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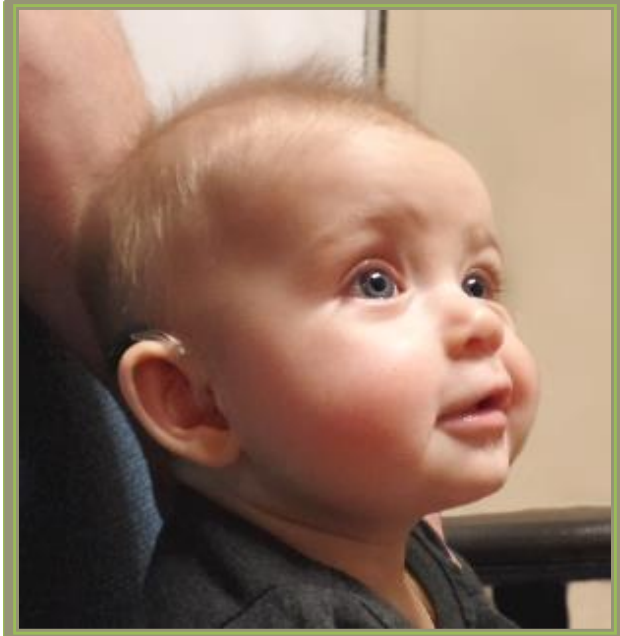
Protocol for the Provision of Amplification



Ontario Ministry of Children, Community and Social Services

Ontario Infant Hearing Program

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The evidence-based clinical protocol statements in this document are the responsibility of the Child Amplification and the Pediatric Audiology Strategies and Systems Laboratories at the University of Western Ontario and detailed endorsement of any specific product or by any other person is not implied. The programmatic, process and outcome review, and contractual statements in this document are the responsibility of the Ontario Ministry of Children, Community and Social Services. We would like to thank Marie Pigeon, April Malandrino, and Jill Witte for their review of the document.

CONTENTS

SECTION 1: INTRODUCTION

This Protocol addresses the provision of amplification (hereafter: 'Amplification') to infants and children who are receiving services from the Ontario Infant Hearing Program (IHP). For the purposes of this protocol, providing amplification includes the processes of prescribing a hearing aid (air or bone conduction) and/or other hearing assistance technologies based on appropriate assessment information, verification that the specified acoustical performance targets have been achieved, fitting the device on the child, and ongoing evaluation of device effectiveness in daily life. Amplification within the IHP does not include the provision of cochlear implants.

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 listed here that are described in separate documents. 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
August 2023	Protocol for the Provision of Amplification 2023.01	Protocol for the Provision of Amplification 2019.01
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 2023.01

The revisions to this version of the Amplification protocol include the following new and revised addenda that reflect updated evidence and procedures: 1) fitting bone conduction hearing devices (BCD) to infants and children; 2) a major revision to the unilateral hearing loss addendum; 3) minor revisions to the mild bilateral hearing loss addendum; and 4) updates to the outcome measurement protocol. In addition, some housekeeping changes to include recent evidence, improved terminology, and clarification, as required, are noted throughout.

Topic	Description	Section
Outcome Measures	Minor revisions to condense and clarify the section.	Section 7.3; Appendix G

Minimal/Mild Bilateral Hearing Loss	Updated to include use of the unaided SII in candidacy considerations for amplification.	Addendum 4
Unilateral Hearing Loss	Revised to incorporate recent evidence-based practice considerations for management options.	Addendum 5
Bone Conduction Device Verification	Added to provide fitting and verification guidelines in the context of the IHP.	Addendum 7

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) Prescriptive targets for bone conduction device verification will be included when they become available
b) New outcome measurement tools may be included
c) Updates to Noise Reduction Addendum to incorporate new evidence
d) Review evidence for use of device-specific apps with hearing aids and children and their families

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 et al., 2017; www.OCHLstudy.org; Moeller & Tomblin, 2015).

For the purposes of this document, a 'hearing aid' is defined as any electronic device, excluding cochlear implants, fitted to the ear or skull and designed to amplify and deliver sound 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, to limit the levels of loud sounds, and often use signal processing and/or streaming to improve signal quality, clarity, or access. 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, as bilateral-contralateral-routing-of-signal (BiCROS), or contralateral-routing-of-signal (CROS), and bone conduction devices (BCD).

Remote microphone hearing assistance technologies are devices used 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 definition includes permanent hearing loss (PHL) of 30 dB HL or more at 0.5, 2 or 4 kHz in any ear, auditory neuropathy spectrum disorder (ANSD), 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 that are likely to resolve spontaneously (see the ABRA protocol for detailed discussion of target disorders and conductive hearing loss). For the latter case, discharge from the IHP to the Ontario Health Insurance Plan (OHIP) based system with caregiver counselling and discretional referral to a physician is the norm.

2.5 AMPLIFICATION CANDIDACY

Infants and young children are considered candidates for amplification if they have been identified by an IHP Audiologist as having PHL. If their family elects it, their child will receive amplification and audiological follow-up services through the IHP until they are 6 years of age (see IHP Guidance Document). Children up to 6 years of age include infants (up to 12 months), toddlers (1 to 2 years), preschoolers (3 to 5 years), and middle childhood (6 years). The provision of amplification in infancy is critical to support optimal outcomes and this protocol includes strategies to achieve this. For simplicity, the term "child" or "children" will be used throughout the document to include the age range that is addressed in this protocol.

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 there are no contraindications, the process of Amplification shall be undertaken in a timely manner (see Section 2.21 for more details).

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 children in this program shall be registered prescribers with the Assistive Devices Program (ADP). The IHP Audiologist who prescribes the hearing device(s) (Prescriber) is responsible for ensuring the device(s) are verified according to this protocol **prior** to being fitted to the child in the IHP.

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 and authorized by the ADP. 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 children 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., SPLogram, 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). This information shall be shared by the Dispenser to the Prescriber for review prior to the initial or subsequent fittings of the devices to the child in the IHP.

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 Hearing Aid Fitting and Verification Checklist found in Appendix H & I of this document can be used for documentation purposes.

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. Consultation with the Western Designated Training Centre (DTC) for Amplification is recommended, as needed, and welcomed, for discussion about challenging scenarios. This does not mean that this protocol is generally discretional and the Audiologists' competency is not required. Protocols are developed for the typical use case of trained pediatric audiologists and unique child and family/caregiver scenarios are natural. When this occurs, clear documentation is a requirement. 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 Amplfication 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 Universal Newborn Hearing Screening.

2.12 CLINICAL DECISION SUPPORT BY DTC

Audiologists who have questions or concerns 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 child in the IHP 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 reviews. 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 checklists found in Appendix H & I to prepare and include it with each child's chart. This will serve as preparation for the future 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. The primary purpose of the review is to determine whether the child or family in the IHP are currently or have been exposed to risk and if so, mitigate immediately. The second purpose is to consider the events that led up to the scenario under review. Regardless 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 provider(s) involved may be subject to adverse event-triggered practice review by a DTC. Early in the review process, the IHP Lead Agency must also notify the MCCSS with information about the circumstances, date of occurrence, and any steps the provider is taking to address or prevent a similar occurrence from happening in the future.

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 and specifications 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.

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 and comprehensive 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 children 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, 2019). 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 three to six months but a completed process of prescription, verification and adjustment, if necessary, and the provision of appropriate hearing aids no later than six months corrected age. This timeline may require that the hearing aid evaluation appointment typically occur by four months of age, which in turn may mean that the audiological assessment and review by an otolaryngologist be completed by about three months, wherever possible. This is reasonably consistent with initiating the assessment process by about six to eight weeks corrected age. Of course, factors such as illness, active middle ear disorders, audiometric uncertainty, and/or child and family readiness may cause significant delays in the timely 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 EHDI programs, but is itself an ambitious target in the population of neonatal intensive care unit (NICU) graduates and unaddressed social determinants of health. 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 a child in the IHP no later than one month from hearing loss confirmation and caregiver election to pursue amplification (JCIH, 2019).

Where not medically contraindicated, the provision of air conduction hearing aids 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. Bone conduction devices (BCD) may be fitted as early as two months of age (Bagatto et al., 2021; IHP BCD Addendum).

There are several challenges that must be taken into account when considering providing air conduction hearing aids to an infant *less than* three months of age. For example, the first three months of life is a period of rapid change in the acoustical and physical properties of the external auditory meatus. This can cause difficulty in achieving a satisfactory and stable earmold fit required for a behind-the-ear hearing aid, and may necessitate many follow-up visits for adjustment or repeat ear impressions to reduce acoustic feedback. 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. Provision of hearing aids by three months of age is encouraged, if possible. Clinicians shall adopt proactive strategies to anticipate these issues (JCIH, 2019).

Infants and children 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 capacity to participate in the process, and/or due to illness in the child, it should be fully documented by the IHP audiologist.

Within the IHP, children 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 children 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 (MBHL Addendum). Children 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 (UHL Addendum). Children who have been identified as having an Auditory Neuropathy Spectrum Disorder (ANSD) component to their sensorineural hearing loss, and where reliable 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 shall be evaluated behaviourally and demonstrate reliable hearing levels, 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). Evaluation by an ENT is strongly recommended to obtain imaging to establish the status of the auditory nerve during this process.

Infants in which no response by ABR is determined in either ear 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 sensorineural hearing loss in both ears is included as part of the candidacy criteria for cochlear implantation. For these children, referral to a CI program is recommended if the family is considering spoken language support for their child.

Infants who have unilateral or bilateral microtia, atresia, and/or stenosis should be considered candidates for bone conduction hearing devices (BCD). For these infants, supporting spoken language through BCDs is a suitable option which can be offered as early as 2 months of age (Bagatto et al., 2021). Surgical candidacy is around 5 years of age and providing access to spoken language through non-surgical BCDs in the early months of life stimulates auditory development. Further information on candidacy, selection, and verification of BCDs for children can be found in Addendum 7 (BCD Addendum).

2.22 LANGUAGE DEVELOPMENT SERVICES

Regardless of whether the child is provided with amplification for their degree of loss, as part of the IHP, language development services for spoken or signed language development (American Sign Language [ASL] or Langue des signes Québécoise [LSQ]) are offered to children with PHL to assist with language acquisition and development. The goal of language development services is to support the child in acquiring a language to the best of his/her ability by the time they enter school. Service providers who are involved with the child and family, including the IHP Prescribing Audiologist, meet with the family a minimum of every 6 months to develop or revisit a Communication Development Plan (CDP) and establish/modify goals based on the child's progress and the family's goals. Language development services are not designed to support development of a child's bimodal bilingualism in spoken and signed language. If a family wishes for their child to also develop the second language, they will be directed to other community programs or online resources. Details about language development services in the IHP and a comprehensive description of roles and responsibilities related to language development can be found in the *Language Development Services Guidelines for the IHP* document.

2.23 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).

2.24 CALIBRATION

The IHP audiologist shall perform at least weekly microphone checks 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.

2.25 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.

2.26 AMPLIFICATION COMPONENTS

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

- A complete description of the child's audiometric thresholds for both ears as described in the IHP Assessment protocols;
- Accurate ear impression(s) for the purposes of fabricating an earmold if fitting an air conduction hearing aid;
- A description of the acoustic characteristics of the child's ear canal(s) in the form of a real-ear-to-coupler difference (RECD) if fitting an air conduction hearing aid;
- DSLv5-child target ear canal sound pressure levels (SPL) for the amplified long-term average speech spectrum for speech at soft, conversational, and loud levels;
- DSLv5-child target ear canal SPLs for defining the maximum power output of the hearing aid;
- Consultation by an otolaryngologist;
- An assessment of the non-electroacoustic needs of the child;
- Verification that the electroacoustic characteristics of the hearing aid(s) adequately match the auditory needs of the child using simulated measurements of the real-ear aided response (REAR);
- Instruction and counseling sessions with the parent/caregiver when the hearing aid(s) are initially 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.

2.27 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 child'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, LittlEARS, 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 H or Appendix I 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.

2.28 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 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. These assessments are mainly, but not exclusively, frequency-specific ABR (FS-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, 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. The ABRA protocol considers and makes provisions for losses that include ANSD or conductive components; and it is understood that some of these may include as the first line of intervention, further testing,

including at times, waiting for behavioural testing. 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*.

3.2 AUDIOMETRIC THRESHOLDS (Minimum Requirements)

The availability of frequency-specific threshold data is important for the prescription of amplification and may be dependent on the method of audiometric assessment used for the initial diagnosis of hearing loss. 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. 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 or 4000 Hz in each ear for bone conducted stimuli (where required). For infants with stenosis/atresia or other conditions that would preclude testing by air conduction, bone conducted stimuli at 500, and 2000 or 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, 3000 Hz) are recommended, but not required for the initial provision of amplification.

Delay in the process pending the collection of discretional 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 in each ear on the ABR and ANSD is not suspected, 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. For unilateral no response cases, please consult Addendum 5 (UHL Addendum) for guidance.

3.3 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. The goal of the consultation is to establish the absence of medical contraindications to amplification and this may occur during the same consult for the etiologic investigation of the PHL (see below). Should there be a delay in the family accessing an appointment, and where obvious medical contraindications are absent (e.g., ear drainage), provision of loaner devices may be pursued at the discretion of the IHP Prescribing Audiologist.

In the IHP context, an assessment by an otolaryngologist shall be recommended to the child's primary care physician or by direct referral (if possible) 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.

3.4 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 targets and responses for a hearing aid, has been shown to be highly repeatable and valid, and is a required element in the Amplification process for infants involved in the IHP.

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.

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 required 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 and children, 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.

3.5 RECD MEASUREMENT

Wherever feasible, IHP audiologists shall measure the child's RECD as part of the Amplification process, 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; Watts et al., 2020). In cases where ear anatomy is similar between sides, RECD values measured from one ear can be used for the other ear (i.e., the IHP audiologist only needs to measure RECD from one ear). In the event that the individual measurement is unobtainable, previously-measured RECD values (if available) or age-related predicted values can be applied (Bagatto et al., 2002). See below for more information.

RECD measurements should be obtained from each child using an IHP approved real-ear hearing aid test system (see Appendix A) following the procedures equivalent to Moodie et al. (1994) and Moodie et al. (2016). RECD values, tester, coupling type (earmold, foamtip, immittance tip), coupler type (HA-1, HA-2, HA-4), ear and test date shall be documented and retained on file. The Hearing Aid Fitting and Verification Checklist (Appendix H) can be used for documentation purposes.

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 or broadband 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 child's ear along with the probe tube. 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.

Coupling to the ear: Software menu items and ear coupling method for coupling should be set to correspond to the coupling method used to obtain audiometric thresholds. 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). Care should be taken to ensure coupler and ear coupling parameters are entered correctly into the verification system for the appropriate transforms to be applied.

Probe tube placement: Strategies for consistent probe tube placement and obtaining a good seal on the child's ear may facilitate accurate measurement of the RECD. It may be helpful to couple the probe tube to an immittance or pediatric foam tip (otoacoustic emission (OAE) or insert earphone) 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 an appropriate insertion depth for infants younger than about 6 months of age (Bagatto et al., 2006). This technique is helpful in coordinating insertion and ensuring a constant depth placement. In cases where severe leaks or shallow probe tube placement is observed in the RECD, a repeat measurement should be attempted, if feasible. Earmold lubricant may also facilitate successful measurement. In toddlers and children, distraction techniques should be used to hold the child's attention away from the procedure. Overall, the range of probe tube insertion depths for real-ear measurements range from 11 mm to adult insertion depths (28-30 mm) over the lifespan of a child. Past the corrected age of about 6 months, individualized probe tube insertion to 5 mm past the end of the earmold is recommended, and ideally the probe tube may be placed to 5 mm from the eardrum using otoscopic monitoring. Use of software-generated probe tube assistants is not recommended at this time, as none have been validated for use with infants or young children.

RECD troubleshooting: It is recommended that RECDs be reviewed to ensure that they are free from the following common errors prior to use for an individual fitting: 1. Probe tube blocking or pinching; 2. Leaks; 3. Shallow probe tube placement, as reviewed in training. It may be most feasible to review the HA-1 equivalent RECD to determine the quality of the measurement (Bagatto et al., 2001; see Appendix A for more information).

RECD re-measurement: Because the RECD changes as a child's ear grows, re-measurement of the RECD is indicated on a regular basis. A common guideline is to re-measure when the earmold is re-made. Clinical workflows can follow an earmold-driven order: re-make the earmold first, then trim tubing to fit, then conduct repeat audiometry with the newly-made earmold, and then measure the RECD and re-adjust the hearing aid. This order of operations ensures that each re-adjustment is made with a valid RECD that has good correspondence with the measured audiogram. In cases where the earmolds are not provided by the IHP prescribing audiologist, the dispenser shall notify the prescriber of the new earmold(s) so that the above-mentioned measures can be made in a timely manner.

Previously-measured RECDs: 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 a 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 when choosing to enter a child's previously-measured RECD where a newly-measured one is unavailable (e.g., a hearing aid review where the earmold has not been replaced, suggesting no change to the child's ear canal acoustics). The RECD coupling type can be entered in the drop down menu shown in Figure 1 below.

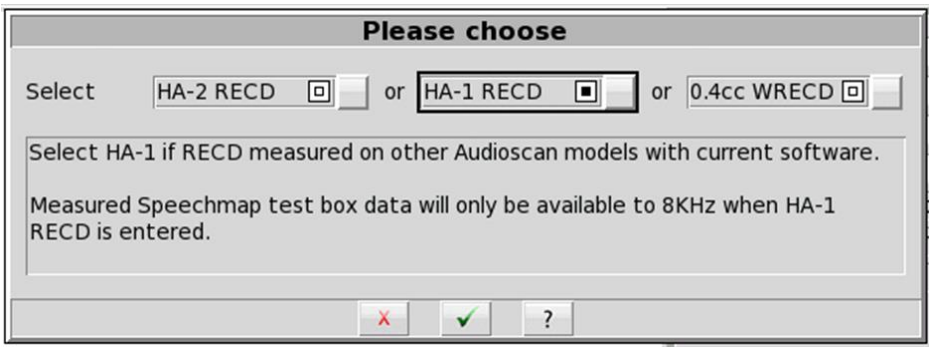


Figure 1: RECD coupler selection screen on the Audioscan Verifit 2

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. For 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://www.youtube.com/@RealEarMeasurement.

3.6 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 and children. 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 child'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 activate/deactivate advanced features, ability to limit volume control ranges, remote microphone system compatibility, and tamper-resistant battery doors are important considerations when providing hearing aids to infants and young children.

Children with confirmed PHL in both ears shall be fitted with bilateral air or bone 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).

Behind-the-ear (BTE) hearing aids are most appropriate for the majority of infants with sensorineural hearing loss 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. 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.

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).

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 BCDs, bone conduction hearing aids on a soft headband shall be considered. See Addendum 7 (BCD Addendum) for further information.

Wireless remote microphone connectivity shall be included on the selected devices. This will enable coupling of assistive technology, such as remote microphone systems, to the hearing aids. Tamper resistant battery doors shall be included on hearing aids for infants and young children. 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.

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 bilateral cochlear implants are no longer eligible for IHP amplification services. Children who use bimodal amplification (cochlear implant on one ear, hearing aid on the other) remain eligible for IHP amplification services for the side

with the hearing aid. There should be regular discussion between the CI audiologist and the IHP amplification audiologist, if they are different practitioners, to ensure consistent messaging and coordinated intervention for the family and child.

4.3 ELECTROACOUSTIC CHARACTERISTICS

When prescribing amplification for an infant or child, 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-child 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.

The use of a systematic, objective approach to electroacoustic selection that incorporates age-dependent variables into the computations for selecting an air conduction hearing aid is required. The formula that shall be used to develop the appropriate electroacoustic characteristics for each child 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, who often have a congenital hearing loss, and for adult patients, whose hearing losses are acquired. This distinction is important in the context of EHDI programs when considering whether the individual expriences hearing loss pre-lingually or post-lingually. Within EHDI programs, most children will have been identified at birth with PHL, and are considered to have congenital hearing loss. They are therefore a suitable candidate for the DSL "Child" targets. Questions arise about continued use of the DSLv5 child versus adult prescriptions when the child reaches adult age (i.e., 18 years), because they still have a congenital hearing loss but have reached adulthood. No direct evidence is available on when or whether to change prescriptions. Young adults who are still engaged in schooling may not wish to make a change to their hearing aid fitting even though they have reached an adult age. As such, changing from DSL "Child" to DSL "Adult" targets may be managed on a case by case basis at the audiologist's discretion. Co-management of this decision may be a strategy to consider. Considerations are listed below.

The difference in DSL targets was based on evidence for adult-child differences in performance ceilings, loudness ratings, and preferences by listening level, with the evidence from adults largely gathered on adults with acquired losses (see review in Scollie et al., 2005). Evidence supports fitting closely to the DSL-prescribed target and bandwidth to match the preferences of children, to support access to speech sounds and longitudinal benefit of hearing aid use for speech and language development, and for speech recognition in quiet (see reviews from www.OCHLstudy.org; Glista et al., 2021; Van Eeckhoutte et al., 2020). Use of the DSL Noise prescription and/or other noise management strategies are also indicated in noisy environments (see review in Noise Management addendum). These two strategies (one fitting for quiet, a different fitting or set of fittings for use in noise) is now commonly-available in most hearing aids and helps to manage exposure to high levels of sound. Long term exposure to aided sound levels with the DSLv5-child prescription is not associated with changes in hearing threshold levels in children (McCreery et al., 2016). However, lifelong management of sound exposure through a combination of noise reduction signal processing, use of lower-gain prescriptions for use in noisy places, and a switch to a non-pediatric prescription at some point in the lifespan can be considered. The recommended exact age or combination of these strategies has not been evaluated in research to date.

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 may be used at the discretion of the IHP prescribing audiologist. Targets and aided responses for the amplified long term

average speech spectrum (LTASS), soft speech, and maximum power output (MPO) across frequency for each ear requiring amplification shall be documented.

For BCDs, DSL targets for percutaneous devices worn by adults are available, however, require further validation for use with children who typically wear transcutaneous devices (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 are further described in Addendum 7, and use the decibels Force Level (dB FL) scale rather than dB SPL (BCD Addendum).

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 or soft headband and hearing aids shall be ordered, with a request for pediatric filtered earhooks, tamper proof battery doors (if applicable), and pediatric care kit.

4.5 OTHER ASSISTIVE TECHNOLOGY

Most infants and children will be candidates for assistive listening technologies and devices other than personally-worn hearing aids. It has been well documented that the use of remote microphone (RM) systems 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 an RM (FM/DM) system may not be used in the first few months of life, when the infant becomes a toddler, they are more likely to spend time in noisy and/or educational environments. 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).

If the IHP audiologist determines that the child is a candidate for other assistive technology, such as an RM (FM/DM) system, the audiologist shall explain the options 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. If the device option is not elected at the time of the initial hearing aid prescription, it is recommended that hearing aid selections be “future proofed” to ensure RM compatibility in future, and that RM systems be discussed with the family during amplification appointments and provided when 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 ELECTROACOUSTIC VERIFICATION

Prior to being fitted to the child, the prescribed hearing aid(s) 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 or FL, 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 G) 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 child'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.

5.2 APPLICATION OF SIGNAL PROCESSING

Automatic feedback suppression technologies should be employed if feedback is noted when the air or bone conduction hearing aid has been placed on the infant's ear following verification. Every attempt to reduce feedback (i.e., good earmold fit, earhook filters, use of lubricant, adjustment of soft headband) should be attempted prior to applying feedback suppression strategies in order to prevent unnecessary attenuation of high frequency output. If applied, verification of the aid shall be conducted following application of these technologies. The application of feedback supression 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 or speech enhancement, automatic program switching, directionality, and frequency lowering processors are continuously evolving. Caregiver or child control of device signal processing is now available for some app-controlled hearing aids. As new technologies and new evidence emerges, IHP clinicians are encouraged to use technologies that meet the listening needs of their patients, and also to consider whether a new technology has been evaluated for use in children, and if not whether and how child-specific considerations should be considered. Specific evidence review and protocols have been developed for frequency lowering, noise management, and remote microphone systems (Addendum 2, Addendum 3, Addendum 6).

5.3 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). Alternatively, use of the EUHA (International Congress of Hearing Aid Acousticians) MPO stimulus may be chosen at the clinician's discretion.

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 and young children 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 to coach them in their skills in daily hearing aid checks.

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., SPLogram, 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 taught 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 or use of chargers for rechargeable devices, 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. Hearing aids may offer a device-specific app that provides an interactive user guide and troubleshooting support; use of these tools is encouraged.

6.2 SHARING 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, which includes a discussion about language development as described in the IHP Language Development Services Guidelines.

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 (FSW) 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. At various points throughout their journey, a family may need 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. If an IHP FSW is unavailable in the region or is unable to provide such support, the IHP Audiologist shall have a local list of connections available for the family and will arrange for the services that are needed.

