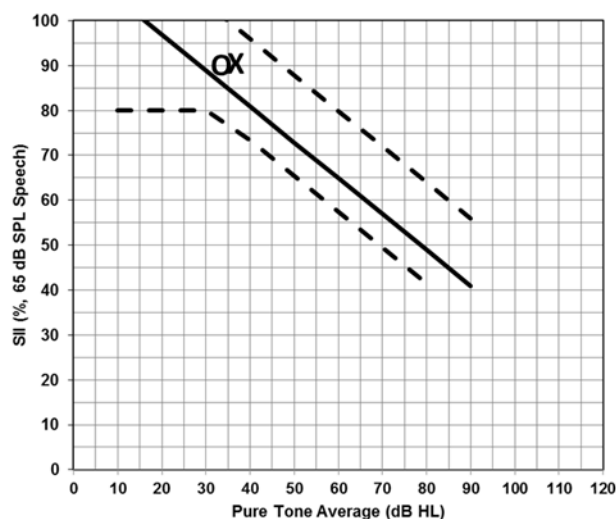
HEARING AID FITTING DETAILS

The IHP Provision of Amplification protocol was followed in order to ensure that Cyrus' hearing aids are providing the necessary access to speech for his degree of hearing loss. Outcome evaluation is designed to be completed following the hearing aid verification stage of the fitting process as it allows one to measure the impact of the fitting. An appropriate hearing aid fitting is often associated with positive outcomes and thus outcome measures are required by the IHP Outcome Measurement Protocol. Monitoring hearing aid fitting details allows the IHP clinician to determine whether an *individual child's fitting* is providing a typical degree of audibility. In addition, this information provides monitoring at the level of the *IHP program as a whole*. The brief fitting details gathered in this protocol will help to determine, for example, the typical rate at which RECD measures are made, or the typical amount of audibility provided by hearing aids given a specified hearing loss. As part of this protocol, two tools have been provided to monitor hearing aid fitting details: 1) the Hearing Aid Fitting Summary; and 2) Aided SII Normative Values. Used together, they provide helpful information for the audiologist, caregivers, and health policy-makers about the hearing aid fitting as part of this outcome measurement protocol.

In this protocol, the aim is to minimize the time needed to capture the hearing aid fitting details. For this reason, the exact fit-to-targets at each frequency and test level are not documented. Instead, the fit-to-targets are assessed by the IHP clinician and the overall amount of audibility provided for low and moderate level speech (via the Speech Intelligibility Index [SII]) and whether or not key protocol elements were measured for each fitting (RECD, MPO) are monitored. A complete Hearing Aid Fitting Summary includes details about the RECD (Measured, Predicted, Used other ear values, Previously measured) and the MPO as well as SII values for soft and average speech inputs (zero to 100). ISCS forms used to document these details are provided regionally.

The SII is a value representing the proportion of speech that is heard by the listener through the hearing aids (American National Standards Institute [ANSI] S3.5, 1997 [R2012]). It is an acoustic measure, not a behavioral prediction. This means that the SII represents the audibility of speech, and is not a prediction of speech recognition scores. The SII provides a value that clinicians, caregivers and teachers can use to conceptualize the proportion of speech that is available to the child. SII values are provided from hearing aid test systems (e.g., Audioscan Verifit®, Interacoustics Affinity®) for various speech inputs. If a clinician has performed multi-level speech-based real-ear verification of the young child's hearing aids, the associated SII values for these measurements would also be provided.

Normative data relating the specific SII values for acceptable hearing aid fittings are available (Moodie et al, 2009; 2017) and can be found in some hearing aid test systems (see Verifit 2 sample below). These were derived from pediatric fit-to-target data from 161 ears. From these data, the SII values were extracted to develop norms by pure-tone average (PTA) for use in the current protocol. Tracking this clinical process outcome is important for interpreting scores on the functional outcomes such as the LittleEARS and the PEACH. The hearing aid fitting details and SII values for Cyrus' hearing aid fitting are summarized on the right. It can be noted that the RECD and MPO were measured and the SII values for an average speech input were 91% for the right ear and 90% for the left ear. This indicated typical audibility in both ears for Cyrus's degree of hearing loss (PTA Right = 33.8 dB HL, PTA Left = 36.7 dB HL). SII values for a soft speech input also indicated typical audibility in both ears.



Hearing Aid Fitting Detail	Right Ear	Left Ear
Real Ear to Coupler Difference (RECD)	<input checked="" type="checkbox"/> Measured <input type="checkbox"/> Predicted <input type="checkbox"/> Used other ear values <input type="checkbox"/> Used previously measured values	<input type="checkbox"/> Measured <input type="checkbox"/> Predicted <input checked="" type="checkbox"/> Used other ear values <input type="checkbox"/> Used previously measured values
Maximum Power Output (MPO)	Yes No	Yes No
SII Soft Value (55 dB SPL)	91	94
SII Average Value (65 dB SPL)	91	90

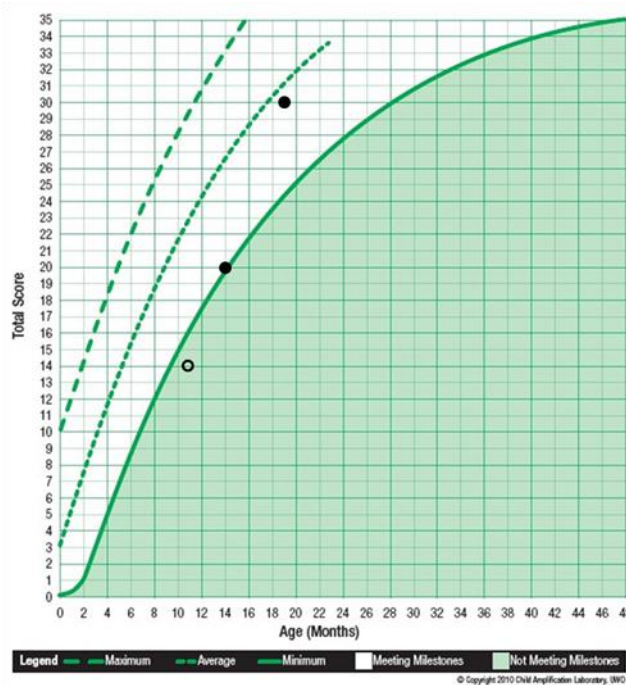


THE LITTLEARS AUDITORY QUESTIONNAIRE

The purpose of the LittleARS Auditory Questionnaire is to assess the auditory behaviour of infants with PHL who wear hearing aids or cochlear implants (Tsaikpini et al, 2004; Coninx et al, 2009). The 35 items in the LittleARS questionnaire assess auditory development during the first two years of hearing in the real-world and tap into receptive and semantic auditory behavior as well as expressive-vocal behavior. The questions are listed in an age-dependent order and are in a yes/no format. The total of all 'yes' answers provide a score that can be compared to average and minimum age-dependent values. These values are provided in one-month age categories based on normative data (Coninx et al, 2009). The LittleARS must be purchased regionally from Med-El.

A longitudinal intervention study was conducted using the LittleARS as part of the UWO PedAMP (Bagatto et al, 2011; 2016). Through this work, it was reported that caregivers and clinicians found it feasible to complete clinically (Moodie et al, 2011). In addition, the questionnaire has been shown to be sensitive to other medical issues besides hearing loss (Bagatto et al, 2011; 2016). The LittleARS has been shown to be useful for monitoring the progression of auditory development in infants and young children who have normal hearing and aided PHL. As part of this protocol, the LittleARS can be used for children from birth to approximately 48 months of age, depending on their score on the tool. A close look at the items on the LittleARS and the PEACH, which has items more appropriate for older children, indicate a stopping rule was needed to make the application of these tools feasible to utilize in a clinical population. Therefore, when a minimum score of 27 or better is achieved on the LittleARS, the child's performance is considered to be at a ceiling score. If ceiling is reached and the child is 24 months of age and older, the tool should no longer be administered. Instead, the clinician can begin to administer the Parent's Evaluation of Aural/Oral Performance in Children (PEACH), either at that appointment or at the next follow-up visit. Children who are younger than 24 months of age and achieve the ceiling score on the LittleARS may not yet be in the developmental range of the PEACH. The clinician should continue to administer the LittleARS until the child is 24 months of age, or interpret low scores on the PEACH knowing the child may not yet be within the developmental range of the tool as supported by recent work (Bagatto et al, 2011).

At Cyrus' hearing aid fitting appointment, his mother completed the LittleARS Auditory Questionnaire to obtain a description of his auditory development without experience with hearing aids. The total 'yes' score of 14 was plotted to intersect at age eleven months and revealed that Cyrus was not meeting auditory development milestones for his age without hearing aids. After three months of hearing aid use (Cyrus was 14 months of age), the score on the LittleARS was 20 indicating that he was meeting minimum auditory development milestones for his age when wearing the hearing aids. Another hearing aid review appointment revealed responses on the LittleARS that totaled 30 at age 19 months. This score was plotted on the LittleARS scoresheet (see right) and indicates that Cyrus was meeting auditory development milestones for his age after about 8 months of hearing aid use.



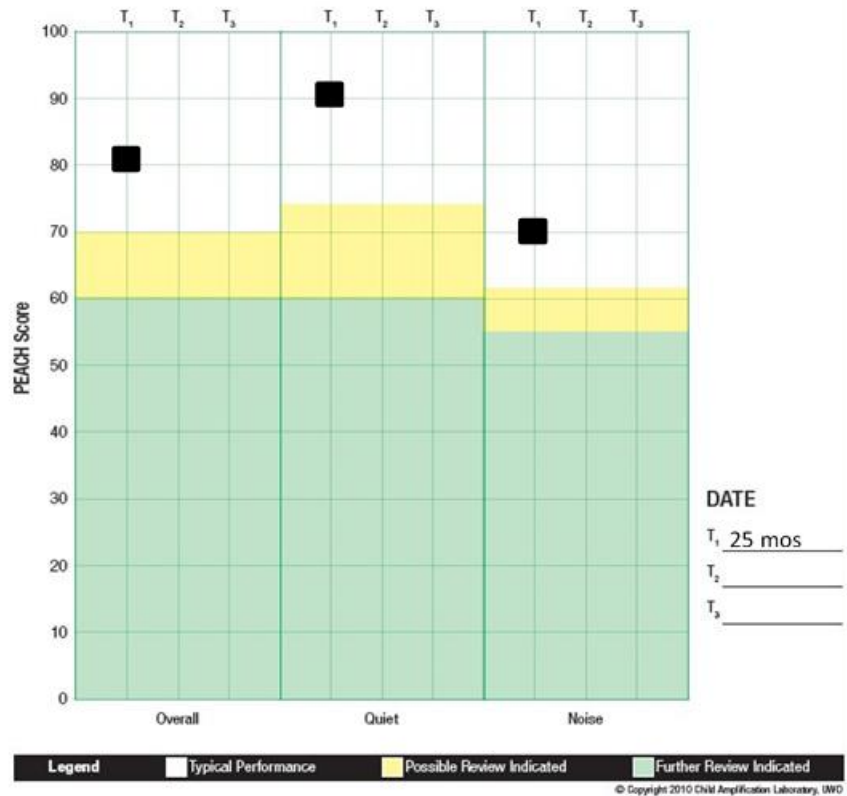
PARENT'S EVALUATION OF AURAL/ORAL PERFORMANCE OF CHILDREN (PEACH)

The PEACH in its original diary form is conducted using a structured interview format and has 13 questions that address quiet and noisy situations, as well as hearing device and telephone usage (Ching & Hill, 2005b). This observation and interview process required for the PEACH Diary was found to be heavy in administrative and respondent burden as reported in a research study (Golding, Pearce, Seymour, Cooper, Ching & Dillon, 2007) and through the Network of Pediatric Audiologists of Canada (Moodie et al, 2011). A Rating Scale version of the PEACH (Ching & Hill, 2005a) has been made available and includes most of the scenarios from the original PEACH Diary (Ching & Hill, 2005b). The PEACH Rating Scale is more acceptable by clinicians and caregivers because the respondent and administrative burden have been reduced (Moodie et al, 2011). The PEACH Rating Scale has been selected for use in the current protocol, with children who have attained ceiling performance (i.e., total score of 27 or greater) on the LittleEARS Auditory Questionnaire. It is provided for use in the IHP as an ISCIS form, available regionally.

