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PROTOCOL FOR AUDITORY BRAINSTEM RESPONSE – BASED AUDIOLOGICAL ASSESSMENT (ABRA)

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LEAD AUTHOR
Martyn Hyde

EDITORIAL GROUP
Marlene Bagatto
Vanessa Martin
Marie Pigeon
Susan Scollie
Jill Witte

CORRESPONDENCE

Vanessa Martin, M.Cl.Sc., Aud (C), Reg. CASLPO
Program Consultant
Early Intervention Policy and Programs Unit
Early Child Development Branch
Strategic Policy and Planning Division
Ministry of Children and Youth Services
101 Bloor Street West, 3rd Floor,
Toronto, ON M5S 2Z7
Tel: 416 327-4872
E-mail: vanessa.martin@ontario.ca

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The sharing of insights and procedures by the British Columbia Early Hearing Program (BCEHP) has contributed significantly to development of this protocol, especially in the areas of adaptive test strategy and procedures related to Auditory Neuropathy Spectrum Disorder (ANSD).

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REVISION SUMMARY

This version of the ABRA Protocol (2016.02) supersedes all previous versions of this document. Notable changes are listed below. They comprise corrections and clarifications of version 2016.01 (issued April 04, 2016) arising mainly through feedback by the editorial group and from IHP audiologists' reviews and experiences to date with that version. There are no substantive changes to the key procedures defined in the previous version. The changes are indexed by the Item numbers or Appendices in 2016.01.

ITEM		DESCRIPTION
1.12	SCREENING BYPASS IN VERY HIGH RISK BABIES	In the Details and Rationale, Ear Canal Atresia and Sibling under 10 years with PHL are explained in more detail as additional Screening Bypass risk indicators that will be implemented when upcoming revised IHP protocols for Screening and for Surveillance are issued. The Sibling with PHL risk indicator is not to be negated by speculative or presumptive causes of PHL reflecting other risk indicators in the affected sibling. Association between a risk indicator and PHL does not determine causation of the PHL, nor does any known risk indicator protect the baby from PHL that is actually caused by another risk indicator or by unknown factors.
3.15	NUMBER OF SWEEPS AND AVERAGES	Discrepancies between sweep counts in averages specified in the Executive Summary and the Details and Rationale sections for this Item number were eliminated. A tonepip threshold upper bracket RP sometimes can be defined clearly with as few as 1024 sweeps followed by 512 sweeps in a separate, confirmatory average, or vice versa.
5.03	MIDDLE-EAR ANALYSIS: ACOUSTIC REFLEXES	Inconsistencies between the Details and Rationale Section 5.03 and Appendix K with regard to stimuli for acoustic reflex measurement were removed. AR testing is discretional. Broad-band noise (BBN) stimuli are preferred to 1kHz tonepips because they are more effective at AR elicitation, but the choice is also discretional.
APP C	SECOND OPINION DTC ACCESS	Second Opinion record reviews by, or referrals to, DTCs are usually instigated by affected families, or occasionally by 3rd parties such as physicians. In contrast, DTC Consultative reviews or referrals are usually initiated by the primary audiologist as part of a clinical decision support interaction with a DTC. Any case that is reviewed by or referred to a DTC on the audiologist's proactive initiative will not be included in any subsequent IHP Standard Practice Review of the audiologist. Second Opinion reviews or referrals are not exempted in this manner.
APP F	IHP NAVPRO STIMULUS TRANSDUCER CALIBRATION	AEP versions currently used in the IHP are AEP 6.2 under Windows XP and AEP 7.2 under Windows 7. Note that both require an open patient file in order to access the calibration drop-down option in Setup, but the previously specified additional steps are required for transducer calibration access under AEP 7.2.
APP G	IHP NAVPRO AEP PROTOCOL SETUP	Several typographical errors, including those relating to Tag setup for 500 Hz test protocols, have been corrected. Note that on Page 89 in Appendix G, the Noise Level stop criterion should be changed from 25 nV to 20 nV.

PROTOCOL EXECUTIVE SUMMARY

This protocol document includes a tabular synopsis of all key protocol elements, followed by expanded sections that may include additional details, rationale, challenges and solutions for each topic area, plus Appendices with selected References and further technical or procedural specifications. There are numerous changes from the 2008 Infant Hearing Program Audiologic Assessment document; the most important areas of change or emphasis are indicated by shading of the topic section number.

The following synopsis can stand alone as a summary of the ABRA protocol. Areas within the 2008 document that relate to protocol for Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA) remain in effect. A separate, revised protocol document for VRA and CPA will be issued in due course.

SECTION 1: THE INFANT HEARING PROGRAM (IHP) SERVICE CONTEXT

	TOPIC	DESCRIPTION
1.01	WHAT IS IHP ABRA?	Auditory brainstem response-based audiological assessment (ABRA) is an audiological assessment that is authorized & funded by the IHP. Its core components include puretone air- and bone conduction threshold estimation & site-of-lesion inference using ear-specific, frequency-specific ABR and tympanometry. Additional techniques may include click-evoked cochlear and neural potentials, distortion product otoacoustic emissions (DPOAE), acoustic reflexes and measurement of RECDs.
1.02	WHO CAN CONDUCT ABRA?	Only Audiologists registered with College of Audiologists and Speech Language Pathologists of Ontario (CASLPO) who are trained and authorized by the IHP to conduct this protocol may provide ABRA services with IHP funding. The IHP audiologist must personally conduct the testing and interpret the results.
1.03	PROTOCOL ADHERENCE IS A REQUIREMENT	All IHP ABRA must be conducted in adherence to this protocol; such adherence is an expectation for continued authorization to provide IHP ABRA services. The protocol includes three classes of procedure: *mandatory*, *conditionally mandatory* in specific circumstances, and *discretional*. Discretional procedures can be carried out provided they do not compromise accuracy or timeliness of the mandatory components. See section 3.03 for details.
1.04	LEGITIMATE DEPARTURE FROM PROTOCOL	It is acknowledged that case-specific situations that justify departure from mandatory protocol elements can arise. Such departures must be noted in the ABR records with a brief explanation. All such notes must be accessible to IHP standard practice review or case audits (see later).
1.05	CHANGES TO THE ABRA PROTOCOL	Prior approval by MCYS is required in order to change substantively any element of this protocol. Program-wide changes can occur only through MCYS directive or by a systematic process that may include survey of Audiologists' experiences or concerns, evidence review and recommendation by a Designated Training Centre (DTC).
1.06	TARGET POPULATION	Candidates for ABRA include all Ontario-resident babies who bypass or do not pass newborn hearing screening, plus children under 6 years of age whose

		hearing is not testable behaviourally with acceptable accuracy.
1.07	TARGET DISORDERS	The IHP target disorder set includes permanent hearing loss (PHL) of 30 dB HL or more at 0.5, 1, 2 or 4 kHz in any ear, ANSD and auditory brainstem pathway disorders that may be detectable using ABR techniques.
1.08	CONDUCTIVE HEARING LOSS (CHL)	The IHP is complementary to OHIP-based, physician-driven audiology services and does not replace them routinely. Purely conductive hearing loss identified by ABRA is not an IHP target unless obviously or presumptively structural, such as in congenital atresia or if a syndrome associated with structural, conductive anomalies is identified or suspected. For minor conductive losses, discharge from the IHP with caregiver counseling and discretional referral to a physician is the norm.
1.09	ABRA OBJECTIVES	In each ear, to detect and quantify hearing loss and, wherever feasible, to infer the site(s) of lesion(s). The overall assessment goes beyond audiometry itself and includes informational and counselling components that help families to become informed, engaged and empowered.
1.10	AGE AT START OF INITIAL ABRA	'Initial ABRA' is the first audiologic assessment in a young infant, typically following either referral from AABR screening or screening bypass for babies at very high risk of PHL. Initial ABRA may involve more than one test session. The first ABRA session is targeted to occur no later than six weeks corrected age. Widespread achievement of this target is a high priority.
1.11	AGE AT COMPLETE INITIAL ABRA	A widely-accepted international performance benchmark is completion of ABRA by three months corrected age at the latest, wherever medically feasible. To improve the provincial level of achievement of this objective is a high priority for IHP Continuous Quality Improvement (CQI).
1.12	SCREENING BYPASS IN VERY HIGH RISK BABIES	Babies with congenital aural atresia, confirmed neonatal meningitis, suspected or confirmed congenital cytomegalovirus (cCMV) infection or who have a sibling under 10 years of age with PHL will usually bypass IHP newborn hearing screening. For babies with meningitis or cCMV, ABRA is targeted to occur as soon as possible after acute recovery. The others listed here should be routed directly to ABRA at no later than six weeks corrected age, as a high priority.
1.13	IHP DESIGNATED TRAINING CENTRES (DTC)	DTCs are authorized by the MCYS to provide IHP support, including advanced training, consultative and ABRA referral services, protocol support and clinical decision support to IHP Audiologists. DTCs also conduct standard IHP practice reviews and implement audits of services as directed by MCYS. The DTCs are the Children's Hospital of Eastern Ontario (CHEO, Ottawa) for ABRA , Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA), Mount Sinai Hospital's Otologic Function Unit (Mount Sinai, Toronto) for ABRA and the National Centre for Audiology (NCA; Western University, London) for Amplification and Outcome Measurement.
1.14	ABRA PROTOCOL SUPPORT BY DTCS	Audiologists who have any question or concern about any aspect of this ABRA protocol are recommended to contact the CHEO or Mount Sinai DTC. This is also a mechanism for protocol clarification and improvement.
1.15	DTC CONSULTATION OR REFERRAL	IHP Audiologists are encouraged to consult a DTC if they wish to discuss ABRA

		procedure, interpretation or next steps in any specific child. Real-time support during testing is not feasible. Email contact is preferred. Records sent by email or fax for review must be de-identified. Audiologists may also elect to refer a baby to a DTC for ABRA. Such referral may be in response to case complexity, difficulty obtaining a satisfactory test, or to secure testing under sedation. The DTC may elect to try unsedated testing first, after review and discussion with the referring Audiologist. See Appendix B for the referral procedure.
1.16	TIMELINESS OF ABRA COMPLETION	Incomplete ABRA after three appointments attended compromises the IHP's primary objective; it is a quality-of-care challenge and a CQI priority. DTC consultation must be considered in a timely manner, then testing under sedation or referral to the DTC may be the next step. Prolonged deferral of assessment, such as to VRA several months later, must be avoided wherever possible.
1.17	CAREGIVER-DRIVEN SECOND OPINION	The IHP does not support repetition of initial complete ABRA unless it is elected by the primary IHP Audiologist or is determined to be appropriate by a DTC, in which cases the process is considered as consultative referral. Where a second opinion request is driven by a caregiver, the Audiologist can offer the option of a DTC review as the IHP's standard procedure. In consultation with the Audiologist, the DTC will examine results and issue a written report on diagnostic inferences and recommendations. The recommendations may include retesting locally or at a DTC. The Audiologist must ensure that the caregiver is aware of the right to seek audiology services outside the IHP, but must be informed that the results of any such testing may have no impact on any future IHP services. See Appendix C for second opinion procedure details.
1.18	ABR TESTING OUTSIDE THE IHP	Results of ABR testing done outside of the IHP must be reviewed by a DTC for validity, accuracy and relevance, prior to provision of subsequent services funded by the IHP.
1.19	ABR THAT IS OUT-OF-PROTOCOL	ABRA results that are suspected by any IHP Audiologist to be substantively non-adherent to the relevant IHP protocol at the time the results were obtained must be reviewed by a DTC prior to being considered in relation to further audiologic services from the IHP.
1.20	CONTINUOUS QUALITY IMPROVEMENT (CQI)	The IHP is required to implement quality assurance and quality management on an ongoing basis, for funding accountability. This is being done through a CQI program that targets all major service components, including ABRA. The CQI includes enhanced training and clinical decision support, as well as performance monitoring. Test timeliness, accuracy, efficiency, protocol adherence and use of supports and referrals are current areas of focus for improvements.
1.21	IHP STANDARD PRACTICE REVIEWS	ABRA providers must participate in document-based practice review. A streamlined process specified by the MCYS will be implemented through DTCs. Practice review is a routine, support-oriented procedure aimed at quality of care verification and improvement. See Appendix D for process specifics.

1.22	ADVERSE EVENT REVIEWS & AUDITS	The IHP is obligated to review instances of possible shortfall in quality of care for individual children and families. Irrespective of how such events come to light, if an adverse event is verified, case-specific clinical remedy will be sought and, depending on the nature of the event, the service involved may be subject to detailed audit by a DTC, where directed by MCYS.
1.23	INFECTION CONTROL (IC) STANDARDS	Infection control practices are typically governed by site-specific, institutional or agency protocols and are outside the purview of this document. If local protocols are not available, generally accepted standards must be applied. The guidelines issued by Speech-Language and Audiology Canada (SAC-OAC) in 2010 are a possible source of further information.
1.24	APPROVED TEST ENVIRONMENTS	With the exception of medical/surgical facilities used for ABRA under sedation or general anaesthesia, ABRA test areas must either satisfy current ANSI standards for manual puretone audiometry or must be specifically pre-approved by the MCYS, through DTC review.
1.25	APPROVED TEST INSTRUMENTATION & SUPPLIES	All instrumentation and supplies used for ABRA must be approved by the MCYS. ABR and DPOAE testing must be done using the Biologic Navpro with appropriate EP and Scout DPOAE software and hardware. Ancillary equipment for tympanometry, acoustic reflex testing and RECD measurement must satisfy the functional specifications detailed in the relevant Appendices and must be approved by MCYS through DTC review.
1.26	APPROVED DEVICE PROTOCOLS & PARAMETERS	All device protocols and parameters **must** be configured **exactly** as specified in relevant Appendices. Departure from specified parameters may compromise ABRA validity or efficiency and will be considered to be out-of-protocol. Setup is recommended to be done by the IHP Audiologist who will conduct the ABRA, with support from a DTC if required. EP and DPOAE Setup may be arranged with the local device supplier (Electro Medical Inc.), for new devices. **Warning: pre-installed Windows 7 EP test protocols from the NavPro manufacturer must not be used but must not be deleted. Such deletion would necessitate a complete system re-install.**
1.27	CLINICAL RECORDS	Clinical records must include the information listed in Appendix D. **Inclusion of the Windows EP List Records table is now mandatory, to document the sequence of test conditions used**.
1.28	PERSONAL HEALTH INFORMATION	Requirements of the Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A must be met. ABRA datafiles stored on laptops and removable media must not be identifiable. Data communicated for approved monitoring and review procedures must be de-identified and code-referenced.

SECTION 2: ABRA PRELIMINARIES

	TOPIC	DESCRIPTION
2.01	URGENCY OF ABRA APPOINTMENTS	Timely attendance for ABRA is critical for achievement of international benchmarks for ABRA completion, yet it remains a significant challenge in many IHP regions. It is affected by timeliness of screening, appropriateness of messaging to caregivers at screening referral, and the effectiveness of ABRA appointment scheduling, all of which are now IHP CQI priorities.
2.02	REQUIRED STATE FOR SUCCESSFUL ABRA	Accurate ABR threshold measurement is possible only in natural or sedated sleep or under general anesthesia (GA). Natural sleep is the first choice, except given long-distance travel or prior failure to sleep, when sedation may be indicated. Success at sleep induction and maintenance depends on the child's age, pre-test instruction adherence, test environment and tester skills. Natural sleep is readily achieved in most infants under 3 months corrected age, but becomes increasingly challenging thereafter.
2.03	PRE-TEST BABY STATE	The baby should arrive for ABRA hungry and tired but not asleep. Variable adherence to pre-test instructions was identified by IHP Audiologists as a barrier to timely ABRA completion. There are large differences in adherence levels across IHP sites. **More effective processes and stronger messaging about pre-test sleep and testing failure are both essential and feasible.**
2.04	TEST ENVIRONMENT & PARTICIPANTS	Test areas should be as conducive as possible to baby sleep and caregiver comfort. Important factors are low sound levels, adequate heating, ventilation, and air conditioning (HVAC), low lighting, good electrical shielding, negligible in-room 60 Hz electrical interference and effective positioning of the equipment and all persons present. Caregiver presence is preferred and their assistance is often effective, given appropriate instruction.
2.05	TONEPIP STIMULUS PARAMETERS	IHP tonepip parameters of 2-1-2 cycle linear rise/plateau/fall modulation **must** be used. The accuracy of ABR thresholds and derived behavioural threshold estimates are specific to these parameters and to all the other parameters and procedures specified in this ABRA protocol (see Appendices E and G).
2.06	STIMULUS CALIBRATION & CHECKING	IHP stimulus transducer calibration settings must be used (Appendix F), **not manufacturer's default values**, with annual electroacoustic checks, daily listening checks and stimulus verification if non-response occurs at high levels. Poor plug contact or defective leads are common causes of stimulus failure or intermittency. Backup transducers and leads are an obvious precaution.
2.07	STIMULUS TRANSDUCERS	IHP-approved insert, supra-aural and bone conduction transducers are required. Inserts must be used for AC testing unless contraindicated anatomically. BC transducers may be discretionally hand-held (with appropriate technique and/or instruction) or secured by a tensor band; hand-held by the Audiologist is preferred, where practicable (see Appendix H).
2.08	ELECTRODE POSITION	The non-inverting electrode must be in the forehead midline, as high and as close as possible to the hairline. The inverting electrodes must be on each mastoid and the common must be on the forehead, with at least 3 cm between the proximal electrode margins.