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 child 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 child to child. Some may require less frequent visits, but for infants identified as having a progressive or fluctuating hearing loss or ANSD component, the regular schedule is especially important. The schedule should be re-assessed on an ongoing, individual basis, with appropriate documentation. Attendance at appointments should be monitored and documented for loss to follow-up.

7.2 FOLLOW-UP VISITS

At each follow-up visit, earmolds shall be assessed for appropriate fit and new earmolds obtained when required. If the child is experiencing excessive feedback with the current earmold(s), feedback suppression technology may be activated in the hearing aid while the child waits to receive their new earmold(s). 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. Otoscopy, middle-ear analysis, and assessment of hearing levels (typically behaviour-based) using the child's (new) earmolds connected to the transducer shall be done (see IHP Assessment Protocols). 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.

Each follow-up visit shall also include an incremental history from the family including use, care, and maintenance of the hearing aids, which should be discussed as parents' questions arise, or as re-instruction is required. Satisfaction with use of the hearing aid(s) and the child's progress shall also be discussed using the IHP Outcome Measurement Protocol. Since 2010, the IHP has implemented a systematic, evidence-based Outcome Measurement Protocol for children who wear hearing aids. The protocol consists of caregiver questionnaires that assess auditory development (i.e., LittlEARS Auditory Questionnaire; Tsaikpini et al., 2004) and auditory performance (i.e., Parents' Evaluation of Aural/Oral Performance of Children [PEACH]; Ching & Hill, 2005) as well as a caregiver 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 [R2017]) are used to support interpretation of functional outcomes. See Section 7.3 below for more details.

7.3 OUTCOME MEASURES

Caregiver-report functional outcome tools are beneficial at the initial stages of outcome monitoring because objective measures of speech detection and recognition are age and development dependent. Objective assessment of functional benefit by the audiologist requires the child to have appropriate motor and cognitive skills to complete tasks reliably. Additionally, objective outcome assessments may not be suitable with children who have complex factors (i.e., co-morbidities). Caregiver reports (i.e., subjective outcome measures) can be completed by the caregiver regardless of the child's developmental level and provide rich and important real-life information. The IHP Outcome Measurement Protocol (aka: UWO PedAMP) shall be implemented with children of varying ages, developmental abilities and degrees of hearing loss, and the impact of these variables on outcomes have been presented elsewhere (Bagatto et al., 2011; 2016).

Validation of the hearing aid fitting shall be done using procedures outlined in Appendix G (Bagatto et al., 2011; 2016). In brief, the systematic, evidence-based protocol includes tools that assess the following dimensions: 1) caregiver report of early auditory development; 2) caregiver ratings of auditory performance in daily life; 3) child's acceptance and use of hearing aids; and 4) effectiveness of service delivery. The interpretation of these tools is supported by assessing the quality of the hearing aid fitting using a measure of speech audibility.

The IHP Outcome Measurement tools consist of the following:

Tool	Purpose	Description
Amplification Benefit Questionnaire	- Acceptance & use of hearing aids - Satisfaction with services	11 items 5 point rating scale
Hearing Aid Fitting Details	- Quality of hearing aid fitting	RECD, MPO, Speech Intelligibility Index (SII), Datalogging
LittlEARS Auditory Questionnaire *(Tsiakpini et al., 2004)*	- Receptive & semantic auditory behaviour - Expressive vocal behaviour	35 items Yes/no response
Parents' Evaluation of Aural/Oral Performance of Children (PEACH) *(Ching & Hill, 2005)*	- Communication in quiet & noise - Responsiveness to environment	13 items 5 point rating scale

Caregiver questionnaires (LittlEARS, PEACH, and IHP Amplification Benefit Questionnaire) are administered and scored by the IHP Prescribing Audiologist at regular intervals. The caregiver-report functional outcomes are supported by documentation of the clinical processes leading to each child's hearing aid fitting, including the real-ear-to-coupler difference (RECD; measured or predicted), and comparison of 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). Datalogging for each device should also be noted at each follow-up appointment to reflect wear time dosage for the child. These hearing aid fitting details shall be documented using the Hearing Aid Fitting and Verification Checklist (Appendix H & I), and/or elsewhere in the patient chart, as appropriate.

Further information about accessing each tool and the clinical administration of the protocol can be found in Appendix G. 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 child in the IHP. In particular, a child who is not achieving age-appropriate development following outcome measures review should receive further review with other team members to understand, and address where appropriate, any barriers and facilitators to progress. Assessment of the quality of the hearing aid fitting and the Audiologist's review of caregiver questionnaires are a routine part of the Provision of Amplification within the IHP. The IHP Outcome Measurement protocol is appropriate for all children in the IHP identified with permanent hearing loss, regardless of amplification use.

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.

The Training Process Document (2022) describes the process for accessing IHP training. In summary, needs for Amplification training are identified to the Western DTC by IHP Regional Coordinators as they arise. Based on the

information provided by the Lead Agency to the Western DTC, training will be arranged with the Audiologist. Details of the length and scope of training are found in the IHP Guidance Document (2017) and the Training Process Document (2022).

If an IHP Audiologist or Dispenser authorized for Amplification does not carry out the provision of amplification for a period of 6-months or more, the IHP Regional Coordinator must advise the Western DTC of the lapse in practice and refresher training will be arranged. 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.

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 child requiring hearing aid amplification through the IHP. The hearing aid test system should provide DSLv5-child 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. Note that target extrapolation is not part of the DSLv5 system, so extrapolated targets are manufacturer-specific and should be used with caution.

2. FITTING PARAMETERS

(a) Age

The real-ear and hearing aid test system must allow the end user to enter the age or birthdate 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) Hearing Aid Type

The real-ear and hearing aid test system must define whether an air or bone conduction hearing aid is to be fitted to the child. This distinction provides targets and verification options based on device type.

(e) 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.
The DSL Method v5.0 also calculates different prescriptions for use with air and bone conduction hearing devices. This variable creates two different prescriptions: the DSL-BC targets use different transforms for force level output delivered through vibrations of the skull from a BCD (Hodgetts & Scollie, 2017). It is recommended that the real-ear hearing aid test system provides the DSL BC targets for fitting BCDs to children. This requires a skull simulator to facilitate verification.

(f) 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:

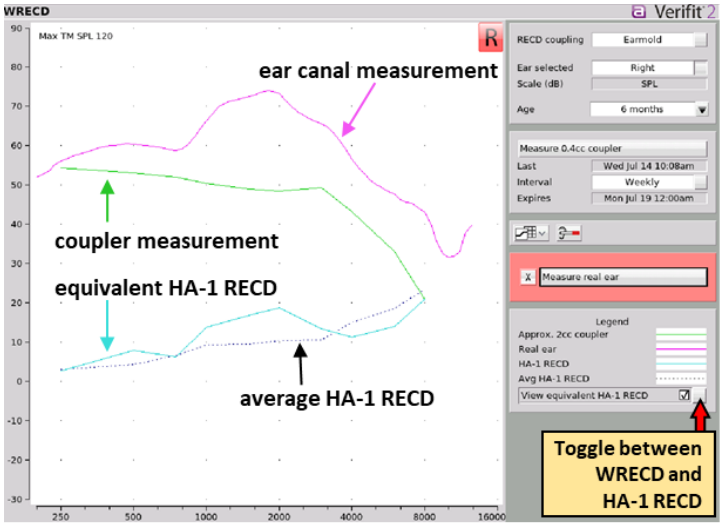
1) insert earphone + foam tip,
2) insert earphone + custom mold,
3) TDH phone,
4) sound field, with specification of azimuth of 0, 45, or 90 degrees
5) frequency specific ABR in either nHL or eHL is preferred. If nHL is supported, the end user must be able to define program-specific corrections to convert nHL to eHL (see *IHP ABRA Protocol*).
6) BCD device type

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 (foamtip, earmold) 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. Certain hearing aid test systems will allow the user to toggle between HA-4 and equivalent HA-1 RECD values in cases where a 0.4cc coupler is used, as shown in the image below.

Some but not all test systems provide corrections that convert foamtip RECDs to/from earmold RECD formats, and that correct for the effects of venting in during fitting to targets using coupler measurements. Such features are preferred because they provide additional verification accuracy for test box verification.



(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 (audiometric or in-situ) 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 on-ear and simulated on-ear or coupler displays, with analysis of the hearing aid in 1/3 octave bands both for percentile analysis and for the long term average speech spectrum. Running speech test signals may include the ISTS signal or any signal that provides equivalent test results. Percentile analysis should be offered for the 99^{th} and 30^{th} percentiles at a minimum. The speech test signals should be equivalent in spectral and dynamic range properties to the ISTS.

A skull simulator supports verification of BCDs using calibrated running speech in a similar way as air conduction hearing aids. The REAR display is referenced to dB Force Level and is described below.

(d) SPL-ogram or Force Level-ogram (FL-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 or FL 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., Remote microphone 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 estimates of true perceptual threshold in dB HL by applying adjustment factors based on empirical, longitudinal validation studies from IHP program data. 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 expressed as 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.

It is important to note that as part of the ABRA protocol, ABR responses are not measured below the minimum response level of 25 dB eHL during ABR assessments. As such, reports indicating "thresholds" of 25 dB eHL, are not necessarily accurate, as true thresholds may be better and could impact hearing aid recommendations and fittings. Conducting hearing assessments below the presentation levels recommended in the ABRA and CBA protocols is at the discretion of the Prescribing Audiologist, with clear documentation, and should not impact service delivery or resources.

APPENDIX C: COUPLING INSERT EARPHONES TO PERSONAL EARMOLDS

During follow-up appointments for children with BTEs, the audiologist shall conduct VRA or CPA using insert earphones. If the child has personal well-fitting earmolds, the insert earphones shall be coupled to them to improve retention in the child's ears and provide a more accurate hearing aid fitting by accounting for earmold acoustics. For a more stable connection between the insert earphone and the earmold, a suggested modification is described below (Figure 1a/b).

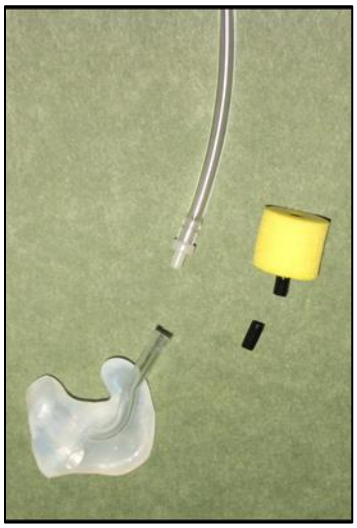


Figure 1a

Figure 1b

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 1a.
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 1b.

Note: Please ensure that the earmold and tubing are not damaged or occluded with cerumen.

Measuring the RECD with the child's personal earmold shall be conducted whenever a new earmold is obtained. In cases where different coupling methods are used for the hearing assessment and the RECD measure (e.g. hearing thresholds measured with earmold and RECD measured with foam tip), verification systems will apply a correction factor to accommodate for the coupling mismatch (Figure 2). Any changes to the child's auditory thresholds and RECD values shall be applied to the hearing aid prescription to ensure appropriate audibility of speech as the child's ears grow and/or audiometric information changes.

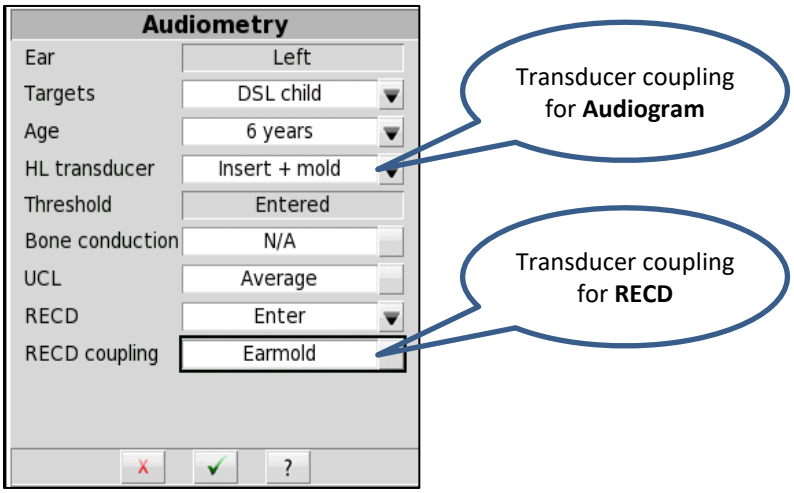


Figure 2: Sample menu for entry of audiometric information into hearing aid test system software.

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. Prepare the parent for what they can expect from the procedure (e.g., child may get upset). Some bracing of the head and torso may be necessary during insertion and hardening of impression material. Let parents know how long they may need to brace the child for, and prepare ways to potentially distract the child until impression is complete.

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 child'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 child'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 child'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 child'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.

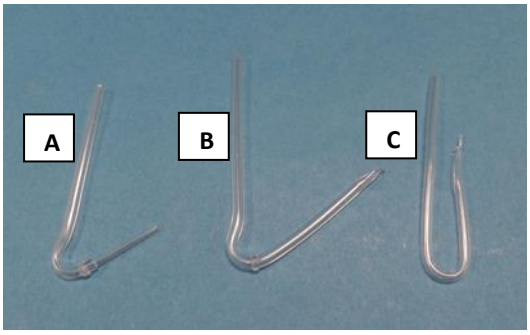
14. Mark the canal for appropriate length and complete the earmold order form.

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/polyvinyl chloride (PVC).

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 1).

Figure 1: 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/PVC 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. Silicone earmolds should be prescribed as soon as the ear canal is large enough to accommodate #13 to #16 tubing with plastic pediatric tube lock. In general, silicone material is less prone to acoustic feedback when compared to vinyl earmolds.

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 properly inserted.

APPENDIX E: ELECTROACOUSTIC VERIFICATION FOR AIR CONDUCTION DEVICES

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. Adjust the aid to provide a close match to the average speech targets for 65 dB SPL and store the curve. A fit within ±5 dB RMSE is preferred, although some steeply sloping or high gain fittings may fall slightly outside of this range. Some systems include normative data for comparison.

3. Choose a high-level (85 – 90 dB SPL) narrowband stimulus or EUHA MPO 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.

4. Choose a 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.

5. 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.

6. Repeat the verification procedure for average and MPO if you made adjustments in Step 5.

7. Repeat steps 1 through 6 with the other hearing aid for binaural hearing aid fittings.

8. 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.

Aided soundfield measurements should not form the basis for the verification of the child's AC hearing aid(s). Aided soundfield threshold testing can be useful for hearing aid validation, counselling and educational purposes, but is not the recommended procedure for verifying amplification for children 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. Families can also be referred to the "Hear On" learning videos if further support is required at the initial fitting or at follow-up appointments (https://www.uwo.ca/nca/fcei/hearon/index.html).

- ☐ Amplification and the speech signal (e.g., explanation of unaided versus 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) including explanation of automatic noise reduction features that have been provided in the fitting, where applicable
- ☐ Review of all items and equipment in the care and maintenance kit provided by the manufacturer
- ☐ Techniques for cleaning earmolds and hearing aids
- ☐ Procedures for battery checks and insertion/removal, or how to charge rechargeable devices
- ☐ Review of how to power the devices on and off
- ☐ Procedures for listening checks of hearing aids
- ☐ Putting hearing aids on the child and securing them – retention and loss-prevention; recommended headband tension for bone conduction hearing aid users.
- ☐ Setting user controls, if applicable
- ☐ 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; hearing aid apps that help with monitoring and troubleshooting.
- ☐ Safety issues (e.g., battery ingestion) and risk mitigation
- ☐ Understanding and combating feedback
- ☐ Protecting the hearing aids from potential hazards (e.g., moisture, pets) and the use of a Dry Aid kit
- ☐ Troubleshooting techniques, including smartphone app installation that provides device-specific user guides and troubleshooting support.
- ☐ Trial periods, warranty and insurance information
- ☐ Financial Assistance information (e.g., Assistive Devices Program, Assistance for Children with Severe Disabilities)
- ☐ Plans for repair of malfunctioning hearing aids
- ☐ Discussion of earmold life expectancy and hearing aid life expectancy
- ☐ Discussion about when to have earmold tubing changed
- ☐ Plans for follow-up contact between the family and clinician including remote support options in smartphone applications.
- ☐ Options to be used at a later date (e.g., T-coil, remote microphones)

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).

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 warranties of up to three years.

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

- Other cleaning tools
- Informational brochures, videos, books, stickers
- Carrying case

APPENDIX G: OUTCOME MEASUREMENT PROTOCOL APPLICATION

Table 1 outlines the IHP PedAMP outcome measurement tools (first column) and the administration schedule for each tool (subsequent columns). In brief, the LittlEARS Auditory Questionnaire shall be administered at the initial assessment, or at a time point prior to initial device use. This establishes a baseline for tracking the child's progress. Routine review of the child's progress continues with the LittlEARS until a score of 27 or greater has been reached AND the child is two years corrected age. The LittlEARS is then replaced by the PEACH once both criteria are met. If the child is older than two years of age and has not reached the ceiling score of 27 or greater, it is up to the Audiologist to consider moving to the PEACH based on the child and family situation. When transition to the PEACH occurs, it shall be used at regular intervals, or as event driven. Additional functional assessments may be introduced by the audiologist at their discretion. The LittlEARS and the PEACH provide the audiologist and caregiver with a measure of auditory skill development over time and is therefore applicable to children with, and without, amplification.

Table 1. Outcome Measurement Tools and Administration Schedule

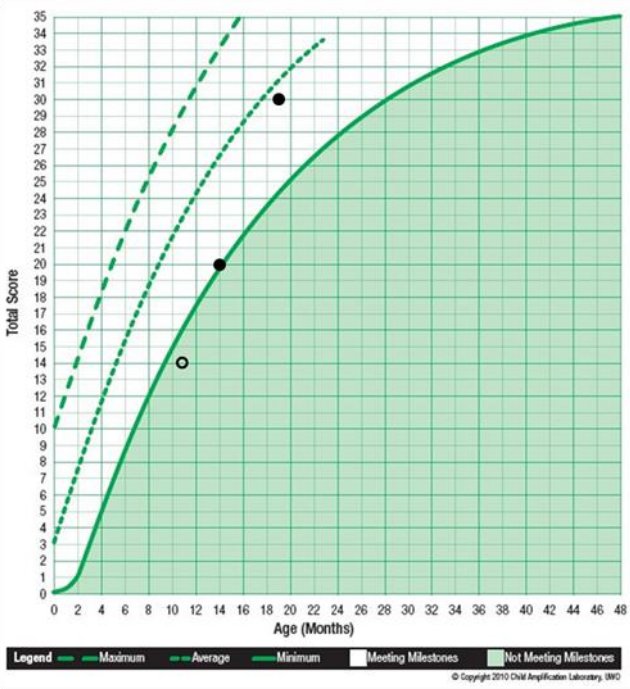
	Initial Assessment	Pre-fitting	Initial Fitting	30 Day Recheck	3 month Recheck	6 month Recheck	Yearly Recheck	Event Driven
LittlEARS	✓ Establish Unaided Baseline: Administer at one of these appointments			✓ If score ≥27 & ≥ 24 mos, stop LittlEARS use PEACH.	✓ If score ≥27 & ≥ 24 mos, stop LittlEARS use PEACH.	✓ If score ≥27 & ≥ 24 mos, stop LittlEARS use PEACH.	✓ If score ≥27 & ≥ 24 mos, stop LittlEARS use PEACH.	✓
PEACH	×	×	×	↓	↓	↓	↓	✓
Hearing Aid Fitting Details	×	×	✓	×	×	×	✓	✓
Amplification Benefit Questionnaire	×	×	×	×	✓	✓	✓	✓

THE LITTLEARS AUDITORY QUESTIONNAIRE

The purpose of the LittlEARS Auditory Questionnaire is to assess the auditory behaviour of infants and young children 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).

The child's performance on the LittlEARS questionnaire (i.e. total number of 'yes' responses) shall be plotted on the corresponding score sheet. In particular, the child's corrected and chronological ages, and total score intersect to identify auditory behaviour performance. Scores that meet, or exceed, age-appropriate developmental targets indicate that the child is meeting auditory development milestones. Scores that indicate that the child is not meeting auditory development milestones shall signal to the audiologist to consider the profile of the child and family and any potential barriers and facilitators to progress. An implementation plan formulated by the caregiver and the entire IHP team shall be considered. The IHP's Individualized Family Service Plan (IFSP) can be used to document and monitor progress. Additional developmental investigations may be indicated if device use and program engagement is appropriate. Referrals outside of the IHP may be indicated and should be reviewed in consultation with the caregiver and/or primary medical professional.

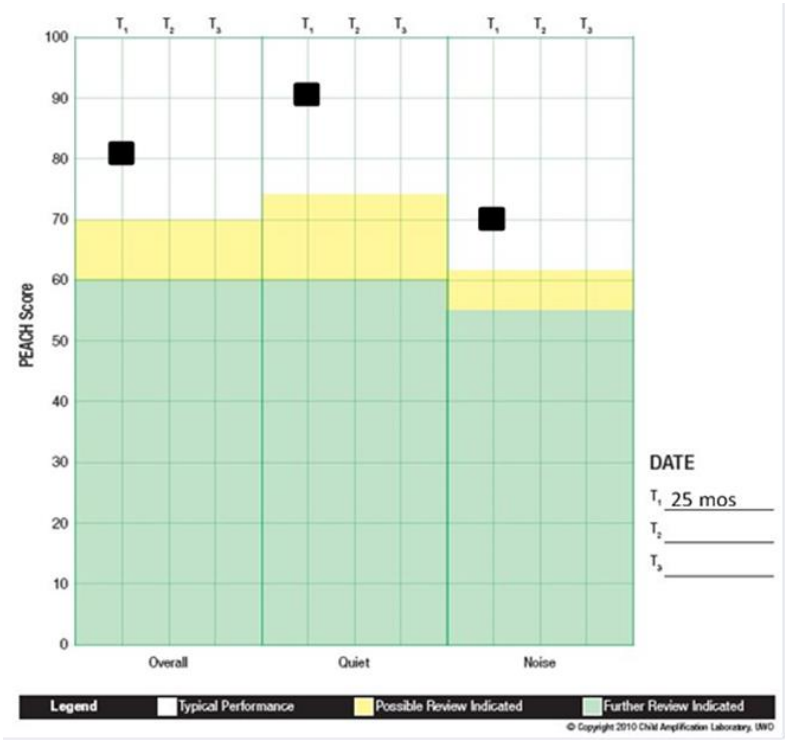


PARENT'S EVALUATION OF AURAL/ORAL PERFORMANCE OF CHILDREN (PEACH) RATING SCALE

The PEACH Rating Scale shall be used as part of this protocol with children who have attained ceiling performance (i.e., total score of 27 or greater and are older than two years of age) on the LittlEARS Auditory Questionnaire.

Caregivers must recall their child's behaviour 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). A longitudinal study confirmed these scoring ranges

on an independent sample (summaries available at www.ochlstudy.org). 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 PHL who wear hearing aids. This tool can assist in identifying whether a child is or is not demonstrating typical auditory behaviors. The PEACH Rating Scale is appropriate for use within the IHP Outcome Measurement Protocol for children identified with permanent hearing loss, whether or not the child has been fitted with a device.



If the child's score(s) fall outside of the typical range, further review is indicated. Case-by-case reasoning shall be used to guide the audiologist and caregiver in identifying potential barriers and facilitators to the child's progress. This may include changes in listening devices or support services to improve progress.

HEARING AID FITTING DETAILS

Children in the IHP fitted with amplification require monitoring of device benefit followed by caregiver report outcome measures review. Positive outcomes of children who wear hearing aids are known to be impacted by audibility provided by the hearing aids and by the "dosage" of hearing aid use, which includes age at hearing aid fitting, audibility of speech, and daily hours of device use (McCreery et al., 2015; Walker et al., 2015; Thompson et al., 2015). The Hearing Aid Fitting and Verification Checklist (Appendix H) was created as an optional tool to assist with tracking the details of the hearing aid fitting at the initial fitting and follow-up hearing aid reviews, in preparation for Standard Practice Reviews. This amplification-specific tool provides a place to document the individualized fitting process (e.g., RECD, MPO), access to speech (i.e., SII) for a given degree of hearing loss, hours of daily hearing aid use (i.e., datalogging), and activation, or not, of other technologies (e.g., frequency lowering, noise reduction). All are known to impact outcomes of children who wear hearing aids.

The Audiologist assesses the hearing aid fit-to-targets by reviewing the Speech Intelligibility Index (SII) values for soft and average speech inputs and comparing them to published norms (Moodie et al., 2017). 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 [R2017]). It is an acoustic measure, not a behavioural 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 by most hearing aid test systems for various speech inputs. If a clinician has performed multi-level speech-based real-ear verification of the child's hearing aids, the associated *aided* SII values for these measurements would be provided and can be compared to the child's *unaided* SII for their given hearing loss. An example of this graphic is displayed below.