The instructions ask caregivers to recall their child's behavior in everyday life over the past week and rate their child's hearing performance across a range of hearing and communication scenarios. The nature of the rating scale allows it to be answered by the caregiver during an appointment with guidance from the clinician. The overall score is summed, along with summed scores for the quiet and noise subscales. Each sum (overall, quiet, noise) is converted to a percentage. An accompanying score sheet was developed as part of the UWO PedAMP and provides assistance with interpretation of individual scores (see www.dslio.com).

The PEACH assesses functional auditory performance in quiet and noisy situations. Using the newly-developed score sheet, scores can be compared to scores derived from children with PCHI who wear hearing aids. This tool can assist in identifying whether a child is or is not performing typical auditory behaviors. Results to date indicate that the PEACH Rating Scale is appropriate for use within the IHP Outcome Measurement Protocol with children who wear hearing aids after they have met a certain criteria on the LittleEARS Questionnaire (Bagatto et al, 2011).

Since Cyrus' recent score on the LittleEARS exceeded 27 and he was older than 24 months of age, the PEACH Rating Scale was administered at his next follow-up appointment (25 months of age) where new earmolds were provided. Audiometry was repeated using the new earmolds coupled to insert earphones and the RECD was measured using the new earmolds. Upon verification of the performance of the hearing aids, it was noted that the SII values for soft and average speech inputs were not significantly different from previous assessments. The MPO was measured in both ears. Responses from his mother on the PEACH revealed that Cyrus was demonstrating typical auditory performance in both the Quiet (91.7%) and Noise (70.0%) subscales (see above). His overall score was 81.8%.



THE IHP AMPLIFICATION BENEFIT QUESTIONNAIRE

The IHP Amplification Benefit Questionnaire (ABQ) is an eleven-item questionnaire that was developed jointly by the IHP and the members of the Child Amplification Laboratory at the University of Western Ontario (see Bagatto, Moodie & Scollie, 2010). Using a five-point rating scale, this tool addresses acceptance and use of hearing aids, auditory performance for different levels of sound, effectiveness of service delivery and overall satisfaction. The final question is open-ended and asks the caregiver about how hearing aid services could be improved within the IHP. It is recommended that the questionnaire be answered by the caregiver after their child has worn hearing aids for *three months or more* so as to give the caregiver a chance to become accustomed to and comfortable with their child's hearing aids and the services offered by the IHP. It should be readministered at follow-up visits thereafter. The ABQ is provided for use in the IHP as an ISCIS form, available regionally.

Initial responses from Cyrus' mother on the IHP Amplification Benefit Questionnaire revealed one to three hours of hearing aid use per day and some willingness of the child to accept his hearing aids. This was verified by checking internal datalogging within his hearing aids. Cyrus' mother reported good responses to sound and a level of comfort troubleshooting the hearing aids. She reported feeling as though the hearing aids were 'worth the effort' and that she was satisfied with the hearing aid services she was provided. More recent responses on the IHP Amplification Benefit Questionnaire revealed an increase in daily hearing aid use to four to eight hours per day and the child being slightly less willing to accept the hearing aids. Other items on the questionnaire remained similar. Strategies to support the child's acceptance of the hearing aids were discussed with Cyrus' mother.

SUMMARY

The IHP Outcome Measurement Protocol consists of several tools that assess auditory development (LittleEARS) and performance (PEACH) in children with PHL. It also includes tools to track important hearing aid fitting details as well as an index of the appropriateness of the hearing aid fitting (e.g., SII) to assist with the interpretation of scores on the functional outcome questionnaires. Finally, this outcome measurement protocol includes a tool that assesses overall service delivery and caregiver satisfaction with hearing aid services for their child. The IHP Amplification Benefit Questionnaire provides a way to measure how the IHP is doing overall. The use of the KTA process framework and The Network of Pediatric Audiologists of Canada facilitated the development of this protocol. The end result of this process is a protocol that is balanced in statistical properties as well as in clinical feasibility, utility and acceptability. The protocol can be used in the final stage of the pediatric hearing aid fitting process where it facilitates the evaluation of the impact of the hearing aid fitting. Access to visual tools to permit rapid scoring supports clinical feasibility and implementation on a regular basis. The IHP Outcome Measurement Protocol will evolve through clinical implementation, and a continued community of practice is considered important for its success.

SECTION 10: PROTOCOL ADDENDA

ADDENDUM 1: AMERICAN ACADEMY OF AUDIOLOGY PEDIATRIC AMPLIFICATION GUIDELINES

INTRODUCTION

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. At the time of the AAA publication, The IHP Protocol for the Provision of Amplification was updated in October 2007 (Bagatto, Scollie, Hyde & Seewald, 2010) with some protocol addenda that followed in 2014. The IHP continues to develop protocol addenda as the need arises. Overall, the procedures described in the AAA 2013 document are generally consistent with current IHP protocols. 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](#)) and noise management ([Addendum 3](#)). 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.

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.

IMPACT FOR THE IHP PROTOCOL

Several content areas of the AAA 2013 Guideline were relevant for updated versions of the IHP Amplification Protocol. Advanced technologies such as directional microphones, noise reduction, and frequency lowering were addressed. In addition, a discussion about borderline pediatric populations and aidable hearing helped to inform additions to the IHP Protocol. The AAA Guideline also supports outcome measurement as an integral part of the pediatric hearing aid fitting process. As such recent updates to the IHP Protocol have included addenda to address these topics in light of new evidence and clinical knowledge.

The following protocol addenda were added to the IHP document in 2014 to further expand on the AAA Guideline and provide IHP audiologists with the necessary tools to apply this knowledge:

1. Frequency Lowering

2. Noise Management
3. Management of Minimal/Mild Bilateral Hearing Loss
4. Management of Unilateral Hearing Loss
5. 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://www.audiology.org/sites/default/files/publications/PediatricAmplificationGuidelines.pdf>

ADDENDUM 2: FREQUENCY LOWERING TECHNOLOGY

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 Provision of Amplification Protocol (2014). 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/ stimuli are suggested for use in the frequency lowering verification protocol (Scollie et al., 2016).
4. A specific verification and fitting procedure using calibrated stimuli, for use when the IHP audiologist elects to use a frequency lowering device, is recommended. This procedure is consistent with the pediatric amplification guidelines suggested by the American Academy of Audiology Clinical Practice Guidelines (2013) and updates the 2014 IHP Frequency Lowering Verification 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 Guidance Document, 2017). 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).

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.

Within the literature, several articles offer a review of the rationale and evidence on frequency lowering devices for managing high-frequency hearing loss (Alexander, 2013; McCreery, Venediktoc, Coleman & Leech, 2012; 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 (Auriemma 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 loss. 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 spoken language development (when spoken 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 amplify a broader bandwidth of sound without the use of frequency lowering technology. A summary of these factors is provided below (Figure 1).

Candidacy Factors for Frequency Lowering:

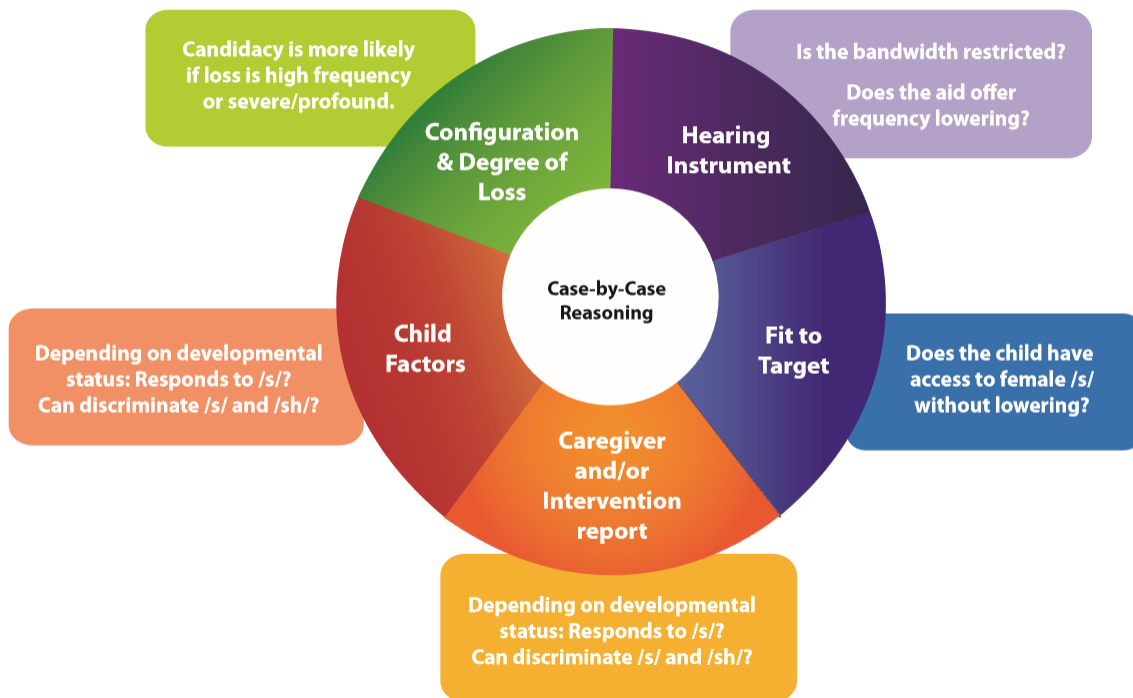
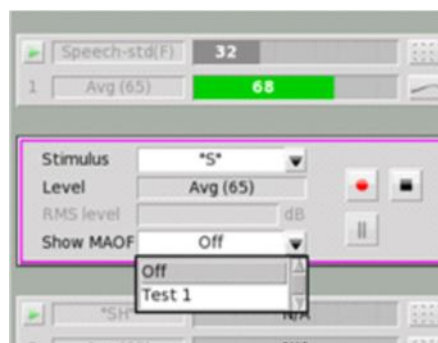


Figure 1. Factors to consider when determining candidacy for frequency lowering devices.

OVERVIEW: THE MAXIMUM AUDIBLE OUTPUT FREQUENCY (MAOF)

Current clinical guidelines recommend that the fitter maximize the output bandwidth available to the listener prior to activating frequency lowering through the use of validated prescriptive targets (AAA, 2013). The fitter can then determine the frequency at which the output of the hearing aid falls below audibility for a given audiogram; this has been referred to as the MAOF: maximum audible output frequency (McCreery et al., 2014; McCreery, Brennan, Hoover, Kopun, & Stelmachowicz, 2013). In this protocol, we verify the hearing aid with a running speech signal, to determine a “range” to use when fitting according to the MAOF. Specifically, the MAOF range spans from the point at which the long-term average speech spectrum (LTASS) crosses the hearing threshold line to the point at which the peaks of speech cross threshold (Figure 2). This range can be used as a target region for frequency lowered stimuli when fine-tuning fittings and can be highlighted in some hearing aid test systems.



Specific stimuli and procedures integrating the MAOF concept are recommended in this protocol (Glista, et al., 2016; Scollie et al., 2016). A display of peak and valley measurements for the LTASS is needed when identifying the MAOF range.

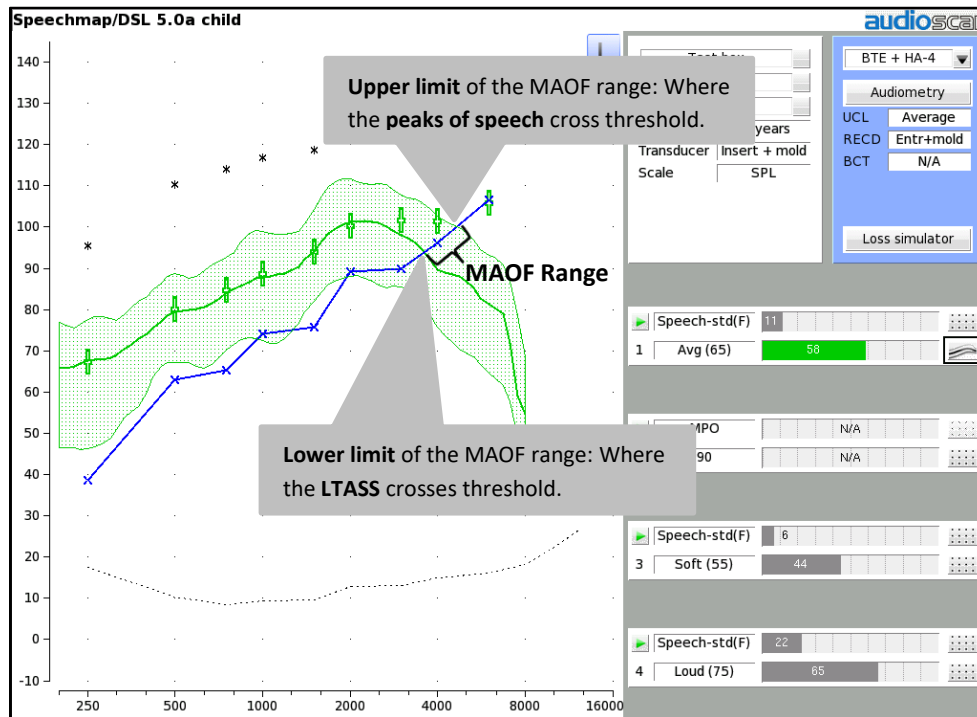


Figure 2. An Audioscan® Verifit2 test box screen measurement of the LTASS (with peak and valley measurements displayed) in reference to the hearing threshold line for an average level presentation level. The MAOF range extends from the point where the LTASS crosses threshold to the point where the peaks of speech cross threshold.