2.09	ELECTRODE IMPEDANCES	High impedances (target under 5 kΩ) increase pickup of electromagnetic and movement artifacts. Furthermore, different impedances at non-inverting and inverting electrodes (target difference under 1 kΩ) degrade the differential amplifier's ability to reject noise present at both electrode sites, which is the case for many types of large noise. These effects will reduce ABRA accuracy and increase testing time.
2.10	RECORDING CHANNELS	For AC tonepip ABR thresholds, a single differential recording channel must be used, with the inverting electrode on the mastoid ipsilateral to the stimulated ear. For BC ABR measurements, two channels must be used, with the high-forehead electrode referenced to each mastoid electrode, forming ipsilateral and contralateral channels.
2.11	THRESHOLD ABR WAVEFORM PRINTOUT	For each test frequency and stimulus route, averaged waveforms should be grouped by descending level and plotted using the 'Match' option, which slightly separates the averages and improves ability to follow individual waveforms. **For BC, at each level the ipsilateral replicate averages must be grouped separately from the contralateral replicates and this ipsi group should be plotted immediately above the contra group.**

SECTION 3: HIGH-EFFICIENCY ABR THRESHOLD MEASUREMENT

	TOPIC	DESCRIPTION
3.01	TEST EFFICIENCY IS CRUCIAL & FEASIBLE	**Improvements in efficiency of IHP ABRA are necessary and achievable**. Several techniques are introduced, each of which is scientifically valid and proven by experience in other programs. Examples include stronger control of EEG noise, more effective and efficient averaging, and stimulus strategies that improve the speed with which crucial clinical information is acquired.
3.02	OPTIMIZING CLINICAL INFORMATION GAIN	ABRA is a decision art quite unlike routine audiometry in a cooperative adult. **In high-quality ABRA, every choice made for the next stimulus condition must be the one that would yield the greatest net clinical impact if the test were to be terminated immediately thereafter.** The shift from standardized, rote procedures to adaptively optimizing the rate of information gain under time constraints is challenging, but is a defining feature of true ABR expertise. The following sections address key aspects of test efficiency optimization.
3.03	MANDATORY & DISCRETIONAL PROCEDURES	There are three categories of procedure: mandatory, conditionally mandatory ('conditional') and discretional. AC ABR thresholds are mandatory at 0.5, 2 and now 4 kHz, with 1 kHz conditional. BC ABR is conditional and may only be done at 2 kHz and/or 0.5 kHz, if indicated clinically. DPOAEs are now mandatory only if part of a conditional sub-protocol for ANSD/retrocochlear lesions, but are otherwise discretional. Tympanometry is always mandatory. Acoustic reflexes are now discretional and should be done using either 1 kHz or broad-band noise (BBN) stimuli, the latter being preferable.

3.04	AC & BC TEST FREQUENCIES	The only stimulus conditions for which ABR normative data and clinical experience are acceptable for use in the IHP are: Air Conduction: 0.5, 1, 2 and 4 kHz Bone Conduction: 0.5 and 2 kHz The research required to extend current normative data, such as to 6 kHz AC or 4 kHz BC, cannot be undertaken in the context of a clinical service program and is outside the mandate of the IHP.
3.05	MINIMUM (S_{MIN}) & MAXIMUM (S_{MAX}) TONEPIP LEVELS	Mandatory minima for stimulus levels are now: AC Smin: 35, 35, 30 and 25 dB nHL at 0.5, 1, 2 and 4 kHz, respectively BC Smin: 30 dBnHL at 2 kHz (any age), 30 dB at 0.5 kHz and 1 year of age or more, and 25 dB at 0.5 kHz under 1 year. These Smin levels are similar to those used in the BC Early Hearing Program. They all equate to perceptual thresholds of about 25 dB HL, reflecting IHP targeted hearing loss of 30 dB HL or more. Current normative data suggest that hearing levels below about 30 dB HL cannot be estimated accurately with standard ABR methods. Maximum AC levels (Smax) are 105, 105, 100 and 95 dB nHL at 0.5, 1, 2 and 4 kHz, respectively; these correspond to about 95 dB HL, for which detailed calculations indicate no known hearing damage risk from tonepip ABRA.
3.06	AMPLIFIER GAIN & MYOGENIC ARTIFACT REJECTION	**Effective protection against large artifacts is critical and cannot be achieved by manual pausing.** A few artifacts can instantly simulate, abolish or distort an ABR. Use 150,000 gain. Start a trial no-stimulus average as soon as the EEG is fairly quiet and lower the rejection criterion amplitude to a point that rejects about 5-10% of sweeps fairly steadily (20-40 sweeps rejected every 10 seconds). Quiet EEG is highly desirable but any average that ends without any rejections usually reveals insufficient artifact rejection and measurements that are at high risk of response judgment errors, if artifacts occurred suddenly.
3.07	DIMINISHING RETURNS IN AVERAGING	The efficiency of averaging in terms of signal-to-noise ratio improvement per unit test time decreases rapidly as the number of sweeps increases (see Table in Details and Rationale Section). Also, the longer the averaging time the more likely is corruption by high-noise bursts, even with optimal artifact rejection. Targeting about 1000 or at most about 2000 sweeps in any single ('primary') average is strongly recommended. Averages can be combined easily and two averages of about 1000 sweeps, for example, are more informative than one of about 2000; the same is true for two of about 2000 versus one of about 4000. See 3.11 for information on exact numbers of sweeps required and the underlying reason why.
3.08	COMBINING AVERAGES IS USEFUL & EASY	If response presence or absence is not clear, use the 'Weighted Add' icon to combine 'primary' averages for any single stimulus condition. Display the combined average above and separated from its 'Matched' primaries. Do not be misled by inevitable similarity between the combined average and its component primaries. The combined average gives the best overall waveform

		estimate, whereas 'matched' primaries allow you to assess reproducibility. If three averages are available and one is very different from the other two, consider combining only the more similar primaries and treating the odd man out as an outlier of questionable value. This is especially useful if the odd man out has much higher RN than the other two primaries.
3.09	RESPONSE JUDGMENT CATEGORIES & CRITERIA	In each ear, for any single stimulus route-frequency-level (such as AC 2k 60, for example), there will be one or more averages but only one overall judgment of ABR presence or absence, aided by defined criteria (see the Details and Rationale Section, Topic 3.09). Each stimulus level must be annotated as '*RP*' (Response Positive), '*NR*' (No Response) or '*Inc*' (inconclusive), by hand on the hardcopy at first printout. Current notations used vary and a program-wide standard approach is required. At each stimulus route-frequency (such as AC 2k), one ABR threshold estimate in dBnHL should be noted next to the threshold bracket waveforms. See 3.13 for conversion of ABR thresholds to estimates of perceptual thresholds.
3.10	RESIDUAL NOISE (RN) & 'NO RESPONSE' (*NR*) JUDGMENTS	The RN is the standard deviation of EEG noise in the accumulating average so far. It decreases as the sweep count increases - doubling the sweeps cuts it by about 30%. To get an average quiet enough that if a small ABR were truly present then it would be identifiable requires a final RN of no more than about 25 nanovolts (nV) or 0.025 µV. Unfortunately, 60 Hz artifact can falsely inflate the RN, so while a low RN is an indicator of acceptable averaged noise, it cannot be made a requirement. **Subjective flatness of the average is essential for any *NR* decision.** Subjective flatness but with a high RN suggests underlying 60 Hz interference.
3.11	NOMINAL VS ACTUAL NUMBER OF SWEEPS	**Targeting multiples of 256 sweeps, e.g. 1024, 1536, 2048, is now mandatory.** With the RN option active (also mandatory), sweeps beyond the last multiple of 256 are automatically discarded by the NavPro. For example, a target count set at 2000 sweeps only yields 1,792 (7x256) actual sweeps averaged, wasting about seven seconds per average. These small losses rapidly accumulate to a significant loss of valuable test time. Averages should be stopped as soon as the accepted sweep count reaches the desired multiple of 256.
3.12	TONEPIP ABR THRESHOLD DEFINITION	Threshold is defined by upper (*RP*) and lower (*NR*) bracket stimulus levels separated by 10 dB or less; the upper bracket is the threshold in dB nHL. An *RP* at an Smin or an *NR* at an Smax levels yield threshold ranges of ≤ Smin or >Smax, respectively, not unique threshold values.
3.13	ESTIMATED HEARING LEVELS	Tonepip ABR threshold estimates in dBnHL must be adjusted by the correction factors listed in Appendix I, in order to derive threshold estimates in dBeHL.The core of ABRA is the estimation of key puretone hearing thresholds in dB HL. This is based on determination of tonepip ABR threshold estimates in dB nHL, followed by adjustments that are based on known, normative statistical relationships between tonepip ABR and VRA-based behavioural thresholds. **Note the changes for AC and BC 500 Hz correction factors from the values previously listed in the 2008 IHP Assessment protocol.**

3.14	THRESHOLD SEARCH & BRACKET PHASES	For each air conduction tonepip threshold frequency, there is a Search phase that gets to the threshold region as quickly as possible and a Bracket phase that focusses on accuracy of response decisions. The 2 kHz Search starts at the Smin value and ascends **in large steps** (30 dB then 30 or 20 dB) to find an *RP* quickly and use its morphology and latency as a detection guide for any lower levels. Descent step size after a 30 dB ascent depends on the *RP* clarity and speed of emergence. The 4kHz Search starts at the 2kHz upper bracket. The 0.5kHz search starts discretionally at 50 dB nHL or at the Smin. **Multiple, inconclusive averages at the starting level should always be avoided in the Search phase. Go up instead.**
3.15	NUMBER OF SWEEPS & AVERAGES	For individual averages, recommended minimum and maximum sweep counts are 1024 and 2048, respectively. Two or three such averages can be combined to give the best response estimate, but more than 3 x 2048 are inappropriate. Single averages of 1024 or 2048 may be used in the Search phase but upper brackets and minimum levels (Smin) require at least two averages. A clear RP upper bracket average may be confirmed with as few as 512 sweeps. A single, subjectively flat lower bracket average with RN under 20 nV and 2048 sweeps may be sufficient discretionarily, but reliable NR decisions at lower bracket levels typically require at least two averages of at least 1024 sweeps each.
3.16	THRESHOLD BRACKET STEP SIZE	**The target threshold bracket width is 10 dB. Brackets of 5 dB must not be done until all mandatory thresholds bilaterally are completed to their 10 dB brackets.** Brackets of 5 dB are never mandatory; if they are considered at all, priority should be placed on levels above 70 dBeHL.
3.17	CONFIRMATION OF UPPER BRACKET RESPONSE	**If there is any doubt at all about ABR positivity at a candidate upper bracket level after two primary averages, go up 10-20 dB for one average, for rapid response confirmation and latency guidance, rather than simply doing more averages at the questionable bracket level.**
3.18	STRATEGY OF STIMULUS FREQUENCY & ROUTE	The top priority is to determine 2 kHz hearing loss presence, severity and type, in each ear that referred on AABR screening or bypassed it. If AC 2k is Response Positive at its Smin, do 4k then 0.5k. If 2k is moderately elevated, immediate BC 2k answers the vital question about permanence as quickly as possible, in case the session is unexpectedly terminated. AC/BC switching is easiest with manual BC transducer placement. **Important: Insert transducers need not be removed for BC testing! Occlusion effects are reported to be negligible in young infants at both 2 and 0.5 kHz.** See the Details and Rationale Section, Topic 3.18, as well as Small & Hu (2011) in Appendix A. **For bilateral screening referral or screening bypass, optimal strategy requires both AC/BC switching and adaptive ear switching, which is routine practice in some programs.** Switching ears is usually easy in younger babies who may be swaddled and supine with bilateral inserts; with proper positioning it is often feasible when testing in a caregiver's arms. If 2k is grossly elevated in the first ear, the key issue is whether the other ear is within normal limits at 2k, which can be checked quickly before exploring thresholds in detail. Subsequent optimal test strategy is dictated by multiple factors and is discretional.

3.19	BC STIMULUS ARTIFACT	Whenever BC at the 2 kHz Smin is *NR*, it is useful to go as high as possible, preferably to 45-50 dB nHL, to show unequivocal threshold elevation. Stimulus artifact can be a problem especially at 0.5 kHz. Artifact size varies across babies, sites and testers, suggesting effects of technique. Electrode leads should run directly away from BC transducers, as far as possible from its leads and very close together. Artifact amplitude will increase x3 for 10 dB stimulus increase. Artifacts under 1 μV can usually be ignored. Very large stimulus artifacts at 50 dB or below are unusual and warrant forensic investigation. A DTC consult is appropriate if routine methods of artifact minimization fail. If artifacts are large enough to be seen clearly in the ongoing EEG, they may trigger rejection of every sweep. This challenge is under further investigation.
3.20	BC RESPONDING COCHLEA INFERENCE	BC testing at 0.5 kHz and/or 2 kHz is mandatory if AC testing yields No Response at 10 dB or more above the Smin. Each suspect ear must be stimulated individually on the ipsilateral mastoid. Two recording channels must be used. In young infants and at near-threshold levels, the responding cochlea has the earlier and usually larger wave V-V'. The latency cue is the more important. If the dominant cochlea is unclear, go down 10 dB (even below the Smin) to try to eliminate response from one channel. If this is unsuccessful, contralateral noise masking is the only other option. Contralateral response dominance results in inability to infer activation of the ipsilateral cochlea just because there is response in the ipsilateral channel. Such response may be a shadow from the other side.
3.21	BC CONTRALATERAL MASKING	Insert masking with broadband noise at 60 dB is appropriate for most situations. Comparisons of masked and unmasked records usually give a clear inference about which cochlea is responding. Masking is not always the first line option because it may not be easy to implement and normative data on ipsi/contra ABR masking effects are limited.
3.22	ELECTROMAGNETIC 60 HZ ARTIFACT & NOTCH FILTERING	Interference from 60 Hz power sources is not unusual and is most problematic for 0.5 kHz testing. It can be recognized by its slow, sinusoidal waveform, wavelength of about 17 ms and sometimes obvious presence at the beginning of the averge. **Often, it can be proven present by no-stimulus averaging.** Checks for sources, electrode impedance and lead position are appropriate. Use of the notch filter is a last resort if 60 Hz activity cannot be controlled, as may be the case in operating rooms, for example. If 60 Hz-like activity is not eliminated by the notch filter, a no-stimulus run may still be informative. Use of the notch filter must be documented on the ABR printout.

SECTION 4: AUDITORY NEUROPATHY SPECTRUM DISORDER (ANSD) SUB-PROTOCOL

	TOPIC	DESCRIPTION
4.01	OVERVIEW	About 8% of infants with PHL have an ANSD component. ANSD, conventional (Outer Hair Cell (OHC)-based) sensory hearing loss (SHL) and conductive hearing loss (CHL) can occur concurrently. The challenge is to identify and disentangle the components and to know when detection of ANSD is not possible. OAEs and Cochlear Microphonics (CMs) are important tools but are not equivalent diagnostically. CM presence does not necessarily rule out SHL or rule in ANSD.
4.02	ANSD SUB-PROTOCOL ENTRY CRITERION	ANSD may be unilateral but is usually bilateral. One condition for ANSD presence is an absent ABR or a highly abnormal waveform with an absent, small or grossly delayed V-V' complex. **In each ear individually, the ANSD sub-protocol using clicks must be done (not necessarily immediately) if at least one AC 2 kHz average done above 75 dB nHL is either flat above 5 ms latency or shows wave V latency greater than 10 ms.**
4.03	ANSD SUB-PROTOCOL TIMING	**The ANSD sub-protocol usually should be deferred until ABR thresholds with 10 dB bracketing are completed in both ears.** Responses at any frequency can inform ANSD interpretation, and ANSD presence may not invalidate all tonepip ABR thresholds. If a second ABRA appointment appears necessary, as is frequently the case, an opportunity to start the second session with OAEs may prove useful and efficient when executing the ANSD click sub-protocol.
4.04	ANSD TEST PROCEDURES	Stimuli are 90 dB nHL clicks (up from 85 dB) at 21.1/s, with a 21.33 ms data window, single channel recording, a bandwidth of 150 Hz to 2 kHz and plotted full-page-width. The basic data unit is two 2048-sweep primary averages, the calculated 4096-sweep combined average and a tube-off or tube-clamped 2048-sweep average. These are done for rarefaction (R) and condensation (C) clicks separately. A specific suite of plots is mandatory and often useful to disentangle stimulus artifact, cochlear microphonics (CM), cochlear Summating Potentials (SP) and ABR (see Details and Rationale Section, Topic 4.04).
4.05	INTERPRETATION OF CM/ABR AVERAGES	Click stimulus artifact is identified using tube-off/tube-clamped records. CM is identified by printing combined averages for R and for C clicks overlayed at the first data point only ('butterfly' plots) and by subtracting the R combined average from the C combined average. SP and ABR are components of the calculated average for R plus C. Comparing R and C averages reveals stimulus polarity effects on the ABR, which are not infrequent.
4.06	CLICK ABR WAVEFORM & THRESHOLDS	Click ABRs occasionally are detectable when tonepip ABRs are not, probably due to their broader cochlear excitation. If this is seen, it may be useful to track the waveform down to an approximate threshold. Second, in the R+C combined average there may be obvious Interruption of the wave I to wave V sequence, with clear early neural waves and delayed or

		absent wave V. This may reflect a retrocochlear lesion that may not be ANSD. Third, there may be marked differences in the R and C combined averages, with V-V' much clearer for one than the other. The R and C records may even appear to be antiphasic in the region from 5 to 10 ms. In all of these situations, approximate click thresholds may be useful but interpretation may be very challenging and consultation with a DTC is strongly recommended.
4.07	DPOAE ROLE	**DPOAE measurement is mandatory only within the ANSD sub-protocol.** Normal DPOAE signal-to-noise ratios (SNRs) indicate functioning OHCs. Present DPOAEs and absent ABR are definitive for ANSD. Definite DPOAE presence at *any* frequency in the set [2, 3, 4 kHz] implies that an ABR should be present. Repeatably absent DPOAEs at 2, 3 and 4 kHz nominal F2 values are consistent with ABR threshold elevation due to OHC dysfunction, if the tympanogram is normal. If tymps are flat, absent DPOAEs may have little or no value for differential diagnosis of conventional SHL and ANSD components.
4.08	ACOUSTIC REFLEX (AR) ROLE	**Acoustic reflex testing is now always discretional in ABRA**. The clinical value of ARs in the context of the detailed ABRA and ANSD protocols is limited. If ARs are done, they are best done with broad-band stimuli, for which ARs are usually the clearest and most likely to be elicited.
4.09	ANSD OUTCOME CATEGORIES	World Health Organization (WHO)-aligned clinical outcome categories are 'Not Suspected', 'Probable' and 'Definite' for an ANSD component, based mainly on quantitative comparison of sensory (OAE/CM) and neural (ABR) measures. Key parameters are CM amplitude, ABR V-V' amplitude and their ratio. The larger the CM or the ratio is, the greater the likelihood of an ANSD component. See the tabulated criteria in the Details and Rationale Section.
4.10	CONDUCTIVE COMPONENTS IN ANSD	Even a slight conductive loss may reduce or abolish DPOAEs; this can lead to missing ANSD. Mid-frequency CHL of 20 dB or more may abolish even the CM at 90 dB nHL, rendering most ANSD undetectable due to the lack of OHC/IHC measures to compare to the ABR. Current recourse when substantial CHL cannot be ruled out is presumptive diagnosis and management as a conventional, possibly mixed loss, with prompt VRA follow-up. Deferral of intervention for several months until VRA is not acceptable, given the low probability of ANSD relative to that of severe/profound SHL.
4.11	DTC CONSULTS & ADDITIONAL TESTS	**It is recommended that in all cases for which ANSD is considered to be Definite or Probable, the CHEO or Mount Sinai DTC should be notified, in order to accumulate important program CQI information.** Moreover, if there are challenges disentangling sensory and neural components or in determining the ANSD outcome category, consultation with a DTC is strongly recommended. Additional testing may be specified, to be done either by the referring Audiologist or at the DTC. Such testing may include very high stimulus rates and additional manipulations of averages, to clarify interpretation of records.