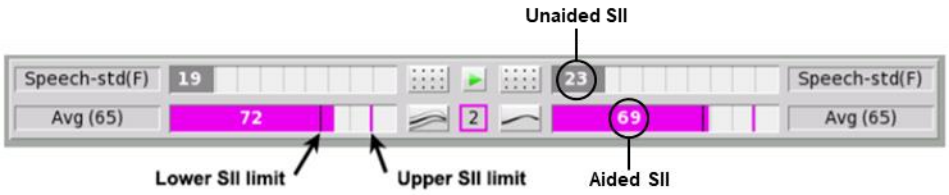


Figure 1: Example of SII normative data displayed on the Verifit 2 (image modified from https://docs.audioscan.com/userguides/vf2manual.pdf)

The individualized SII should fall between the lower and upper SII limits (i.e., the SII normative range based on pure tone average) to ensure optimal auditory access. A review of the fitting process is recommended if an optimal SII has not been achieved.

Completion of the Hearing Aid Fitting Checklist (Appendix H & I) is at the discretion of the IHP Audiologist. Hearing aid fitting details shall be documented in the patient chart.

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 et al., 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.

SUMMARY

The IHP Outcome Measurement Protocol consists of several tools that assess auditory development (LittlEARS) 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). Taken together, these tools 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 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.

APPENDIX H: AIR CONDUCTION 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 discretional 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.

FITTING DETAILS

Transducer used to assess hearing thresholds:
□ insert earphones + personal earmold
□ insert earphones + foam-tip
□ ABR
□ Other: _____

RECD for verification: □ new □ previously measured
RECD Coupler: □ HA-1 □ HA-2 □ 0.4cc WRECD
RECD Coupling type: □ foam-tip □ 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	□ within ±5 dB of DSL targets □ SII within normative range	□ over targets	□ under targets
	L ear	□ within ±5 dB of DSL targets □ SII within normative range	□ over targets	□ under targets
Average level speech (65 dB SPL)	R ear	□ within ±5 dB of DSL targets □ SII within normative range	□ over targets	□ under targets
	L ear	□ within ±5 dB of DSL targets □ SII within normative range	□ over targets	□ under targets
Maximum power output (MPO)	R ear	□ within ±5 dB of DSL targets	□ over targets	□ under targets
	L ear	□ within ±5 dB of DSL targets	□ over targets	□ under targets

CONSIDERATION OF ADVANCED AMPLIFICATION TECHNOLOGIES

Noise management	Candidate?: □ yes □ no Verification documented? □ yes □ no	Feature Enabled?: □ yes □ no _____dB of noise reduction
Frequency lowering	Candidate?: □ yes □ no Verification documented? □ yes □ no	Feature Enabled?: □ yes □ no
Remote microphone	Candidate?: □ yes □ no Verification documented? □ yes □ no	Feature Enabled?: □ yes □ no
Feedback suppression	Candidate?: □ yes □ no □ considered status of earmold(s)	Feature Enabled?: □ yes □ no New earmold(s) required? □ yes □ no
Directional microphone	□ pinna matched/omni □ fixed □ adaptive	
Data-logging	Feature Enabled?: □ yes □ no	hrs/day of use: _____

Comments: _____

APPENDIX I: BONE CONDUCTION HEARING AID FITTING AND VERIFICATION CHECKLIST

FITTING DETAILS

BCD Coupling:

□ Soft headband → tension adjustment completed? ❑
□ Surgical with abutment
□ Adhesive
□ Other: _____

Transducer used to obtain fitting thresholds:

□ ABR bone oscillator
□ Audiometric (behavioural) bone oscillator
□ Bone conduction hearing device (in-situ)
□ Other: _____

ELECTROACOUSTIC VERIFICATION

Verified using skull simulator: □ yes □ no

Were adjustments made? □ yes □ no
If yes, please explain:_____

OTHER VERIFICATION

Other verification method:

□ Sound Field Aided Pure Tones □ Sound Field Aided Ling 6 □ Other: _____

Were adjustments made? □ yes □ no
If yes, please explain:_____

CONSIDERATION OF ADVANCED AMPLIFICATION TECHNOLOGIES

Noise management	Candidate?: □ yes □ no Verification documented? □ yes □ no	Feature Enabled?: □ yes □ no _____dB of noise reduction
Remote microphone	Candidate?: □ yes □ no Verification documented? □ yes □ no	Feature Enabled?: □ yes □ no
Feedback suppression	Candidate?: □ yes □ no □ considered position of BCD □ no	Feature Enabled?: □ yes □ no Is the device tightly secured? □ yes
Directional microphone	□ pinna matched/omni □ fixed □ adaptive	
Data-logging	Feature Enabled?: □ yes □ no	hrs/day of use: _____

Comments: _____

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 et al., 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 updated and/or added to the IHP document in 2023 to further expand on the AAA Guideline and provide IHP audiologists with the necessary tools to apply this knowledge:

1. Management of Minimal/Mild Bilateral Hearing Loss

2. Management of Unilateral Hearing Loss
3. Bone Conduction Devices

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

Link to AAA 2013 Pediatric Amplification Guideline:

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

ADDENDUM 2: FREQUENCY LOWERING 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 audiologist. 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 et al., 2004). Extended bandwidth beyond 4500 Hz has been shown to improve word learning rates and phoneme discrimination in noise for older children, when compared to restricted bandwidth conditions (Pittman, 2008; Van Eeckhoutte et al., 2020). 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 can still limit our ability to provide audibility of high-frequency speech sounds, particularly for more severe losses and sloping configurations. Clinically available hearing aids 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 (Van Eeckhoutte et al., 2020; Glista & Scollie, 2018; Alexander, 2013; McCreery et al., 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 (see review by Glista and Scollie, 2018). 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. Children demonstrate a greater need for audibility of high-frequency cues in speech (see review by Stelmachowicz et al., 2004), and audibility of average-level speech peaks is now possible to 8000 Hz on average for children with mild to severe hearing loss (Van Eeckhoutte et al., 2020). 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).

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; 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 (see image below).

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.

There may be situations where only the LTASS, but not the peaks of speech, cross the threshold line (eg., only partial audiometric data is available; configuration of the child's audiogram), in which case it may be necessary to extrapolate an estimation of the threshold line to obtain an MAOF range for fitting frequency lowering (see Case Example D for more information). Furthermore, for more mild losses or flat configurations, the hearing aid output (LTASS and peaks of speech) may not intersect with the threshold line at all, suggesting that high frequency speech stimuli are audible in the absence of frequency lowering activation.

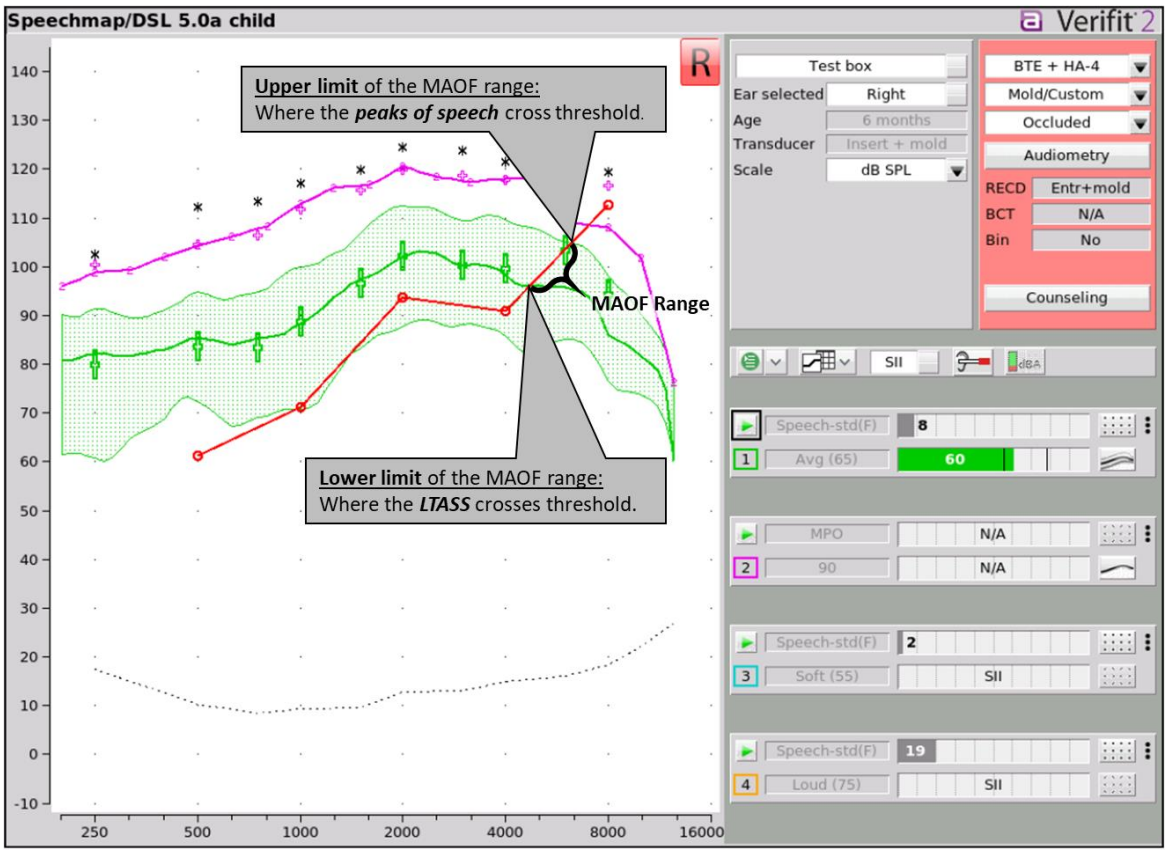


Figure 2. An Audioscan® Verifit2 test box screen measurement of the LTASS (with peak and valley measurements displayed) in reference to the hearing threshold line for an average presentation level. The MAOF range extends from the point where the LTASS crosses threshold to the point where the peaks of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

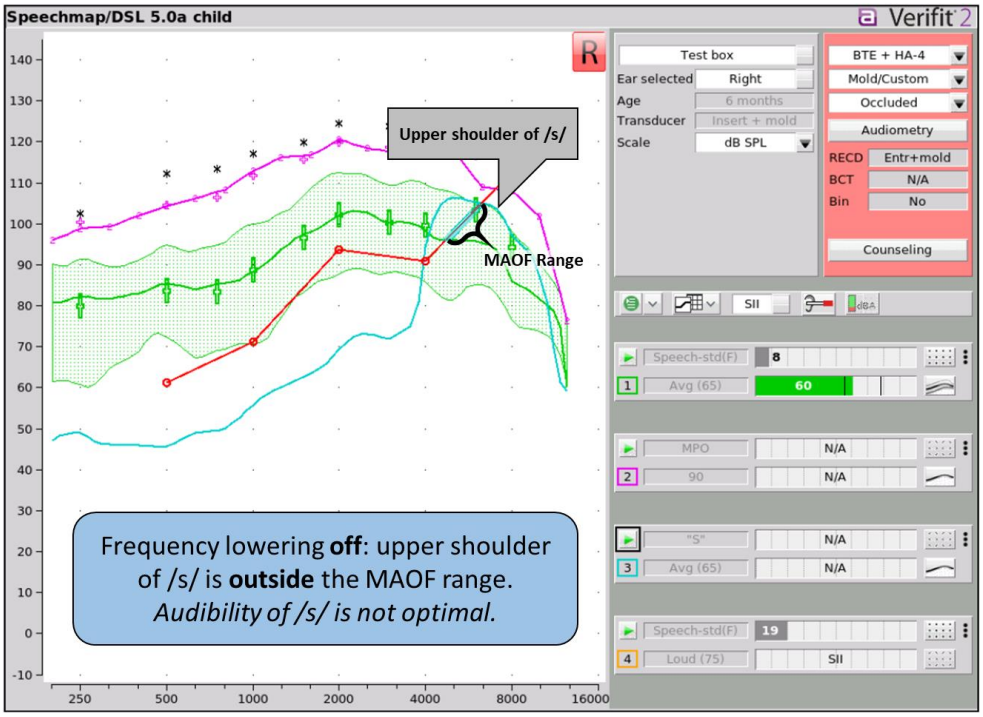


Figure 3. Test box measurement of an /s/ spectrum in reference to the MAOF range measured with frequency lowering turned off and at a presentation level of 65 dB SPL.

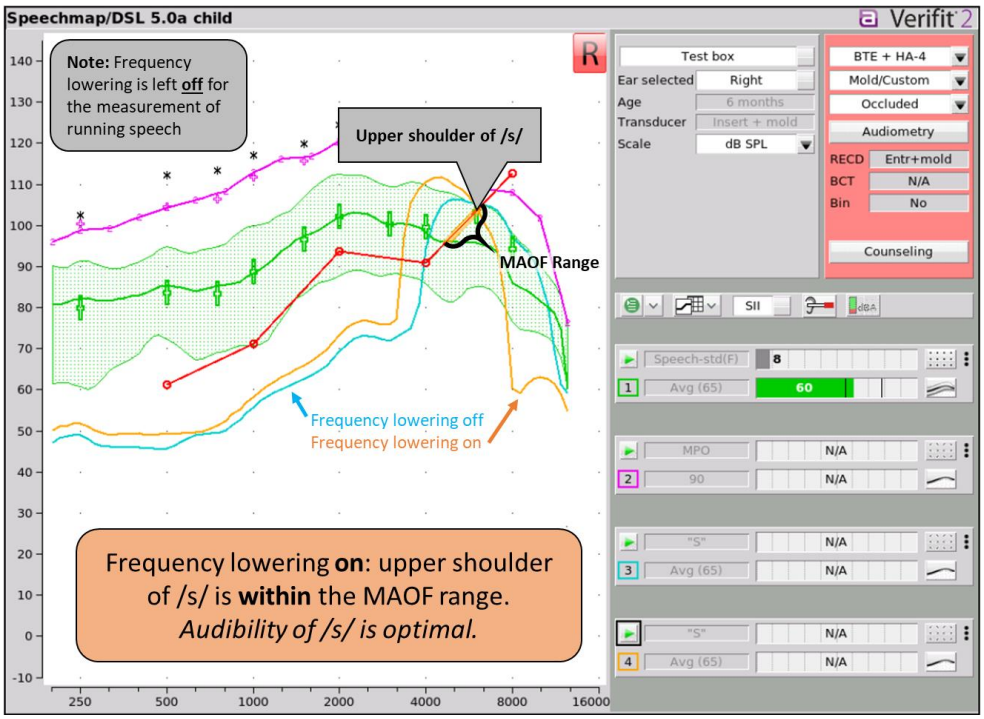


Figure 4. Test box measurement of an /s/ spectrum in reference to the MAOF range measured with frequency lowering turned on and at a presentation level of 65 dB SPL.

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 <u>without</u> 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.
- ✓ Note that the upper shoulder is located on the right side of the /s/ curve, at the point where the curve starts to steeply slope downward.

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 as possible.
- ✓ 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-ʃ/ overlap.

- ✓ Measure the aided /ʃ/ to make a <u>descriptive</u> measure of the frequency separation between /s/ and /ʃ/. This measure may help with counselling or troubleshooting difficulty with discrimination between /s/ and /ʃ/. Because of the fine-tuning steps above, the weakest possible setting of frequency lowering has already been determined and therefore the separation between /s/ and /ʃ/ is likely

already maximized. Listening checks are also useful for these purposes and should be completed after frequency lowering is verified.

Upon completion of this fitting protocol, re-enable noise reduction if this is a component of the fitting. Note that the test box speech stimuli do not need to be re-run after frequency lowering has been activated to obtain new aided speech spectra. Associated SII values do not need to be recalculated based on the fitting with frequency lowering activated.

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 (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 (pink).

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-ʃ/ overlap which is undesirable. Functionally, this could result in /s-ʃ/ confusion, or "slurred" /s/ perceptions.

The strength was then decreased from the fine-tuned setting and /s/ was re-measured (yellow). This created a fitting where the /s/ fell 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.

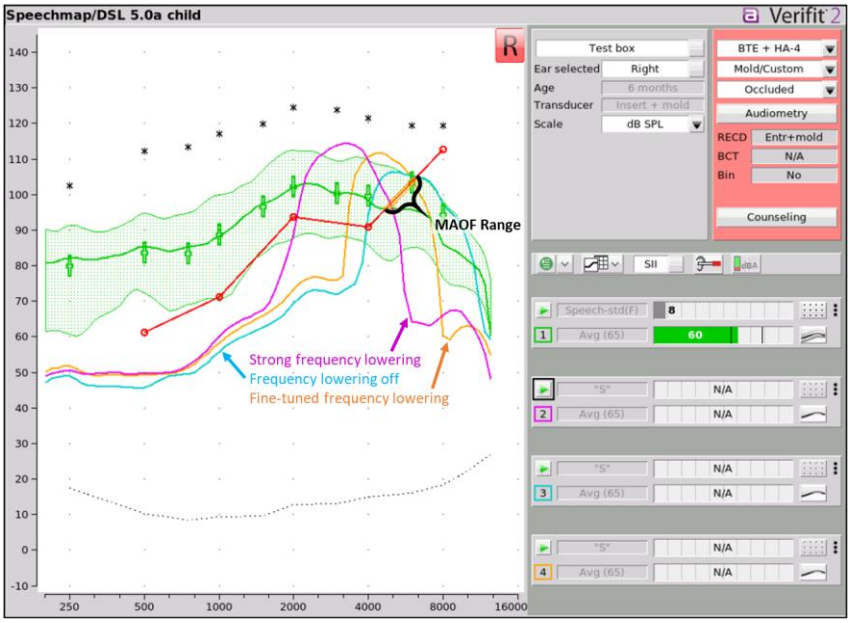


Figure 5. Measurements of the /s/ spectra, relative to the MAOF range, for the off setting (blue), a fine-tuned setting (orange), and a strong setting (pink).

CASE EXAMPLE C: OPTIONAL DESCRIPTIVE MEASURES OF /ʃ/

A calibrated /ʃ/ stimulus is provided for optional use in description of fittings or troubleshooting because frequency lowering can increase spectral overlap, which can in some cases result in /s-ʃ/ confusion. This is more likely when the frequency separation between these two sounds is very small. To ensure there is sufficient separation between these two phonemes, the lower-shoulders of each stimulus should have a minimum 1/3-octaveband separation (see Glista et al., 2016 for more details).

To illustrate this, the response for /ʃ/was measured (blue) to describe spectral separation between /s/ and /ʃ/. 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 /ʃ/ were also measured at the stronger frequency lowered setting (Figure 7). We can see that, compared to the fine-tuned setting, the /s-ʃ/ overlap has been increased. This may result in poorer sound quality and less ability to discriminate between the fricatives for the child.

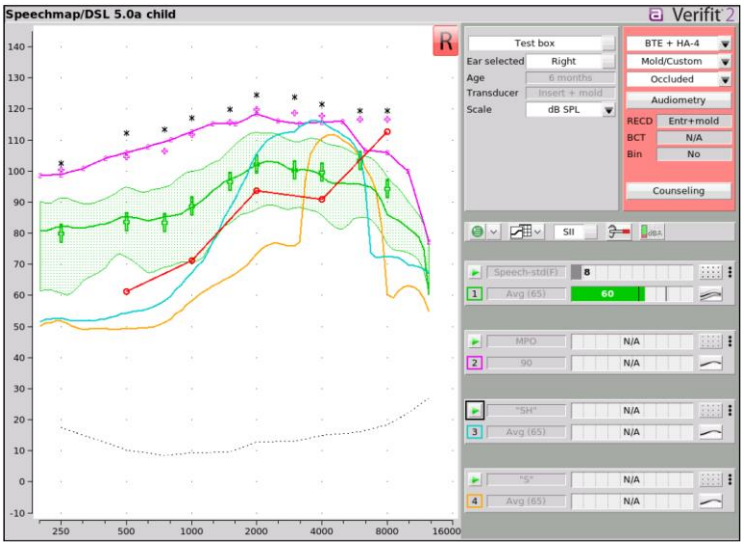


Figure 6. Test box measurements of the LTASS (green) and /s/ (orange) and /ʃ/ (blue) at the fine-tuned frequency lowering setting, for a presentation level of 65 dB SPL.

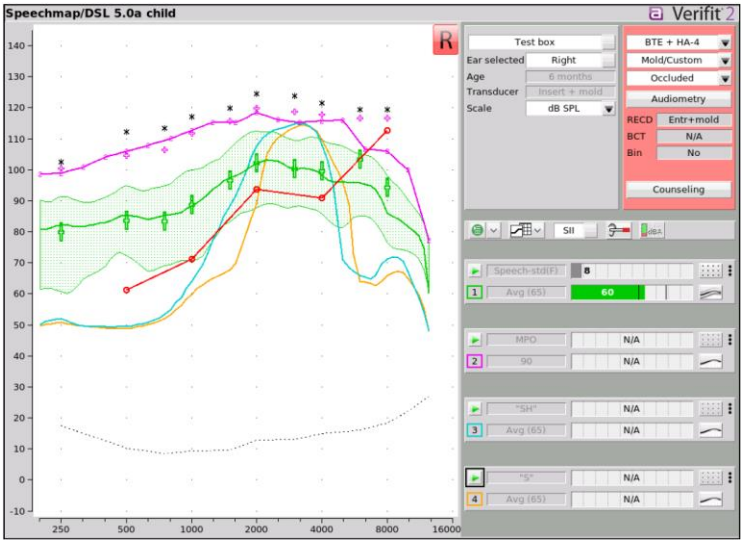


Figure 7. Test box measurements of the LTASS (green) and /s/ (orange) and /ʃ/ (blue) at a stronger frequency lowering setting, for a presentation level of 65 dB SPL.

CASE EXAMPLE D: ILLUSTRATING THE CHALLENGES OF PARTIAL AUDIOMETRIC DATA

This six month old was assessed via frequency specific ABR. Results revealed a moderately-severe sensorineural hearing loss in both ears. Threshold estimates in the right ear were 60 and 70 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.

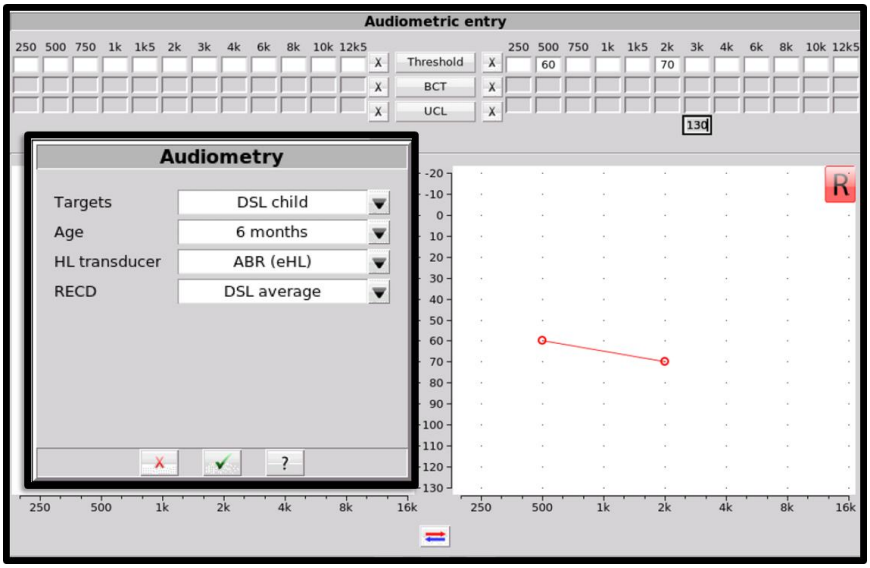


Figure 8. Hearing threshold information for Case D entered into the Audioscan® Verifit. The infant was not tolerant of measured RECDs at the initial fitting. As a result, the audiologist used DSL average RECD values for the initial fitting with the goal of measuring an RECD using the child's earmold at a future appointment.

The initial fitting of the hearing aid is shown below (Figure 9). Although the audiogram is incomplete, some hearing aid test systems are able to generate prescriptive DSL targets for missing thresholds by extrapolating from the existing threshold information. The fit to target for average speech is acceptable for the case below, although it is worth recalling that all of the targets above 2000 Hz have been extrapolated and are therefore speculative. 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 locate the MAOF range of the fitting to determine audibility of /s/ stimuli.