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 (Figure 3), the hearing aid response meets DSL targets within 5 dB up to 3000 Hz. Therefore, audibility of average level speech (green) is not available above 4000 Hz; the audible 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/ (including the upper shoulder) falls outside of the MAOF range and below the hearing threshold line (pink); /s/ is not audible without frequency lowering (Figure 3). With frequency lowering enabled (Figure 4), the upper shoulder of the /s/ stimulus falls within the MAOF range and above the hearing threshold line; /s/ is audible with frequency lowering enabled (pink). This fitting uses a weak frequency lowering setting, placing the /s/ near the upper limit of the MAOF range. A listening check revealed good sound quality and discrimination between /s/ and /ʃ/.

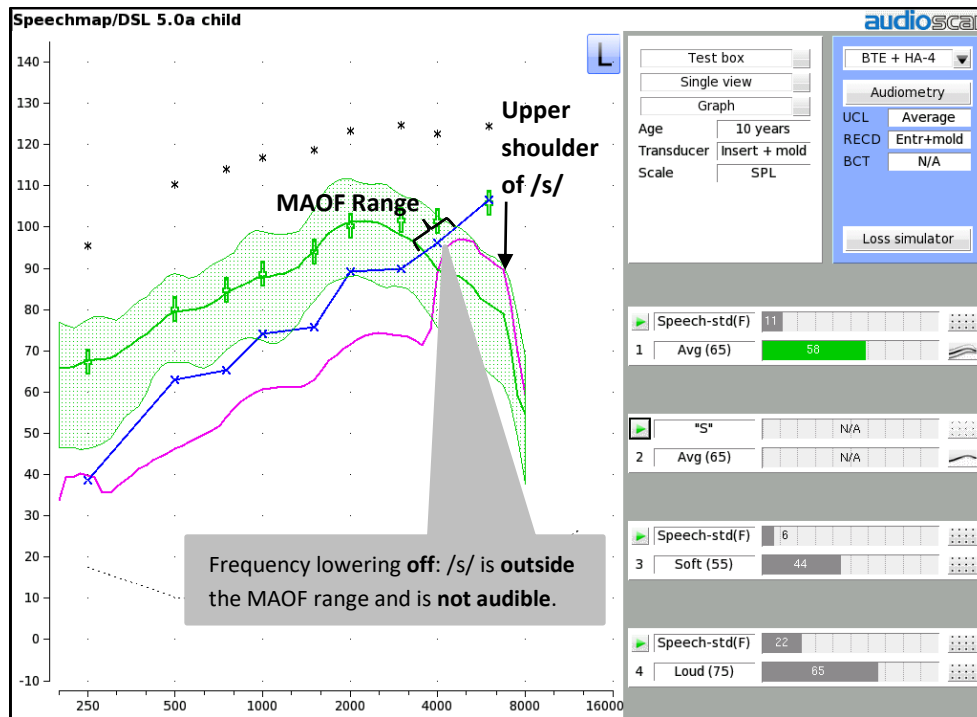


Figure 3. Text box measurement of an /s/ spectrum in reference to the MAOF range measured with frequency lowering turned off and at a presentation level of 65 dB SPL.

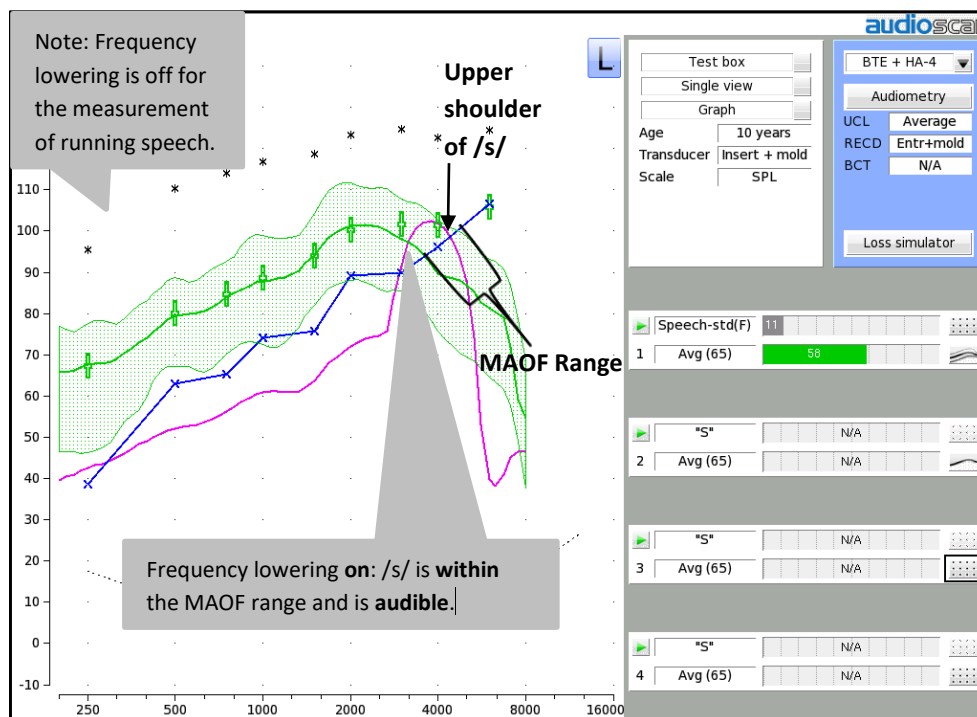


Figure 4. Text box measurement of an /s/ spectrum in reference to the MAOF range measured with frequency lowering turned on and at a presentation level of 65 dB SPL.

RECOMMENDED PROTOCOL

The following clinical protocol for verifying frequency lowering hearing aids is designed to assist clinicians in determining when to use frequency lowering and at what setting, within the context of IHP protocols. This protocol has been modified from that published in Glista et al., 2016 and Scollie et al., 2016.

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 for multi-level speech and when assessing MPO.

2. Determine candidacy for frequency lowering.

In addition to the candidacy factors stated above, this step allows you to determine if electroacoustic verification suggests that frequency lowering may improve high-frequency audibility. This requires the fitter to assess audibility of the /s/ stimulus with and without frequency lowering enabled.

- ✓ With frequency lowering OFF and noise reduction OFF, measure the calibrated /s/ at 65 dB SPL. Determine if the calibrated /s/ is audible and if the upper shoulder falls within the MAOF range. If it does not, the candidacy criterion for frequency lowering has been met.

3. Enable frequency lowering and adjust to optimize.

Start by enabling the manufacturer default setting in the hearing aid. The final setting should use the least amount of frequency lowering needed to obtain audibility of /s/.

- ✓ With frequency lowering ON, measure the response for the calibrated /s/ at 65 dB SPL. Assess whether the /s/ is audible and falls within the MAOF range. Pay special attention to whether or not the full spectrum of the /s/ is audible, using the upper shoulder of /s/ to assist with the assessment.
- ✓ Fine-tune the frequency lowering setting until the upper shoulder of /s/ falls within the MAOF. It is recommended that the final setting employ the weakest possible settings, placing the /s/ stimulus at the upper edge of the MAOF range and as close to the peaks of speech.
- ✓ Optimize frequency lowering settings for each ear individually (see FAQ for more information).

4. Provide post-fitting supports.

- ✓ Access counseling materials for caregivers, therapists, or anyone else that may do a listening check on the hearing aids with frequency lowering enabled. Sound quality may differ from conventional hearing aids, and caregivers may require support on this topic. One approach is to alert caregivers or therapists that sound quality may differ from previous hearing aids and/or with the same fitting without frequency lowering enabled. Having the caregiver perform a listening check at the fitting appointment will allow them to better understand what they should be listening for on a daily basis.
- ✓ 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/, the fitting may need to be adjusted to provide more gain or output (e.g., within the fitting software or via new earmold), and/or by adjusting the frequency lowering settings. Some fitting cases can provide additional challenges in this regard, so feel free to request fitting support if needed.

5. Optional measure: Assessing /s-/ overlap.

- ✓ Measure the aided /f/ to make a descriptive measure of the frequency separation between /s/ and /f/. This measure may help with counselling or troubleshooting difficulty with discrimination between /s/ and /f/. Because the fine-tuning steps above, the weakest possible setting of frequency lowering has already been determined and therefore the separation between /s/ and /f/ is likely already maximized. Listening checks are also useful for these purposes and should be completed after frequency lowering is verified.

Upon completing of this fitting protocol, re-enable noise reduction if this is a component of the fitting.

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 3.3:1 compression ratio. The calibrated /s/ was measured and can be seen below in pink (Figure 5). Using the weakest possible frequency lowering setting, we can achieve a fine-tuned setting where the upper shoulder of /s/ falls at the upper edge of the MAOF range.

For illustrative purposes, the strength of the cut-off and compression ratio were increased 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 hypothesize that a stronger setting such as this one would cause increased /s-/ overlap which is undesirable.

The strength was then decreased from the fine-tuned setting and /s/ was re-measured (yellow). This created a fitting where the /s/ feel outside the MAOF range, resulting in reduced audibility (approximately 1 dB SL). This would not be considered an optimal setting.

Overall, this exploration of settings illustrates the need to fine-tune each child's frequency lowered fitting based on a valid approach. The recommended protocol ensures consideration of the child's hearing loss, ear canal acoustics and the response of the chosen hearing device when choosing a frequency lowering setting.

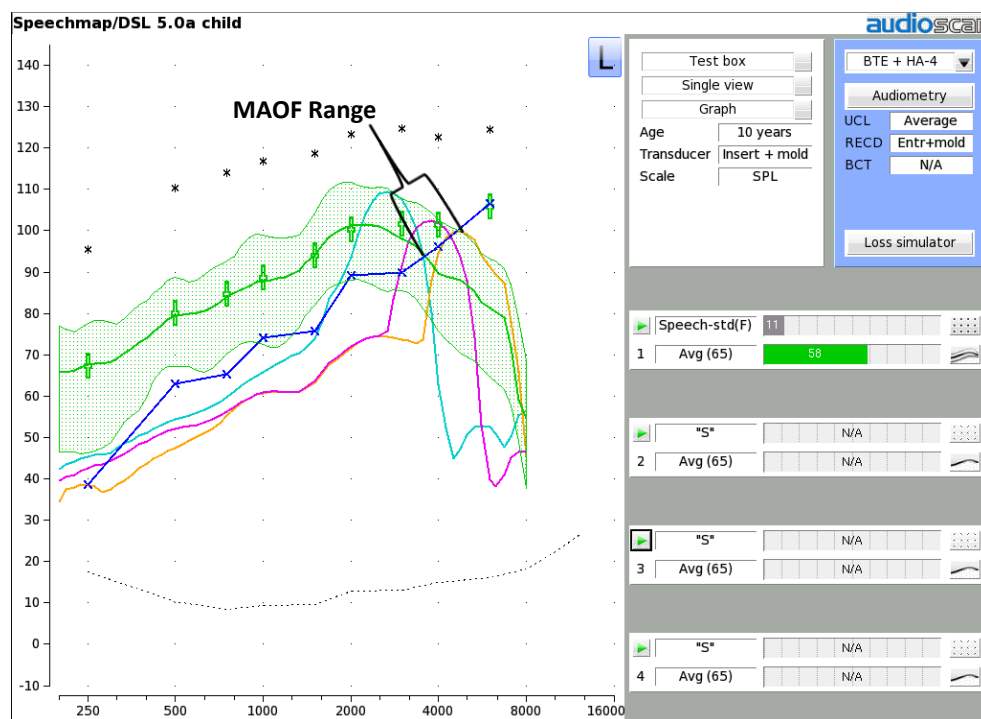


Figure 5. Measurements of the /s/ spectra, relative to the MAOF range, for the fine-tuned setting (pink), a stronger setting (blue) and a weaker frequency lowered setting (yellow).