4.12	EARLY MANAGEMENT	For definite or probable ANSD, tonepip and click ABR thresholds are either indeterminate or may overestimate true thresholds, but they can still give useful upper bounds for perceptual thresholds. If the baby's age and behaviour permit it, repeat ABRA after 4-8 weeks may be informative. More typical is to wait for prompt VRA at about 6 months of age, to clarify thresholds and inform interventions. If VRA is predicted or proven to be impractical, threshold estimation using cortical potentials (LCPs) is available at the Mount Sinai DTC. Key points about ANSD and sources of valid information must be identified. Hearing loss and speech perception deficits vary widely. Most affected children experience significant speech perception deficits in noise. Amplification is beneficial in at least half of cases, as are CIs in others. Fluctuating hearing is an occasional finding but is not typical. Improvement in hearing over time is possible but is not well-established.
4.13	ANSD FIELD ENTRY IN THE IHP DATABASE	The data system (HCD-ISCIS) allows ANSD categories of 'Not Suspected', 'Possible' and 'Present'. The last two terms correspond to the preferred clinical wording of 'Probable ANSD component' and 'Definite ANSD component', respectively. Permanent Hearing Loss should be entered as 'Yes'. Hearing threshold estimates in dBeHL should be entered, even though they are likely to be biased.
4.14	POST-ABRA REFERRALS	Completion of ABRA, including the determination of ANSD outcome categories, is the responsibility of the primary Audiologist with support by a DTC if needed. When the ABRA is finished, referral to specialized centres other than a DTC is discretional and is beyond the scope of this protocol.

SECTION 5: ANCILLARY PROCEDURES

	TOPIC	DESCRIPTION
5.01	DISTORTION PRODUCT OTOACOUSTIC EMISSION (DPOAE) TESTING	**DPOAEs are mandatory only as part of the ANSD sub-protocol. In other scenarios, they are of limited value and are discretional.** The approves devices (Navpro) supplies and protocol (Scout DPOAE software with parameters specified in Appendix I) must be used. DPOAEs must be measured for nominal f2s of 1, 1.5, 2, 3 and 4 kHz, in descending frequency order. To determine response presence or absence, stimulus levels, DPOAE amplitude, noise levels, reproducibility and frequency profile are relevant. For a single f2, presence requires 8 dB above the noise and a test-retest difference of under 5 dB. For two or three adjacent frequencies, SNR of at least 5 dB at each f2 is sufficient. Replicated DPOAE traces should be superimposed and left and right ear traces plotted side by side. The related tables are also required.

5.02	MIDDLE-EAR ANALYSIS: TYMPANOMETRY	Tympanometry is required and IHP-approved devices, supplies and protocol must be used (see Appendix J). It must be done with a 1 kHz probe for infants under six months corrected age and a 226 Hz probe for older children. It must be repeated if not clearly normal. 1 kHz tympanograms must be plotted with hardcopy retained on file. Normal 226 Hz tympanograms need not be plotted. Compensated peak static immittance criteria are age dependent and are given in the Details and Rationale Section 5.02.
5.03	MIDDLE-EAR ANALYSIS: ACOUSTIC REFLEXES	**Acoustic Reflex (AR) measurement is now always discretional**. ARs have limited value as a cautionary flag if present when ANSD has been inferred as Definite or Probable. They also may be contributory if ABR thresholds are poorly defined yet severe hearing loss has been inferred.
5.04	REAL-EAR-TO-COUPLER DIFFERENCE (RECD) MEASUREMENT	RECDs are discretional and of obvious value in a context of imminent amplification fitting. They also have value in longitudinal threshold comparisons that may be affected by anatomical changes in individual ears with increasing age, for example in avoiding false-positive inference of hearing loss progression. **RECD instrumentation is now specified functionally (Appendix A of the IHP's Protocol for the Provision of Amplification, Version 2014.01, November 2014). The required procedure is described in the IHP Amplification Protocol (v 2014.01).**

PROTOCOL TOPIC DETAILS & RATIONALE

SECTION 1: THE ONTARIO INFANT HEARING PROGRAM (IHP) SERVICE CONTEXT

1.01 WHAT IS IHP ABRA?

IHP ABR-Based Audiologic Assessment (ABRA) is a detailed, multi-component assessment process for confirmation and characterization of hearing disorders that:

a. Includes hearing threshold estimation and auditory brainstem pathway function evaluation using the ABR;
b. Is authorized by the Ministry of Children and Youth Services (MCYS), an IHP Designated Training Centre, (DTC, see below), or an IHP Regional Coordinator; and
c. Is funded by the IHP.

In most cases, ABRA will be the first Audiologic Assessment on any given child. Complete ABRA usually requires a single test session, because the baby will sleep for the test and hearing will be found rapidly to be within normal limits. In other cases, such as those for which a hearing loss is found, additional test sessions may be required to complete the Assessment.

1.02 WHO CAN CONDUCT ABRA?

ABRA must be carried out only by persons who:

a. Are Audiologists registered and in good standing with the College of Audiologists and Speech-Language Pathologists of Ontario (CASLPO);
b. Are authorized by the MCYS to conduct ABRA (henceforth 'IHP Audiologist');
c. Have satisfactorily completed IHP-designated training in this protocol, OR are currently providing ABR-based Assessments under the 2008 protocol and have participated in the updating process associated with the release of this protocol.

At any given clinical encounter, the designated IHP Audiologist is completely responsible for both the conduct of the testing and the interpretation and reporting of the results. These activities cannot be delegated. Where consented, students or other observers may attend the testing but may not participate directly. The presence of any observer must not compromise the effectiveness, efficiency or appropriateness of any aspect of the audiologist's technical activities or interactions with the child and the family.

If an IHP Audiologist authorized for ABRA does not carry out IHP ABRA for a period of six months or more, the IHP Regional Coordinator must advise the MCYS of the lapse in practice. The MCYS will contact one of the DTCs for refresher training. Clinical decision support and performance monitoring may also be recommended. IHP Audiologists may seek such support, monitoring or refresher training on their own volition at any time.

Authorization to provide ABRA services may be withdrawn at the discretion of the MCYS.

1.03 PROTOCOL ADHERENCE IS A REQUIREMENT

This protocol replaces and overrides all previous IHP documentation relating to ABR-based Audiologic Assessment issued before December 1, 2015. Sections of the 2008 Audiologic Assessment Protocol v3.1 related to Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA) remain in effect, pending a separate update release for VRA/CPA anticipated later in 2016.

Many features of this ABRA protocol were contained in a draft upon which all IHP audiologists were invited to comment several months ago, and many did comment. Some adjustments were made as a result. This protocol will be released in its final form to all IHP coordinators and ABRA-authorized IHP audiologists on April 04, 2016. There will be a six-week period for audiologists to become familiar with the protocol and try out its techniques. As of May 16, 2016, this protocol goes into effect as the required, current protocol for all IHP ABRA. Various support services and events will occur over the following months to facilitate complete transition. Standard Practice Reviews relating to protocol adherence are targeted to begin in October, 2016.

This protocol is based on extensive review of published evidence, analysis of program outcome data from the IHP and from other programs worldwide and, where necessary, from expert consultations globally. The protocol is considered to be evidence-based. Its purpose is to promote the highest possible quality of clinical services, as reflected in service effectiveness, equity and cost-efficiency.

Experience indicates that if significant deficiencies in the quality of care do occur, they are usually associated with a clinical error or omission that is in non-conformance with protocol. Therefore, program due diligence requires that protocol adherence be specified, facilitated and monitored. Clinical adverse events that are deemed attributable to protocol non-adherence are not defensible programmatically, in contrast to events that could be deemed unpredictable or idiosyncratic.

1.04 LEGITIMATE DEPARTURE FROM PROTOCOL

Special situations may arise in individual cases, wherein departure from procedures specified in this protocol may be judged by the Audiologist to be appropriate and clinically justifiable. It isexpected that this will occur occasionally, not routinely. When an Audiologist does elect to depart from protocol, the reason must be documented on the clinical ABR records. The reasoning should be brief but cogent and clinically defensible. The three core issues underlying this requirement are quality of care, program risk management and the ability of any IHP process of records review to evaluate adherence to protocol. If the departure is documented and reasonable, then the departure would not be considered as a non-adherence event.

1.05 CHANGES TO THE ABRA PROTOCOL

Systematic changes to ABRA protocol locally or regionally can only be authorized by MCYS. Such changes may be prompted by regional or local characteristics or challenges, sometimes affecting specific groups of service recipients. The process for systematic change is led by a regional coordinator. It includes documentation of the proposed change, its rationale and anticipated impact, followed by submission to MCYS; this may be followed by evaluation, discussion, modification and explicit authorization.

A different type of protocol change process arises if any individual IHP Audiologist has a significant concern regarding a specific protocol element. The first step is to discuss the issue with a DTC Audiologist, to ensure that the element and its rationale are fully understood. This raising of issues is welcomed as a way to resolve misconceptions or miscommunications and, potentially to facilitate protocol improvement.

As already noted, the IHP ABRA protocol is based on comprehensive evidence reviews as well as decades of clinical experience. Many data sources are evaluated on an ongoing basis by the DTCs. This can result in specification of procedures that differ from opinions of individuals or the conclusion of specific published reports. Raising an issue may trigger discussion, re-examination of evidence and provincial consensus development process, prior to province-wide or region-specific protocol change, if the case for change is substantiated.

The negative effects of unaddressed protocol concerns include misunderstandings, clinical errors and opinion-driven non-adherence to protocol. Variations in viewpoint are inevitable but raising of concerns gives an opportunity to re-examine procedures and change them where change is justified, or at least render a mandatory element discretional if the evidence for it is determined to be inadequate. Engaged professionals are a major resource for protocol evolution and improvement.

1.06 TARGET POPULATION

The target population for ABRA includes neonates or young infants who:

a. Refer on the IHP Universal Newborn Hearing Screening (UNHS) protocol; or
b. Bypass screening in accordance with IHP protocol; or
c. Cannot be tested successfully by behavioural methods, or
d. Any other child under 6 y authorized for testing by a Regional Coordinator, a DTC or the MCYS.

1.07 TARGET DISORDERS

A target disorder is an audiologic phenotype that renders any qualifying child with the disorder a candidate for IHP services. IHP target disorders in the defined target population are:

a. Permanent hearing loss (PHL) of 30 dB HL or more at any frequency in the range 0.5 - 4 kHz, in any ear.
b. Auditory Neuropathy Spectrum Disorder (ANSD).
c. Retrocochlear disorders that may be detectable using the ABR.

The qualifier 'permanent' embraces most hearing losses caused by disorders of the cochlea or the brainstem auditory pathways. It also includes so-called 'structural' conductive losses, which are associated with abnormalities affecting sound conduction through the external or middle ear structures. The essence of the 'permanent' attribute is that the hearing loss will not resolve spontaneously and, therefore, will confer a sensitivity loss indefinitely in the absence of any intervention.

The IHP target disorder definition is more inclusive than that of many programs internationally, in that unilateral, mild and frequency-specific impairments are included, as well as ANSD and certain retrocochlear disorders such as space-occupying or demyelinating lesions affecting the auditory brainstem neural pathways.

IHP target disorders do not include hearing losses less than 30 dB HL or outside the range 0.5 - 4 kHz. At its core, the IHP is a system of care based on newborn hearing screening and such non-target losses do not satisfy World Health Organization (WHO) criteria for population screening that include proven burden of the disorder, accurate screening and confirmatory tests, effective interventions and acceptable benefit-cost balance. For a review and discussion of the WHO criteria, see Hyde (2011). In principle, a hearing loss may be clinically significant yet not satisfy WHO population screening criteria. Hearing losses designated as 'slight' are an example. However, this protocol addresses ABR-based threshold measurement and there is no good evidence that ABR techniques can quantify hearing loss of less than 30 dB reliably, nor is there any good evidence that current OAE or ABR-based screening tests and protocols could detect such losses with acceptable accuracy. In fact, there is good evidence they cannot do so.

1.08 CONDUCTIVE HEARING LOSS (CHL)

CHL that is not 'permanent' is not an IHP target disorder. The term 'permanent' is not easy to define operationally and parametrically. It reflects duration of continuous presence of the hearing loss, given usual otologic care. But how long, how constant, and what if 'usual otologic care' is not forthcoming or is ineffective? The simplest approach is to identify scenarios that are classifiable as permanent or not and then cover other scenarios by making them discretional but guided by defined principles.

First and foremost, the ABRA Audiologist must demonstrate presence of hearing loss of severity and frequency within the target disorder range. If a sensory/neural component is ruled out, primarily by bone conduction ABR, the loss is deemed to be conductive. Absence or complete closure of the external auditory canal automatically confers permanence, but in all other cases, presence of conductive loss must be established audiometrically. If a syndrome that is known to be associated with conductive loss is already documented or is suspected by the Audiologist, the CHL may be presumed to be permanent. The same is true if a non-syndromic anomaly or external or middle-ear structure has been identified or is suspected.

Where there is no sensory/neural hearing loss and a relevant syndrome or anomaly are not suspected, classification of permanence is presumptive and is at the Audiologist's discretion, based mainly on tympanometry and ABR-based thresholds. For example, if the tympanogram using an age-appropriate probe frequency is clinically flat and the ABR threshold elevation is only at 0.5 kHz and less than about 55 dB nHL, it is reasonable to infer that the loss is likely to be attributable to a transient middle-ear disorder. Of course, actual presence of middle-ear fluid usually can only be determined definitively by careful otoscopy in experienced hands.

The significance of the provisional classification of CHL permanence is that the IHP is not a systemic replacement for Ontario's medically-driven Ontario Health Insurance Plan (OHIP) system for pediatric hearing health care but, rather, is complementary to it. The management of middle-ear disorders is a medical/surgical matter that should normally fall under the OHIP system, as should associated diagnostic audiologic assessment. Given the common occurrence of middle-ear disorders in infants, routine inclusion of their audiologic management would overwhelm IHP resources and compromise the quality of care for those who actually do have Permanent Hearing Loss. The usual course of events, given detection at ABRA of minor, conductive hearing loss that is audiologically suggestive of middle-ear disease and asymptomatic, is to discharge the affected infant from the IHP, with appropriate caregiver information and counselling concerning self-referral to a physician if signs or symptoms of active middle-ear disorder occur. Such discharge does not preclude the infants from re-entering the IHP if and when external audiometric or otologic evidence suggesting a structural conductive or sensory/neural hearing loss component emerges and is confirmed by IHP audiologic assessment.

There may be discretional exceptions to IHP discharge where it is known that OHIP audiology services are unavailable locally or are inaccessible in a timely manner. If ongoing, such exceptions must be authorized and periodically reviewed by the Regional IHP Coordinator, with MCYS approval. Alternatively, the Audiologist should seek authorization of exceptions on a case-by-case basis.

With discretional exception of minor, conductive losses isolated at 0.5 kHz and accompanied by a flat tympanogram, detection of clinically significant hearing loss indicates referral to a physician. The criteria for and the timing of such referral are also at the discretion of the Audiologist. One view is that immediate referral of infants with isolated CHL is premature, given that watchful waiting is the usual course. It is also wasteful of valuable medical resources, with little tangible benefit to the child and family. One option is that if the CHL at 0.5 kHz is substantial, wherein it may include a loss at 2 kHz, the infant should be re-tested after a waiting period to allow resolution of the loss. On this view, the 'complete' initial ABRA includes confirmation of CHL stability. A merit of this approach is that CHL obstructs accurate and complete assessment, one reason being that BC ABR thresholds are inherently more variable than air-conduction thresholds. If the CHL has resolved on retest, definitive ABRA is then concluded and an arguably premature medical referral is avoided. In contrast, if the CHL is sustained the more informed medical referral is fully justified.

The length of the wait period is discretional. If the infant failed newborn screening then that failure could be considered the first detection of loss, shown later to be conductive. If the initial ABRA occurred at say 8 weeks corrected age, then only a four-week delay before retesting could be sufficient to establish CHL presence over a three-month period, consistent with medical guidelines for management of Otitis Media. A longer delay gives more time for disorder resolution, but may result in the infant being both too old for easy ABRA and too young for reliable VRA. For these reasons, the retest interval is at the Audiologist's discretion.

Finally, as for the situation in which there is a conductive overlay on an S/NHL, any CHL is a complicating variable that can decrease the accuracy of ABRA and complicate or prevent effective audiologic management of the infant. This is a longstanding challenge that is not specific to the IHP. The management process in the presence of conductive overlays is at the Audiologist's discretion.

1.09 ABRA OBJECTIVES

The main objectives of ABRA are to:

a. Determine the presence or absence of a target disorder;
b. Quantify hearing loss laterality, component types, severities and configuration with sufficient accuracy and efficiency to inform and facilitate timely, appropriate provision of IHP intervention services elected by the family;
c. Achieve a. and b. by three months corrected age where feasible medically; and

d. Discuss test results with families in such a manner as to facilitate understanding, acceptance and positive engagement to the greatest extent feasible.