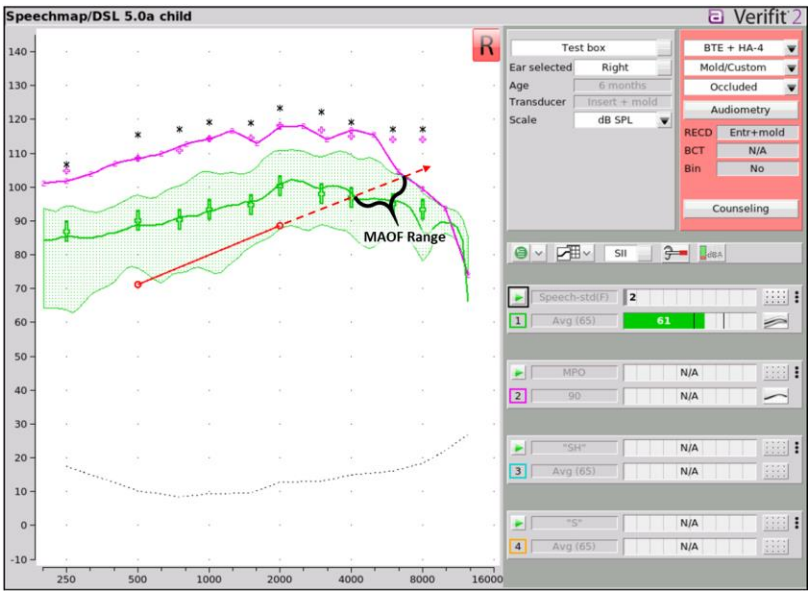


Figure 9. Test box measurements of average (green) speech, and the MPO (pink).

Candidacy for frequency lowering was determined using the calibrated /s/ with frequency lowering off (Figure 10) and on (Figure 11). By extrapolating the hearing thresholds in the high-frequencies (dotted red line), we estimate that the /s/ is not optimally audible without frequency lowering activated, indicating that this infant is a candidate for frequency lowering. With frequency lowering activated and finetuned, the /s/ is lowered to a region where the signal is likely audible.

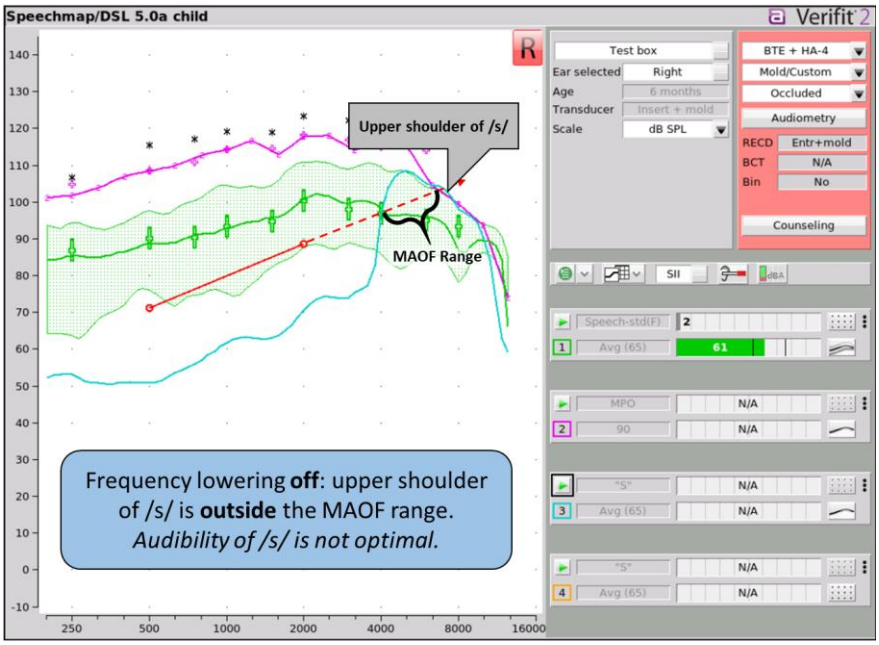


Figure 10. Measurement of the /s/ spectrum, relative to the MAOF range using extrapolated hearing thresholds, with frequency lowering OFF.

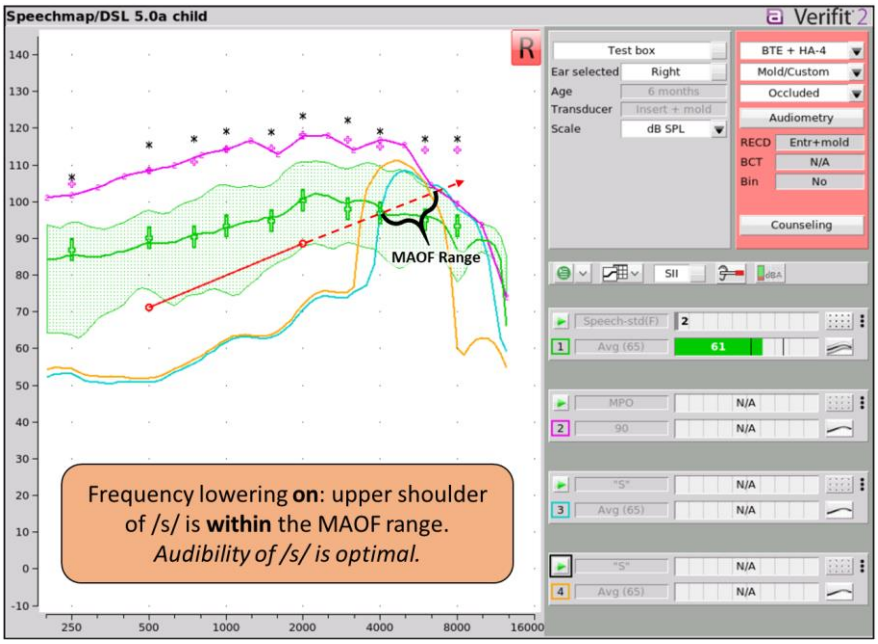


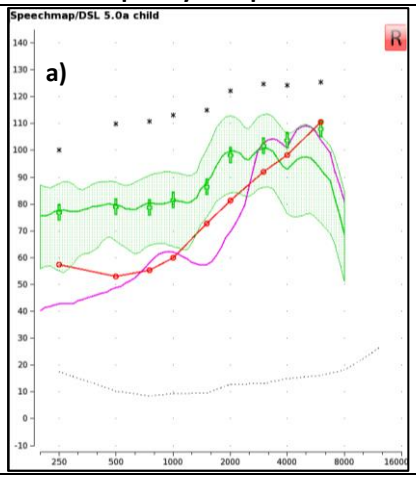
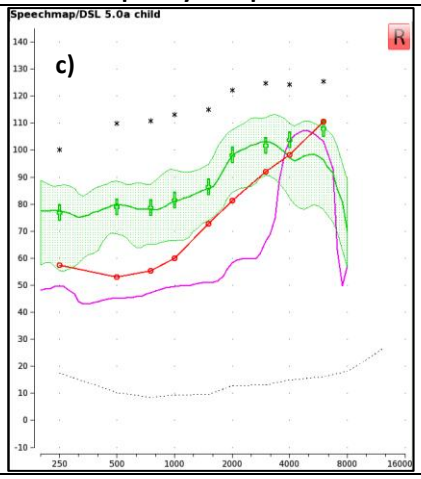
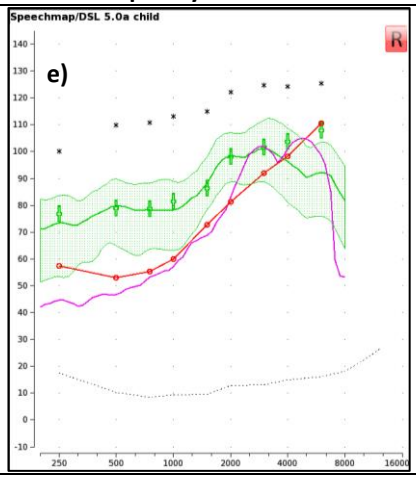
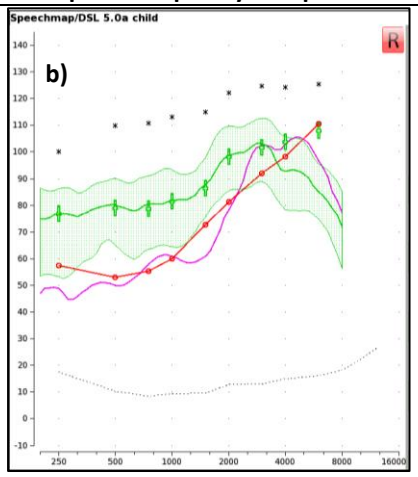
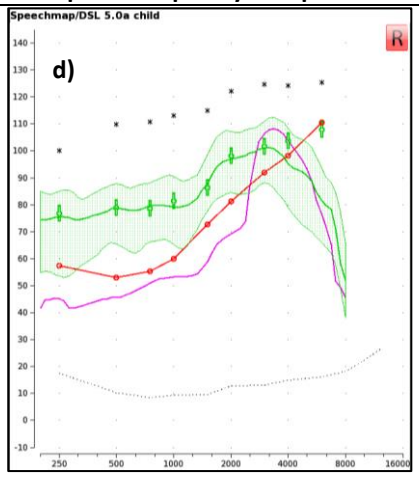
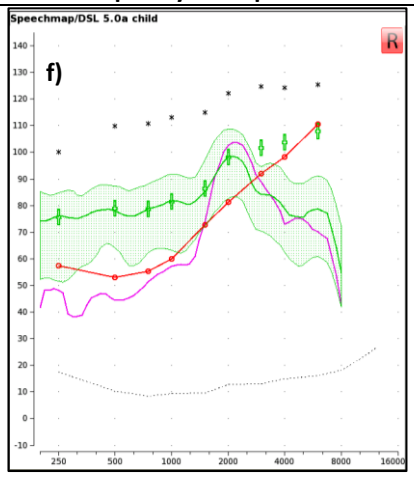
Figure 11. Measurement of the /s/ spectrum, relative to the MAOF range using extrapolated hearing thresholds, with frequency lowering ON.

A listening check was completed to assess sound quality and phoneme discriminability. Further exploration using the calibrated /ʃ/ speech signal could be used for counselling purposes. Evaluation of efficacy of this setting can be determined at follow-up appointments with use of caregiver reports and/or outcome measures. Once a more detailed audiogram is available, these settings can be re-evaluated.

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.

Frequency Composition	Frequency Compression	Frequency Translation
		
Adaptive Frequency Composition	**Adaptive Frequency Compression**	**Frequency Transposition**
		

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.

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.

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.

Transposition: This type of technology uses linear frequency transposition to lower a high-frequency portion of the signal – refer to f) 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.

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, composition, 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. Experimental studies comparing benefit in children across types of lowering are not available at this time.

FREQUENTLY ASKED QUESTIONS

The following is a list of frequently asked questions for frequency lowering technology. For more information, please review Glista & Scollie (2018).

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 listener 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 /ʃ/, decreased use of the device, the child's reluctance to wear the device, or reported complaint about sound quality.
   - In a case discussed by Scollie, Glista & Richert (2014), a child who was an experienced frequency lowering user, was refitted with new hearing 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 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. The pass band of modern hearing aids has improved and /s/ is now often audible for most losses without frequency lowering. That said, checking the /s/ audibility takes seconds, and is a good crosscheck of the provided bandwidth.
   - 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 these sounds 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 audiologist. 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 addendum 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 et al., 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 et al., 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 et al., 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; and/or (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.

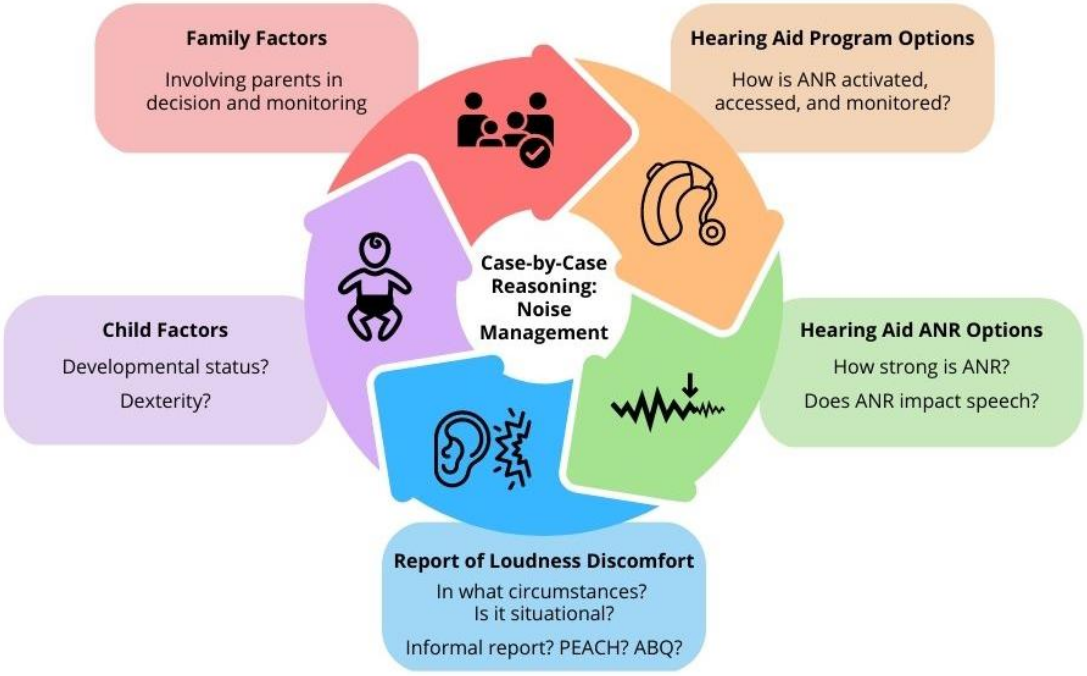


Figure 1. Candidacy and Device Considerations in Noise Management for Children who use Hearing Aids

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 et al., 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) and is preferred for use in real-world environments (Glista et al., 2021).

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 (Glista et al., 2021; 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 may not be convenient and also has not been tested in younger children or in a broad clinical population that includes children with medical or developmental challenges. For these reasons, automatic switching is preferred. Validated prescriptions that have been evaluated in children include the DSL5-Child Noise target and the NAL-NL1 target.

AUTOMATIC PROGRAM SWITCHING

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

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

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

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

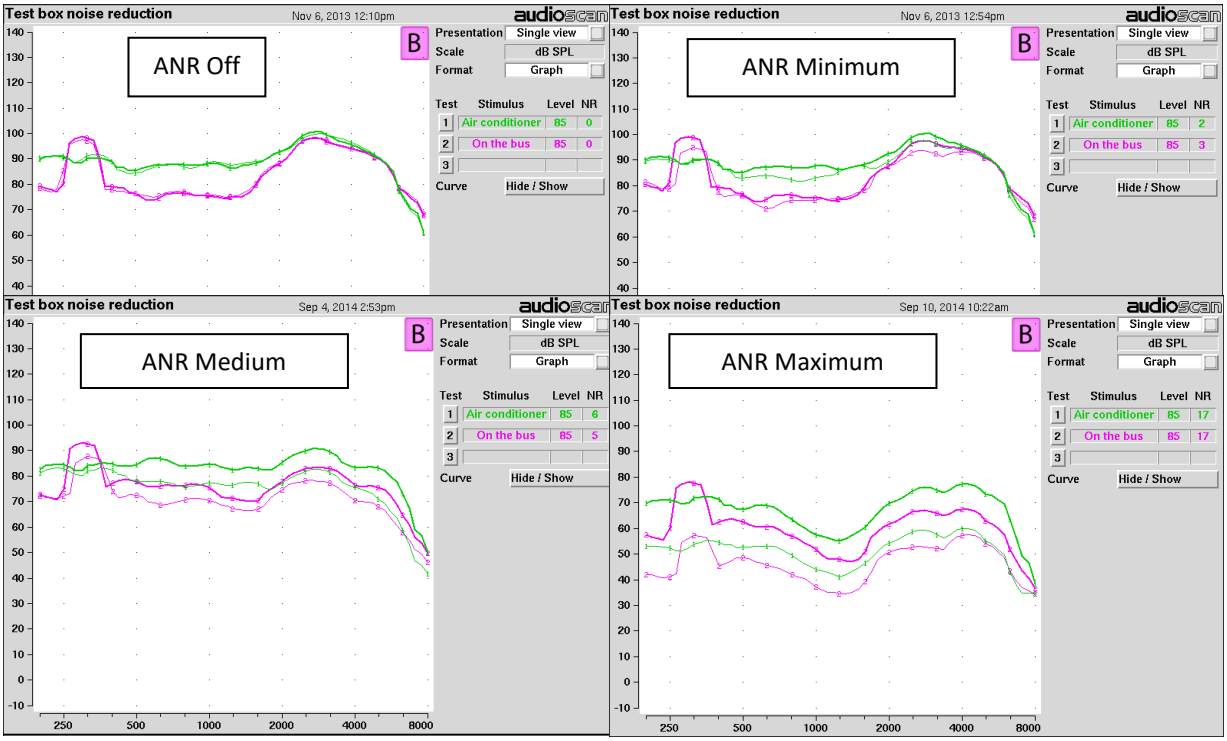


Figure 2. Test results for ANR strength testing across processor settings.

TYPICAL PERFORMANCE RANGES FOR ANR PROCESSING

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

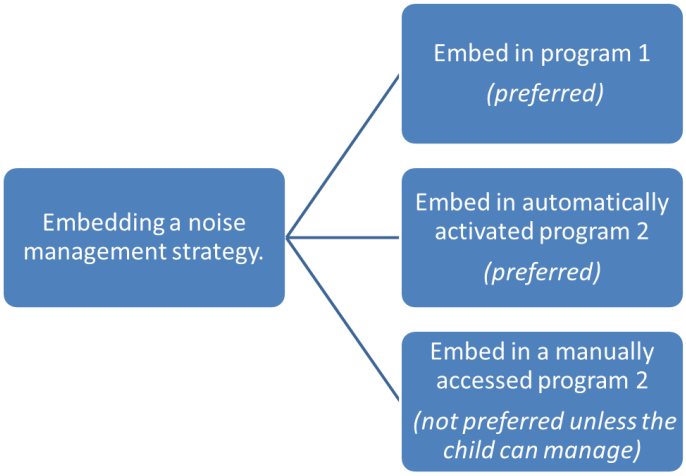
IHP clinicians are advised to consider the objectively measured strength of ANR systems when interpreting whether a noise management strategy has or has not been effective for an individual child.

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.

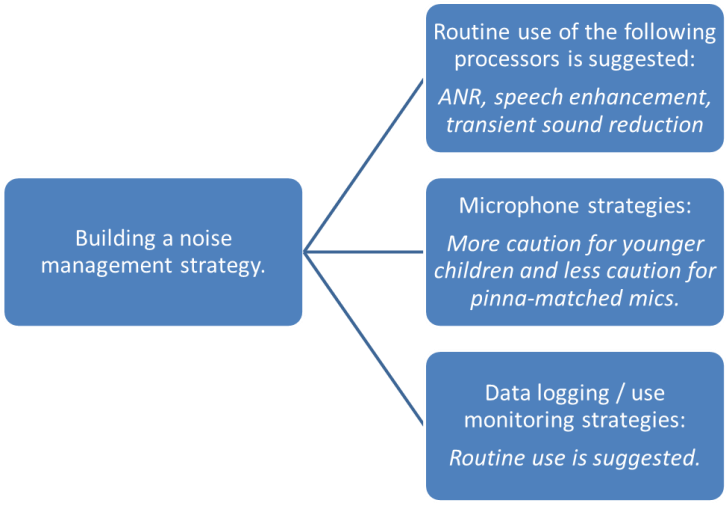
Some hearing aids provide environmental classification and switching between programs, while others do not. For this reason, the noise management strategy may be embedded in an automatically accessed second program, or it may be embedded in the hearing aid's main program. Either of these options allow 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.**
    - **a.** Does the child or caregiver report any loudness discomfort, either informally or formally (on the PEACH or IHP- ABQ)? Under what circumstances does loudness discomfort occur?
    - **b.** Is the hearing aid use time per day limited, and if so, is it limited because of loudness and/or noise issues? Under what circumstances does loudness discomfort occur?
2) **Consider practical factors in planning a noise management strategy.**
    - **a.** Child Factors: Does the child have the cognitive/developmental/dexterity abilities to monitor his or her own environment and manually choose between hearing aid programs?
    - **b.** Family Factors: Involve the caregivers in choosing to provide noise management in order to facilitate their awareness, engagement, and monitoring.
    - **c.** Hearing Aid Options: What noise management features does the hearing aid offer? How strong is the noise reduction, and how can it be accessed (via automatic or manual programs?) and monitored (via data or use monitoring?).
3) **Verify the shape and gain of the hearing aid fitting without ANR.**
    - **a.** Begin by verifying and tuning the hearing aid to optimize the fitting without ANR. Ensure that the aided speech spectra meet DSL prescriptive targets and provide a broad bandwidth of audibility.
    - **b.** Check whether the Loud 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?**
    - **a.** Can you embed it within the hearing aid's only program?
    - **b.** Can you embed it in an automatically accessed second program?
    - **c.** Can you embed it in a manually accessed program?
5) **Program the noise management strategy, by adding features to the noise management program.**

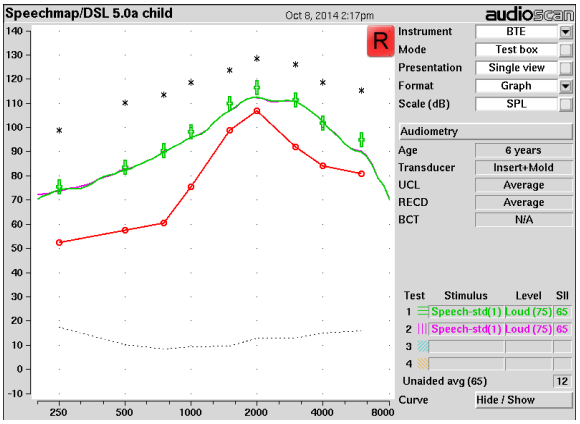
6) **Verify the noise management strategy: Does it attenuate speech in quiet?**
   - **a.** Run a 75 dB SPL speech signal to the hearing aid, with and without the noise management strategy enabled.
   - **b.** The two curves should be highly similar.
   - **c.** *Because this step rarely produces any concern, it is sufficient to run this when learning a new make/model/processing scheme, and does not need to be performed on a case by case basis unless there are concerns.*

7) **Verify the noise management strategy: Does it attenuate high-level noise?**
   - **a.** Measure a noise reduction signal such as "Air Conditioner" or "Vacuum" in the Noise Reduction tests for 30 seconds. Note the overall amount of attenuation (NR) provided as a measure of strength of processing.
   - **b.** Consider strengthening the processor if the tests provide fewer than 3 dB of attenuation.

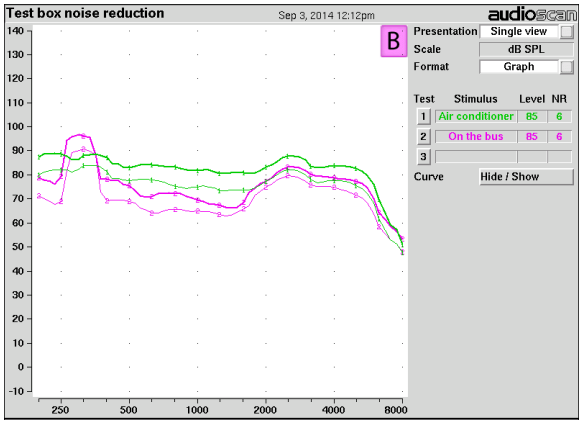
8) **Counsel on appropriate use and monitor outcomes at the next visit.**
   - **a.** Does hearing aid use increase, including in situations of concern?
   - **b.** Does loudness discomfort decrease, including in situations of concern?
   - **c.** **Steps to consider if problems are not resolved:**
     - **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.