CASE EXAMPLE C: OPTIONAL DESCRIPTIVE MEASURES OF /j/

A calibrated /j/ stimulus is provided for optional use in description of fittings or troubleshooting. Because frequency lowering can increase spectral overlap, which can in some cases result in /s-j/ confusion. This is more likely when the frequency separation between these two sounds is very small.

To illustrate this, the response for /j/ was measured to describe spectral separation between /s/ and /j/. The electroacoustic results depicted here (Figure 6) matches with the listening check, in which the clinician could clearly discern the two fricatives. Both /s/ and /j/ were also measured at the stronger frequency lowered setting (Figure 7). We can see that, compared to the fine-tuned setting, the /s-j/ overlap has been increased. This may result in poorer sound quality and less ability to discriminate between the fricatives for the child.

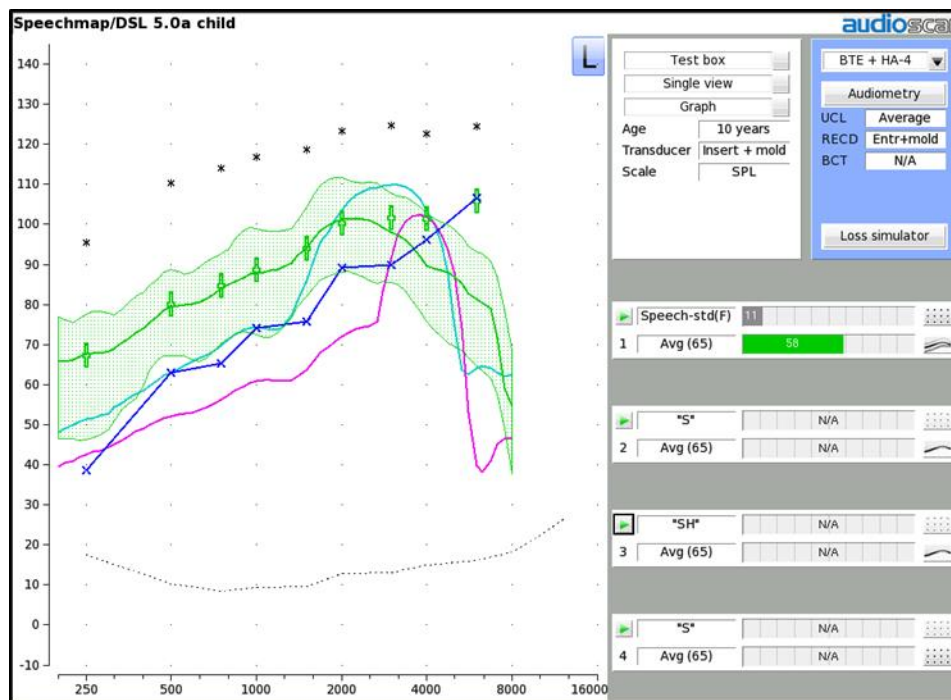


Figure 6. Text box measurements of the LTASS (green) and /s/ (pink) and /j/ (blue) at the fine-tuned setting, for a presentation level of 65 dB SPL.

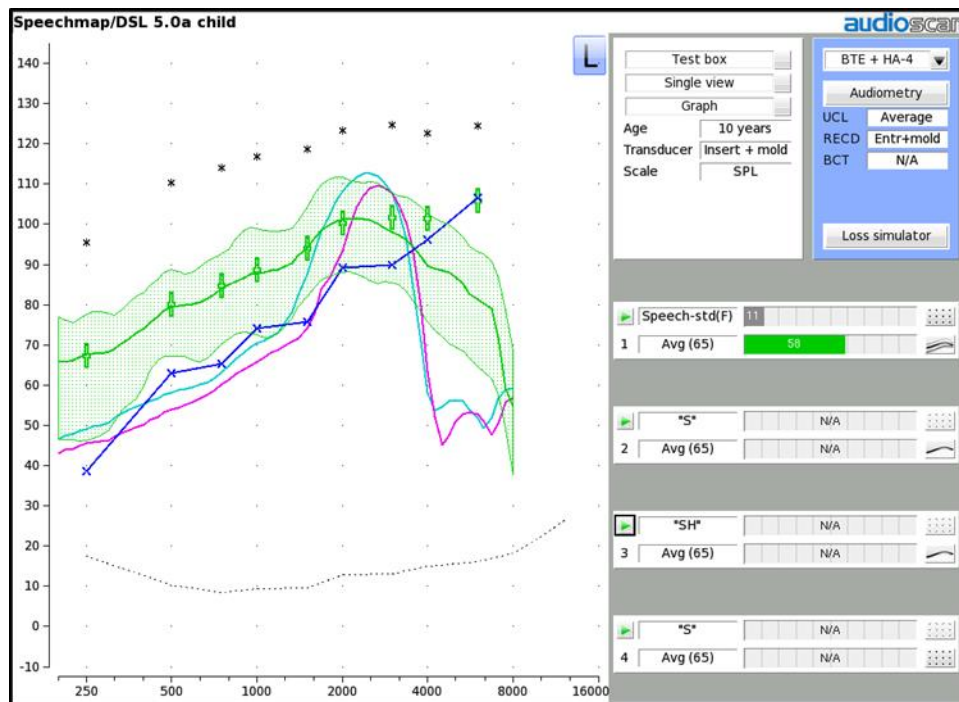


Figure 7. Text box measurements of the LTASS (green) and /s/ (pink) and /j/ (blue) at a stronger setting, for a presentation level of 65 dB SPL.

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 (Figure 8). 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.

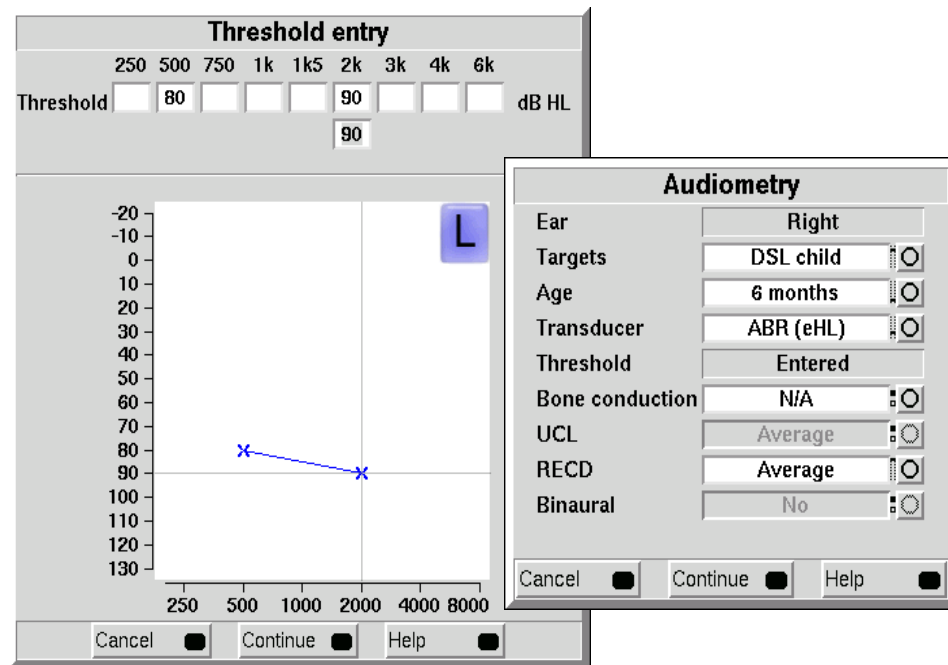


Figure 8. Hearing threshold information for Case D entered into the Audioscan® Verifit.

The initial fitting of the hearing aid is shown below (Figure 9). 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.

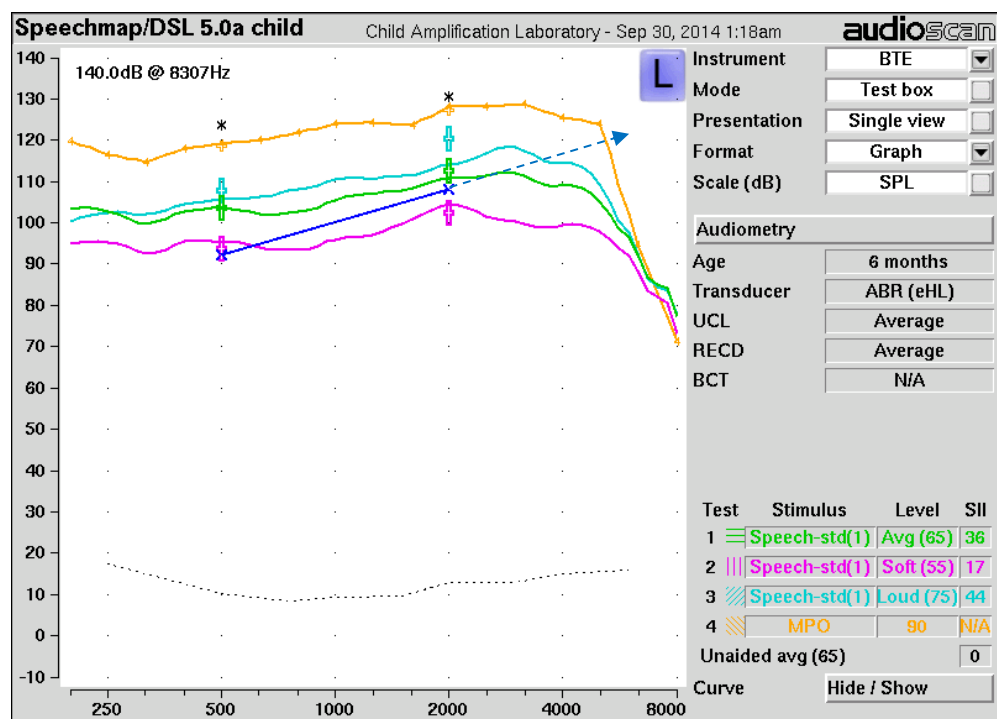


Figure 9. Text box measurements of soft (pink), average (green) and loud (blue) and for the MPO (yellow) measured at a presentation level of 65 dB SPL.

Candidacy for frequency lowering was determined using the calibrated /s/ (pink) with frequency lowering off (Figure 10) and on (Figure 10). By extrapolating the hearing thresholds in the high-frequencies (dotted blue line), we estimate 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. A listening check was completed to assess sound quality and phoneme discriminability. Further exploration using the calibrated /j/ 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 and/or outcome measures. Once a more detailed audiogram is available, these settings can be re-evaluated.

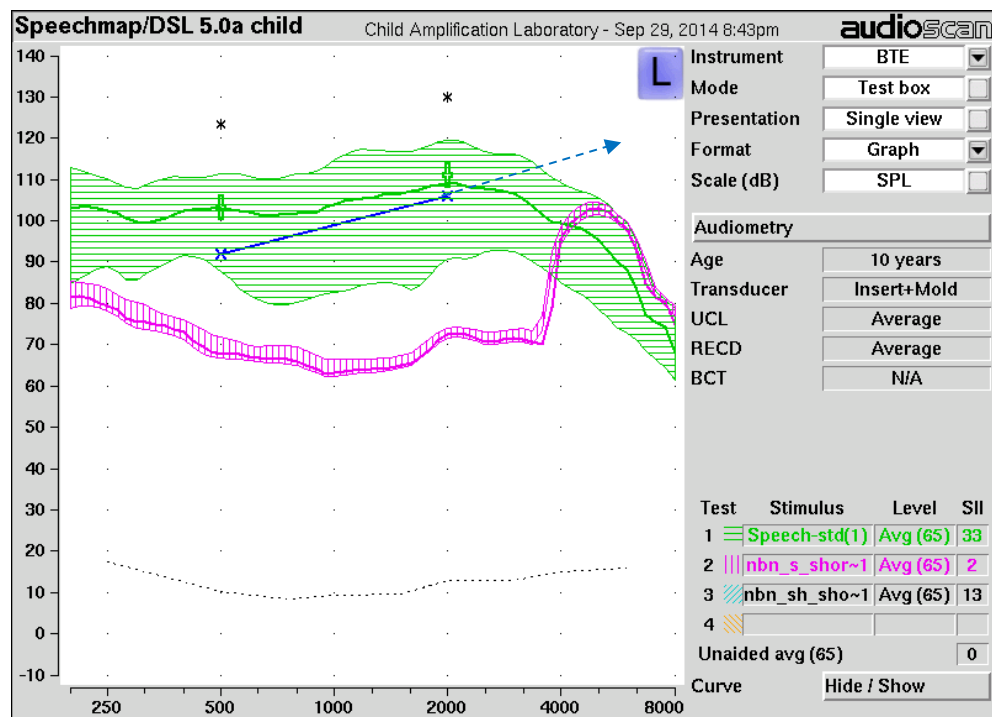


Figure 9. Measurement of the /s/ spectrum, relative to the MAOF range using extrapolated hearing thresholds, with frequency lowering OFF.