Objective d. reflects the fact that accurate and efficient ABRA is ineffective unless it leads to prompt and appropriate action by the family. Therefore, laying the groundwork for successful intervention is considered a key component of ABRA that is primarily the responsibility of the Audiologist conducting the Assessment.

1.10 AGE AT START OF INITIAL ABRA

ABRA must be targeted to begin between six and eight weeks corrected age or within four weeks of hospital discharge to home, for babies whose perinatal hospital stay extends beyond 44 weeks gestational age. The 6-week target minimum allows some time for transient external or middle-ear conditions to resolve, increasing the accuracy and efficiency of IHP ABRA. The 8-week maximum allows sufficient time to complete the ABRA in most cases provided that appropriate appointment scheduling procedures are utilized.

Assessment initiated by the IHP is always conditional upon the recipient's medical condition being appropriate and stable. The timing just specified refers to the first ABRA appointment attended after discharge from hospital. If the baby's treating physician orders ABR testing before discharge from hospital, whether in natural sleep, under sedation or under general anesthesia in the context of a medical/surgical procedure, compliance with such a signed order is at the Audiologist's discretion and is a regional policy matter. It is reasonable to alert the ordering physician to the IHP protocol target and rationale, where feasible. If the order is clearly outside target, billing of the procedure to OHIP should be considered, where feasible. If this ABRA protocol cannot be followed by virtue of the test context or timing, the test is to be considered out-of-protocol and its relevance to subsequent IHP testing is to be determined in discussion with an IHP DTC.

For ABRA to begin at about six weeks, screening must be completed well before that. Current program performance in this regard is under evaluation as part of IHP's current activities in screening CQI. In so far as the total delay of the start of intervention is the sum of periods spent in the screening and the ABRA processes, the acute challenges of delivering babies to ABRA in a timely fashion increase the need for extraordinarily efficient and timely Assessment processes.

1.11 AGE AT COMPLETE INITIAL ABRA

The international performance benchmark is **completion** of the initial Assessment by age three months; this timeline is typically necessary in order to begin intervention by the key benchmark of six months, where PHL is found. Examples of 'beginning intervention' include fitting of verified hearing aid(s), or first attendance at an appointment for communication development services. It does **not** include purely administrative preparatory steps such as 'enrolment' in intervention**. In accordance with the benchmark, IHP ABRA is targeted to be completed at or before three months corrected age.**

Timely completion of ABRA in turn depends on timely screening and referral. Because the majority of babies referred from screening will not have a target hearing loss, ABRAs typically will be completed in one session and the three month benchmark is relatively achievable. However, when sensory/neural hearing loss is present, and particularly if there is concurrent conductive loss, several appointments may be required to complete the ABRA and these must also fall inside the three month completion target. It is these cases to which the three-month benchmark most critically applies, not just to the majority of referrals who have hearing within normal limits. This means that the timing of screening referral and initial ABRA generally must be such as to accommodate the delays inherent in booking of one or even two follow-up ABRA sessions.

The entire scientific rationale and justification for population newborn hearing screening is based on achievement of these benchmarks. Every month of delay beyond the benchmark for ABRA completion reduces the potential benefit of screening, as the age at identification of hearing loss increases towards what would have occurred typically in the absence of population screening.

It is the challenge of the Regional Lead Agency to develop and implement processes that enable the achievement of the timeline benchmarks to the fullest possible extent. It is the challenge of each IHP Audiologist to take all reasonable steps within her or his control to facilitate the earliest possible access to ABRA appointments. Key performance indicators would be the percentiles of babies whose ABRA was completed by three months corrected age, computed separately for three groups of babies: those who bypass screening (see later), AABR refers at risk and AABR refers not at risk. A plausible criterion for excellence would be 90%.

Other important factors include rapidly decreasing likelihood of accurate and complete testing as well as rapidly increasing costs as babies grow older. Babies under about two months sleep a lot and are usually easy to test accurately and quickly, whereas babies over four months can be difficult or even impossible to test in natural sleep. If PHL is present, several test sessions may be needed and cumulative delays compound the difficulty and cost of an adequate assessment. Testing under sedation is a limited and expensive resort with finite associated risk.

1.12 SCREENING BYPASS IN VERY HIGH RISK BABIES

There are several reasons why babies with certain, specific indicators of very high PHL risk should bypass newborn screening and be routed directly to ABRA. One basic principle is that screening becomes less and less appropriate, the higher the *a priori* likelihood of PHL presence; current screening technology has substantial false-negative rates due to multiple sources of random error and, furthermore, AABR screening with broad-band transient sounds (clicks or chirps) is not sensitive to hearing loss in restricted frequency regions of the cochlea. Another concern is that screening is a discrete event that can miss emergent or progressive PHL, especially in babies at substantial risk for deterioration in auditory system structure and/or function following an identified environmental insult (such as certain *in utero* or neonatal infections). A fourth concern is that passing a screen is likely to reduce a family's vigilance with respect to late onset or progressive hearing loss, yet the likelihood of the latter increases in babies at very high risk of PHL, even if hearing were normal or near normal at the screen.

Since 2013, babies who are identified promptly with either:

a. **Confirmed meningitis, irrespective of the pathogen (viral, bacterial, fungal), or**
b. **Confirmed Congenital Cytomegalovirus (cCMV) Infection,**

have bypassed IHP UNHS in accordance with the current IHP Screening Protocol (Ontario Infant Hearing Program Hearing Screening Protocol and Support Document Version 2, July 7, 2013). Such babies have received a series of audiologic assessments beginning with ABRA, with timing according to risk-specific IHP Intensive Surveillance Sequence (ISS) schedules.

In serologically confirmed meningitis, the common belief that only bacterial meningitis is a genuine risk indicator for PHL *per se* is not well-proven. Issues in meningitis risk include the time of onset of PHL and its progression. In bacterial meningitis, there is also risk of ossification of the cochlea that may compromise cochlear implantation. ABRA must be done as soon as is medically practicable following recovery from the acute phase of the illness, but in accord with the timelines stated earlier. If initial ABRA is normal, follow-up Assessment in three months is indicated, by age-appropriate methods. Detection of any sensory/neural abnormality indicates referral to a Cochlear Implant program.

If meningitis is suspected but confirmatory information is not accessible, screening is discretional. The decision to do ABRA or to defer to later VRA is also discretional and must be evaluated on a case-by-case basis. The conservative approach of routing to immediate ABRA has little downside, compared with the potential harm of missing an emergent PHL for several months. If a treating physician sees fit to refer the baby for ABRA on the basis of presumptive meningitis, the baby is at risk due to the physician determination itself and the ABRA should be done as soon as medical status permits.

Suspected and confirmed congenital CMV (cCMV) infection should be treated equivalently, with initial ABRA as soon as is medically feasible and appropriate. Issues are the high probability of both congenital and late-onset PHL, as well as frequent comorbidities that may complicate or prevent later behavioural testing. Initial ABRA should be done as soon as possible after acute recovery. Short-term follow-up in those babies whose initial ABRA is normal typically would include repeat ABRA after about three months and

VRA at 10-12 months, each subject to clinical feasibility. Currently, annual assessment thereafter is recommended, because of the lengthy time course over which delayed expression of PHL may occur following cCMV infection.

Two additional risk indicators will be added to the screening bypass list in the near future, when revised versions of the IHP Screening and Surveillance Protocols are released. They are included here for completeness, as an alert and because the other revised protocols are anticipated well before the end of calendar 2016. Additional revisions may include changes in surveillance arising from recent evidence on patterns of expression of non-congenital hearing loss.

The first addition is the situation in which there is an obvious, clearly recognisable anatomic anomaly of the external ear canal:

c. Unilateral or bilateral congenital aural atresia or meatal stenosis such that an ear insert cannot be placed easily (new addition).

In the past, an atretic ear has not been the subject of program-wide screening policy. Such ears have been handled according to local policy and practice. When this bypass rule comes into effect, the intent is to avoid inappropriate or persistently ineffective attempts to place a probe in a clearly absent or restricted ear canal entrance. Essentially, it is the occurrence of the obvious anatomical anomaly that triggers the screening bypass, not the success or failure of heroic efforts to insert the eartip.

Any baby who has a malformation **of one or both ears** such that successful insert earphone placement for screening appears unlikely should bypass screening and be routed directly to ABRA. If only one ear has a clear anomaly, screening of either ear should still be bypassed; in the presence of a unilateral obvious anomaly, covert or invisible anomaly in the other ear is plausible and, in any case, initial ABRA is always an assessment of both ears.

In any atretic or otherwise grossly malformed ear, the usual issues are cochlear status and whether there is a functioning air conduction pathway. Air conduction testing by supra-aural earphones is recommended, given that incomplete ear canal occlusion is often difficult to determine by cursory otoscopy. There is no intensive follow-up sequence, only normal, clinical follow-up contingent upon the initial ABRA findings and typically including VRA as soon as it is likely to be viable. Follow-up with special programs for infants with congenital ear malformations is recommended where such programs are accessible, such as at CHEO, the Hospital for Sick Children and elsewhere. Other management options are at the Audiologist's discretion.

The second additional bypass criterion is:

d. A sibling aged 10 years or less with definite PHL (new addition).

Clear evidence of definite PHL in a baby's sibling under 10 years of age is a condition that warrants screening bypass and direct referral for timely ABRA. **If the family's verbal report is the sole source of information about sibling hearing status, the family report is sufficient to establish this risk indicator only if the affected sibling attends a Provincial School for the Deaf OR wears a hearing aid OR is fitted with a Cochlear Implant.**

If the sibling's PHL is judged by the screener to be well-established, the target baby's screening should be bypassed. If the sibling's PHL were to have a recessive genetic etiology, the target baby would have a very high risk of sensory/neural PHL that may include frequency-specific hearing loss, in which case the click AABR may be false-negative.

Note also that any presumed, inferred or reported cause of the sibling's hearing loss is irrelevant with respect to both the bypass decision and the target baby's at-risk status. A *presumptive* cause of the sibling's PHL, such as concurrent congenital infection or a syndrome, is not necessarily the definitive cause. The true cause is almost never known with certainty, except perhaps if there were a genetic investigation revealing a proven dominant mutation or proven homozygosity for a recessive mutation. Even a negative standard gene panel does not rule out any but the most common genetic anomalies and there are hundreds of untested and/or unknown mutations for childhood PHL.

While AABR screening can occur after 34 weeks gestational age, ABRA itself should not be initiated by the IHP before about 40 weeks gestational age (GA) because neurodevelopmental immaturity can cause ABR interpretive difficulty, inaccuracy and inefficiency. ABRA at less than 40 weeks is contraindicated except when it is ordered by a treating physician as part of medical management, such as for the purpose of deciding whether to initiate antiviral therapy in babies with congenital CMV.

Irrespective of satisfying the gestational age criterion, ABRA within about a week of birth may be prone to errors associated with transient perinatal conductive hearing loss due to unresolved debris or fluid in the external or middle ear. As noted in Section 1.10, the preferred age at initial ABRA is six weeks corrected age.

1.13 IHP DESIGNATED TRAINING CENTRES (DTC)

Three DTCs support the IHP and report directly to the MCYS: the Audiology Department at CHEO (Ottawa), the Otologic Function Unit at Mount Sinai Hospital (Toronto), and Western University's National Centre for Audiology (London). CHEO and Mount Sinai are the DTCs for ABRA and matters relating to this protocol.

The DTCs support activities including evidence review, technology assessment, protocol development and support, clinical decision support, outcome measurement and various aspects of Quality Assurance and Continuous Quality Improvement (CQI), including Audiologist training, IHP practice reviews and adverse event audits.

Needs for ABRA training are identified to MCYS by IHP Regional Coordinators as they arise. If approved, MCYS will select the DTC involved, determine the priority of the training and arrange its scheduling with the DTC.

ABRA training is typically a three-day hands-on course, involving technical tutorials, clinical observation, familiarization with instrumentation, hands-on testing of at least four babies, in-depth discussion of results and rapid, intensive chart reviews. This is followed by monitoring of the trainee's clinical results in the field, prior to their release, until procedures and interpretations are considered satisfactory by the DTC expert. This initial monitoring process typically may take 15-25 new cases. It is expected that trainees with be engaged in their clinical practice within two weeks of completing the hands-on training component.

Refresher training may be requested by any IHP Audiologist at any time, through the Regional Coordinator and MCYS.

1.14 ABRA PROTOCOL SUPPORT BY DTCS

This protocol includes several substantial changes from the 2008 protocol. IHP Audiologists providing ABRA services are strongly encouraged to contact directly a DTC if they have a question or concern about any aspects of the new protocol. While peer-to-peer consultation is sometimes helpful, the response of a DTC is definitive. Furthermore, by discussion with Audiologists in the field, the DTC is able to develop awareness of protocol areas that may require clarification or modification for all IHP Audiologists. All interactions with a DTC are confidential.

1.15 DTC CONSULTATION OR REFERRAL

Even the most skilled ABRA Audiologists may be confronted by difficult challenges of procedure, interpretation or next-step planning. There are many aspects of ABRA for which the underlying scientific evidence is lacking or for which expert consensus is incomplete. In many respects, ABRA is in part evidence-based and in part a clinical art. Clinical decision support from DTCs is not about what is right or wrong or about evaluating the Audiologist – it is about information transfer, two heads being better than one and how to do the best job in services for the infant.

Challenges often arise in situations that involve, for example, an ANSD component or mixed conductive/cochlear hearing losses. It is recommended that such cases be referred promptly to a DTC if there is any difficulty of procedure or uncertainty in interpretation

(see Appendix B). Some problems in repeated testing and some referrals may be avoided easily by discussion of initial results with a DTC.

ABRA support has been provided by Mount Sinai Hospital since 2001 and by CHEO since January 1, 2015. The support may involve answering questions about procedure, protocol or interpretation, discussing a concern or challenge, commenting on next steps in a current case or arranging a referral for further ABRA at the DTC. Real-time support during actual ABRA testing is currently impractical. While every effort is made to provide prompt feedback, it is helpful if support requests are timed such that the need for DTC response within 24 hours is minimized. Response within 48 hours is targeted with best efforts.

The preferred contact method is email. Clinical records for review may be faxed or sent as email attachments. All records **must** be de-identified and assigned an unique alphanumeric ID to facilitate DTC record-keeping and referencing.

Audiologists may sometimes wish to initiate a consultative referral for ABRA at a DTC. Reasons for this may include inconsistent results, records that are difficult to interpret or persistent challenges achieving a satisfactory test. Alternatively, the Audiologist may wish to procure testing under sedation. After discussion and reviewing case materials to date, where appropriate the DTC first may elect to attempt testing in natural sleep, which may be more practicable in a DTC context with additional in-house supports.

When an infant is referred to a DTC for ABRA, the report from the DTC is sent to the referring Audiologist. The DTC acts as an expert laboratory or clinic providing a service to the referring Audiologist, who typically will retain responsibility for further case management on a local basis.

There may be a perceived conflict when a DTC is involved in both clinical decision support and some aspects of CQI that include routine IHP review of Audiologists' records. Audiologists are hereby assured that any specific case raised for discussion with a DTC for decision support will not be included or referenced specifically in any CQI or audit activity involving that Audiologist and the DTC.

1.16 TIMELINESS OF ABRA COMPLETION

A significant challenge is that completion of ABRA often does not occur in the timely manner defined by international benchmarks for EHDI programs. The two usual ways of quantifying timeliness are age at completion of ABRA and the time interval between referral to ABRA and its completion. Absolute age at completion is clearly dependent on age at referral from AABR screening and age at the first ABRA appointment attended. Late referral is a current focus of IHP screening CQI. Delay between referral and first appointment attended depends upon the efficiency of both referral generation and ABRA appointment booking by audiology facilities. Both of these elements are also CQI priorities.

It is presumed here that ABRA scheduling tactics such as reserved 'emergency' appointments, pre-linked appointment pairs that allow rapid follow-up to complete unfinished ABRAs, and age-driven appointment priority are routinely practiced by IHP audiology facilities that offer ABRA services. Excellent testing quality is of limited value if timely access is undermined by suboptimal appointment scheduling.

This protocol item addresses the duration of initial ABRA, the time from the first assessment appointment attended through to the point of completion. Two obvious causes of delay are inadequate test conditions and audiologic complexity. The situation of interest here is one of little useful clinical information having been obtained after several ABRA attendances. Common causes include the baby being too old to sleep readily, developmental and/or behavioural factors, mismatch of appointment timing and diurnal sleep patterns, caregiver non-adherence to pre-test instructions, ineffective sleep induction techniques and inefficient testing strategy. The over-riding imperative is that ineffective testing cannot simply be repeated indefinitely - something has to be changed.

Babies who fail AABR screening bilaterally are especially compromised if testing is not timely. In such babies, if the ABRA is **not** completed within **three** attended sessions, the Audiologist's options depend on the specific causes of non-completion. If the primary cause is audiologic complexity or difficulty with response identification or interpretation, a DTC must be consulted promptly. If the primary cause is insufficient sleep time or nonadherence to pretest instruction, the Audiologist should either arrange ABRA under

sedation at a local facility (if available) or consult/refer to a DTC, which may also result in testing under sedation. Deferral to later VRA-based assessment is the least desirable option, acceptable only if the baby would be over four months corrected age at the date of the earliest available appointment for sedated ABRA **and** there is no clear contraindication to successful VRA at six months of age.

Babies with difficult-to-complete ABRA must be discussed with the Regional Coordinator. Every IHP Audiologist and Regional Coordinator must be familiar with the MCYS policy document relating to DTC referral (see Appendix B) and must have in place a well-defined process for securing testing under sedation, wherever feasible. Testing under sedation must be done by an IHP Audiologist who is authorized for ABRA and in accordance with this protocol to the fullest extent possible.

A 'substantially completed' ABRA means that enough information has been obtained within the three sessions attended to determine whether there is a need for prompt management and to define at least approximate amplification requirements, where amplification is indicated and elected.