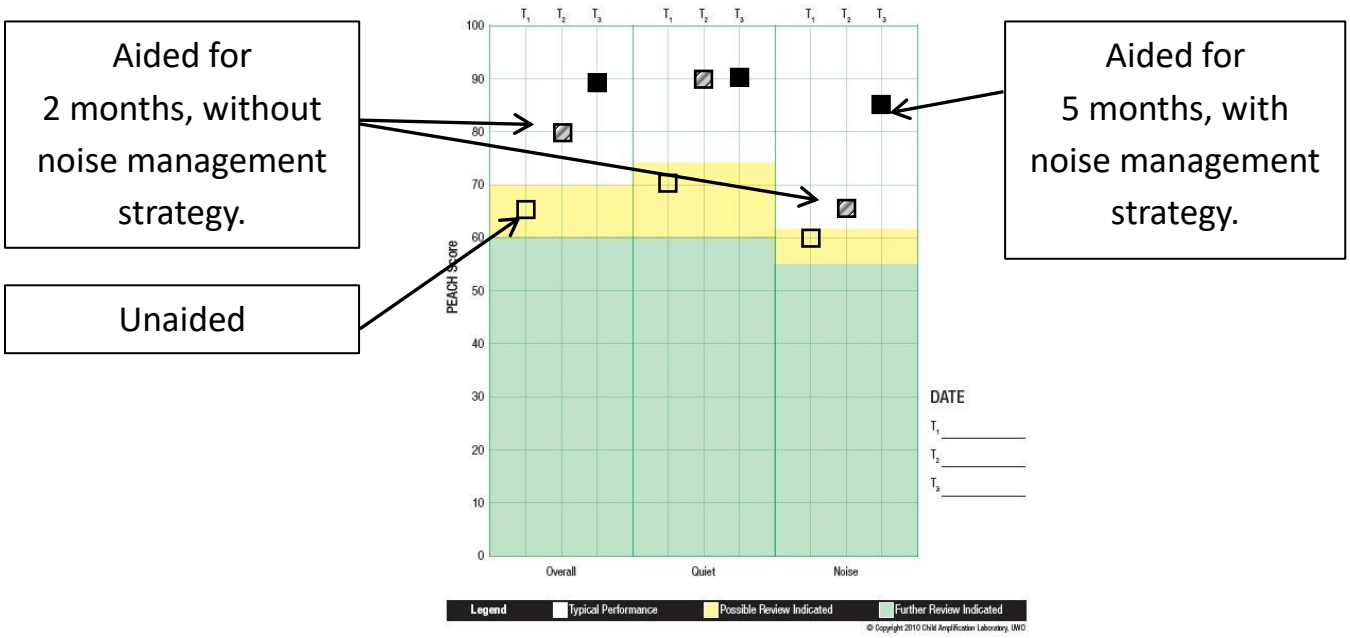
When the noise management strategy is enabled, an average of 6 dB noise reduction is noted when 'Air conditioner' and 'On the bus' signals are delivered to the hearing aid.

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 Amplification Protocol (Appendix G). 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 automatically-activated 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.



ADDENDUM 4: CONSIDERING HEARING AIDS FOR INFANTS & CHILDREN WITH MINIMAL/MILD BILATERAL HEARING LOSS[1]

SUMMARY

Evidence suggests that the majority of children with minimal/mild, permanent, bilateral hearing loss (MBHL) are at greater risk for academic, speech-language and social-emotional difficulties than their normal hearing peers. As such, it is reasonable to assume that appropriate and timely hearing technology could mitigate the negative impact of such losses. Historically, there has been no evidence-based way to predict which children will experience difficulties and which will follow a typical course of development. This made early intervention recommendations unclear within several pediatric amplification guidelines and protocols. The absence of more specific management guidelines presented a challenge to pediatric audiologists who work with families of infants and children with MBHL as they lacked the evidence to support clear amplification recommendations. Previous versions of this protocol have provided several considerations for the IHP Prescribing Audiologist to review with the family when considering hearing aids for children who have MBHL. In addition, recent work by McCreery and colleagues (2020) has provided an audibility-based hearing aid fitting criterion to support candidacy considerations for children with MBHL. 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 clinical reasoning and shared decision-making with the family 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 behavioural difficulties when compared to their normal hearing peers (Bess et al., 1998; Bess & Tharpe, 1984; Most, 2004; Wake et al., 2004). Furthermore, a largescale longitudinal study of academic outcomes in children with hearing loss has found that children with MBHL demonstrate nominally worse scores in oral language, spelling, and writing when

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

compared to children with moderate degrees of hearing loss (Tomblin et al., 2020). The authors speculate that this is presumably because the latter access intervention services earlier and wear hearing assistive devices more regularly when compared to children with MBHL. As such, it is reasonable to assume that appropriate and timely hearing technology, combined with consistent usage, could assuage the negative impact of such losses. Toward that end, several hearing technology options have been recommended for these children (Tharpe et al., 2003; 2008) but evidence-based guidance regarding these fitting practices has been lacking. Extant consensus-based and evidence-based protocols and guidelines have consistently recommended the selection of amplification for children with MBHL by considering a number of factors in consultation with the family (e.g., Bagatto et al., 2010) with consideration for whether the degree of loss could interfere with normal development (e.g., American Academy of Audiology [AAA], 2013). Until recently, additional guidance has not been forthcoming resulting in uncertainty about hearing aid recommendations with this group of children (Fitzpatrick et al., 2013). McCreery and colleagues (2020) investigated a subsample of children in the longitudinal Outcomes of Children with Hearing Loss (OCHL) study and used a data-driven method to determine an audibility-based hearing aid fitting criterion for children with MBHL as a way to help standardize amplification recommendations.

There remain many other factors when considering recommending hearing technology to the child and family. As such, a decision support guide is provided herein that is designed to help Ontario Infant Hearing Program (IHP) clinicians compile information in a systematic way 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 systems (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 systems 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], 2019).

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.

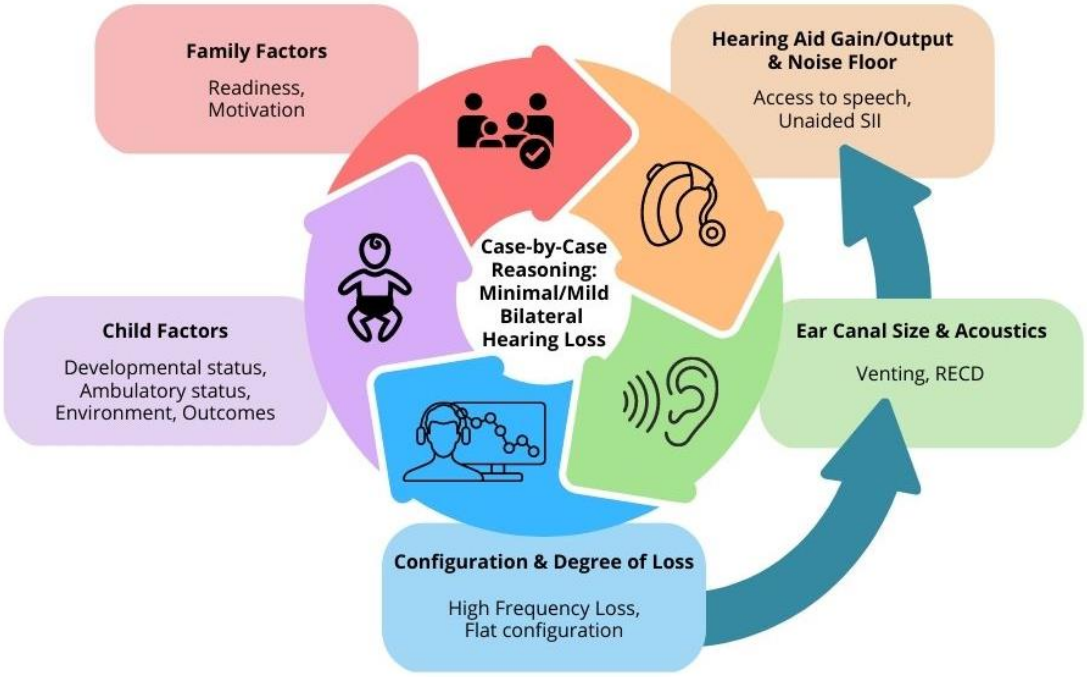


Figure 1. Factors to consider when determining the appropriateness of a hearing aid for an infant/child with MBHL.

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

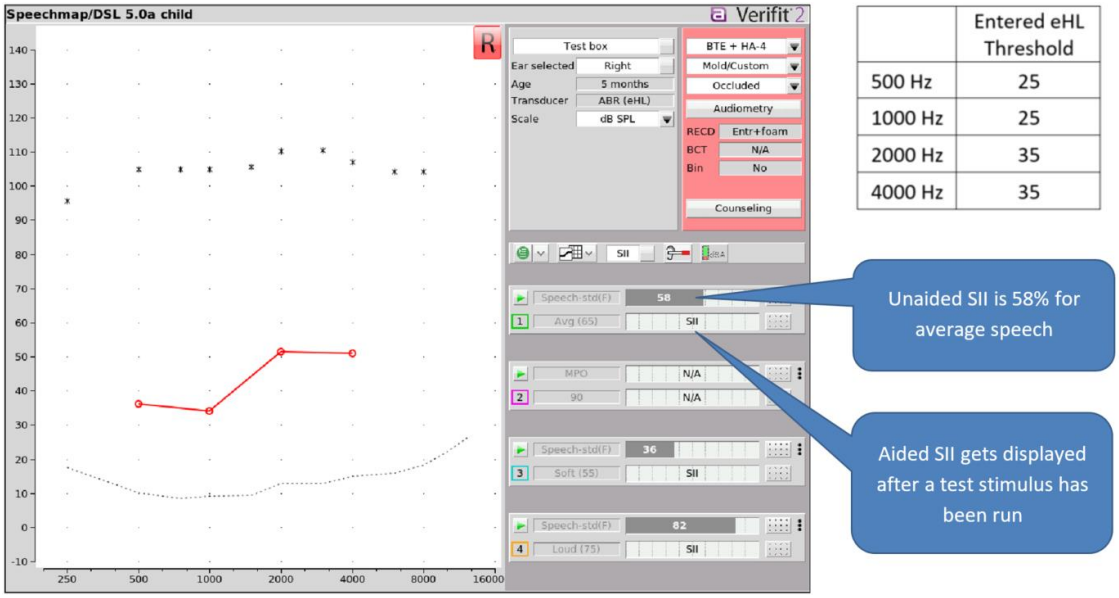
b) Permanent High Frequency: pure tone thresholds > 25 dB HL at two or more frequencies above 2000 Hz

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 et al., 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 population for IHP services includes children with PHL of "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 likely indicative of normal audiometric status within our program, given expected responses to low-level stimuli in children under 3 years of age. 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.

Using only audiometric information to guide hearing aid recommendations for children with MBHL does not capture all the factors involved for the child and family, which may result in some ambiguity in the outcomes for this group of children. As has been previously recommended, measuring the RECD to convert HL thresholds to SPL provides information about speech audibility through SII values on an SPLogram. Generating individualized DSL targets will provide information regarding the amount of gain needed from a hearing aid in addition to providing aided SII values for comparison. To refine this strategy, McCreery and colleagues (2020) recommend if the unaided SII value is greater than ~80%, the child with MBHL is likely to develop language skills on par with their normal hearing peers. This SII value was determined by examining a subsample of children from the OCHL study to determine the relationship between a child's unaided SII to their receptive and expressive vocabulary, as well as syntax, to determine the point at which children with hearing loss started to fall below their normal hearing peers (McCreery et al., 2020). Through various statistical models, they found that children with an unaided SII of ~80% or lower were at greater risk of developing communication difficulties. This, in combination with the other factors described in this addendum, provide a systematic way of considering amplification recommendations in this population.

The unaided SII can be obtained by entering the child's audiometric thresholds into hearing aid verification equipment, along with a measured RECD if available (average age-appropriate RECD values could be used in the absence of a measured RECD, although this is not preferred; see Figure 2). The reason for incorporating the RECD into the unaided SII value is to better reflect the impact of the child's own ear canal acoustics on their hearing thresholds.



	Entered eHL Threshold
500 Hz	25
1000 Hz	25
2000 Hz	35
4000 Hz	35

Figure 2. Unaided speech intelligibility index (SII) display for a child with MBHL from the Verifit2. This child would be considered a candidate for hearing aids based on the audibility-based fitting criterion alone.

EAR CANAL AND EARMOLD ACOUSTICS

The external ears of infants and young children are significantly smaller than those of adults (Bagatto et al., 2002; Feigin et al., 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 children 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. This is in line with suggestions from McCreery et al. (2020) to use measured RECDs to obtain accurate unaided SII values for candidacy considerations. As the child 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 3).

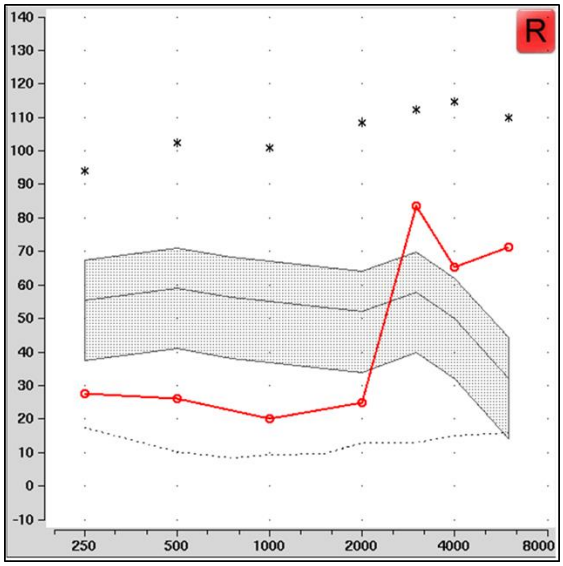


Figure 3. An example of unaided speech (shaded region) audibility for a child with a mild high frequency hearing loss (open circles). The x-axis is frequency (Hz) and the y-axis is sound pressure level (SPL) at the eardrum. Note that no amplification is required in the low frequency region, but is needed in the high frequency region. A vented earmold may help reduce the impact of upward spread of masking, may facilitate sound localization, and may provide access to unaided sound in the low frequency range.

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 child 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 4). 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 sytems allows a test of the internal noise produced by the hearing aid (see below).

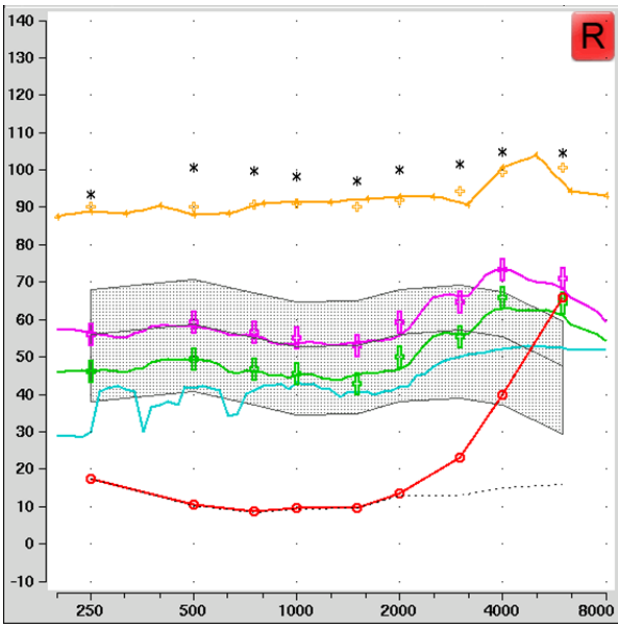


Figure 4. An example of a low-gain hearing aid fitting. The x-axis is frequency (Hz) and the y-axis is sound pressure level (SPL) at the eardrum. The blue line is the hearing aid's noise floor which may be heard by the listener. Note that soft aided speech (green line) is not much better than the noise 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 aided SII values shown in Figure 4 for both soft and average level 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 et al., 2012; Glista et al., 2014) 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 (Appendix G), but clinicians may use them at their discretion.

CHILD FACTORS

The individual characteristics of a child with MBHL and their 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 et al., 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 et al., 2011). For example, as seen in Figure 5, the auditory development of children with MBHL who have not been provided with hearing aids was assessed using the LittlEARS Auditory Questionnaire (Tsiakpini et al., 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 (Appendix G) can be used for this purpose.

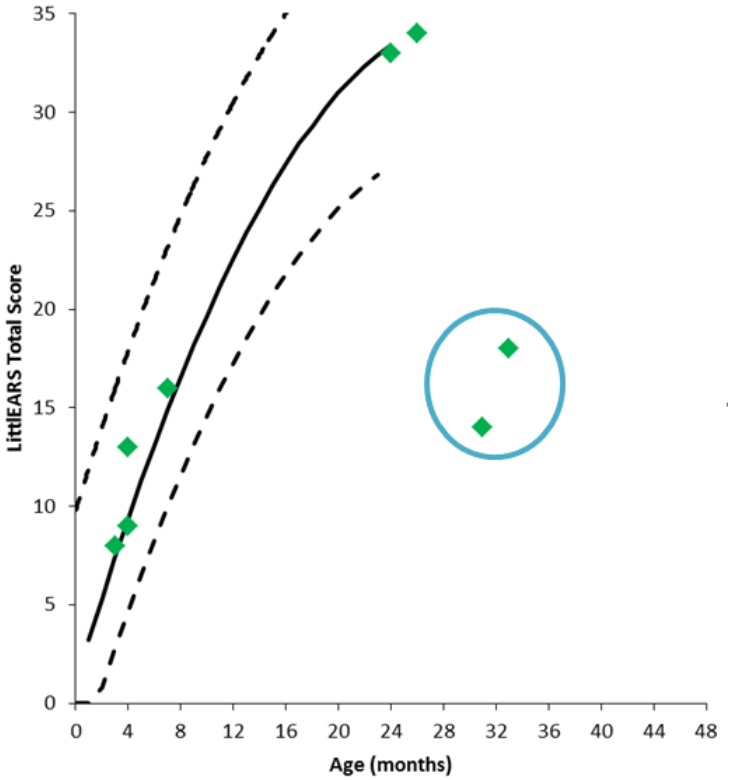


Figure 5. An example of LittlEARS scores (y-axis) by age (x-axis) for children with unaided MBHL. The solid line represents the average LittlEARS scores for normal hearing children and the dashed lines are the upper and lower 95% confidence intervals. The diamonds represent individual child's LittlEARS scores. The diamonds that are circled are children with comorbidities.

Another factor to consider is the ambulatory status of the child, rather than 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 the signal-to-noise ratio. A tool that takes speaker-listener-distance into consideration is the Situational Hearing Aid Response Profile (SHARP; Brennan et al., 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 6 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. 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. The implementation of the SHARP could be combined with the audibility-based hearing aid fitting criterion (McCreery et al., 2020) to provide parents with a better understanding of their child's audibility needs in various listening situations.

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 versus 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 systems 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 or not (AAA, 2011; Addendum 6). The child's listening environment is an important consideration when selecting hearing technology for children with MBHL.

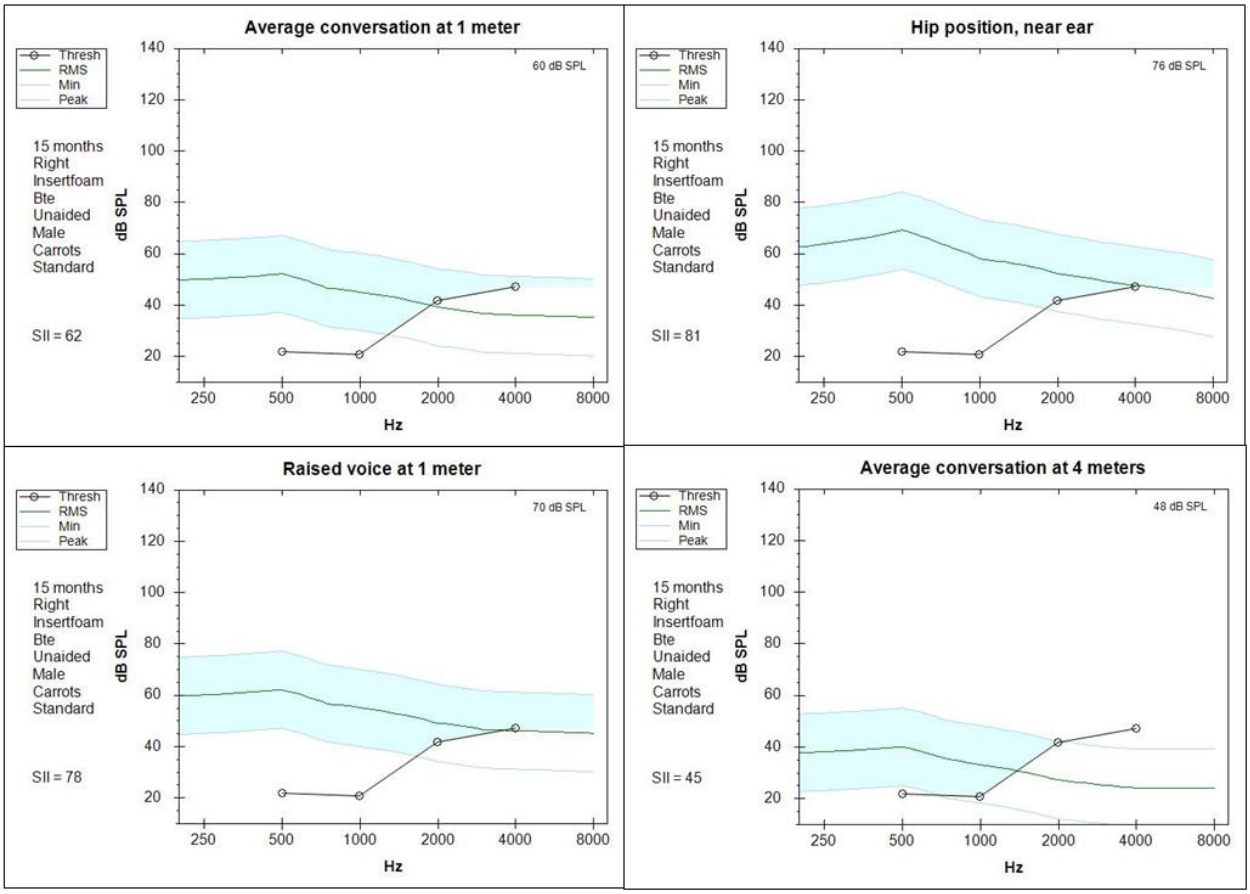


Figure 6. Examples of the audibility of speech for a given hearing loss in SPL at various levels and distances for a child with MBHL. SII values are provided to inform the index of speech audibility.

FAMILY FACTORS

Another very 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.

Pediatric audiologists often face a number of challenges when counselling parents on the impacts of MBHL. First, with this degree of loss, the child will have enough residual hearing to respond to the majority of sounds such that parents are less concerned that there is a hearing issue. Second, from a parental perspective, the classification of the hearing loss as being "minimal/mild" frequently results in decreased concern, and thus a decreased sense of urgency for pursuing amplification (Sapp et al., 2022). Lastly, there is often inconsistency in the usefulness of hearing aids among professionals on their team, leading to confusion among parents regarding next steps (Fitzpatrick et al., 2015). The audibility-based hearing aid fitting criterion by McCreery et al. (2020) can help

mitigate the effects of the latter point by helping to standardize when a hearing aid should be recommended for children with MBHL.

A recent survey-based study by Sapp et al. (2022) found that parents had a tendency to show less concern for children with MBHL when hearing loss descriptions were classification-based (i.e., saying that the loss was mild in nature) when compared to other descriptors based on audibility (i.e., unaided SII values), and hearing loss simulations. In fact, parents who were exposed to the audibility-based condition for a hypothetical child with MBHL chose significantly more intense intervention options ("two hearing aids" or "cochlear implants", compared to "no intervention necessary" or "preferential seating"), relative to parents exposed to the classification-based condition. In addition to using an audibility-based approach to describing the loss, the IHP recommends that audiologists describe the risks associated with MBHL on longterm outcomes for the child in order to explain that the impacts of this degree of loss may not manifest until child is older. Caregivers should be apprised of the benefits and limitations of a hearing aid fitting for their child and, where possible, these should be illustrated through the use of outcome measures (e.g., LittlEARS, Ling 6(HL) Detection Task). Providing hearing aids on loan to the family for a trial period provides a real-world demonstration that can be invaluable in this process.

It is important to remember that even if the family is agreeable to pursuing amplification for their child with MBHL, consistent hearing aid use for this group may be a challenge, resulting in limited improvement in auditory access and outcomes (Walker et al., 2013). Here, the unaided SII can be used as a comparison for aided audibility to provide more motivation for increased wear time. A supportive and fluid approach to case management should be used to foster an encouraging environment for parent and child in these complex situations.

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 7). This guidance is based on the definitions of MBHL for both flat and high frequency configurations (Bess et al., 1998), the audibility-based fitting criteria (McCreery et al., 2020), 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.

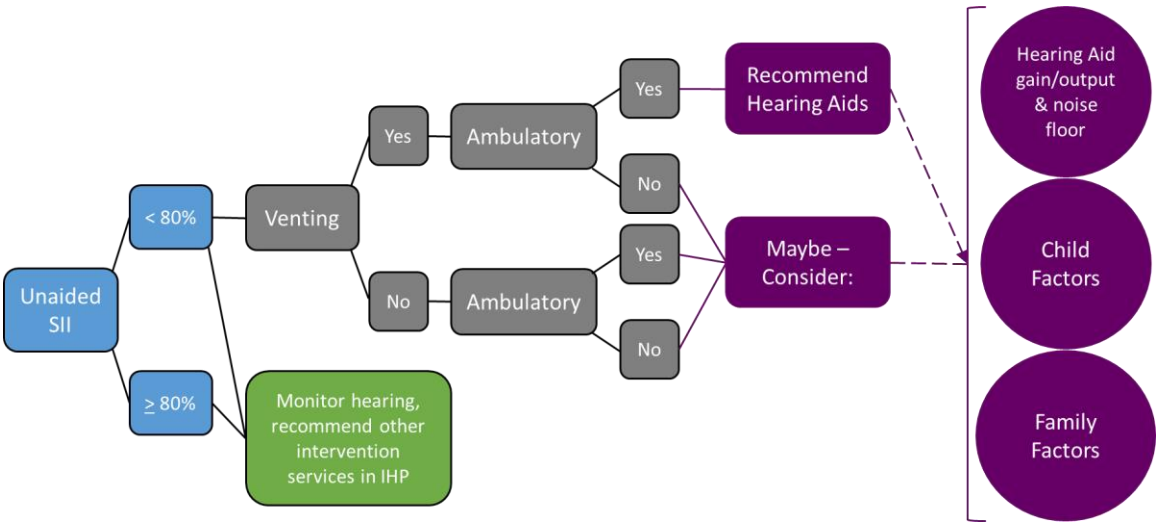


Figure 7. Decision support guide for clinicians considering hearing aids for infants and children with MBHL.