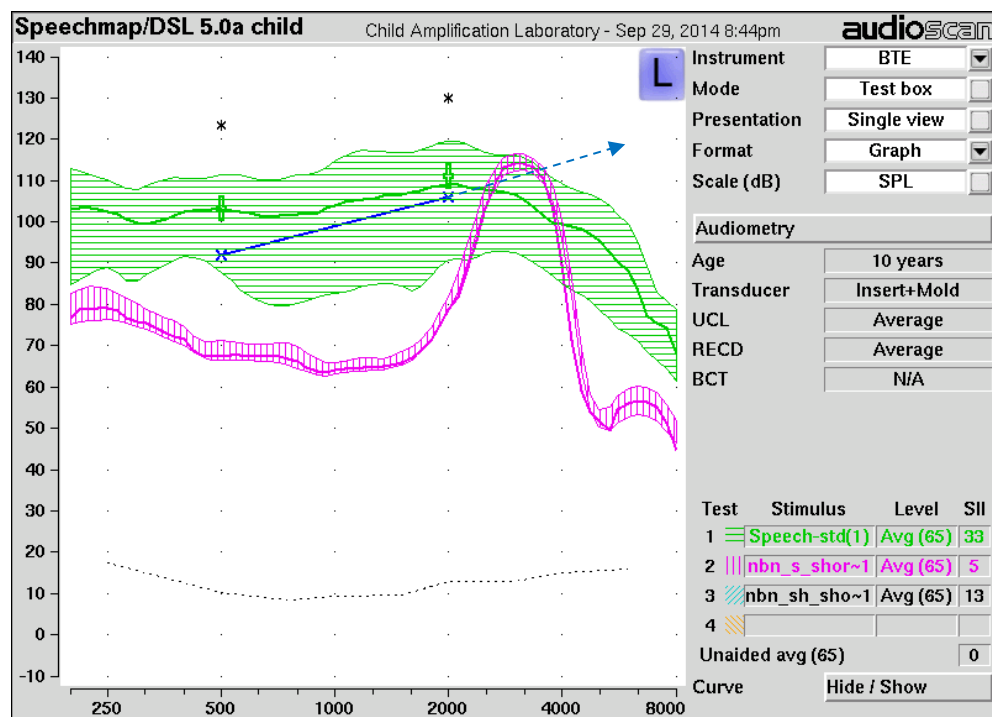
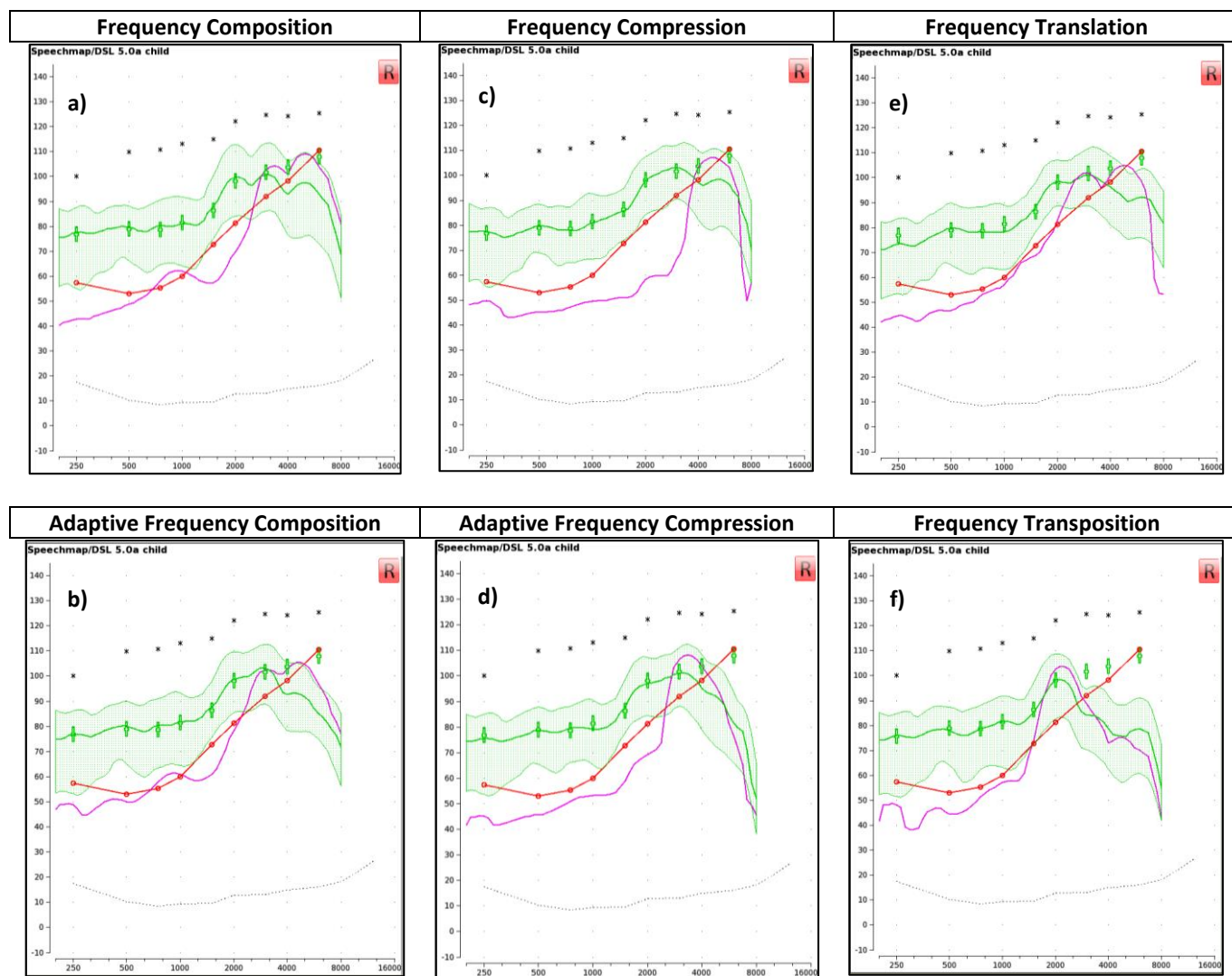


Figure 10. Measurement of the /s/ spectrum, relative to the MAOF range using extrapolated hearing thresholds, with frequency lowering ON.

CASE EXAMPLE E: ILLUSTRATING DIFFERENCES IN FREQUENCY LOWERING TECHNOLOGIES

This section presents six different types of frequency lowering fitted to the same hearing loss. The 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 illustrated below (Table 1). Note: The terminology used in the fitting software to describe the settings and parameters for each type of frequency lowering differs across manufacturers. Although different frequency lowering settings were used to achieve each of the measurements presented in Table 1, the results are all considered acceptable. This is due to differences in the nature of the signal processing associated with each type of lowering.

Table 1. Repeated measurement of the LTASS and /s/ stimulus for the same case study fitted with various types of frequency lowering.



Why do the measurement results look different across frequency lowering types?

These differences are mainly due to the frequency response of the device in combination with the nature of the frequency lowering signal processing associated with each device. A brief description of some of the differences between frequency lowering technologies is provided below.

Composition: Frequency composition is available in non-adaptive and adaptive forms – refer to a) and b) in Table 1 for the corresponding measurements. Both produce an /s/ signal that appears double peaked and broader in comparison to some of the other examples. This is due to the lowered signal being superimposed on the original signal, resulting in a double-representation of the /s/ signal. The lowered /s/ has been placed within the MAOF range (with the lower peak as the reference), using the weakest possible setting for both types of frequency composition. This type of lowering is currently available in Bernafon and Oticon devices. The following link describes fitting and verification considerations specific to Oticon devices and in agreement with those discussed in this document: <http://www.oticon.co.za/~asset/cache.ashx?id=44377&type=14&format=web>.

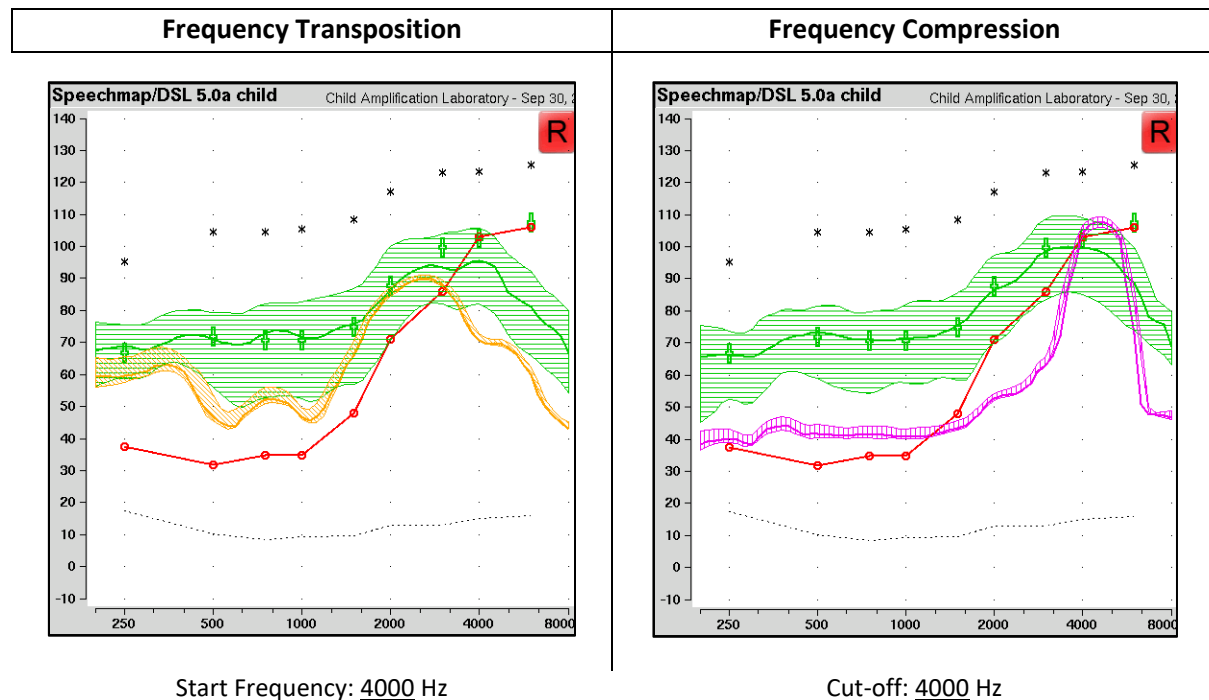
Compression: Frequency compression is also available in non-adaptive and adaptive forms – refer to c) and d) in Table 1. Both produce an /s/ signal that is narrower in comparison to some of the other types of frequency lowering. For this type of lowering, high-frequency information of the signal is being compressed to a smaller bandwidth. In the examples above, this device is set to the weakest possible setting where the /s/ still falls within the MAOF range. This type of lowering is currently available in Phonak devices. The following link describes fitting and verification considerations specific to Phonak devices and in agreement with those discussed in this document: https://www.phonakpro.com/content/dam/phonakpro/gc_hq/en/products_solutions/pediatrics/documents/best_practice_protocols/best_practice_protocol_sound_recover2_pediatric_verification.pdf.

Translation: Frequency translation uses an adaptive form of lowering – refer to e) in Table 1. This type of lowering produces an /s/ stimulus with a double peak. 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. This type of lowering is available in Starkey devices.

Transposition: This type of technology uses linear frequency transposition to lower a high-frequency portion of the signal – refer to e) in Table 1. The /s/ stimulus in this example appears narrower than some of the other examples as it captures the lowered signal only; the high-frequency information above as well as the original signal is filtered out. Frequency transposition has been applied using the weakest possible setting, while still placing it within the MAOF range. This type of lowering is available in Widex devices.