1.17 CAREGIVER-DRIVEN SECOND OPINION

Routine repetition of ABRA is not authorized by the IHP. Occasionally, after the results of the initial ABRA are explained the caregiver may express a strong wish for a second opinion, which may include repeating the ABRA (see Appendix C). There are several possible reasons, including poor understanding, denial of the findings and lack of confidence in the testing. Any caregiver expressing a strong desire for a second opinion must be informed of their right to have their child's records reviewed by an independent expert at an IHP DTC. If this satisfies the caregiver, the Audiologist may proceed with the review procedure. The DTC will examine the records, discuss them if necessary and issue a review report to the Audiologist. In most such cases to date, on DTC review the primary Audiologist's findings are found to be valid and appropriate. If necessary, the DTC may discuss alternative courses of action; occasionally, referral to a DTC for re-assessment may be indicated.

Any family always has a right to seek testing outside of the IHP. The issue that arises and must be explained to the family is that testing over which the IHP has no jurisdiction cannot be assumed to be a valid basis for subsequent receipt of IHP services. That is the situation for ABRA, because of the complex technical and procedural requirements for valid testing, as specified in this protocol.

1.18 ABR TESTING OUTSIDE THE IHP

ABR testing by persons who are not specifically authorized by the IHP to conduct ABRAs must be reviewed by a DTC before they can be considered in relation to further audiologic services from the IHP. Authorization to provide VRA or amplification services does not confer authorization to conduct ABRA.

1.19 ABRA THAT IS OUT-OF-PROTOCOL

ABRA results that are suspected by any IHP Audiologist to be substantively non-adherent to the relevant IHP protocol at the time the results were obtained must be reviewed by a DTC prior to being considered in relation to further audiologic services from the IHP.

1.20 CONTINUOUS QUALITY IMPROVEMENT (CQI)

Accountability and transparency imperatives oblige the IHP to show that its targets for all major components are achieved and its protocols followed. Therefore, the IHP is implementing more intensive CQI sub-programming for key service areas. These activities are considered to be essential due diligence for program integrity and sustainability, are widely endorsed and are implemented in most leading UNHS-based programs worldwide.

CQI for ABRA has multiple components that are directed towards enabling and supporting Audiologists to deliver the highest possible quality of care to affected children and their families. The key indices of quality are effectiveness, equity and efficiency, which are reflected in the accuracy, completeness, timeliness and consistency of Assessments.

The CQI components include enhanced training, improved protocols, increased clinical decision support and protocol support, more systematic referral procedures, more intensive process and outcome evaluation, family experience surveys, systematic program practice reviews and enhanced processes for audit of potential adverse events. Other internet-based quality improvement tools (such as an interactive library of case examples and Question and Answer (Q&A) scenarios) are under consideration.

1.21 IHP STANDARD PRACTICE REVIEWS

The IHP is obligated to demonstrate that its protocols are followed and its objectives are being achieved. To this end, authorization to provide IHP ABRA requires that samples of each Audiologist's clinical records be reviewed periodically as part of the CQI program. The IHP ABRA Practice Review and Key Performance Indicators (KPIs) are currently under development.

Standard Practice Reviews for ABRA will be carried out by the CHEO and Mount Sinai DTCs. All IHP Audiologists providing ABRA services will be reviewed at regular intervals according to a schedule determined by MCYS. The reviews are intended to be a constructive and helpful mechanism to improve practice. Their burden and obtrusiveness will be minimized. Audiologist feedback on review effectiveness will be sought.

1.22 ADVERSE EVENT REVIEWS & AUDITS

Adverse Event Reviews (AERs) are completely different from Standard Practice Reviews. They occur as an obligatory program response to specific events or findings that suggest a significant program deficiency. Such events or findings may relate to groups of babies (such as an inference of concern from database process or outcome patterns) or to individual families, such as a concern arising from family complaint, an anomalous pattern of care or a poor outcome.

If an AER by a DTC indicates that any specific care recipient is likely to have been significantly disadvantaged as a result of non-adherence to this protocol or any other deficiency of IHP services, an Adverse Event Audit (AEA) may be initiated at the discretion of MCYS. An AEA is a more rigorous, comprehensive and goal-directed type of AER, the goals of which include full documentation of events, remediation of case-specific disadvantage to the extent possible and implementation of program adjustments as necessary to avoid recurrence.

1.23 INFECTION CONTROL (IC) STANDARDS

All Assessments must be conducted in full compliance with any and all pertinent standards of the local ABRA facility relating to IC. In the absence of specific facility standards, generally accepted standards apply. The IHP does not presume to specify protocols in relation to IC. It does, however, require that where applicable standards exist locally, regionally or provincially, they must be adhered to rigorously with respect to each and every component of IHP service provision.

1.24 APPROVED TEST ENVIRONMENTS

With the exception of medical/surgical facilities used for testing under sedation or general anesthesia, ABRA must be conducted in an environment complying with current ANSI standards for manual puretone audiometry (ANSI (R2013). American National Standard Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms. ANSI S3.1-1999. New York: Acoustical Society of America.).

Any environment considered for ABRA in natural sleep that does not satisfy this ANSI standard must be discussed with a DTC, approved by the MCYS and be deemed satisfactory with respect to lighting, HVAC, visual distraction, transient and steady-state acoustic noise levels, electromagnetic artifact and audibility of toneburst ABR stimuli at IHP mandatory minimum levels.

1.25 APPROVED TEST INSTRUMENTATION & SUPPLIES

All instrumentation and supplies used for ABRA must be approved by the MCYS. ABR and DPOAE testing must be done using the Biologic Navpro with appropriate EP and Scout DPOAE software and hardware. Ancillary equipment for tympanometry, acoustic reflex testing and RECD measurement must satisfy the functional specifications detailed in the Appendices and be approved by the MCYS through DTC review.

1.26 APPROVED DEVICE PROTOCOLS & PARAMETERS

All device protocols and parameters **must** be configured **exactly** as specified in the Appendices. Any departure from the specified parameters may compromise ABRA validity or efficiency and will be considered to be out-of-protocol. Setup is recommended to be done by the IHP Audiologist who will conduct the ABRA, with support from a DTC if required. Windows EP and Scout DPOAE Setup may be arranged with the device supplier (Electro Medical Inc.), for new devices.

Warning: pre-installed Windows 7 EP test protocols from the NavPro manufacturer must not be used but must not be deleted. Such deletion would necessitate a complete system re-install.

1.27 CLINICAL RECORDS & DATABASE REPORTING

ABRA records and reports must adhere to the requirements of the IHP, CASLPO and pertinent privacy legislation. The records must be held securely as hardcopy in clinical case files. Hardcopy records must be sufficient to fully specify the subject, tester, test date and location, test parameters, source data (including ABR test averages, DPOAE graphics and numerics, MEA graphics and numerics), interpretation and contingent recommendations. The records must contain all information specified in Appendix D.

ABR printouts must now include the test session listing of records that details the exact order of acquisition of averages. This is obtained by choosing the List Records icon at the screen top centre and then printing the list.

As part of ABRA CQI, the importance of timely data entry into the HCD-ISCIS database system is emphasized strongly. After each ABRA session, Audiologists must complete the HCD-ISCIS report and send it to the regional lead agency within ten business days. If completion of an ABRA requires an additional appointment that can be scheduled within one calendar week, the HCD-ISCIS report may be deferred to include the results from the ensuing Assessment. Holding a pending report for more than two ABRA sessions or ten business days is not acceptable.

1.28 PERSONAL HEALTH INFORMATION

Management of all personal health information arising from IHP service provision must comply with all current legislation of the Government of Ontario.

Transmission of personally-identifiable health information must be consented by a family member or authorized caregiver. Individual case information transmitted by fax, hardcopy or email, such as for IHP training follow-up, IHP internal clinical decision support, Standard Practice Reviews or Audits must be uniquely code-indexed and rendered personally non-identifiable to unauthorized third parties.

ABR and OAE records held in databases on IHP NavPro laptops or archived onto removable media must not be personally identifiable by unauthorized persons. Filenames must comprise alphanumeric codes; code key lists must be held securely at a separate location from that of the NavPro.

SECTION 2: ABRA PRELIMINARIES

2.01 URGENCY OF ABRA APPOINTMENTS

Once a baby has failed AABR screening or has been routed to bypass screening, the need for timeliness of ABRA from its initiation to its completion cannot be overemphasized. First, there is harm due to caregiver anxiety that accumulates over time. Second, in order to meet international performance benchmarks and gain the greatest benefit from newborn screening, the initial ABRA process must be completed by three months corrected age, wherever this is feasible. This requires an early ABRA start, to allow for additional test sessions that are necessary in many babies who have hearing loss and to accommodate inevitable delays due to unforseen events such as baby indisposition or competing caregiver demands. Third, as babies get older, natural sleep becomes increasingly challenging to initiate and maintain for the required length of testing. This can lead to incomplete ABRA, reduced test accuracy, inconclusive results and increased program resource consumption, including possible need for testing under sedation. The delay of a few weeks between final AABR referral and the first ABRA appointment is indicated in order to facilitate resolution of transient, perinatal ear conditions, ease of handling the baby and some undisturbed caregiver acclimatization to their new circumstance and daily routines. Despite this strong rationale, achievement of timely entry into ABRA continues to show substantial geographic variation throughout the IHP.

It is essential that the caregiver understands the purpose and importance of prompt assessment. This begins with the AABR screener giving appropriate and timely explanation and messaging, which should be reinforced at every opportunity through the ABRA appointment booking process. Families must be made aware of the importance of securing the earliest available appointment, the reasons for the pressure of time and the possible consequences of delay, especially the necessity of sleep and its increasing difficulty over time. The key message is that the sooner the test is done, the quicker, easier and more accurate it is likely to be. Families also should be made aware that ABRA appointments are a scarce resource for which many other families are waiting, so (i) they should make every effort to keep the appointment and (ii) if they become aware of inability to attend, they should **immediately** notify the ABRA provider site and rebook as soon as possible.

While the timeliness of screening referral and subsequent program administration processes in seeking appointments for ABRA are rate-limiting, there are clear indications that access limitations to timely audiology appointment are an important additional delay factor the size of which varies geographically throughout Ontario. Factors that are reported to facilitate prompt appointments and high attendance rates include:

- Immediate ABRA booking at the time of AABR referral, wherever feasible. This has long been identified as a standard-of-care practice, eg., by the national Newborn Hearing Screening Program in England. Trials of immediate booking by screeners at the point of final AABR referral are in progress in Ontario.
- Appointment slot filling taking due account of the 6-8 week target dates (i.e., not filling all available slots simply on a first-come, first served basis).
- Maintaining reserved (non-routine, protected) slots for unexpected, high-priority/urgent appointments.
- Automatic allocation of prompt, linked follow-up slots for rapid ABRA completion in a proportion of primary slots (such as one in five, depending on referral population characteristics).
- Reinforcing key messages at every booking/reminder contact, both in writing and verbally.
- Maintaining a short-notice waiting list to fill late-notified non-attendance.
- Routine two-week and two-day appointment reminders and confirmation requests.

In situations of irremediable limitation of access to timely ABRA appointments, ABRA appointment filling should be done in such a way as to maximize program benefit within existing resource constraints. It is important to minimize the occurrence of late access to ABRA for babies who have the highest likelihood of having PHL, such as those who bypass screening, who are at high initial risk of PHL, or who fail AABR screening bilaterally. It is known that the likelihood of PHL is much lower in babies who fail unilaterally, especially if not at risk. Scheduling of ABRA for low-likelihood babies should not saturate available appointments in such a way as to cause late access for babies with high likelihood of PHL. A relatively simple way to do this is to allocate babies into a stream of appointments that has priority levels mixed and tuned according to the observed characteristics of the local, referred population.

2.02 REQUIRED STATE FOR SUCCESSFUL ABRA

ABR threshold estimation can only be done with acceptable accuracy and efficiency in natural sleep, sedated sleep or under general anesthesia. Natural sleep is highly preferable and must be tried first unless in exceptional circumstances. Natural sleep is rarely difficult to achieve in babies under about eight weeks of age but it becomes progressively more challenging as age increases, such that testing of babies over about four months of age is often time-consuming, inefficient and potentially inaccurate or incomplete.

Routinely successful induction of natural sleep in a wide range of babies is an adaptive skill that takes time and experience to acquire. It is important that the test environment be conducive to sleep, so it should be dimly lit, quiet and free from visual distractions or other disturbances. Eye contact, engaging facial expressions and verbal communication should be avoided. Physical restriction, gently rhythmic movement and soothing, simple sounds all may be helpful at the right time. Over-engagement with the baby is best avoided – the more interesting the scenario is, the more wakeful the baby is likely to remain.

Testing in sedated sleep may be indicated by:

- A known adverse behavior or medical condition,
- Failure to achieve useful duration of natural sleep at up to two previous appointments,
- Any predisposing factor that renders testing failure unacceptable (such as major access difficulty), or
- A recommendation by a DTC.

Testing under sedation usually requires strong emphasis on testing a limited number of high-priority stimulus conditions, efficiency of averaging and progressive accuracy. A rational approach is to prioritize AC 2 kHz threshold bracketing to within 20 dB initially, determine BC 2kHz normality or abnormality, then add an AC 10 dB interpolation step if conditions permit. Examples of poor strategy for sedated testing are: spending too much time proving ABR presence or absence at minimum stimulus levels, especially at 0.5 kHz, pursuing an abnormal 2 kHz threshold with 10 dB bracketing then running out of time before the BC testing can be done, or in a bilateral referral, getting unnecessary detail in one ear before even probing 2 kHz in the second ear.

All pertinent safety standards of the Assessment facility relating to administration of sedative agents must be followed. Written informed consent, medical referral and specification of sedative and dosage, dose administration by medical/nursing staff, supervision and monitoring of the infant during and after sedation and adequate access to emergency services are strongly recommended.

Testing under general anesthesia is sometimes undertaken where medically appropriate and opportune. Protocol may be radically abbreviated to accommodate test time restriction. Again, 2 kHz testing with progressive precision is appropriate. In the operating room (OR), notch filtering at 60 Hz should be tried immediately (due to extreme pressure of time) if 60 Hz interference is seen.

2.03 PRE-TEST BABY STATE

Most ABRA testing facilities in Ontario utilize testing schedules with targeted appointment start and stop times. A typical duration for a routine ABRA appointment is 1.5-2 hours. In that time, it is usually desirable that the baby sleep for at least half an hour, in which period a baby without PHL normally can be confirmed as such. Typically, it is desired that the baby arrive for the appointment

hungry and tired, though not overtired. After cursory otoscopy and ABR electrode attachment, the baby can be fed and prepared for sleep. It usually follows that the baby should be neither fed nor allowed to sleep within about an hour prior to the appointment.

It is essential that families understand very clearly that successful ABR testing depends on their following pretest instructions carefully. The real underlying message to the family is that if the baby does not sleep readily for at least half an hour, the session is unlikely to be useful and will probably be a waste of valuable time and resources that could have been used to test another baby who could have slept. It is also likely to be a wasted time and effort on the family's part. The strength and explicitness of this message differ according to the test facility's standard procedures, the Audiologists' level of comfort and assertiveness and the specific context. In a group practice or institutional situation in which staff who make family contacts for appointments may vary in their engagement and communication skills, obligatory scripts may be helpful to encourage strong and appropriate messaging. Presenting the pre-test requirements in a poorly formatted reminder letter or in a bored monotone phone call almost guarantees lack of family understanding and adherence.

There are clear indications that the degree to which families adhere to pre-test instructions varies across ABRA test facilities in Ontario. Multiple factors are involved and some of those factors are within the scope of influence of the ABRA Audiologist. The best that reasonably can be done is that families hear and fully understand the message, then make an honest effort to comply with the instructions. The bare minimum process requirement to achieve this is that the messages are very simple, brief, clear, strongly directive and consistent, and are presented repeatedly both written and verbally. Written messages must be formatted effectively. The bluntness and formatting clarity required are often underestimated. Examples are:

DO NOT feed your baby within one hour before the appointment time, unless it is necessary medically!

You will be feeding your baby at the beginning of the test.

DO NOT let your baby sleep within one hour of the appointment time!

Your baby MUST sleep during the test or it will not be successful.

If you are driving OR bringing other children as well as your baby, someone MUST come with you!

You cannot keep your baby awake properly while driving or looking after other children by yourself!

In verbal contacts, identical messages and wording are required, preferably followed by reinforcement and verification that the messages are understood – not, of course, by simply asking 'do you understand?'!

2.04 TEST ENVIRONMENT & PARTICIPANTS

The infant's safety and comfort are paramount and the infant must be monitored continuously. It is strongly recommended that the tester and ABR/OAE instrumentation be inside the soundroom with the baby or infant.

Requirements for approved test facilities were noted previously in Section 1.24. The optimal test environment for ABRA is an audiometric soundroom that is electrically shielded. Soundrooms that are not shielded can be acceptable electrically if they are not adjacent to strong sources of electromagnetic (E/M) fields, such as heavy electrical equipment, elevators, HVAC motors, diathermy equipment, large scanners, etc. If a soundroom is shielded, then for optimal effectiveness against external fields, shield continuity (e.g., window mesh) and good grounding are important. Regardless of such shielding, AC mains power cable routing within the soundroom must be appropriately encased in grounded metal conduit and, to the extent possible, outlets that are unused should have metal cover plates.

HVAC is important, especially for infant comfort, sleep promotion and stable electrode-skin attachment (which is affected by sweating). Lighting control is important for sleep promotion; battery-powered LED task lighting is optimal with respect to power line

interference. Fluorescent bulbs and tubes are the least desirable option, giving limited control and high likelihood of electromagnetic interfertence at 60 Hz and its higher harmonics.

Presence in the test room of the baby's caregiver is common practice and is recommended but discretional. The majority of initial ABRA in the IHP is done with the baby, caregiver and Audiologist inside the test room. In some cases, the Audiologist tests the baby alone, which requires special attention to optimal positioning of the equipment, baby, cot or bassinet and tester. If special assistance is required, additional personnel such as a nurse, second Audiologist or other assistant may be required. Usually, caregivers are helpful for monitoring inserts or electrodes or for holding BC transducers. Careful instruction is usually necessary for the latter.

As is to be expected, caregivers vary in their knowledge of the most appropriate techniques to encourage an infant to sleep, and instruction may be needed to optimize their effectiveness in assisting ABRA. It is not reasonable to expect a lay individual to possess the understanding and skills that may be gained from testing hundreds or even thousands of babies. However, caregiver engagement with the ABRA process can contribute substantially to understanding of test results, the building of trust and the creation of a communicative relationship with the Audiologist that may prove crucial in subsequent management, should the baby be proven to have PHL.