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

Permanent unilateral hearing loss (UHL) is identified in infancy through Ontario's Infant Hearing Program (IHP) and comprises approximately 15% of children with permanent loss. Evidence suggests that most of these children are at increased risk for academic, speech-language, and social-emotional difficulties than their normal hearing peers (Bess et al., 1986, 1998; Bess & Tharpe, 1988; Lieu, 2004, 2013, 2015). Currently, there is no way to predict which children will experience difficulties (McKay et al., 2008; McKay, 2010). This variability in performance has resulted in the evolution of technology recommendations within pediatric amplification guidelines and protocols (Bagatto et al., 2010, 2016; Kuppler et al., 2013). Recent work has offered preliminary evidence of a critical period for auditory reorganization in children with cochlear implants (Gordon et al., 2015; Lieu, 2015; Sharma et al., 2016). This work lends support to the notion of early intervention, including hearing aids, for children with UHL, where audiologically appropriate. The provision of hearing aids to children with permanent hearing loss, of any degree and configuration, should consider the unique characteristics of the child and family.

Speech-Language and Audiology Canada's (SAC; Speech-Language & Audiology Canada, 2020) position statement indicates that UHL "has important consequences for development in areas such as auditory communication, and academic and social functioning. These [impacts may] include: the loss of binaural listening and its impact in noisy listening environments, particularly spatial listening; increased listening effort; higher prevalence of vestibular difficulties; difficulties in auditory, communication and cognitive development; and academic functioning." The position statement aligns with previous and current research indicating that children with UHL of any degree are at risk for at least some developmental difficulties (Bagatto et al., 2019). Further, many of the affected domains are difficult to assess in the IHP population when the infant is undergoing rapid development and early intervention decisions are being considered. The importance of early hearing detection and intervention for children with UHL are highlighted in recent publications that will be summarized herein to support IHP Audiologists' management recommendations for children in the IHP with UHL. This addendum aims to:

1. Summarize current research about the impact of UHL in the pediatric population;

2. Introduce and summarize a Consensus Practice Parameter about pediatric UHL developed by an international panel of experts; and

3. Describe hearing aid management options for children in the IHP with UHL.

End of summary.

CONSENSUS PRACTICE PARAMETER

An international panel of hearing health care experts developed a consensus practice parameter (CPP) specific to the audiological assessment and management of UHL in children (Bagatto et al., 2019). The following sections summarize the topics included in the CPP, endorsed as a suitable guide for IHP Audiologists working with children with permanent UHL. It is recommended that the CPP document be reviewed by the IHP Audiologist for more detailed information. The CPP aligns with the American Academy of Audiology clinical practice guideline which indicates that children with "aidable" unilateral hearing loss be considered candidates for amplification (American Academy of Audiology, 2013).

AUDIOLOGICAL MONITORING AND ETIOLOGIC INVESTIGATION

Children in the IHP with permanent UHL, regardless of amplification status, shall have their hearing levels monitored routinely in both ears. Approximately 10% of children diagnosed with permanent UHL progress to bilateral hearing loss (Fitzpatrick et al., 2014, 2017; Haffey et al., 2013). A recent study showed that close to 50% of children with UHL showed deterioration in one or both ears over time (Fitzpatrick et al., 2023). Further, a substantial number of children show progression of hearing levels in the affected side over time when the other ear remains in the normal range (Friedman et al., 2013). In addition, children under the age of 3 years are at substantial risk of developing transient middle ear dysfunction, which may impact their functional listening abilities (Al-Salim et al., 2021; Graydon et al., 2017). Through regular audiological monitoring, any change to hearing levels can prompt a management review which may involve changes to technology recommendations. Audiological monitoring of the affected ear may be discontinued once profound sensorineural hearing loss has been documented ***and*** imaging results have shown auditory nerve absence. Audiological monitoring for an ear with auditory nerve deficiency shall continue according to IHP protocols. Auditory nerve deficiency is an umbrella term encompassing a variety of auditory nerve conditions, which may impact hearing sensitivity.

As noted within this IHP protocol, children identified as having PHL will be referred to an otolaryngologist. For children with UHL, it is important that the otolaryngologist's etiologic investigation include imaging within a timely manner. Results of an imaging study provide insight into the integrity of the auditory nerve, which may inform technology recommendations. For example, up to 50% of children with profound UHL have an abnormal or absent auditory nerve. Auditory nerve abnormalities can occur in ANSD-type losses. As such, hearing levels on the affected side may be better than severe to profound (Cinar et al., 2019; Pollaers et al., 2020; Vos et al., 2022). Research highlights that auditory nerve status cannot be assumed from audiometric testing alone. As such, timely imaging is critical to support the family, and audiologist, with determining available treatment options. Additionally, children with UHL are at higher risk for balance issues. Vestibular malformations may also be identified through imaging (Cushing et al., 2019).

DEVELOPMENTAL MONITORING

Within an individualized, family-centred approach to management, the CPP recommends monitoring developmental outcomes for each child with UHL, regardless of amplification status, and in a variety of domains. Monitoring should include: (1) speech-language, psychosocial, auditory, and academic or pre-academic development; (2) (re)assessment of hearing technologies; and (3) considerations for family-centred counseling. Child-specific, parent-specific, and education-specific measures are appropriate developmental considerations. Developmental monitoring using the current IHP amplification protocol schedule, and outcome measurement tools (i.e., LittlEARS; Amplification Benefit Questionnaire) is suitable for children with UHL, though it is recognized that the outcome measures have not been specifically designed to measure the impacts of UHL in children. Updates to the outcome measures addendum will be provided as new tools are available and considered. Assessment of sound localization and speech perception in noise are domains for future consideration.

TECHNOLOGY SUPPORT

Recommendations for hearing assistance technologies for children with UHL is the role of the IHP Habilitation Audiologist. Although further research is necessary to clearly define some technology management recommendations, the various options for children with UHL are described below and are categorized based on the usable hearing in the affected ear.

USABLE HEARING UNILATERALLY

The CPP describes conventional air conduction hearing aids as "a first-line treatment if the affected side is moderate to severe in degree, regardless of the child's age" (Bagatto et al., 2019). Similarly, the SAC position statement indicates that current evidence supports amplification for children with UHL, when of interest to the family, for any degree of loss where the device (either air or bone conduction) can provide adequate access to the speech spectrum (SAC, 2020). Further, the AAA guidelines support amplification for an ear with "aidable" hearing (AAA, 2013). Amplification for an ear with usable hearing (i.e., aidable) is becoming customary practice internationally (Mattiazzi et al., 2023).

Usable hearing in infants and young children has not been clearly defined in clinical guidelines or protocols. Hearing thresholds alone do not predict the functional benefit of hearing aid use by the child with UHL, especially when the degree of loss in the affected side is significant. Device benefit is also impacted by the integrity of the auditory system to deliver clear signals to the brain. For individuals with UHL who have auditory nerve abnormalities, speech intelligibility and sound quality may be negatively impacted. These effects can be directly measured in adults; however, these measures or reports are often not possible for IHP infants and young children, especially in the early stages of habilitation. Therefore, imaging of the affected side during initial management discussions with the family provides vital information about the potential usable hearing of the affected side, beyond what has been measured audiometrically. Knowing that imaging and speech perception measures may not be available during the initial stages of management, determining whether a hearing aid can provide improved access to speech through verification to DSL Child Targets provides some information for the habilitation process. Families should be counselled on the possibility that, in the absence of imaging and speech perception measures, the child may have "limited usable hearing unilaterally" (sometimes referred to as single sided deafness) which may impact the benefit of the hearing aid provided, even if access to speech through the hearing aid is optimal (Picou et al., 2020).

If a hearing aid is fitted and verified for a child with UHL following the best practices described in this protocol, and results in improved access to speech compared to no hearing aid in the affected ear, amplification is a suitable recommendation based on family readiness and close monitoring. There is no evidence that the provision of amplification following best practice protocols is harmful in cases where imaging and speech perception measures have yet to be obtained from the child. Currently, there is no adjustment within the DSL v5.0 fitting formula to account for a UHL configuration in children. DSL Child Targets should be used for the affected ear with adjustments made as necessary based on parental report and outcome measures. If the family chooses to pursue a hearing aid (either air or bone conduction) on the affected side, a remote microphone (RM) system shall be recommended for specific listening situations where distance, noise, and reverberation are present. Application of the current fitting and verification protocol for amplification shall be followed. An ear level RM system should not impair the child's access to speech on the normal hearing ear.

It is recognized that managing children with UHL is a challenging practice area. IHP Audiologists can consider fitting loaner device(s) when management information is pending during the habilitation process and as further information about the child and family are being gathered and shared (see Figure 2). These devices (air or bone conduction) are considered a short-term solution (ideally no more than 3-months) and assist with providing early intervention. A trial with a loaner device may also guide the IHP Audiologist and family with respect to determining functional benefits as a future treatment plan is considered.

For children with UHL and an auditory neuropathy spectrum disorder (ANSD) component, behavioural assessment is necessary to establish ear-specific hearing levels to inform hearing aid recommendations. As with bilateral ANSD, amplification for children with UHL and an ANSD component shall be considered when reliable behavioural hearing thresholds have been established.

Children with mild UHL require additional considerations. IHP Audiologists are directed to Addendum 4 for MBHL within this protocol for further information.

A bone conduction device (BCD) shall be considered for children who have permanent conductive or mixed UHL and who are not candidates for air conduction devices. IHP Audiologists are directed to the Addendum 7 for BCDs in this document for candidacy, fitting, and verification procedures.

LIMITED USABLE HEARING UNILATERALLY

Limited usable hearing unilaterally (LUHU) is a term used to describe a unilateral sensorineural hearing loss, often of profound degree on the affected side, characterized by the apparent or predicted lack of benefit from an air conduction hearing aid (Picou et al., 2020). Historically referred to as single-sided deafness (SSD), LUHU is determined by imaging studies that confirm structural limitations of the cochlea and/or auditory nerve, and/or a lack of measurable hearing thresholds in the affected side.

Management options for children with LUHU may include cochlear implantation, BCD on the affected side, a contralateral routing of signal (CROS) device, or an RM system fit to the normal hearing ear. A recent publication by Griffin and colleagues (Griffin et al., 2022) compared speech in noise performance for children with LUHU. Unaided performance was compared to the aided condition for several non-surgical treatments. Children with LUHU and no technology performed as well as children with normal hearing bilaterally when the signal of interest was directed to the normal hearing ear. When noise was presented to the ear with LUHU, an ear-level RM system fitted to the normal hearing ear showed the largest gain improvement when compared to a CROS fitting, a BCD fitting, or a BCD coupled to an RM system fit to the ear with LUHU (Griffin et al., 2022).

An air conduction hearing aid is not a suitable recommendation for children with LUHU. For children with profound UHL, who may also have LUHU, the amount of gain needed from an air conduction device is unlikely to provide appropriate speech access and, more importantly, may result in crossover of the amplified signal to the normal hearing side. This crossover is an acoustic fact that may not be consistently measurable in individual children. Crossover is likely to have a maturational component and is currently not well understood in the pediatric population (Mackey et al., 2016). As such, the detriment imposed to the normal hearing side from an air conduction device on the affected side does not support this type of fitting for children with LUHU.

LUHU AND COCHLEAR IMPLANTATION

Children with LUHU are characterized by the lack of measured or predicted functional benefit from a hearing aid. In these cases, cochlear implantation (CI) evaluation is a viable option when available and of interest to the family (SAC, 2020; CPP, 2019). Research supports improved audibility for speech, improved localization, and improved binaural listening following cochlear implantation on the affected side (Arndt et al., 2015; Polonenko et al., 2017; Thompson et al., 2022). Additionally, a health technology assessment was completed by Ontario Health (Quality) in 2020 to examine the incremental quality of life cost for cochlear implantation specifically for individuals with UHL (Anonymous, 2020). Recently, the provincial Ministry of Health has approved the use of CIs in children with UHL. Unilateral CIs are available to children at each of the CI programs in Ontario. Evaluation and preparatory criteria for unilateral CI in children are currently under development by the cochlear implant programs (CIP)s. The IHP Audiologist shall consult with their regional CIP for current candidacy considerations, and to review the suitability of a hearing aid trial on the affected side prior to CI evaluation.

LUHU AND BONE CONDUCTION DEVICES

BCDs are an option for children with LUHU. There is little evidence describing the efficacy of this treatment in young children. Peters and colleagues (Peters et al., 2015) completed a systematic review of the literature and reported moderate gain in subjective improvement of speech communication in adults. High level evidence was reportedly lacking. A BCD fitted on the affected side provides similar access to sound as a CROS hearing aid. Sounds on the side with the BCD will be transferred via bone conduction to the normal hearing cochlea. Little is known about the best fitting practices of BCDs for LUHU in children. IHP Audiologists should consider recommending these devices in consultation with the family and the Western DTC for amplification.

LUHU AND CONTRALATERAL ROUTING OF SIGNAL (CROS)

A CROS device typically consists of a microphone fitted to the affected side, and a receiver fitted to the side with normal hearing. The microphone and receiver are often similar in appearance to a behind-the-ear device and communicate through a Bluetooth connection. There are several variables to consider when fitting CROS devices in children. A CROS device can improve awareness of sound on the affected side, which can be an important safety consideration. However, a CROS device does not restore sound localization nor binaural listening benefits (Pedley et al., 2017). The use of a CROS device in a noisy setting, like a classroom, can present challenges for the listener. For example, if noise is presented to the affected side (i.e., the side with the microphone), this can impede the listener's ability to understand the signal of interest as the noise is routed to the side with normal hearing (i.e., the side with the receiver). Adults and older children often have the capacity to adjust their positioning or remove the device(s) entirely to prevent any detrimental impacts to hearing. Adaptive directionality in newer CROS systems may provide some support for listening in noise. However, these adaptive strategies have not been studied in children. CROS systems are now equipped with remote microphone capabilities, which may be beneficial for younger listeners. It is important to note that a CROS fitting should not occlude access to speech for the normal hearing ear, and therefore requires a large enough ear canal to accommodate an open fit earmold. As such, this type of fitting will not be feasible for infants and young children until their ear size can accommodate an open fitting.

LUHU AND REMOTE MICROPHONE (RM) SYSTEMS

An RM system fitting for the normal hearing ear is another management option. As Griffin and colleagues (2022) have shown, this solution results in the greatest performance gain for listening in noise when compared to a CROS fitting, a BCD fitting, or a BCD fitted with an RM system. It is again important to note that an RM system fitting to the normal hearing ear should not occlude access to speech. An open earmold fitting is indicated and the timing for this fitting will depend on the child's ear canal size. An RM system fitting has the added benefit of reducing the impacts of distance between the listener and the signal of interest. The negative impacts of noise and distance for those with unilateral hearing loss have also been documented (Griffin et al., 2019; Reeder et al., 2015). Technology to support the listener in these settings would likely improve speech reception and reduce fatigue.

CARE PLAN FOR AUDIOLOGISTS

Within the CPP, a care plan was offered to guide management decisions. This tool is provided in Figure 1 below with some modifications for the IHP context. To summarize, air or bone conduction technology shall be considered for children with usable hearing on the affected side. Additionally, an RM system should accompany the hearing aid when the child needs support for listening in challenging environments. For children with LUHU, technology options to consider are CI, RM system, CROS, or BCD. Imaging results and considering child and family characteristics are paramount for any technology recommendation.

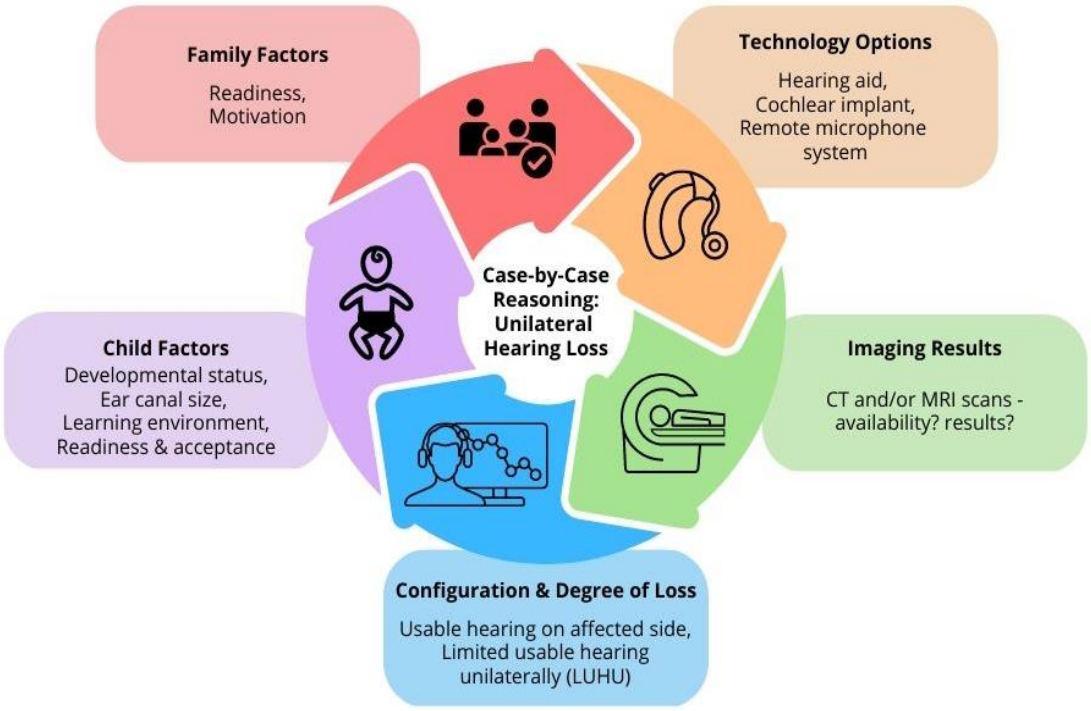


Figure 1. Care plan for audiologists managing infants and children with unilateral hearing loss. Adapted from the Consensus Practice Parameter (2019).

Furthermore, Figure 2 below summarizes the elements discussed throughout this addendum to provide clinical decision-making support in the case-by-case reasoning for infants and children with UHL.

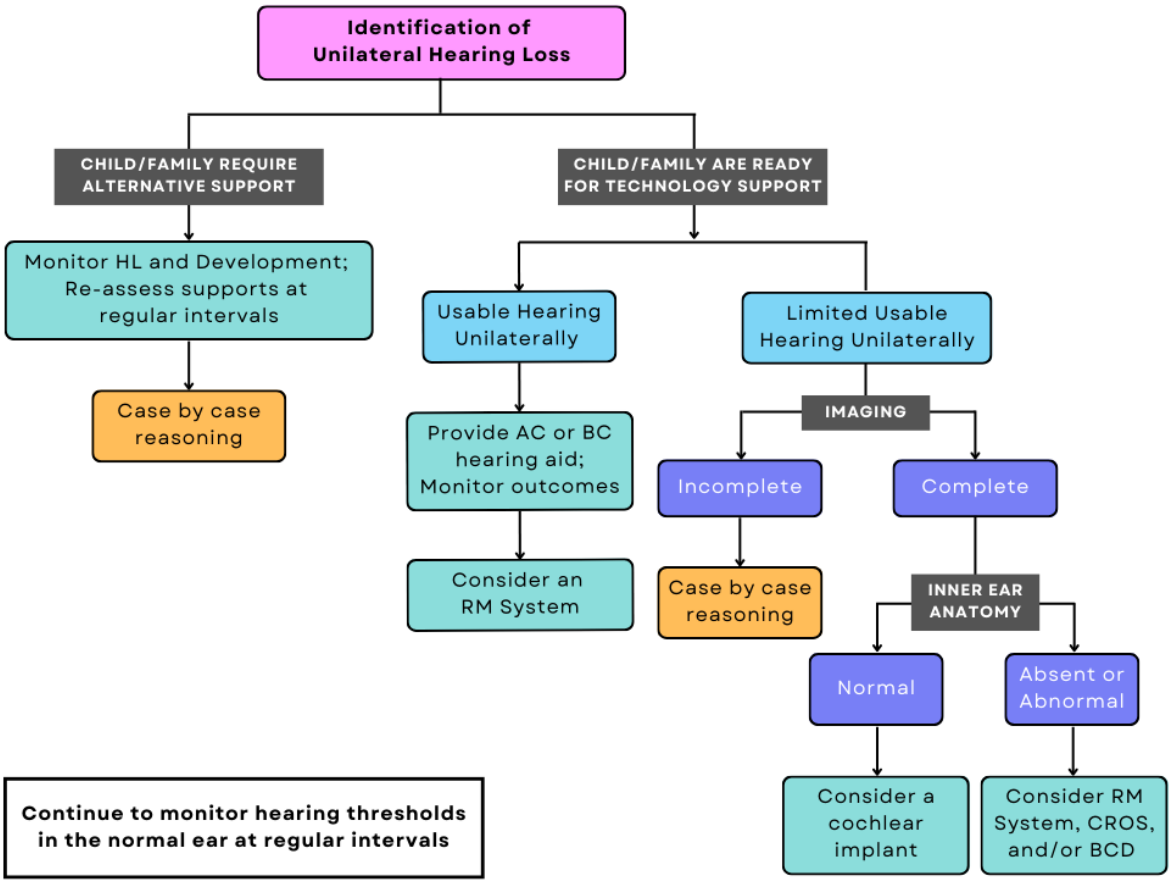


Figure 2. Factors to consider when determining management options for an infant/child with UHL.

INFORMATIONAL COUNSELING

Informational counseling is a vital component of working with IHP infants and children who have UHL and their families (CPP, 2019). Several areas should be addressed by the IHP Audiologist who is often the first point of contact for families as they navigate UHL and the various treatment options.

The following areas shall be discussed with families:

1) Evidence-based counseling: whenever possible, the IHP Audiologist shall share current evidence related to UHL and treatment options. Similarly, families should be informed about topics that do not yet have an evidence base.

2) Family-centred, shared decision-making: meet the family where they are and acknowledge that this is a challenging situation. Porter and colleagues (Porter et al., 2021) outline the challenges in decision-making for families, and professionals, for children with UHL.

3) Consider the whole child: provide technology recommendations based on audiological information, the child's developmental age and status, and family preferences in keeping with their values and beliefs, and financial considerations.

Please review the CPP for further details about working with this challenging management situation. Case-by-case reasoning is a critical and ongoing strategy.

CONCLUSION

Children with UHL are identified within the IHP and are eligible for support services. Audiological management decisions pose a challenge for families due to the evolving evidence. Approximately 15% of children on the IHP provincial caseload have UHL. The SAC Position Statement and a Consensus Practice Parameter for assessment and management of UHL in children provide recent evidence and recommendations to support this Addendum. In addition, the IHP's loaner hearing aids and current Outcome Measurement Protocol support management and monitoring for infants with UHL.

ADDENDUM 6: REMOTE MICROPHONE SYSTEMS

SUMMARY

It has been well documented that the use of remote microphone (RM) systems (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 et al., 1996). Guidelines for the selection and verification of RM systems are necessary to support their use with children involved with the Ontario Infant Hearing Program (IHP).

This document aims to:

1. Introduce and endorse RM system 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 (RM) systems 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, hearing aids provided to children within the IHP are required to ensure compatibility with RM systems. This has included Direct Audio Input (DAI) systems in the past via audioshoes with internal or external receivers. These have largely now been replaced with device-integrated wireless receivers. RM compatibility with these technologies enables coupling of RM system(s) to the hearing aid(s) when deemed appropriate.

If the IHP audiologist determines that the infant or young child is a candidate for an RM system, the audiologist shall explain the option to the family and facilitate careful consideration and informed choice. If the device option is elected by the family, the audiologist shall provide the appropriate prescription to the parents, and/or facilitate access to service provision, as soon as is appropriate.