The nominal settings chosen in the manufacturer fitting software to produce the examples above differed greatly across the types of lowering. 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 (note: both the cut-off and start values denote the starting point for frequency lowering). Differences in the signal processing used to achieve lowering for transposition versus compression would suggest that a set value of 4000 Hz would yield differing results. The spectrum of the calibrated /s/ signal was measured, as shown below (Table 2):

Table 2. Measurements of the LTASS and /s/ stimuli for a hearing loss fitted with frequency transposition and frequency compression, along with the nominal settings chosen for illustrative purposes.



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 composition and 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 composition, 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 across types of lowering 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 a broad bandwidth of audibility without frequency lowering activated by assessing audibility of high-frequency phonemes. If the signal is either inaudible or not falling outside of the bandwidth of the device, complete further assessment with frequency lowering activated. It is recommended that these measurements be completed using an average presentation level.
 - In the case that the listeners is having difficulty understanding soft speech, consider measuring the calibrated /s/ at 55 dB SPL and assessing audibility. Decisions regarding activation of frequency lowering in this case are at the discretion of the audiologist and should consider caregiver reports.
- 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 /j/, 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 aids 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 where /s/ falls within the MAOF range and/or within the band-pass of the device and audibility of /s/ is maximized.

- 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) Which type of frequency lowering should we use?
- A brief description of the different types of frequency lowering is provided above. 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.
- 7) 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.

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 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.

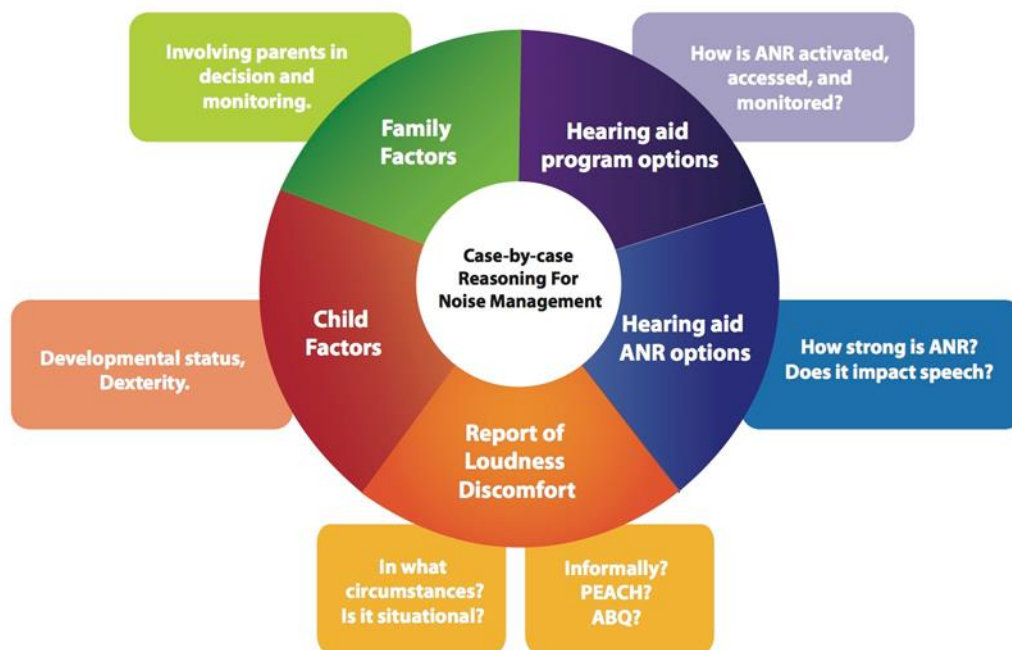


Figure 1. Candidacy and Device Considerations in Noise Management for Children who use Hearing Aids

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 ANR 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:

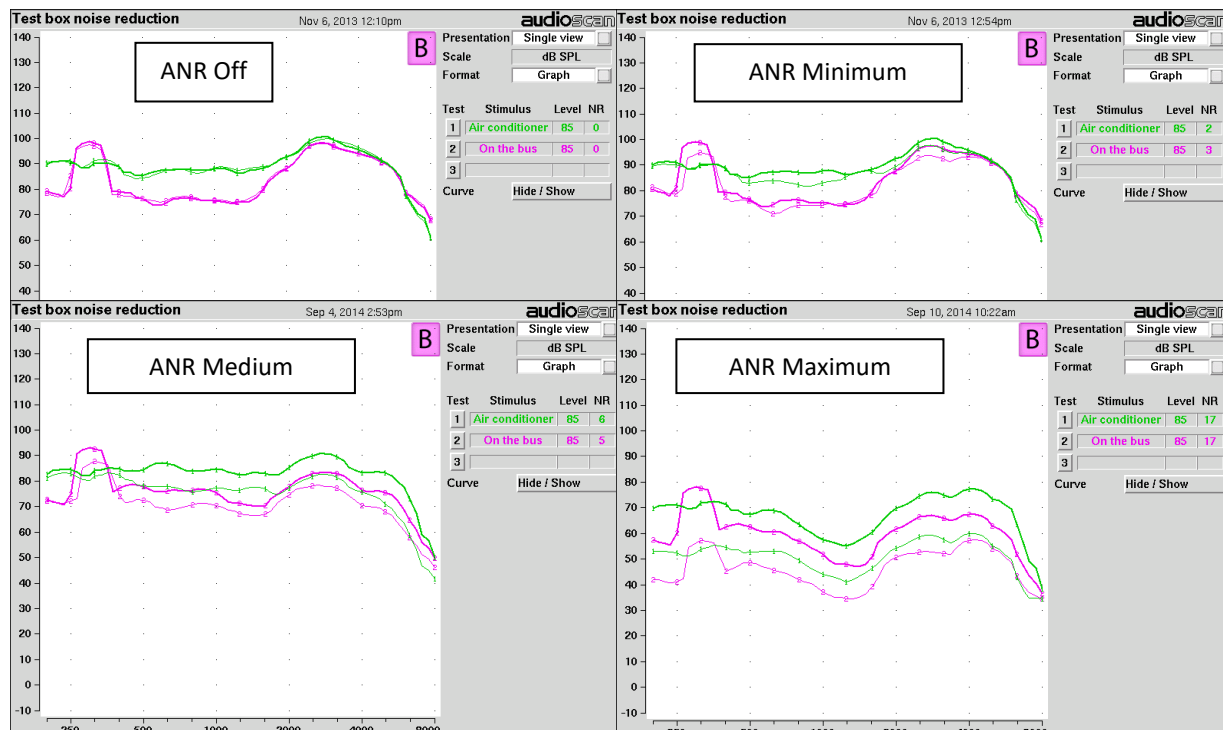


Figure 5. Test results for ANR strength testing across processor settings.

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 (Scollie et al, 2016)

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).

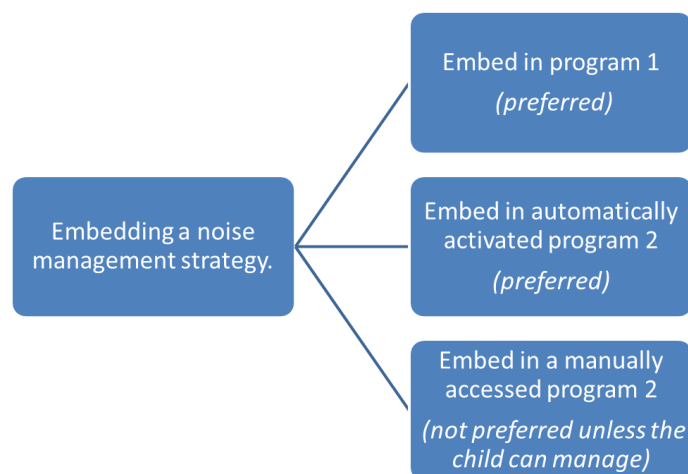
IHP clinicians are advised to consider the objectively measured strength of ANR systems when interpreting whether a noise management strategy has or has not been effective for an individual child.

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.

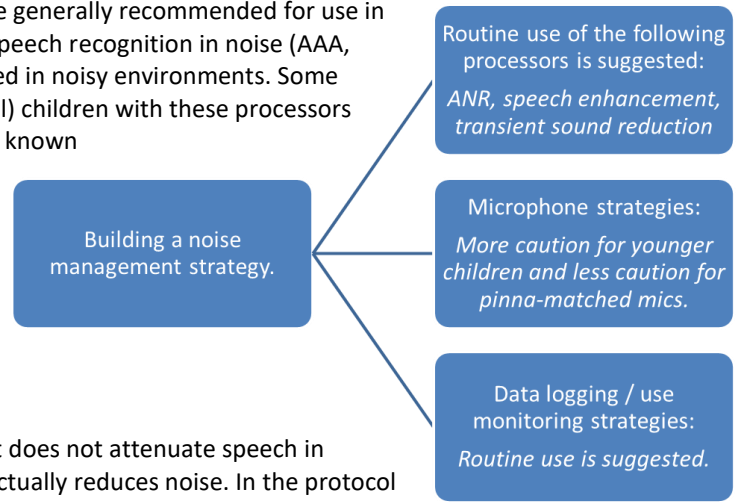
Some hearing aids provide environmental classification and switching between programs, while others do not. For this reason, the noise management strategy may be embedded in an automatically accessed second program, or it may be embedded in the hearing aid’s main program. Either of these options allow 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.

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.

- 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?
- 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.

- 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?
- Family Factors: Involve the caregivers in choosing to provide noise management in order to facilitate their awareness, engagement, and monitoring.
- 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.

- 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.
- Check whether the Loud and/or MPO 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?

- Can you embed it within the hearing aid's only program?
- Can you embed it in an automatically accessed second program?
- Can you embed it in a manually accessed program?

5) Program the noise management strategy, by adding features to the noise management program.

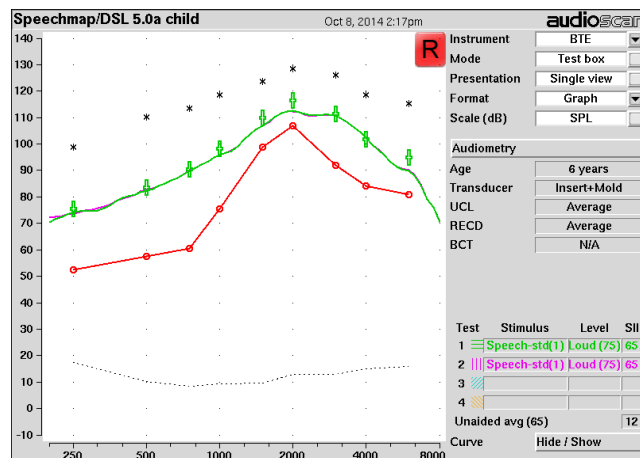
6) Verify the noise management strategy: Does it attenuate speech in quiet?

- Run a 75 dB SPL speech signal to the hearing aid, with and without the noise management strategy enabled.

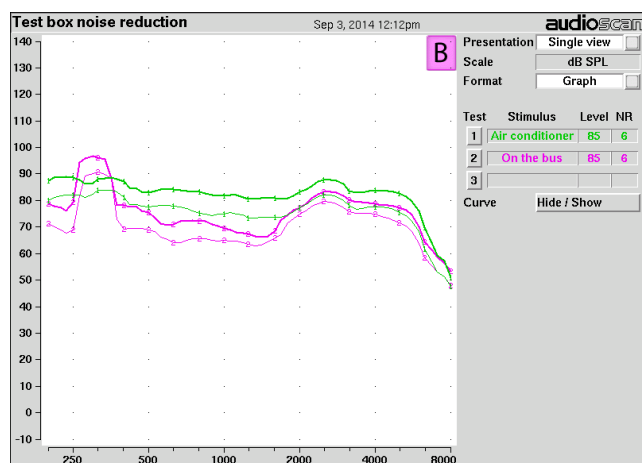
- b. The two curves should be highly similar.
 - c. *Because this step rarely produces any concern, it is sufficient to run this when learning a new make/model/processing scheme, and does not need to be performed on a case by case basis unless there are concerns.*
- 7) **Verify the noise management strategy: Does it attenuate high-level noise?**
- a. Measure a noise reduction signal such as “Air Conditioner” or “Vacuum” 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 aid 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. Other noise reduction stimuli available in this system include 'Vacuum' and 'Multi-talker Babble'.

Test 1: ANR Off

Test 2: ANR On

Thick line: at onset of signal.

Thin line: after 30 seconds.