If a caregiver is present during the testing, it is important that the Audiologist pay special attention to appropriate communication of information as the test proceeds. Surveys of caregiver experience with diagnostic assessments in other programs indicate that caregiver satisfaction is often less than ideal, most frequently as a result of not being kept at least minimally informed about what is going on. A running commentary by the Audiologist is neither appropriate nor practicable, given the technical demands of ABRA, but reasonably frequent, brief explanations of what is being done can alleviate the caregiver's sense of being 'kept in the dark' and lacking control. Discretion and good judgment in communication are essential if the Audiologist is facing what appears to be a baby with major PHL. However, in that situation, some of the groundwork for imparting difficult news and encouraging acceptance and positive engagement can begin. One way of viewing this is that the process of intervention begins with the process of diagnosis, though some would argue that it really begins during the process of screening.

2.05 TONEPIP STIMULUS PARAMETERS

IHP ABR and OAE testing must be done using the Biologic Navigator Pro system. ABR application software in current use include Biologic AEP v6.2.0 under MS XP Pro and Biologic EP v7.2.1 under Windows 7 Pro. The Biologic Scout DPOAE application software is also used. All application test protocol and parameter files must be configured exactly to IHP specifications (see Appendices).

The core of ABRA is estimation of hearing thresholds using tonepip ABR methods. The accuracy of the threshold estimates so obtained depends upon many details of the stimulation and recording methods specified in this protocol. Part of the estimation process involves re-analysis of normative data on the relationship between ABR thresholds and subsequent behavioural thresholds obtained by VRA that were obtained by Stapells and his colleagues. The re-analysis involved switching dependent and independent variables, variable range restriction and censoring in linear and quadratic regression, use of nonparametric methods and data transformations. The results of this underlie the numeric bias adjustment factors ('correction factors') that are used to convert ABR thresholds in dB nHL to estimates of perceptual thresholds in dB HL.

The correction factors used in this protocol are specific to the stimulus parameters, recording and analysis techniques described in this document. Use of any other types of stimuli, including Blackman tonepip envelopes and changes in nominal tonepip frequency, or changes in any of several specific aspects of ABR recording and analysis (such as averaging strategy or Residual Noise criteria) will render the threshold estimation process invalid and of unknown bias and precision. Conversely, the correction factors used here cannot be assumed to be valid for stimulation and recording methods that differ from those specified in this protocol.

This protocol specifies the use of constant correction factor values for an ABR threshold range from 30 to about 90 dB nHL. These correction factors do not apply for ABR thresholds less than 30 dB nHL, for which range the predictive strength of ABR thresholds obtained by methods such as those detailed here is not established. There is also a weak tendency for differences between ABR and

VRA thresholds to decrease at high dB nHL values; this effect is to be expected from the known characteristics of auditory single-unit tuning curves in individuals with various degrees of conventional sensory hearing loss. However, the effect is small in terms of estimated behavioural threshold accuracy and is offset by the use of 5 dB steps in bracketing of high ABR thresholds.

It should be noted that the IHP tonepip stimuli are specified to have trapezoidal envelopes with linear rise and fall; the rise, plateau and fall times are 2-1-2 cycles. Such stimuli may not be optimal for ABR elicitation; for example, the net energy-equivalent duration of the 4 kHz stimulus is only about 0.6 ms, whereas the wave V stimulus energy integration time for maximum amplitude is probably at least 2 ms. Conversely, the 0.5 kHz stimulus 4 ms rise time is arguably too long. However, the original choice of cycle-based tonepip envelope was dictated by the availability of high-quality normative data for these particular stimuli and the wealth of clinical and research experience gained with these stimuli has cemented the rationale for their continued use.

2.06 STIMULUS CALIBRATION & CHECKING

Manufacturer's default calibration files for ABR stimuli must not be used, because their experimental and psychophysical basis is not available for evaluation. The calibrations to be used are based on the high-quality, published findings of Stapells and his coworkers, and are detailed in Appendix F.

ABRA tonepip and click stimuli must be calibrated electro-acoustically, annually. Listening checks for air and bone transducer malfunction or intermittency in leads and connections must be done at least at the start of each day's testing. A backup insert and bone-conduction transducer, as well as spare leads, should be available at all times.

In the course of clinical testing, immediate stimulus checks must be done whenever ABR absence is seen unexpectedly or is seen at the maximum level used for any stimulus type and route. The most common cause of stimulus insufficiency is eartip blockage.

2.07 STIMULUS TRANSDUCERS

All stimulus transducers must be of the type specified by the IHP. Where inserts are contraindicated anatomically, supra-aural earphones (TDH/MX41) may be tried discretionally, such as to determine the patency of a very small ear canal or a vestigial opening.

For BC ABR testing in infants, transcranial sound transmission losses can vary across infants from about 5 to 30 dB (Yang & Stuart, 1990). Therefore, each ear must be tested individually, with transducer placement on the mastoid supero-posterior to the canal opening of the test ear. The transducer must be held firmly in place either by a disposable Velcro band or tensor bandage, or by finger pressure perpendicular to the transducer rear surface (see Appendix G for clinical tips). Application force measurements are unnecessary, but positioning must be consistent and the pressure must be light but firm. Many family members are able to apply the BC transducer correctly, given clear and simple instruction on what to do, what not to do and when to alert the Audiologist to a placement issue.

Note that it is not necessary to remove an ear insert tranducer when testing a given ear by bone conduction ABR. Evidence to date indicates that occlusion effects are clinically insignificant (see Small et al. 2007) and this is supported by substantial clinical experience with ABR thresholds in other EHDI programs.

2.08 ELECTRODE POSITION

ABR electrodes must be of a type approved by the IHP. The non-inverting electrode must be placed on the midline forehead as high and as close to the hairline as possible. An inverting electrode must be on each mastoid process and the common electrode must be on the lateral forehead at least 3 cm from the non-inverting electrode.

A common error is non-inverting electrode placement too low on the midline forehead, at which point ABR wave V amplitude loss will occur, relative to points higher on the midline. On the International EEG Federation's 10-20 System for Electrode Placement, the

goal is to position the non-inverting electrode as close as possible to Fz, not at the mid-forehead frontal pole denoted as Fpz. Using sticky pads on the skin, the anterior proximity to Fz is usually limited by the position of the hairline. See American Electroencephalographic Society (1994).

2.09 ELECTRODE IMPEDANCES

Effort must be made to obtain impedances of 5 kΩ or less for all electrodes and, even more importantly, impedance differences for each forehead-mastoid pair of no more than 1 kΩ.

Differences in non-inverting and inverting electrode contact impedance reduce the ability of the differential amplifier to reject input signals common to these two electrodes. This ability (common-mode rejection, CMR) is important to achieve the best ABR-to-noise ratio from the head. Large signals from the heart, for example, are similar at the forehead and mastoid and greatly reduced by differential recording. The same is true for signals from distant, off-body sources such as radio waves, for which the body acts as an antenna.

Note that the ABR usually seen in a differential recording has the actual ABR at the mastoid subtracted from the actual ABR at the high forehead. Wave I, for example, is mainly skin-negative and periauricular, so it appears in the difference waveform as a positive signal. Wave V is more broadly scalp-positive and larger in the midline.

CMR reduction depends on the absolute difference in impedance, so 2 kΩ of difference is twice as bad as 1 kΩ. The lower both impedances are, the smaller the difference will tend to be, so it usually makes sense to reduce the larger impedance. When the baby is deeply asleep and the EEG is quiet, loss of CMR may not matter, but when the baby is lightly asleep or dozing intermittently and the EEG noise is larger, loss of CMR may determine whether ABR testing is successful.

Higher but equal absolute impedances have negligible direct effect on CMR but they increase artifact voltage pickup due to electromagnetic current induction in the electrode leads or across the baby's scalp. E/M current may be induced by any rapidly changing E/M field surrounding the electrode leads, such as may be generated by AC 60 Hz power leads, outlets, switches, lights, dimmers or other nearby electrical devices. Fluorescent lights can be problematic due to higher harmonics of 60 Hz. Battery-powered LED lighting does not cause E/M current induction and is readily available at low cost.

2.10 RECORDING CHANNELS

For AC ABR thresholds a single recording channel with the inverting mastoid electrode ipsilateral to the stimulated ear must be used. For BC ABR thresholds, two channels must be used with the inverting electrodes on the posterosuperior mastoid areas ipsilateral and contralateral to the stimulated ear.

For AC ABR threshold measurement, the practical benefit from recording with two channels is negligible. Doubling the number of displayed or plotted averages increases clutter and the difficulty of waveform organization and rapid visual inspection. A discretional exception is severe, unilateral loss, wherein two-channel recording might reveal a contralateral responding ear at high stimulus levels. Similarly, two channels might reveal a stimulated ear or electrode connection error by showing a lateralized wave I on the wrong side, but such errors are so basic that they should not occur.

In BC threshold estimation, inference of which cochlea is responding to the stimulus usually requires comparison of ABR characteristics from channels ipsilateral and contralateral to the stimulated mastoid. Furthermore, much larger BC stimulus artifact in the ipsilateral channel can flag inadvertent stimulus or electrode errors.

2.11 THRESHOLD ABR WAVEFORM PRINTOUT

Consistent and optimal organization of waveform printouts facilitates rapid visual inspection and interpretation, as well as review by other persons such as colleagues or DTCs. It also expedites any type of review, including training or updating reviews, consultations, second opinions, standard performance reviews or adverse event audits. Therefore, a standard format is necessary and is mandatory.

For all ABR thresholds, averages should be printed half page width, usually with two columns of averages forming a page. For AC thresholds, averages are grouped by ear, by frequency within each ear and ordered by descending level within each ear-frequency. All primary averages for a specific stimulus condition must be plotted using the 'Match' format option; this overlays averages with a small baseline separation, which has three advantages. First, it separates the averages' identifying character strings ('tag strings'). Second, it improves the ability to track along each average waveform, which is often helpful in assessing reproducibility and identification of large noise artifacts in individual averages. Third, the automatic separation of averages is not subject to waveform identification bias that can easily arise when the examiner is free to adjust vertical positioning to superimpose potential response waveforms. That practice of arbitrary vertical shifting is to be avoided in record printouts, though it may be subjectively helpful in the course of data acquisition, to assess reproducibility and averaging needs.

For BC ABR, for each stimulus ear-frequency-level, ipsilateral and contralateral averages or groups of averages are obtained. The ipsi and contra groups for a given level should be treated together as a unit, with the contra immediately below the ipsi, and with these units ordered overall by descending stimulus level. This facilitates the visual comparison of ipsi and contra waveforms and their trends across levels, usually necessary in order to identify which cochlea is being activated preferentially by the given stimulus.

SECTION 3: HIGH-EFFICIENCY ABR THRESHOLD MEASUREMENT

3.01 TEST EFFICIENCY IS CRUCIAL & FEASIBLE

In the IHP, as well as in many other programs worldwide, timely and accurate completion of ABRA is a challenge. Continuous effort and ingenuity are needed to increase the efficiency of ABR threshold measurement in particular, without loss of accuracy and, preferably, with increased accuracy and reduced errors or omissions. The emphasis here is on improvements in procedure that will increase the rate of clinical information gain and reduce the likelihood of significant clinical decision errors or omissions. Most of the protocol elements specified here are routinely practiced by the most skilled ABR testers globally. Even with rigorous adherence to this protocol, there is ample room for the additional exercise of great clinical skill and high-level judgment. For example, pervasive clinical questions are 'in how few averages can I define this ABR threshold to an acceptable level of precision and adherent to protocol?' and 'if this baby wakes up in one minute, have I done absolutely the best possible job in obtaining the most critical clinical information in the time I had available?'

The following ten points illustrate some key aspects of more efficient testing that will be explained in more detail in the subsequent sections:

- **Throughout threshold estimation, make every choice of the next stimulus condition the one for which determining ABR presence or absence will have the greatest impact on clinical management, given what you already know or do not know at that precise moment of choice.**
- **Don't allow high-amplitude EEG into a good average; use automatic artifact rejection more effectively.**
- **The bigger the average, the less efficient it becomes in terms of information gain per unit test time. Use sweep counts of about 1,000 to 2,000 sweeps and combine no more than three of them, where necessary.**

- **Start initial testing in a referred ear. The information gain from testing a passed ear is much smaller, as is the probability of a significant Permanent Hearing Loss in a passed ear.**
- **Start at the minimum stimulus level but go up in large steps (30 then 20 dB) to get a clear response latency and waveform guide as quickly as possible.**
- **Use a strategy of progressive refinement of threshold accuracy. Do not use 5 dB brackets unless and until you have finished all 10 dB threshold bracketing.**
- **Go to BC early when AC at 2 kHz is abnormal, to establish loss type right away. Consider switching ears early in bilateral refers.**
- **Use 10 dB ascent only to confirm response at a lower level, not for threshold searching.**
- **Proving response absence is often far more time-consuming than proving response presence, so try to minimize doing it.**
- **More than three averages per stimulus condition are rarely useful; go up instead.**

3.02 OPTIMIZING CLINICAL INFORMATION GAIN

ABR threshold measurement must be done with the highest possible clinical efficiency, assuming that testing can be terminated at any time with no further attendance. Each and every choice of next stimulus condition must be such that clinical management will depend strongly on the answers obtainable for the chosen condition.

Common situations that limit the efficiency of threshold measurement are:

- Getting bogged down in threshold accuracy before answering bigger clinical questions.
- Using ascending step sizes that are too small, losing time getting to threshold bracketing regions.
- Lengthy or repeated averaging when response is highly questionable (i.e., chasing shadows), rather than going higher to get a clear guideline response.
- Not doing BC early enough and/or switching ears early enough.

The general strategy of successful ABRA is the opposite of standard audiometry in a cooperative adult subject, which typically plods inexorably by rote from a standard beginning to the end. In an infant, the required mindset is that the testing may be terminated permanently at any moment, perhaps after the very next average. This means that the next stimulus condition (route, frequency, level…) to be chosen must be the one that will make the biggest difference to clinical management, of all the stimulus choices available. If this strategy were followed continuously, then no matter when the session does end, it would not have been possible to get more valuable clinical information in the time that turned out to be available.

Pressure of time is constant in newborn or infant ABRA. It is very difficult to achieve consistently accurate and complete initial ABRA followed by appropriate intervention within the timelines established as international benchmarks. There is never any time to waste taking measurements that are not clinically important. Moreover, it is quite common across most EHDI programs that many Assessments are incomplete, uncertain or not timely. The need for a top-down approach with progressive refinement of information obtained cannot be overstated.

The first question to be answered in ABRA is whether any ear that gave a UNHS Refer has a target PHL. If the UNHS Refer is unilateral, the Referred ear is the starting point, whereas if bilateral, the starting ear is a matter of convenience.

Absence of hearing loss is answered by ABR detection at the lowest appropriate stimulus levels across the target frequency range, denoted as Smin values. In the range 0.5 to 4 kHz, the most valuable of all single answers in relation to early language development and the epidemiology of hearing loss in newborns is at 2 kHz.

Most babies referred from UNHS will have normal or near-normal hearing. It follows that the initial starting condition must be the AC 2 kHz Smin. Starting higher at 2 kHz is inefficient because usually a clear ABR will be obtained at Smin.

If there is no response at the 2 kHz Smin, important clinical questions are: (1) how big is the loss, (2) is it permanent, (3) what about other frequencies and (4) what about the other ear? Of these questions, the one with the greatest clinical impact is arguably (2) is it permanent? This suggests that going to BC early is efficient. Even if the loss were minor, its sensory nature would be crucial.

An efficient alternative when there is no response at the 2 kHz Smin is to immediately go up 30 dB. Getting a positive response quickly at about 60 dB nHL is much more informative than getting an inconclusive or negative result having gone up by only 10 dB, for example. In addition, getting no response at 60 dB has major clinical impact, is much more informative than getting no response at 40 dB and avoids time wastage chasing shadows. Epidemiological evidence to date suggests that severe conventional hearing loss and/or ANSD may be more prevalent than moderate hearing loss; mild conductive loss is probably the most prevalent overall but not necessarily so at 2 kHz.

If no response were obtained at 60 dB, is it better to go to, say, 80 dB or to BC? You know that there is a substantial hearing loss, so its permanence has become crucial. Before going to BC, however, there is a case for immediate shift to 4 kHz at a level such as 80 dB, because there is a substantial likelihood of an important no response to be gained at 4 kHz with only a minute or two of recording.

When going to BC, a question is whether to start at the BC 2 kHz Smin or a higher level, given no response for AC at 30 or 60 dB. The Smin has priority because the ability to state that BC is normal has major clinical impact.

Next, especially relevant in bilateral UNHS referral, is the question of whether the other ear has a PHL. The more severe the hearing loss in the first ear is, the more important it is to determine whether the other ear could be normal or near-normal. It can be argued that with a bilateral refer, testing 2 kHz on the other side to a significant PHL becomes a higher immediate priority than extending the testing of the first ear to 500 Hz. For example, if the session were abruptly terminated, would you rather be able to say whether the other ear is OK at 2 kHz or that the first abnormal ear is flat or sloping?

There are two important general points here. First, information theory tells us that in a situation of choosing between two alternatives, the more probable one is relative to the other, the less information is gained by knowing the answer; when one answer is almost certain, discovering that it is true yields little new information. It follows that the greatest information gain occurs when the alternatives are equi-probable.

The second point is that the relative clinical importance of a given stimulus condition changes as the answers come in from other stimulus conditions, so the whole process of choosing the most influential next stimulus condition is dynamic and constantly evolving as the Assessment proceeds.

3.03 MANDATORY & DISCRETIONAL PROCEDURES

A complete ABRA must include cursory otoscopy, ABR testing and Middle Ear Analysis (Tympanometry). The ABR testing must include AC tonepip ABR threshold estimation; where indicated, it may include BC tonepip ABR and a sub-protocol for evaluation of ANSD as well as other retrocochlear disorders that commonly affect the ABR. MEA must include tympanometry and may include acoustic reflex testing.