CLINICAL PRACTICE GUIDELINES

The American Academy of Audiology (AAA) developed clinical practice guidelines for remote microphone hearing assistance technology for children and youth from birth to 21 years (2011). It should be noted that the term “remote microphone hearing assistance technology (RMHAT)” used in the AAA guideline, is synonymous with the term “remote microphone (RM) system” that is used in this protocol, and both terms will be used interchangeably within this addendum. The AAA guideline, which is based on peer-reviewed and non-peer-reviewed evidence, as well as consensus practice, provides a comprehensive guide to the application of RM systems 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 an RM system 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 RM systems 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 an RM sytem to infants and children within the IHP. It is also important that the introduction of the RM system 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.

RM VERIFICATION

For personal RM systems coupled to hearing aids, the AAA Guideline recommends a “transparency protocol” in which the output of the RM/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 RM 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.

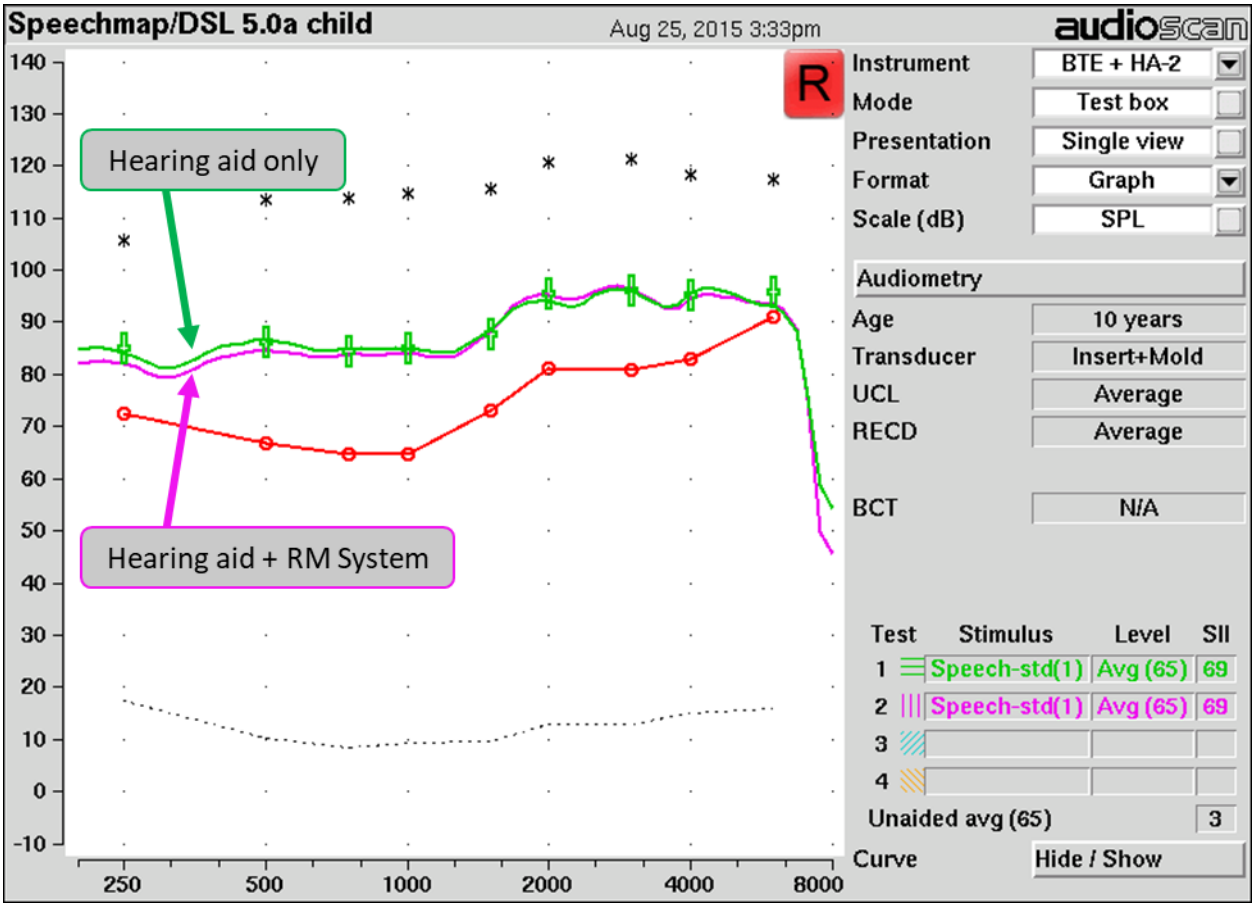


Figure 1. Example of the Ear-level RM Transparency Verification Protocol.

CONCLUSION

For many children within the IHP, RM systems 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 criteria and verification support for IHP Audiologists considering RM systems for their young patients.

ADDENDUM 7: PROVISION OF BONE CONDUCTION DEVICES

SUMMARY

Bone conduction hearing devices (BCD) are a management option for children within the IHP who have unilateral or bilateral conductive or mixed hearing losses who cannot wear conventional air conduction hearing aids. They can also be used for children who have limited useable hearing unilaterally (LUHU), commonly known as single sided deafness (SSD; see Addendum 5: UHL Addendum). The provision of BCDs to infants and children is within the scope of practice of CASLPO-registered Audiologists. The following is a summary of the best available evidence and expert consensus for the provision of BCDs to children based on a clinical consensus document (Bagatto et al., 2021). As further knowledge is accrued, this addendum will be revised.

TYPES OF BONE CONDUCTION DEVICES

BCDs transmit sound through vibration of the skull to the cochlea and are often categorized as passive drive or direct drive. Coupling to the skull is achieved either through surgical placement of a portion of the BCD under or through the skin, or non-surgically held in place with a soft headband or adhesive on the mastoid bone of the skull. Transmission *across* the skin is transcutaneous and *through* the skin is percutaneous. Details of each category of device are described in the following sections.

1. ***Direct Drive***
    - ***a.*** **Percutaneous** devices transmit sound vibrations directly through an abutment surgically implanted through the skin and into the mastoid bone of the skull;
    - ***b.*** **Active transcutaneous** devices contain an external sound processor connected via magnet to a surgically implanted transducer under the skin.
2. ***Passive Drive***
    - ***a.*** **Non-magnetic** transducers are held on top of the skin of the mastoid bone by a soft headband or adhesive that holds it in place. No surgery is required;
    - ***b.*** **Passive transcutaneous** devices consist of a magnetic processor surgically implanted under the skin with sound vibrations transmitted through the skin by an external transducer placed on the mastoid bone.

For the majority of the children in the IHP, non-magnetic transcutaneous BCDs (i.e., 2.a. above) are suitable. This is because the age of surgical candidacy for BCDs is around age 5 years and older (Wade, 2002). One reason for this criteria is that currently available BCDs require a particular skull thickness (i.e., at least 3mm) to accommodate the device. Given the majority of children in the IHP are under 5 years of age and not older than 6 years of age due to eligibility for IHP services, this addendum focuses on the provision of non-magnetic transcutaneous BCDs for children that do not require surgery.

CANDIDACY

Infants and children who meet the following criteria are considered candidates for non-magnetic transcutaneous BCDs within the IHP:

1. Unilateral or bilateral conductive hearing loss with an air-bone gap of > 30 dB eHL/HL and bone conduction PTA ≤ 25 dB eHL/HL; or
2. Unilateral or bilateral mixed hearing loss with an air-bone gap of > 30 dB HL and bone conduction PTA ranging from > 25 dB HL to ≤ 60 dB HL; and
3. Contraindications for using air conduction hearing aids (e.,g., microtia/atresia, recurrent ear infections); and

4. Contraindications for surgical placement of BCHD.

Note: PTA is calculated using 0.5, 1, 2, and 4 kHz. If thresholds at 1 kHz are not available, PTA is calculated from the other three frequencies.

Infants and young children who have limited useable hearing unilaterally (LUHU), which is often the case with profound unilateral sensorineural hearing loss, may be considered for a BCD. This group is not the focus of this addendum. Please refer to the Unilateral Hearing Loss Addendum within this protocol for further guidance.

ASSESSMENT FOR CANDIDACY

Infants and children who may be candidates for BCDs must undergo an IHP Assessment adhering to current IHP protocols. Due to the different types of hearing loss that candidate children in the IHP present with (i.e., conductive or mixed), some modifications to IHP Assessment protocols may be necessary to appropriately determine candidacy for BCDs. These modifications shall be documented by the IHP Audiologist. The following are some considerations when conducting a hearing assessment for infants and children who may receive a BCD(s):

- Air conduction thresholds through ABR or VRA/CPA may not be possible to obtain with the child due to the presence of microtia and/or atresia. Bone conduction thresholds therefore become the priority for a complete assessment; and
- For CBA testing, masking noise shall be used whenever possible to obtain bone conduction thresholds for unilateral atresia cases.

One low and one high frequency bone conduction threshold is necessary for the affected ear(s) to be fitted with the BCD. In particular, bone conduction thresholds at 500, and 2000 or 4000 Hz for the affected ear(s) shall be obtained prior to initiating the provision of amplification. Threshold estimates at other frequencies (e.g., 3000 Hz) are recommended, but not required for the initial provision of amplification.

SELECTION AND PRESCRIPTION CONSIDERATIONS

Considerations for selecting transcutaneous BCDs for infants and children are listed below and are similar to air conduction devices:

- Tamperproof battery door
- Direct audio input or Bluetooth for connection to remote microphones
- Datalogging
- Feedback management
- Access to noise management strategies
- Ability to disable volume control and program button
- Optimized speech audibility
- Connectivity to skull simulator for device verification

Current BCDs that are available for children have most of the above capabilities. It is recommended that children who have the candidate hearing loss bilaterally be considered for a binaural fitting with generally similar benefits as binaural fittings with air conduction devices. This is because bone conduction interaural attenuation in children is typically greater than in adults, ranging from 10 to 30 dB HL (Lau & Small, 2021).

Bone conduction devices with high maximum force level output (MFO), such as power devices, should be considered in order to maximize headroom within the fitting. This becomes an essential piece when the infant presents with a mixed hearing loss due to the added sensorineural component.

DSL BCD PRESCRIPTIVE TARGETS

DSL targets for direct drive (percutaneous) BCDs are available and can be applied within some hearing aid test systems (i.e., Audioscan Verifit; Hodgetts & Scollie, 2017). The current DSL targets have been validated for use with percutaneous devices using an abutment in adults only (Hodgetts & Scollie, 2017; Scollie et al., 2018). They may be used when fitting transcutaneous BCDs to children, with some important considerations, which are described in the verification section below. One important consideration relates to the nature of the delivery of the sound vibrations (i.e., across the skin versus through the skin) and how that influences the prescriptive targets. In particular, the loss of dB force level due to sound vibrations being absorbed when delivered across the skin, or transcutaneously, requires careful consideration for DSL targets. Skin transmission causes attenuations mainly in the high frequency region and can be approximately 5 dB at 1 kHz, up to 25 dB at 6-8 kHz (Kurz et al., 2014).

Further, individual device characteristics impact the prescriptive targets in a way that air conduction devices do not. For example, the maximum force output (MFO) of the BCD plays an important role due to the gain limitations of the sound processor and the likelihood of distortion and/or saturation at higher levels that is not typically a concern with air conduction devices. These factors are currently areas of ongoing investigation for consideration in the development of DSL BC targets for non-magnetic transcutaneous devices.

Even without DSL BCD transcutaneous targets, skin transmission loss as well as individual device characteristics can be compensated for using additional steps within the pediatric BCD fitting process. In particular, measuring frequency-specific thresholds using the BCD device to be fitted, also known as in-situ testing, is necessary once it is developmentally appropriate for the child. This will individually account for the child's skin transmission loss when using the BCD and include the device characteristics when conducted during the fitting and verification process. If in-situ testing with the BCD is not possible due to the child's developmental capabilities, or device type, application of ABR or VRA audiometric bone conduction thresholds may be used for the fitting until in-situ testing is possible. A delay in the provision of the BCD should not occur while waiting for in-situ testing to be completed. Adjustments to the fitting process based on this common clinical scenario are described below.

ASSESSMENT FOR FITTING: IN-SITU TESTING WITH THE BCD

When fitting BCDs to children in the IHP, it is recommended that in-situ thresholds with the prescribed device(s) be obtained as soon as possible to account for the individual child's skin transmission loss and device characteristics when wearing the transcutaneous BCD(s). Since this requires methods similar to conditioned behavioural audiometry (i.e., VRA, CPA), success is likely when the child is developmentally able.

In-situ testing using the BCD(s) provided to the child are as follows: (see Figure 1).

1. Shall be conducted in a sound-treated room, whenever possible.
2. Equip the room with VRA reinforcers as described in the IHP *Audiometric Assessment for Children Aged 6 to 60 months* protocol.
3. Situate a computer equipped with the BCD fitting software on the examiner side of the room and ensure the device can be connected through to the test side, where the child is seated.
    a. Device-to-computer connection can be accomplished by using the patch panel of the sound treated room for passage of a connecting cable (e.g., USB extension cord). Place the programming device (e.g., NoahLink or HiPro2) inside the sound treated room.
    b. The BCD computer is used to present stimuli and should therefore be in close proximity to the examiner.
4. Connect the selected BCD to the fitting software and ensure communication from the examiner side of the room through to the test side.
5. Couple the BCD to the child's mastoid with the appropriate headband tightness and seat the child in the sound treated room.

a. Headband tightness should allow for two adult fingers to fit underneath comfortably. Evidence of the headband being placed on the child (i.e., reddish skin) should not occur.
b. Typical placement is on the child's mastoid process.

6. Present test stimuli from the fitting software on the BCD computer directly to the BCD and conduct a threshold search as described in the IHP *Audiometric Assessment for Children Aged 6 to 60 months* protocol.
    a. Frequencies tested should include a minimum of one low and one high frequency bone conduction threshold in each ear to be fitted. For example, 500 and 4000 Hz.
7. In-situ thresholds obtained using this approach are used in two ways:
    a. They will be included in the fitting software and are therefore used to generate a manufacturer's default fitting based on the manufacturer's proprietary software, and
    b. They will be entered into the hearing aid test system for verification.

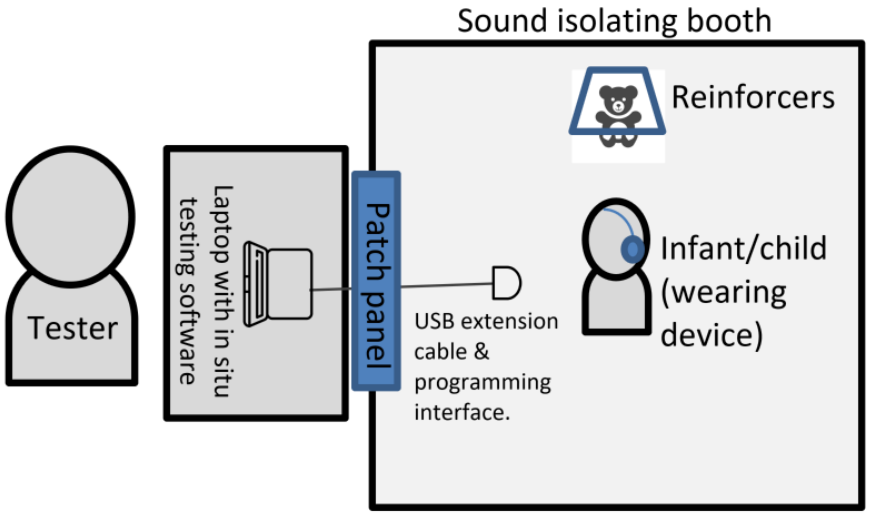


Figure 1. Recommended equipment configuration for enabling conditioned behavioural audiometry procedures during in-situ audiometry with bone conduction hearing devices.

WHEN IN-SITU TESTING IS NOT AVAILABLE

In-situ testing will most often be unavailable during the early months of life when reliable conditioned behavioural audiometry is not possible and ABRA is the assessment strategy applied. When in-situ testing with the BCD is not possible due to the child's developmental capabilities, application of ABR (eHL) bone conduction thresholds shall be used for the fitting until in-situ testing is possible. In some cases, early attempts at audiometric VRA may be successful and in-situ testing is unavailable due to habituation or time. Application of VRA (HL) bone conduction thresholds shall be used at the clinician's discretion. A delay in the provision of a BCD shall not occur while waiting for in-situ testing to be completed.

As a result of completing the IHP ABRA or CBA protocol, audiometric bone conduction thresholds are available for the child to be fitted with BCD(s). Research indicates that audiometric bone conduction thresholds are better compared to in-situ thresholds obtained with transcutaneous BCDs on a soft headband (Gascon et al., 2022). Differences of as much as 5.93 dB at 250 Hz, to 40 dB at 6000 Hz have been noted, and reflect transducer and device characteristics as well as skin transmission loss (Gascon et al., 2022).Therefore, **values for audiometric bone conduction (BC) thresholds that predict in-situ BCD thresholds shall be applied**. The predicted in-situ BCD thresholds are used for fitting the BCD, rather than the measured BC audiometric thresholds. Based on research

done at the National Centre for Audiology (NCA), values for children fitted with non-surgical BCDs will be applied in the following clinical scenarios:

1) **When BC Audiometric Thresholds are Measured at IHP Minimum Test Levels**
    - Apply 20 dB to predict the in-situ BCD threshold
    - The IHP Assessment Protocols indicate minimum test levels of 25 dB eHL/HL. It is possible that the infant's audiometric BC thresholds are better than the minimum test level. Using a 20 dB predicted in-situ BCD threshold accounts for potentially better thresholds as well as differences between audiometric and in-situ BCD thresholds, as mentioned above.
2) **When BC Audiometric Thresholds are Elevated**
    - Add 10 dB to each elevated audiometric BC threshold (in eHL or HL) to predict the in-situ BCD thresholds.
    - This correction accounts for the differences between audiometric and in-situ BCD thresholds for the reasons mentioned above, and considers the elevated audiometric BC thresholds from the cochlea to reflect the infant's mixed loss.

Similar to the ABR nHL to eHL corrections, the corrections for mixed losses use the measured audiometric bone conduction thresholds to predict in-situ thresholds for children being provided with a BCD. One important difference is that the **10 dB correction is added to each elevated BC audiometric threshold** to predict the in-situ BCD thresholds for the mixed component of the loss. Whereas **a flat 20 dB value** is applied for frequencies where BC audiometric thresholds are measured at the IHP minimum test levels, as is the case for conductive losses. **If a child has a combination of BC audiometric thresholds at IHP minimum test levels (i.e., conductive) and elevated BC audiometric thresholds (i.e., mixed component) at different frequencies, apply the appropriate value for that frequency** (see Figure 2)**.** Examples for each clinical scenario are provided below. For these applications, further validation is necessary and is an ongoing area of investigation at the NCA.

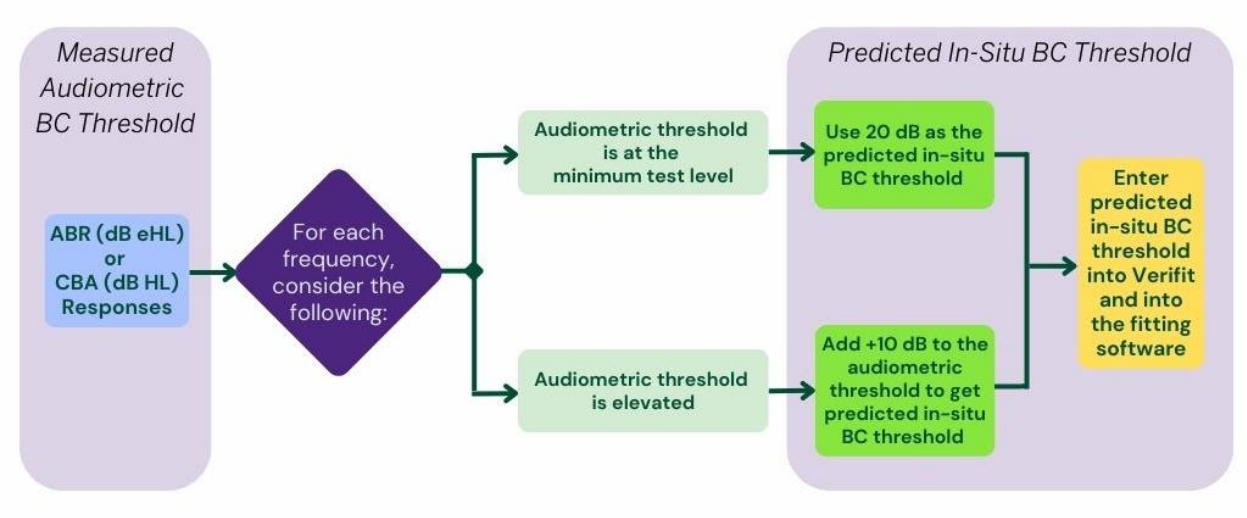


Figure 2. Obtaining predicted in-situ BC thresholds from audiometric thresholds when in-situ testing is unavailable.

VERIFICATION

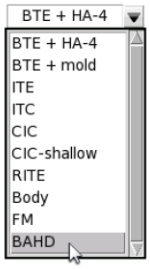
In the absence of the availability of prescriptive targets and clinical tools to measure the force level (FL) output of BCDs, aided thresholds were a common method for verification. The limitations of behavioural verification are well-documented and not recommended for verification of air or bone conduction hearing devices to infants and young children. Among the limitations are the lack of normative ranges of aided thresholds when verifying hearing aids in children with various degrees of hearing loss. Further, they do not provide the exact speech and maximum output levels provided by the fitted device in order to verify whether the child is accessing speech optimally. As such, objective verification of BCDs using a clinically available skull simulator shall be conducted. Skull simulators are available for the Audioscan® Verifit 1 and 2 (Figure 3).

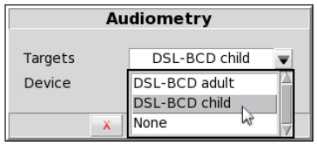
Figure 3: Audioscan Skull Simulator

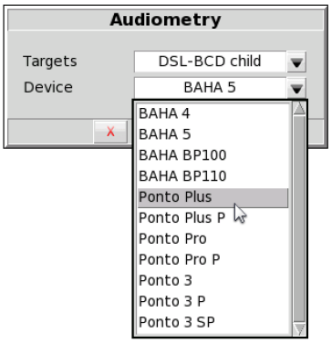
A skull simulator is similar to a 2cc coupler used with traditional air conduction hearing aids with the difference being the BCD can be attached for output measures. With this tool, the dB force level output (dB FL), which is the reference measure for BCD, is converted to an electrical signal.

A skull simulator is used for verifying BCDs in children in a similar way as a 2cc coupler is used to verify air conduction hearing aids. The test box of the hearing aid system is used and cooperation of the child is not required. The test box offers a controlled environment with which to deliver speech signals at various input levels and a maximum input to assess the maximum force level output (MFO) of the device to be fitted. The goals of verification of a BCD on a skull simulator are the same for air conduction hearing aids: to ensure appropriate speech access that is comfortable and safe across a wide range of frequencies. The following steps describe the verification of BCDs for children:

GENERATE BCD TARGETS







1. In Speechmap, select “BAHD” as the instrument type.
2. Choose fitting rule: DSL-BCD Child.
    a. Note: Percutaneous targets have not been validated for children at this time
3. Select device to be fitted from drop down menu.
4. Enter measured or predicted in-situ BCD thresholds into the test system and the fitting software.
5. DSL speech-based and output targets will be generated and are used to verify the BCD in dB FL output.

MEASURE THE FORCE LEVEL OUTPUT USING A SKULL SIMULATOR

1. Calibrate the coupler microphone used for BTE fittings.
2. Disconnect the coupler microphone and connect the skull simulator into the coupler microphone port (see photo).
    a. The skull simulator faces different directions depending on which side the BCD will be fitted

i. Red visible for a right ear fitting
ii. Blue visible for a left ear fitting


Position for left device


Position for right device

3. An artificial abutment is part of the skull simulator to support connection of some BCDs for verification.
4. Snap the BCD onto the abutment of the skull simulator. A rocking motion placement may be necessary to successfully snap the device in place.

5. Position the reference microphone 1 to 3 mm from the front BCD microphone opening (i.e. the microphone closest to the ref mic).
6. Close the lid as much as possible. The VF2 should close completely, however the VF1 will not.
7. Ensure the BCD is connected to the fitting software and the manufacturer's default fitting has been applied.
8. Deliver signals from the hearing aid test system as described in earlier sections of this protocol (Section 5: Verification of Amplification).

Since current DSL targets for children fit with BCD(s) have not been validated at the time of this addendum, it is important to view these targets descriptively, rather than as a guideline to fitting the device (as would be the case with air conduction devices). These targets can be used as a quality control measure and for baseline purposes.

CASE EXAMPLE 1: APPLYING PRESCRIPTIVE TARGETS USING A TRANSCUTANEOUS DEVICE

This case illustrates an example of a manufacturer's default fitting of a BCD with the recommended settings displayed. In-situ thresholds were entered into the Verifit and the fitting software. Although the correct device was selected, the targets are significantly different than the output of the bone conduction device. **Recall that the targets shown are for percutaneous devices, and have not yet been developed or validated for use with transcutaneous devices.** Therefore, at this time, you should only make adjustments if your outcome measures, observations, and/or reports from the child or family are available for guidance. This protocol component will be updated when validated targets become available for this device category.