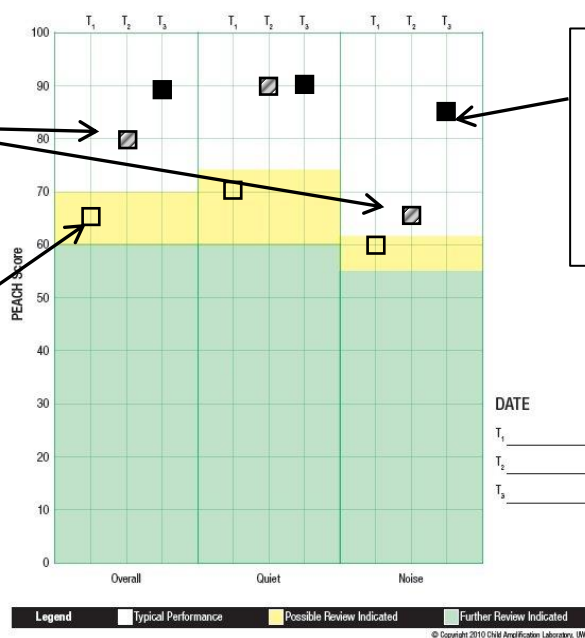
CASE EXAMPLE B: ILLUSTRATING THE ROLE OF MONITORING AND FOLLOW UP

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.

Aided for
2 months, without
noise management
strategy.

Unaided



Aided for
5 months, with
noise management
strategy.

ADDENDUM 4: DECISION SUPPORT GUIDE FOR HEARING AID USE IN INFANTS & CHILDREN WITH MINIMAL/MILD BILATERAL HEARING LOSS¹

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 is currently 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.

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

¹This 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.

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 Protocols). 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.

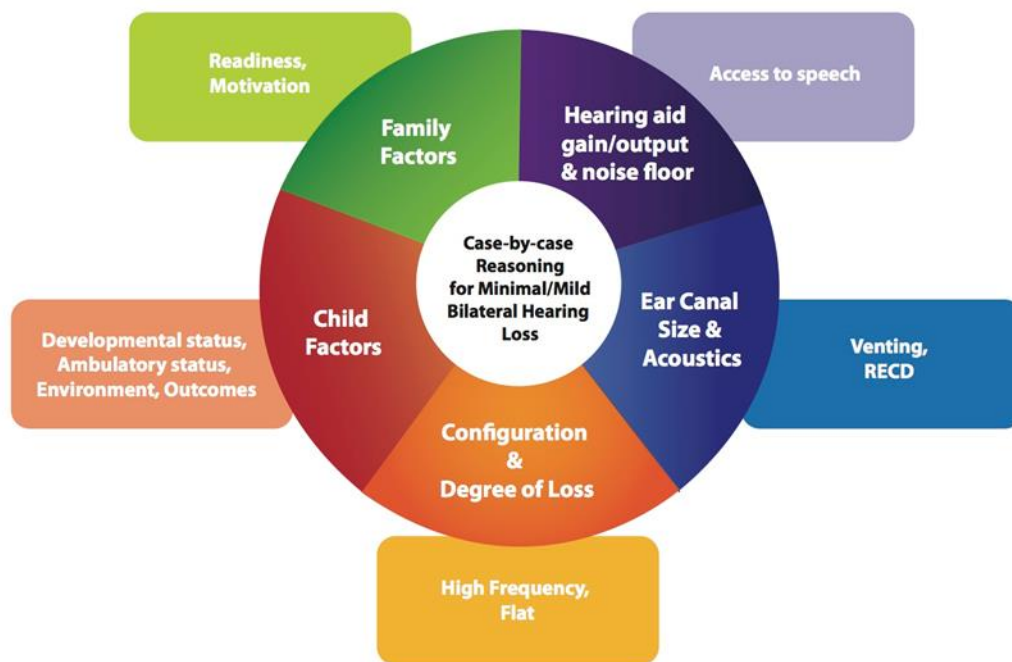


Figure 1. Factors to consider when determining the appropriateness of a hearing aid for an infant or child with MBHL.

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 Protocol for Audiometric Assessment for Children Aged 6 to 60 Months. 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 greater than 25 dB HL at any frequency in the range of 0.5-4 kHz, in either ear....not including loss attributable to non-structural middle ear conditions”. IHP assessment procedures often elicit an estimated or minimum response from the infant or child at 25 dB eHL or HL. This is considered to be “IHP normal” within our program. It is possible that a child may have a 25 dB threshold at one

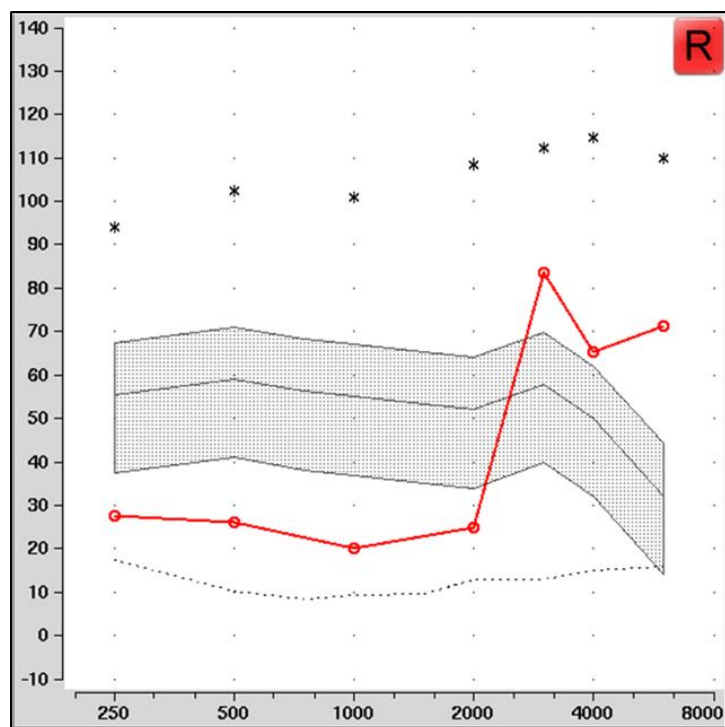
frequency and a 30 dB threshold at another in the same ear, in which case, the decision algorithms provided in this document may provide some guidance.

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 2. 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.

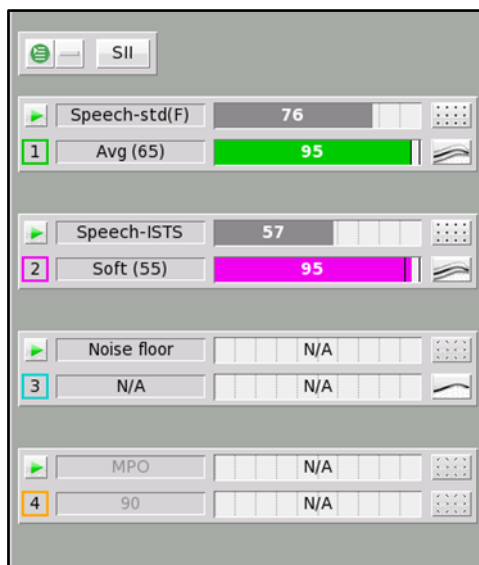


An occluding earmold will not allow sound to escape in the low-frequency region thus providing amplification in an area where little or no hearing aid gain is needed. This may interfere with the hearing aid benefit necessary in the

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. A noise floor measurement within some hearing aid test systems allows a test of the internal noise produced by the hearing aid (see below).



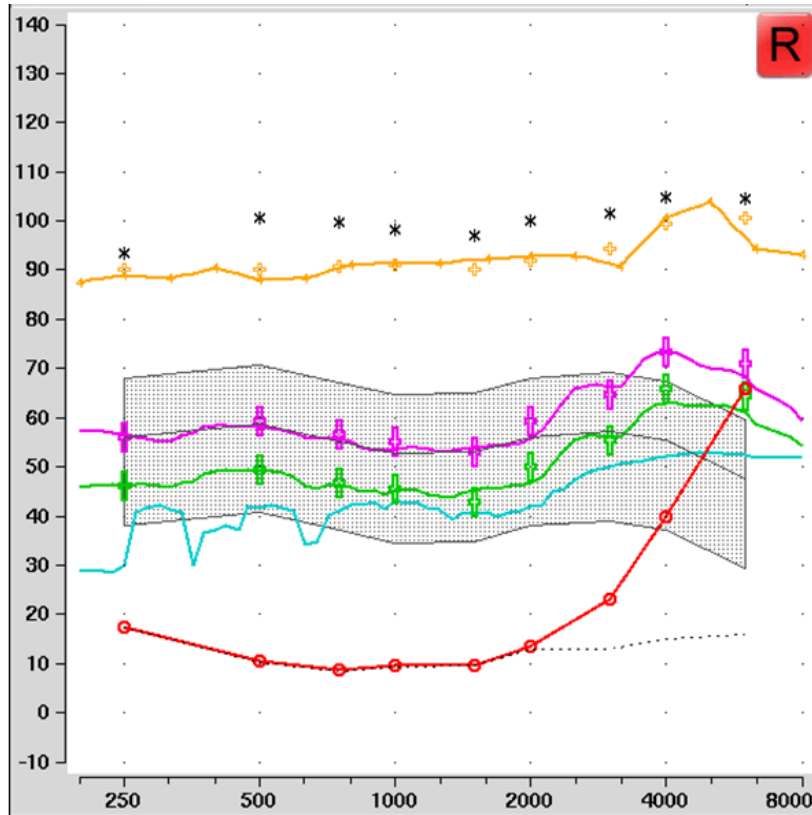


Figure 3. An example of a low-gain hearing aid fitting. The x-axis is frequency (Hz) and the y-axis is sound pressure level (SPL) at the eardrum. The blue line is the hearing aid's noise floor which may be heard by the listener. Note that soft aided speech (green line) is not much better than the noise 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 LittleEARS 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.

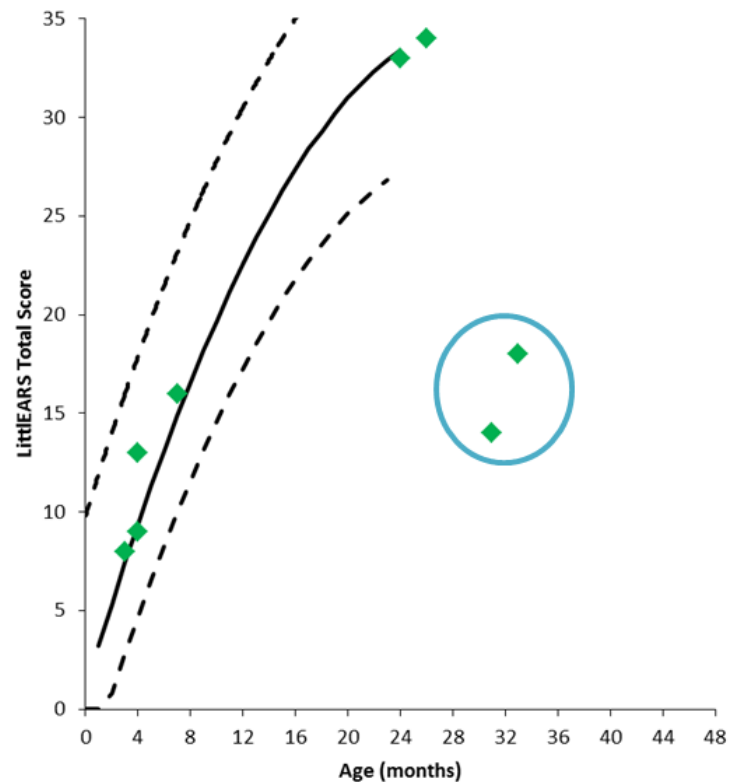


Figure 4. An example of LittleEARS scores (y-axis) by age (x-axis) for children with unaided MBHL. The solid line represents the average LittleEARS scores for normal hearing children and the dashed lines are the upper and lower 95% confidence intervals. The diamonds represent individual child's LittleEARS 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.