ABRA test components are specified below. The tests are grouped as procedures that must always be done (Mandatory), procedures that are must be done if a specific situation occurs (Conditionally Mandatory) and procedures that may be done if the Audiologist so chooses (Discretional).

Mandatory Procedures

- Cursory otoscopy
- AC ABR thresholds at 2 kHz, 4 kHz and 0.5 kHz with 10 dB final bracketing
- Tympanometry at 1 kHz under 6 months corrected age, 226 Hz at 6 months or more

Conditionally Mandatory Procedures

- BC ABR threshold at 2 kHz if AC 2 kHz is abnormal
- BC ABR threshold at 0.5 kHz if 0.5 kHz is the only AC threshold abnormality.

  If AC 2 kHz **and** 0.5 kHz are both abnormal, BC 2 kHz is Mandatory and BC 0.5 kHz is Discretional.
- AC ABR threshold at 1 kHz (10 dB bracketing), if AC 2 kHz minus AC 0.5 kHz exceeds 25 dB nHL.
- Sub-protocol for ANSD or retrocochlear disorders, if there is no clear tonepip ABR wave V-V' at 15 ms or less for any 2 kHz level tested above 75 dB nHL. The sub-protocol Includes:

  Rarefaction and condensation clicks (separated) at 90 dB nHL, for assessment of:
  - Cochlear microphonic potentials (CM)
  - Cochlear summating potentials (SP)
  - ABR wave presence, morphology, latency, amplitude
  - Approximate click ABR thresholds

  DPOAE amplitude and noise measurements at 1, 1.5, 2, 3 and 4 kHz nominal f2.

Discretional Procedures

- DPOAE amplitude and noise measurements at 1, 1.5, 2, 3 and 4 kHz nominal f2, where ANSD is not suspected.
- Ipsilateral acoustic reflexes (preferably to wide-band noise bursts).
- AC ABR thresholds at 2 and 4 kHz with 5 dB bracketing (over 70 dB nHL), if all mandatory measurements are completed and time permits.
- RECD determination, where non-ANSD PHL is confirmed and time permits.

Component Test Priorities and Order

Cursory otoscopy is a required preliminary in any Assessment. Its purpose is to detect foreign bodies, canal occlusion and any other physical condition of the ear that may invalidate or otherwise contra-indicate the Assessment or indicate referral to a physician. Otoscopy is usually followed by electrode attachment, then feeding to promote sleep.

At the first ABRA session, tonepip ABR thresholds are the immediate priority as soon as the infant sleeps. Other procedures such as tympanometry (mandatory) or DPOAE (discretional) are usually deferred because they are secondary to ABR and can interfere with falling asleep. One of the facets of successfully inducing sleep in many babies is minimization of auditory, visual and somatosensory stimulation.

Because abnormal AC tonepip ABR thresholds trigger BC measurements, direct hard evidence of conductive hearing loss is usually obtained thereby. Tympanometry is usually deferred at least to the end of the first session. Its findings complement ABR-based inferences and provide limited cross-validation of ABR air-bone gaps.

Acoustic reflex measurements are now discretional. They have limited value as a crosscheck when ABRs are absent at high stimulus levels, in that reflex presence contradicts inference of both ANSD and profound conventional cochlear hearing loss. In general, reflex presence may be clinically informative whereas reflex absence is rarely so.

After the tonepip thresholds are substantially completed, if the 2 kHz ABRs are absent or abnormal at high levels then ANSD presence must be evaluated, using both OAEs and the click ABR ANSD protocol. These tests are normally deferred to the end of the first ABRA session.

Following a completed standard ABRA, in a small proportion of cases more advanced procedures such as threshold estimation with auditory late cortical potentials or more complex ANSD testing to disentangle receptor and neural potentials may be indicated under specific circumstances, such as inability to measure hearing thresholds by ABR or VRA, or inability to interpret results of the standard ANSD protocol (see Section 4). The need for such procedures is identified by a DTC consult and additional procedures would normally be done at a DTC.

3.04 AC & BC TEST FREQUENCIES

AC tonepip ABR thresholds may be measured only at nominal frequencies of 0.5, 1, 2 and 4 kHz, where 2, 4 and 0.5 kHz are mandatory and 1 kHz is conditional. AC testing at other frequencies must not be done because there are no adequate normative data on the relationships between ABR and perceptual (behavioural) thresholds at other frequencies, for the type of stimuli specified in this protocol.

BC 2 kHz must be done if AC 2 kHz shows no response at the minimum level. BC 0.5 kHz must be done if AC 0.5 kHz is the only abnormality, but is discretional if both AC 0.5 and 2 kHz are abnormal. Inference of conductive loss at 0.5 kHz does not imply that a loss at higher frequencies also must be conductive, whereas if a loss at 2 kHz is purely conductive it is reasonable to assume that a loss at 0.5 kHz is also conductive. BC testing must not be done at any other frequency than 0.5 and 2 kHz, again because there are no normative data of adequate quality.

While BC ABR norms at other frequencies such as 4 kHz would be desirable and may be utilized in some programs, the available normative data do not satisfy reasonable quality standards required by the IHP. Clinical data collected in the course of program implementation are not a sufficient basis for norming. Clinical service programs such as the IHP do not have the mandate or the resources to implement appropriate the clinical research paradigms that would be necessary to establish BC ABR norms at 4 kHz. Local, small sample norming would be completely insufficient and while frequently suggested, it almost always is statistically invalid and clinically inappropriate.

3.05 MINIMUM (Smin) & MAXIMUM (Smax) TONEPIP LEVELS

The IHP target disorder set defines the lower limit of puretone hearing loss (25 dB HL) that it is desired to measure. This defines mandatory minimum stimulus levels (Smin) that depend on stimulus frequency and route and are in the range 25-35 dB nHL. Lower levels must not be used, primarily because the relationship between behavioural thresholds and ABR thresholds obtained with common, clinical protocols is currently unknown or non-existent at ABR threshold levels that correspond to about 25 dB HL or less. This is to be expected, given the typical variability of individual measurements of both ABR and VRA thresholds.

Absolute maximum levels for tonepips (Smax) are determined by the upper limit of transducer linearity. In terms of damage risk to the cochlea, there is no good evidence of auditory system damage risk for the tonepips used in ABR threshold measurement. Even at the highest tonepip levels with the largest feasible, high-frequency SPL increases in small canals taken into account, conventional

noise exposure calculations indicate no damage risk. However, this is not necessarily the case for click stimuli (see later). Smax values are typically in the range 95-105 dB nHL.

There are, however, unanswered questions about the nature and origin of large positive or negative waveforms that are sometimes seen under 5 ms latency at very high stimulus levels. E/M artifacts, transducer nonlinearity and ringing, amplifier ringing, unusual cochlear receptor potentials and vestibular potentials are all possibilities.

Is there much clinical value in being able to differentiate hearing thresholds of, say, 90 vs 100 dB HL? The contribution to clinical management of such a discrimination is not obvious. Unless the benefit of such a distinction becomes established as substantial, it is reasonable to set a provisional maximum of 95 dB HL.

3.06 AMPLIFIER GAIN & MYOGENIC ARTIFACT REJECTION

A fixed preamplifier gain of 150,000 is usually appropriate. Gain should not be decreased if the EEG noise level increases during the test – smaller bad data is not better data. The proper course is to determine the cause of the increase and make every effort to fix it at the source.

Large myogenic artifacts in the ongoing EEG are the most common cause of inefficient and inaccurate ABR thresholds. Active management of artifact rejection levels by the Audiologist was not emphasized sufficiently in previous ABR testing protocols. This must change in the interests of faster and more complete ABRA. The statistical principles are compelling and the practical demands are minimal. The result will be a substantial reduction in time spent accumulating averages that are needlessly long or unknowingly corrupted by myogenic artifact.

In the past, artifact rejection occurred only when the EEG amplitude exceeded the EEG display limits. In effect, the actual artifact rejection limits were set by the amplifier gain. In that situation, when the EEG is quiet, the trace might occupy only a small fraction of the display y-scale.

A quiet, flattish EEG trace with fluctuations that occupy only a small fraction of the distance between the reject limits (or the display limits if that is where the reject limits are set) should be regarded as good because it is quiet but dangerous because there is very little protection against sudden, large myogenic artifacts. Any average with zero sweeps rejected is a clear indicator of artifact rejection limits that are too large relative to the size of the EEG fluctuations.

When an average accumulates from quiet EEG with reject limits that are too high, large myogenic noise that is just not large enough to trigger rejection can enter a previously well-behaved and valid average. Only a few sweeps of such large myogenic noise can simulate, distort or abolish a genuine ABR and destroy the ability to make reliable judgments of response presence or absence. The smaller the ongoing EEG fluctuations are, relative to the actual rejection limits, the less protection there is against this high-variance contamination of the average. At sweep acquisition rates of 21 or 39 per second, it is impossible to pause averaging fast enough to prevent this type of contamination; a good average that is either flat or is beginning to show clear response can be contaminated irreversibly in less than one second. Once his has happened, it is almost impossible to undo the damage by continuing to add more sweeps. Fortunately, this problem can be largely avoided by using more appropriate artifact rejection settings.

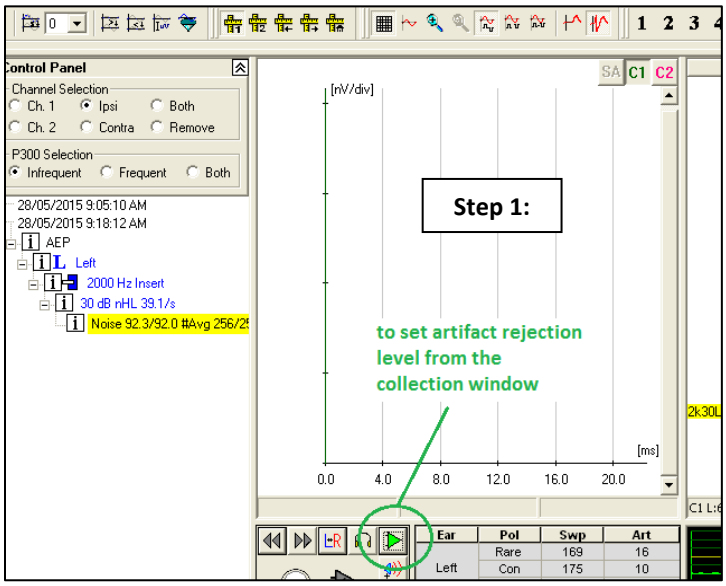
The effective solution is to decrease the artifact rejection limits, moving them inward to a position such that even a quiet, ongoing EEG causes occasional sweep rejection. Artifact reject levels must be set so that when the EEG is quiet, about 5-10% of sweeps are rejected routinely. In threshold work, that is a ‘tick-over’ rate of about two or three rejected sweeps per second on average

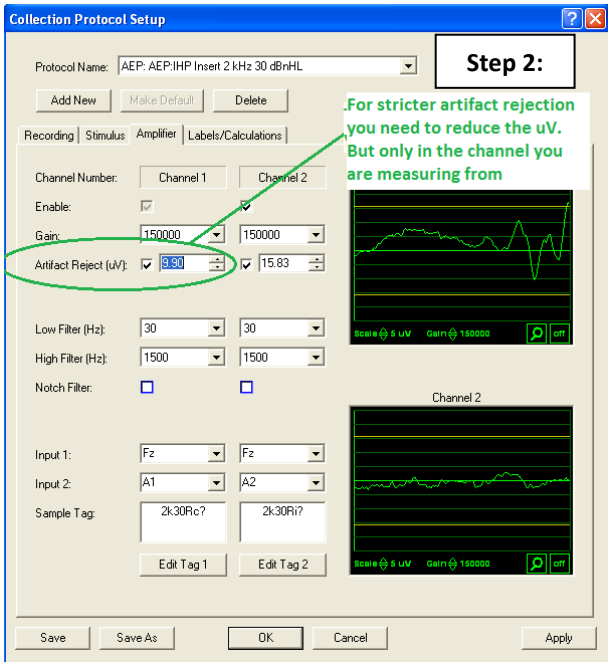
Ssee **Figures 3.06 1, 2 and 3** below for how to set the artifact rejection.

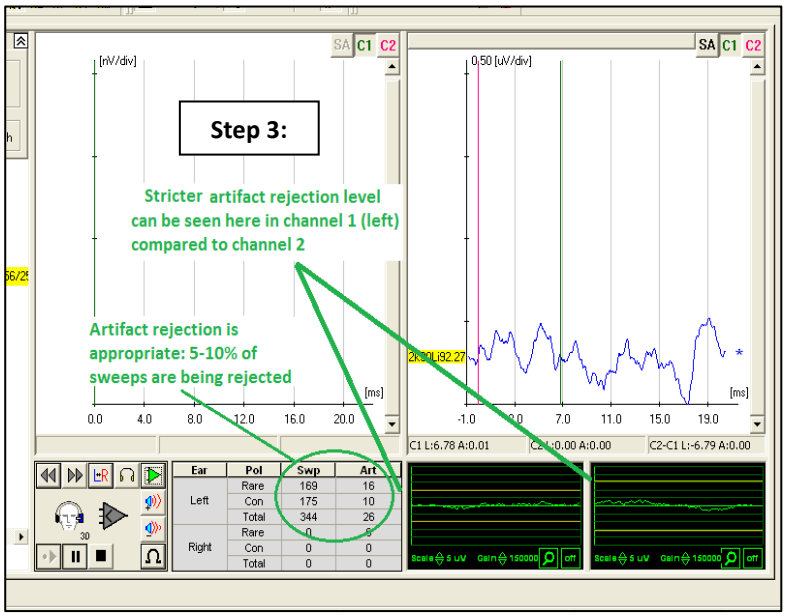
A side-effect of adjusting the rejection limits to get fairly constant artifact rejection tick-over for quiet EEG is that the rate of sweep rejection over time or across averages becomes a more useful, quantitative indicator of EEG quality and myogenic interference

levels. This can improve subjective EEG assessment skills, warn about impending baby activity levels and assist effective the pausing and resumption of averaging.

Figures 3.06.1, .2 and .3. ***Procedure to set appropriate Artifact Rejection levels.***







3.07 DIMINISHING RETURNS IN AVERAGING

The standard model of signal-to-noise ratio enhancement by averaging is one of a constant ABR (signal) added to random EEG noise that has constant variability over time (the statistical term is 'stationary noise'), as reflected in its underlying standard deviation (SD). Under that model, as the average progresses the value of the underlying ABR does not change because the average value of a constant is the constant itself. But, the standard deviation of the averaged noise decreases as a result of partial cancellation of positive and negative noise values. After N sweeps, the SD of the averaged noise is the original SD divided by the square root of the number of sweeps averaged. Therefore, the signal to noise ratio (SNR) increases by the square root of N; this is known as the 'root N law'. Because the improvement in SNR follows the root N law, the amount by which the SNR improves in a fixed period of time decreases steadily as averaging progresses. What this means is: the larger an average is, the smaller the improvement obtained by continuing to average for a fixed number of sweeps.

The NavPro is able to calculate and display the SD of the average as it accumulates and this value is referred to as the 'residual noise' or RN of the average. If the EEG noise is truly stationary, the RN will tend to decrease steadily as the number of sweeps averaged increases. The value will fluctuate, because the EEG is random noise and samples from a random process will show some variability, but the larger the N, the smaller the fluctuation will be and the smaller the RN itself will be.

Note that if the EEG at the baby's head is contaminated by bursts of myogenic noise with a large SD, this makes the source noise non-stationary and violates the root N law. However, the stronger the artifact rejection, the more the high-SD sweeps are filtered out and the better the stationarity of the accepted sweeps becomes. Thus, good artifact rejection increases conformity with the root N law.

The Table below shows the RN in nV, which is basically the amount of wiggle in the average that is due to noise, after various numbers of sweeps, along with the reduction in RN achieved by adding another 1000 sweeps. Every extra 1000 sweeps takes about half a minute of test time. For example, going from 1000 to 2000 sweeps reduces the RN by 18.4 nV or about 37 nV of improvement per minute. In contrast, going from 4000 to 5000 sweeps reduces the RN by only 3.4 nV, or about 7 nV per minute. This means adding another 1000 sweeps to the first 1000 is more than five times as effective in reducing noise in the average as adding another 1000 to an existing 4000 sweeps!

Table 1: This example is constructed for a fairly noisy EEG situation with a source noise SD of 2 microvolts or 2000 nanovolts (nV), yielding an RN of 63.2 nV after averaging 1000 sweeps (2000/root 1000) :

Sweeps	RN (nV)	Change per 1000 sweeps
1000	63.2	-
2000	44.8	18.4
3000	36.4	8.4
4000	31.6	4.8
5000	28.2	3.4
6000	25.8	2.4
7000	23.8	2.0
8000	22.4	1.4

Now consider the best way to spend about two minutes of averaging time. You could average for, say, about 4000 sweeps, which at 39.1 per second means about 100 seconds. An alternative is to do two separate averages of about 2000 sweeps. As will be shown in

the next section, you can combine the two 2000s into a 4000 with a few keystrokes, but what you have with the two replicate averages of 2000 sweeps is the ability to assess the reproducibility of the waveforms.

You could, of course, get four averages of about 1000 sweeps or even eight averages of 500 sweeps in roughly the same total time as a single average of 4000 sweeps. The problem is that at some point the variability of the individual averages becomes so large that reproducibility cannot be usefully assessed subjectively. The best solution for 4000 sweeps-worth of test time is probably two smaller averages of about 2000 sweeps, though the statistics of a proof of this are beyond the scope of this document. Similarly, in situations for which 2000 sweeps may be sufficient, the better choice is usually two replicates of about 1000 sweeps.