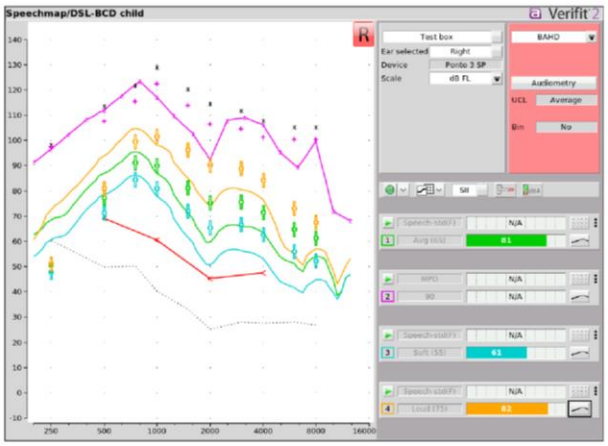


Figure 4. Example of transcutaneous hearing aid output using percutaneous DSL targets.

VALIDATION

Outcome measures for children who have been provided with BCD(s) are similar to those recommended in this protocol. Please refer to Appendix G: Outcome Measure Protocol Application. However, it is important to note that the tools used within the current Outcome Measurement protocol have not been characterized for children who wear BCDs. Further, the SII norms provided are not available for BCDs and should not be compared to current SII norms.

The following case examples demonstrate application of the BCD Addendum to various clinical cases that follow the development of a child.

CASE EXAMPLE 2A: A CLINICAL CASE WITH CONDUCTIVE HEARING LOSS AND PREDICTED IN-SITU THRESHOLDS

Katie was diagnosed with unilateral microtia and atresia at birth. She is now 4 months old and is receiving her first bone conduction hearing device on the affected side. Her most recent assessment was completed at 3 months through ABR and indicated a conductive hearing loss (i.e., measurable bone conduction thresholds at minimum test levels). Since Katie was not old enough for in-situ testing at the time of the initial fitting, a value of 20 dB was inputted, across frequency, into the Verifit and fitting software to verify the BCD using the skull simulator prior to fitting.

BC Threshold	Stimulus Frequency			
	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABR (eHL)	25	25	25	25
Predicted in-situ threshold entered in Verifit and fitting software	20	20	20	20

Predicted in-situ thresholds were entered into the BCD fitting software and used to calculate an appropriate amount of gain for the given device configuration (i.e., on softband). The BCD was then verified on the Verifit 2 against DSL-BCD child targets to provide a baseline description of the fitting. The BCD output was not adjusted to match targets.

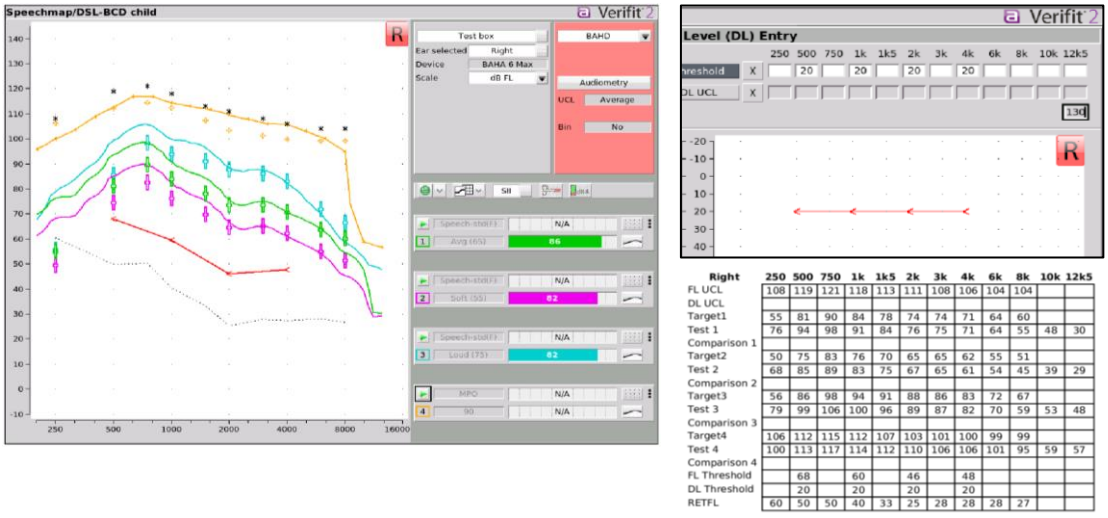


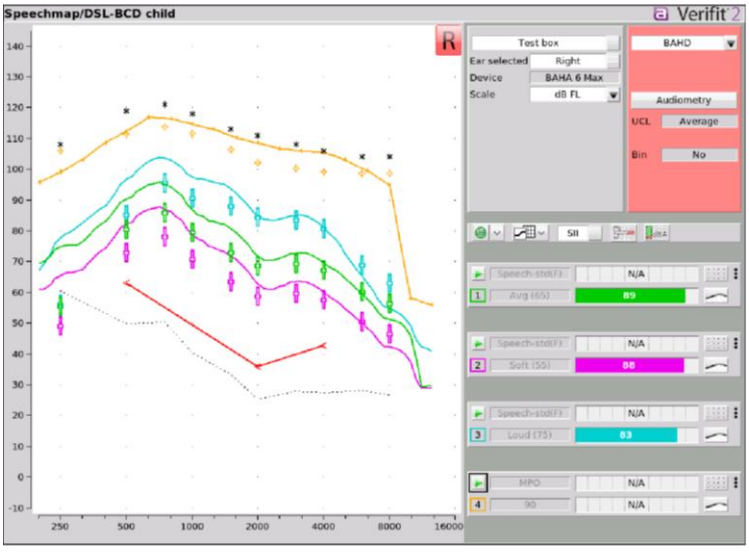
Figure 5. Using predicted in-situ thresholds to verify a pure conductive loss for Case 2A.

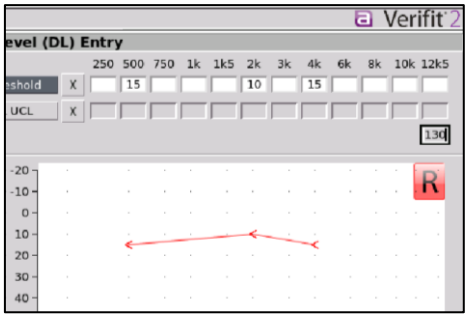
CASE EXAMPLE 2B:
A CLINICAL CASE WITH CONDUCTIVE HEARING LOSS AND MEASURED IN-SITU THRESHOLDS

Katie is now 8 months old. She is developmentally ready for VRA testing. In-situ thresholds were obtained using her BCD and inputted into the Verifit and fitting software, without correction, to generate targets and re-verify the device. The use of predicted in-situ values were not needed because they were measured directly.

BC Threshold	Stimulus Frequency			
	500 Hz	1000 Hz	2000 Hz	4000 Hz
Measured VRA in-situ threshold	15	-	10	15
In-situ threshold entered in Verifit and fitting software	15	-	10	15

The measured in-situ thresholds were entered into the BCD fitting software and used to calculate an appropriate amount of gain for the given device configuration (i.e., on softband). The BCD was then verified on the Verifit 2 against DSL-BCD child targets to provide a description of the fitting. The BCD output was <u>not</u> adjusted to match targets.





Right	250	500	750	1k	1k5	2k	3k	4k	6k	8k	10k	12k5
FL UCL	108	119	121	118	113	111	108	106	104	104		
DL UCL												
Target1	55	81	86	80	73	69	70	67	60	56		
Test 1	75	90	95	87	81	72	73	70	60	51	46	30
Comparison 1												
Target2	49	73	78	71	64	59	60	58	50	47		
Test 2	65	82	87	79	72	63	63	60	50	42	37	29
Comparison 2												
Target3	56	85	96	91	88	84	84	81	69	63		
Test 3	78	97	104	97	94	85	85	81	65	55	49	41
Comparison 3												
Target4	106	111	114	112	107	102	100	99	99	99		
Test 4	99	112	116	115	111	108	106	105	100	95	58	56
Comparison 4												
FL Threshold		63				36		43				
DL Threshold		15				10		15				
RETFL	60	50	50	40	33	25	28	28	28	27		

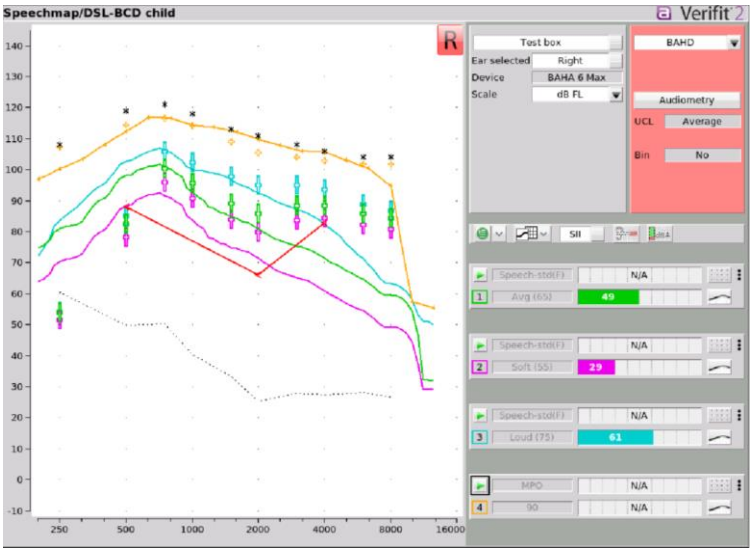
Figure 6. Using in-situ thresholds measured with the child's BCD to generate targets and verify for Case 2B.

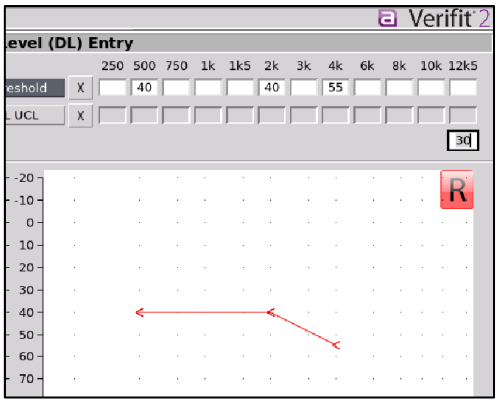
CASE EXAMPLE 3A:
A CLINICAL CASE WITH MIXED HEARING LOSS AND PREDICTED IN-SITU THRESHOLDS

Adam was born with Down Syndrome and at his initial ABR appointment around 4 months of age, the Audiologist noted a mixed hearing loss in the right ear. After the eHL corrections were applied, additional corrections for fitting the BCD were calculated and inputted into the Verifit and fitting software.

BC Threshold	Stimulus Frequency			
	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABR (eHL)	30	-	30	45
Correction	+10	-	+10	+10
Predicted in-situ threshold entered in Verifit and fitting software	40	-	40	55

The predicted in-situ thresholds were entered into the BCD fitting software and used to calculate an appropriate amount of gain for the given device configuration (i.e., on softband). The BCD was then verified on the Verifit 2 against DSL-BCD child targets to provide a baseline description of the fitting. The BCD output was <u>not</u> adjusted to match targets.





Right	250	500	750	1k	1k5	2k	3k	4k	6k	8k	10k	12k5
FL UCL	108	119	121	118	113	111	108	106	104	104		
DL UCL												
Target1	54	83	101	96	89	86	88	88	86	84		
Test 1	81	98	101	93	85	81	75	71	65	60	54	32
Comparison 1												
Target2	52	78	96	91	84	80	84	85	82	81		
Test 2	70	88	92	84	75	71	65	61	54	49	44	29
Comparison 2												
Target3	54	85	106	103	98	95	95	94	89	87		
Test 3	83	103	106	100	97	93	87	82	71	63	58	50
Comparison 3												
Target4	107	114	117	114	109	106	104	103	102	102		
Test 4	100	112	117	114	112	110	106	106	101	95	57	56
Comparison 4												
FL Threshold		88				66		83				
DL Threshold		40				40		55				
RETFL	60	50	50	40	33	25	28	28	28	27		

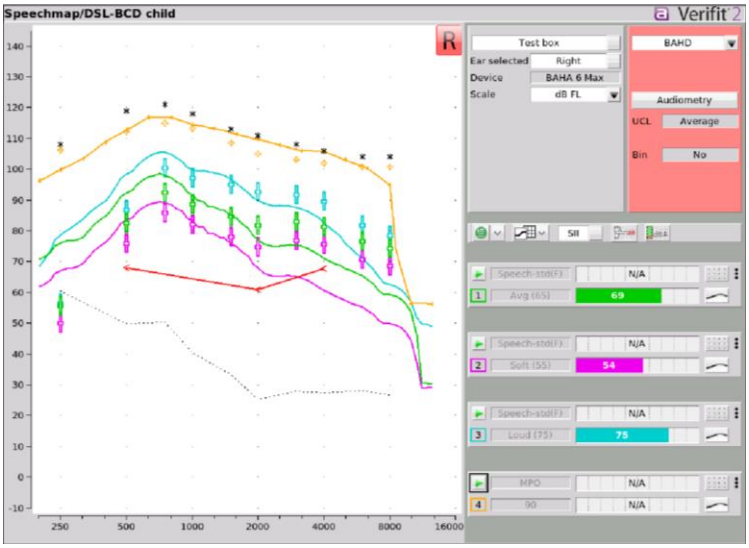
Figure 7. Using predicted in-situ thresholds to verify a mixed loss for Case 3A.

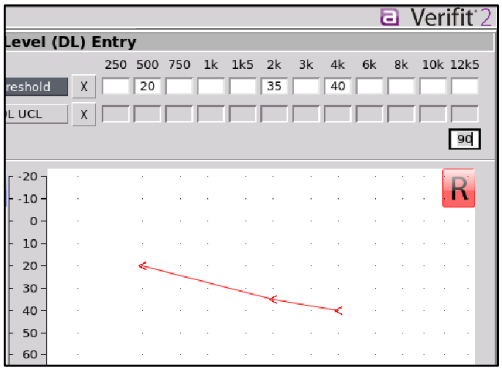
CASE EXAMPLE 3B:
A CLINICAL CASE WITH MIXED HEARING LOSS AND MEASURED IN-SITU THRESHOLDS

Adam is now 14 months of age and is capable of doing reliable VRA testing. In-situ thresholds were obtained using his BCD and inputted into the Verifit and fitting software to re-verify the device. No corrections were used for this process because in-situ thresholds were measured.

BC Threshold	Stimulus Frequency			
	500 Hz	1000 Hz	2000 Hz	4000 Hz
Measured VRA in-situ threshold	20	-	35	40
In-situ threshold entered in Verifit and fitting software	20	-	35	40

The measured in-situ thresholds were entered into the BCD fitting software and used to calculate an appropriate amount of gain for the given device configuration (i.e., on softband). The BCD was then verified on the Verifit 2 against DSL-BCD child targets to provide a description of the fitting. The BCD output was <u>not</u> adjusted to match targets.





Right	250	500	750	1k	1k5	2k	3k	4k	6k	8k	10k	12k5
FL UCL	108	119	121	118	113	111	108	106	104	104		
DL UCL												
Target1	56	83	93	89	85	82	83	82	77	74		
Test 1	76	92	98	92	85	77	75	71	65	59	54	30
Comparison 1												
Target2	50	76	86	82	78	75	77	76	71	69		
Test 2	67	83	89	83	76	68	65	61	55	50	44	29
Comparison 2												
Target3	56	87	101	97	95	93	92	90	82	79		
Test 3	79	98	105	100	97	90	88	83	71	63	57	49
Comparison 3												
Target4	106	112	115	113	109	105	103	102	101	101		
Test 4	100	113	117	115	112	110	106	106	101	95	56	56
Comparison 4												
FL Threshold		68				61		68				
DL Threshold		20				35		40				
RETFL	60	50	50	40	33	25	28	28	28	27		

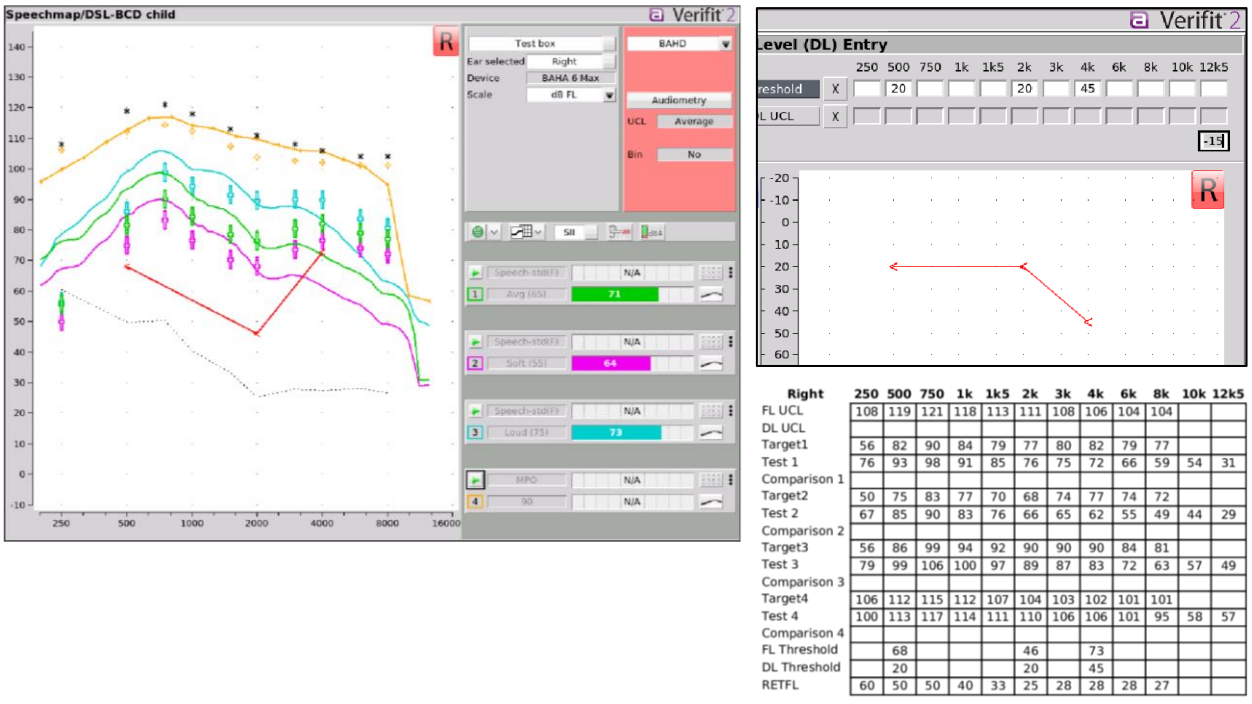
Figure 8. Using in-situ thresholds measured with the child's BCD to generate targets and verify for Case 3B.

CASE EXAMPLE 4A:
A CLINICAL CASE WITH CONDUCTIVE AND MIXED LOSS COMPONENTS USING PREDICTED IN-SITU THRESHOLDS

Ahmed was born with Crouzon Syndrome and after a few ABR appointments, the Audiologist noted a conductive hearing loss in the left ear and a hearing loss with mixed components in the right ear. After the eHL corrections were applied, additional corrections for fitting the BCD were calculated and inputted into the Verifit and fitting software. Only procedures for the right ear are shown in this example.

BC Threshold	Stimulus Frequency			
	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABR (eHL)	25	-	25	35
Correction	Flat 20	-	Flat 20	+10
Predicted in-situ threshold entered in Verifit and fitting software	20	-	20	45

The predicted in-situ thresholds were entered into the BCD fitting software and used to calculate an appropriate amount of gain for the given device configuration (i.e., on softband). The BCD was then verified on the Verifit 2 againt DSL-BCD child targets to provide a baseline description of the fitting. The BCD output was <u>not</u> adjusted to match targets.



Right	250	500	750	1k	1k5	2k	3k	4k	6k	8k	10k	12k5
FL UCL	108	119	121	118	113	111	108	106	104	104		
DL UCL												
Target1	56	82	90	84	79	77	80	82	79	77		
Test 1	76	93	98	91	85	76	75	72	66	59	54	31
Comparison 1												
Target2	50	75	83	77	70	68	74	77	74	72		
Test 2	67	85	90	83	76	66	65	62	55	49	44	29
Comparison 2												
Target3	56	86	99	94	92	90	90	90	84	81		
Test 3	79	99	106	100	97	89	87	83	72	63	57	49
Comparison 3												
Target4	106	112	115	112	107	104	103	102	101	101		
Test 4	100	113	117	114	111	110	106	106	101	95	58	57
Comparison 4												
FL Threshold		68				46		73				
DL Threshold		20				20		45				
RETFL	60	50	50	40	33	25	28	28	28	27		

Figure 9. Using predicted in-situ thresholds to verify a loss with conductive and mixed components for Case 4A.

CASE EXAMPLE 4B:
A CLINICAL CASE WITH CONDUCTIVE AND MIXED LOSS COMPONENTS USING MEASURED IN-SITU THRESHOLDS

Ahmed is now 16 months of age and is capable of doing reliable VRA testing. In-situ thresholds were obtained using his BCD and inputted into the Verifit and fitting software to re-verify the device. No corrections were used for this process because in-situ thresholds were measured.

BC Threshold	Stimulus Frequency			
	500 Hz	1000 Hz	2000 Hz	4000 Hz
Measured VRA in-situ threshold	25	-	35	35
In-situ threshold entered in Verifit and fitting software	25	-	35	35

The measured in-situ thresholds were entered into the BCD fitting software and used to calculate an appropriate amount of gain for the given device configuration (i.e., on softband). The BCD was then verified on the Verifit 2 against DSL-BCD child targets to provide a description of the fitting. The BCD output was <u>not</u> adjusted to match targets.

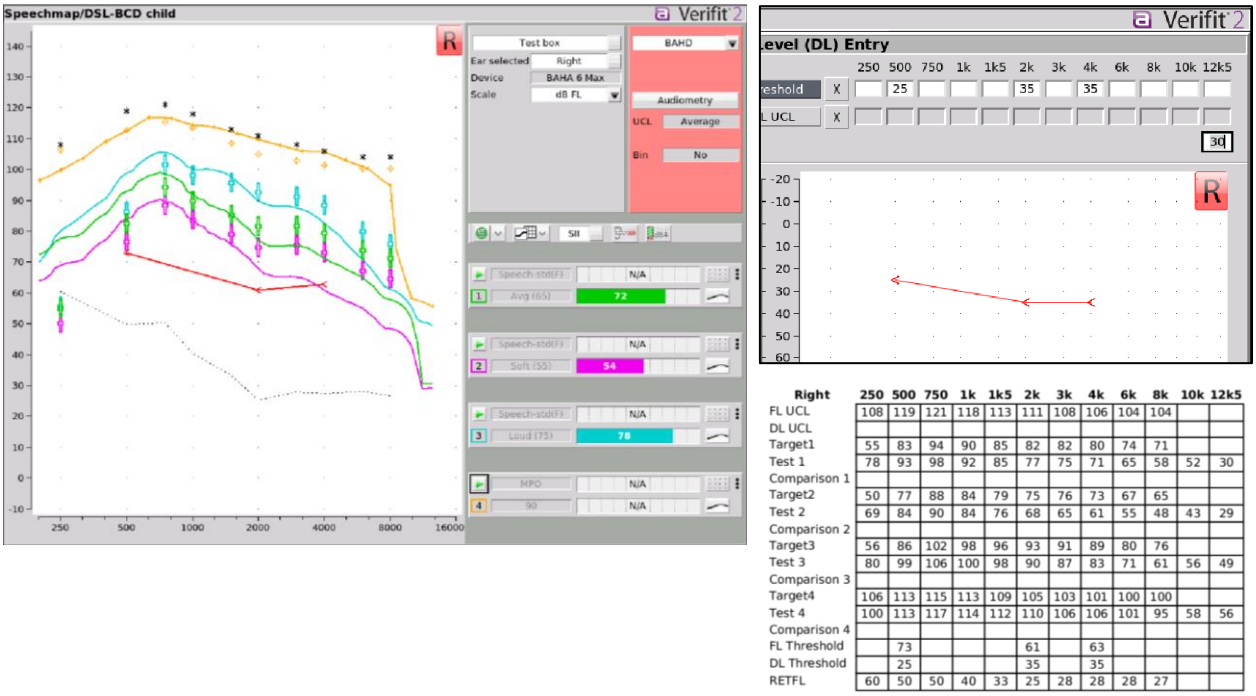


Figure 10. Using in-situ thresholds measured with the child's BCD to generate targets and verify for Case 4B.

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