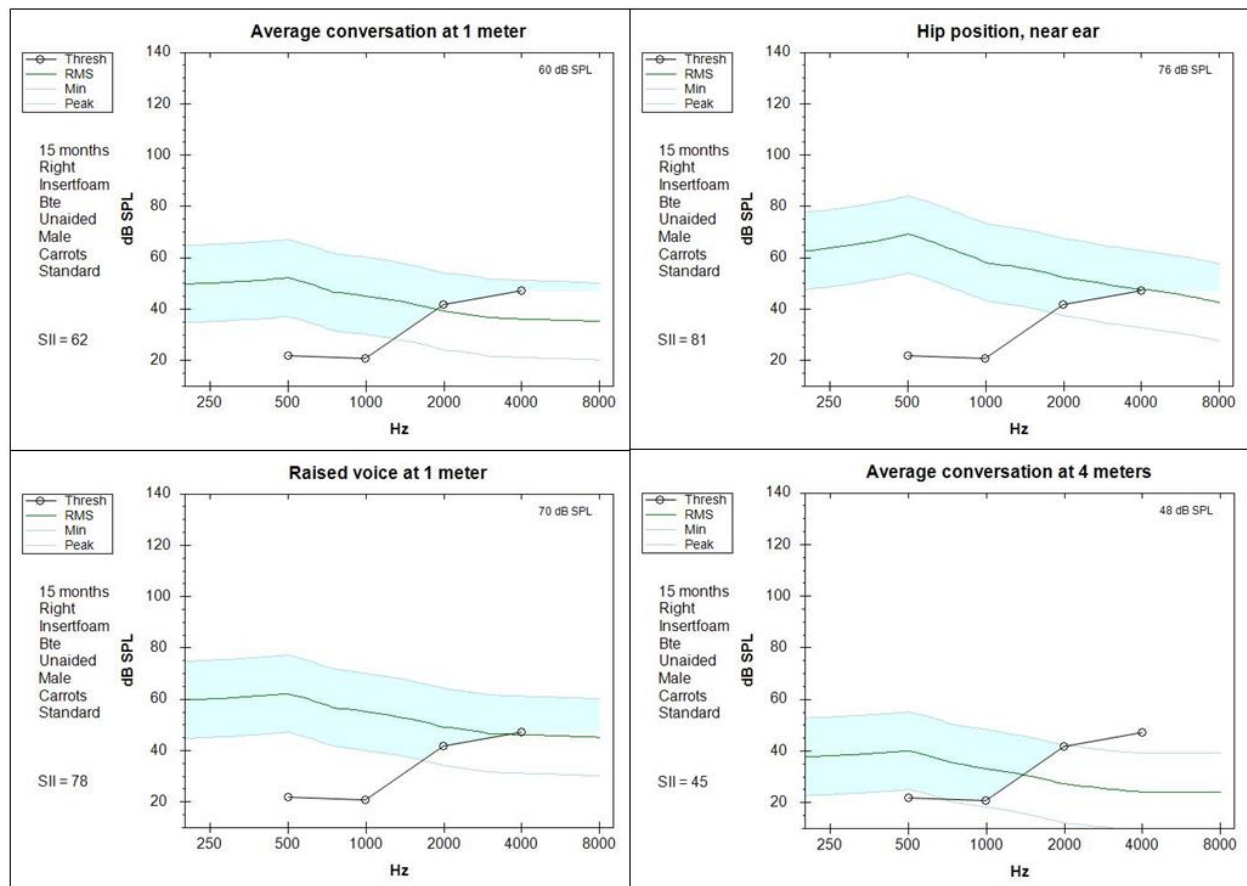


Figure 5. Examples of the audibility of speech for a given hearing loss in SPL at various levels and distances for a child with MBHL. SII values are provided to inform the index of speech audibility.

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., LittleEARS, 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.

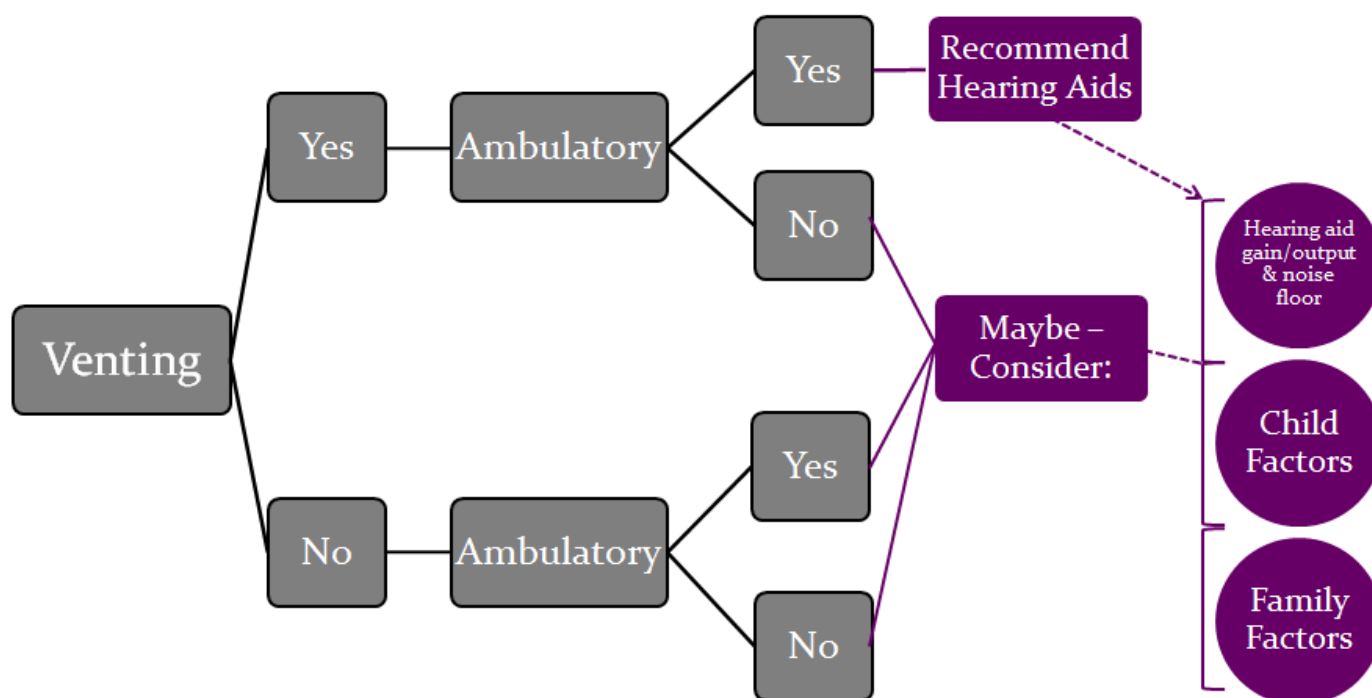


Figure 6. Decision support guide for clinicians considering hearing aids for infants and children with MBHL.

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.

ADDENDUM 5: MANAGEMENT OF INFANTS & 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, 2014, 2018) 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 IHP 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).

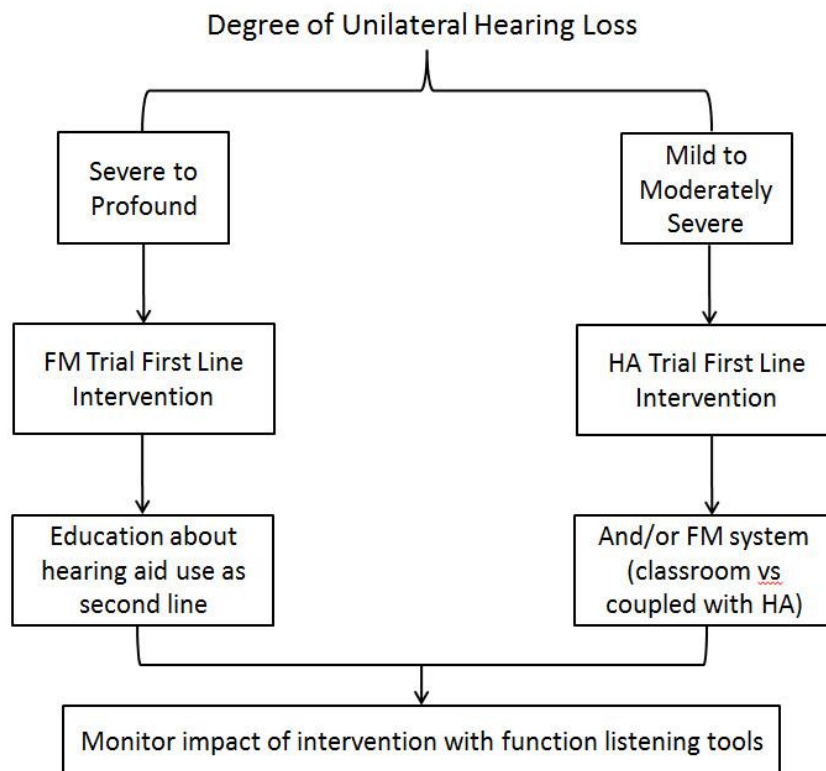


Figure 1. Summary of management recommendations for children with permanent sensorineural unilateral hearing loss. Copyright 2009 Cincinnati Children's Hospital Medical Center.

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 Protocol, 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 LittEARS 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, Richter & 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. 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).

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 IHP. 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).

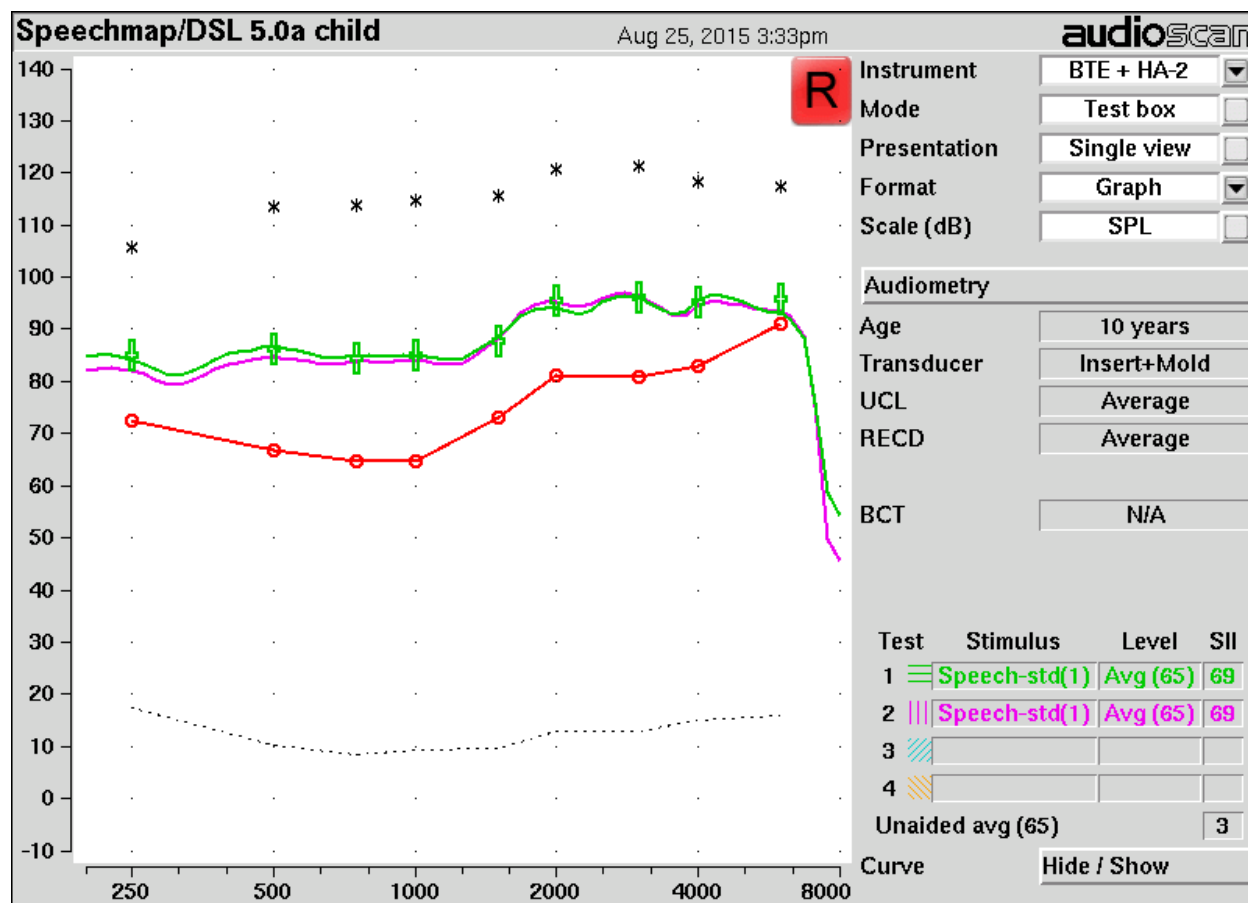
A GUIDE TO THE GUIDELINE

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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End IHP Protocol for the Provision of Amplification Version 2019.01