The practical bottom lines are:

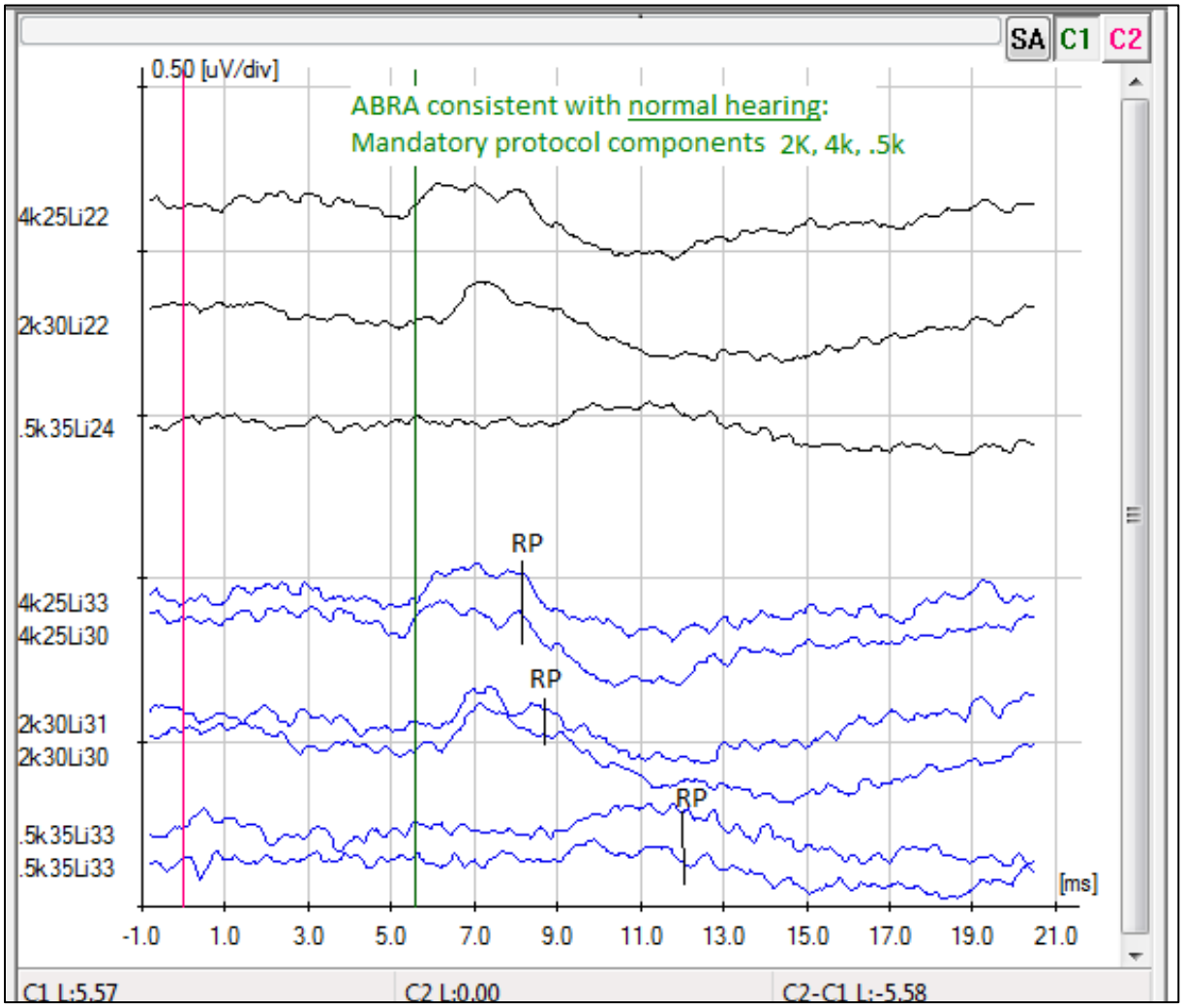
- **Averaging rapidly becomes less and less efficient the more you do it.**
- **The first 1000-2000 sweeps are by far the most valuable, and**
- **If things are not becoming clear by about 4000 sweeps total, they will not become much clearer within a practicable amount of test time, so change the stimulus conditions (eg., go up 10 or 20 dB) instead of plodding on with more averaging.**
- **The longer you average, the higher the likelihood of encountering a period of increased myogenic artifact, the impact of which will depend on how well you have set the artifact reject limits. Even if the artifact is successfully rejected, it is still a period in which no useful data are collected.**
- **Replicate smaller averages allow subjective assessment of waveform reproducibility and a single overall average is easy to create, so nothing lost as long as the smaller averages are themselves of reasonable size and there are very few of them. Assessing reproducibility across say 5 or 10 even smaller averages is not recommended and is a completely different and more difficult pattern recognition problem than comparing two or at most three averages of reasonable size.**

3.08 COMBINING AVERAGES IS USEFUL & EASY

Two or more primary averages for identical stimulus conditions can be combined if the primary average or averages do not immediately give a clear picture of response presence or absence. When this occurs, it will usually be at a threshold bracket or a minimum level. Typically, two or three averages will be combined, to get the largest possible average. The most effective display or plot of primary and combined averages for a given stimulus is as level-specific grouping with the combined average above and just separated from the primaries that are stacked as close as possible together but preferable such that each trace can be followed.

See **Figure 3.08.1** below. A combined average must never be plotted overlapping its component primaries, because that creates a false illusion of reproducibility, which is inevitable because the combined average is made up from its primaries. The advantage of the combined average is that it is usually the best single sample estimate of the true waveform. It is, essentially, just a ‘grand average’ of several measurements that simply happen to be waveforms in time.

Figure 3.08.1. ***Combining primary averages.***
Here is a normal ABR that illustrates the effect of combining averages on the Residual Noise levels. Note that when the two primaries have similar RNs and sweep counts, combining them will lower the RN by 30-40% from the worse-valued primary. The combination would not be necessary clinically in this case, because of the good replication of the primary averages. Combination is often most helpful when the primaries are more variable, or for gaining a low RN when facing a marginal NR decision.



The result of a single data acquisition and averaging run will be called here a 'primary' average. Two or more primary averages are very easily combined by simply highlighting them in the display and then hitting the left-hand waveform icon for 'weighted add'.

The result is actually an overall average of all the sweeps in the component averages, with appropriate accounting for different numbers of sweeps. The 'unweighted add' option should **never** be used. Here, the weighted sum will be called a 'combined average'. A combined average's identifying tag string will contain the sum of the numbers of accepted sweeps in the component averages and will be bolded in a plot, but has no specific label to distinguish it as a combined average.

As noted earlier, each of the primary averages is also an estimate of the true waveform, but will usually have larger variability than the combined average. The primaries are used to assess reproducibility of any candidate response waveform. They also contain, both in their amount of amplitude fluctuation and in their associated Residual Noise level in the tag strings, information about the underlying variability of the EEG in each of them.

3.09 RESPONSE JUDGMENT CATEGORIES & CRITERIA

For any given stimulus route (AC or BC) and frequency, there are three common overall outcomes from any given ABRA session:

- The ABR threshold (T) is considered bracketed, in the sense that there are two stimulus levels separated by no more than 10 dB, with the lower level having no response and the higher level having response (T = upper bracket level);
- There is no response at the highest level tested, which yields a lower bound for the (unknown) threshold (T > highest level tested), or
- There is response at the lowest level tested, which yields an upper bound (T ≤ lowest level tested).

Both the levels and the crucial bracket or boundary decisions must be documented routinely (see Figure below). This greatly facilitates reporting, retrospective review or evaluation of threshold estimates, of particular value in serial testing or in cases of unexpected change or discrepancy across measurements.

Response detection judgments *at each threshold bracket level and at each range boundary* must be categorized and hardcopies annotated as 'Response-Positive (*RP*)', 'No Response (*NR*)' or 'Inconclusive (*Inc*)'. For each such stimulus level, there is one, single response judgment that applies to the entire set of averages at that given level. *RP* and *NR* decisions reflect high confidence and are NOT the result of guesswork or a 'balance of probabilities'. *Inc* decisions are required whenever neither *RP* nor *NR* can be determined with confidence. Annotation of additional levels other than brackets or boundaries is discretional.

An *RP* decision at any threshold upper bracket level (or at an Smin) requires:

- At least one average (primary or combined) of at least about 2000 sweeps that has a negative-going deflection with peak-to-trough amplitude at least 50 nV (0.05 μV) in the interval 6 to 20 ms;

- Subjective repeatability of a negative-going deflection in the interval from 6 to 20 ms between either two or three averages, one of which must have at least about 2000 sweeps; the repeatability must be higher in the putative response region than for any other region of similar duration in the average. Note that if subjectively repeatable deflections are seen at several locations throughout the average, the repeatability at a plausible response latency loses significance and reliance on latency trend with stimulus level becomes more influential.

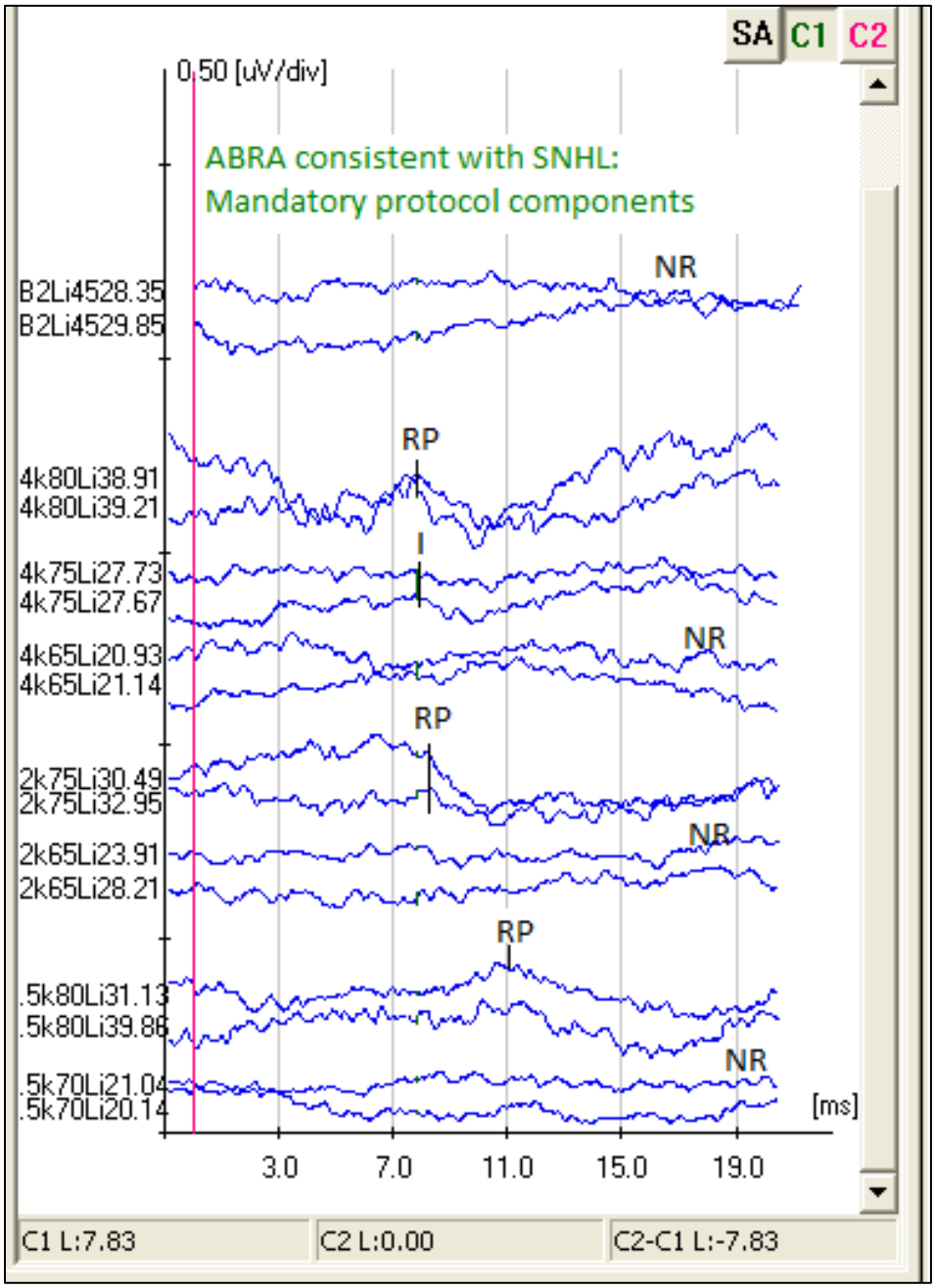
- Deflection latency no less than that of the similar feature for the same stimulus at any higher level that gave an *RP* decision.

- Absence of any *NR* decision for the same stimulus route and frequency at a higher level in the same test session.

Note that for any primary average the sweep count recommended minimum is about 1000 sweeps and the recommended maximum is about 2000 sweeps. The solitary exception to the 1000-sweep minimum is in the confirmation of a clear response-positive single primary average that appears to be an upper bracket level and so must be replicated; in that case, the confirmatory replicate may be stopped at about 500 sweeps if it clearly supports the response presence. See section 3.11 for important notes about exact numbers of sweeps targeted. See **Figure 3.09.1** below for examples of response judgment annotation.

Figure 3.09.1. ***Examples of response judgment category annotation.***
Note the confirmation of the 2k abnormality with the NR for BC at 45 dB; the BC artifact is small, so BC at 55 would also have worked, but is not critical. Ideally, the 4k NR should be proven with a combined average, and the 'I' could be confirmed with a 3rd run, to resolve the exact threshold. The same could be said for the 0.5k NR, though the inference shown is almost certainly correct. ***Note that***

'Inconclusive' should now be annotated as 'Inc', not as 'I'. Note also that the four-digit RN values reflect the usein this example of an EP software version that is not current. Current software gives only two-digit RN values.



An NR decision is NOT simply the absence of an RP decision. For a valid NR decision, it must be true that if a response were present then it would surely have been recognized. Therefore, to decide on NR, EEG noise conditions and averaging tactics must have been good enough to detect the minimal ABR waveform required for an RP decision.

An *NR* decision at any lower bracket level or at an Smax requires:

- At least one average of at least about 2000 sweeps for which the maximum and minimum amplitude in the range 6-21 ms differ by no more than 50 nV (0.05 microvolts) in the combined average, **and**
- At least one primary average of about 2000 sweeps that is subjectively 'flat', **and**
- Absence of any RP decision within the same test session at the same level or lower.

An *Inc* decision applies to any scenario that is neither *RP* nor *NR*. A common example is an *Inc* caused by noisy averages that are not quite flat enough to qualify as *NR*. The usual action in that case is to add one average of 2048 sweeps and form a new combined average, which may achieve the required flatness. A more difficult scenario is an *Inc* caused by limited repeatability of a candidate response waveform. In this case, the best action is usually to go up by 10 or 20 dB, which should rapidly produce a *RP* response template or latency/waveshape guide, if the *Inc* were actually response-positive.

3.10 RESIDUAL NOISE (RN) LEVELS & 'NO RESPONSE' (*NR*) JUDGMENTS

The data model underlying averaging is that the signal (ABR) is identical for each stimulus and the electrical noise from all sources (brain, musculature, etc.) is random with constant standard deviation (SD), a condition called 'stationarity'. In that case, the signal to noise ratio (SNR, the ratio of ABR amplitude to noise SD) increases from its value in a single sweep by the factor root N, where N is the number of accepted sweeps in the average. The ABR is assumed constant but, in contrast, there is partial cancellation of the stationary random noise. As N increases, the average becomes less and less variable, converging either to a flat zero line or to a nonzero response waveform. The SD of the averaged noise is called the 'Residual Noise' or RN level. The RN is displayed continuously as the average progresses and its two-digit value in nanovolts (nV) is printed in the identifying tag string for each average. Outdated EP software versions used to display the RN to two decimal points, which overwrote the beginning of the averaged waveform. Because the RN is clinically meaningful only with integer values, current software puts only an integer RN value into the tag string, which also avoids overwriting the waveform.

The earlier section on artifact rejection addressed an issue of bursts of high-amplitude noise in a background of quiet EEG. This is a situation called noise 'non-stationarity'. It violates the root N law because a burst of high noise can cause the RN to suddenly increase dramatically. Screwing down the artifact reject limits so that they surround ongoing, quiet EEG more closely can be thought of as a method of improving the stationarity of the accepted activity such that averaging more closely obeys the root N law.

In the real world, a 'small' ABR would be no bigger than about 0.1 µV (100 nV) peak-to-peak for the positive-negative complex V-V', typically the most prominent ABR waveform feature in threshold estimation. The SD of fairly quiet EEG in infant ABR measurement is about 1 µV, so the SNR in the raw EEG (a single sweep) is about 0.1. After about 2000 sweeps, for which root N is about 45, the SNR is 4.5 and the SD of the averaged noise would be about 1/45 µV which equals 0.022 µV or about 22 nV. A random process with mean zero and SD 22 nV will fluctuate over time within about ± 2 SD from a zero baseline, or ± about 44 nV. An averaged ABR of about 100 nV would be easily visible and usually highly replicable. In fact, it can be shown that an ABR V-V'as small as only about 50 nV peak-to-trough will be detectable most of the time, given typical, quiet EEG and an efficient averaging protocol based on primary averages of about 2000 sweeps.

If we require that a response of only 50 nV must be detectable with quite high probability, then we require that the RN be no greater than about 20 nV; this will mean that the V-V' for the smallest response deemed acceptable is at least twice the RN, which adds up to reasonable detectability in a reasonable time-frame for a typical signal, noise and test time scenario.

It is easy to fail to detect a genuine ABR. All that is required is to do too little averaging. But in order to decide that a response is absent in a valid and reliable way, we must achieve sufficient statistical power to be able to detect the smallest ABR that would be considered as of interest. Only then can failure to observe any such ABR be interpreted as that it is really not present. If we define the minimum ABR to be 50 nV, then it can be shown statistically that an RN of about 20 nV is a reasonable net target for the averaging at any given stimulus condition for which we wish to conclude that there is no response.

An RN of about 20 nV is a reasonable target to be able to make an *NR* decision, but it is not a 'hard' target in the sense of being rigid or mandatory. A problem with RN calculated by the NavPro is that is sensitive to 60 Hz electromagnetic artifact. The RN really is intended to reflect only random EEG noise, but if substantial 60 Hz artifact is present it will inflate the RN over its true value. Depending on the stimulus repetition rate and the number of sweeps averaged, the 60 Hz may or may not be apparent in the final average waveform. The result is that occasionally an average may look quite flat, but the RN will be large, such as 30 or even 40 nV.

It follows that if the RN is below about 20 nV, subjective flatness of the average can confidently be interpreted to mean absence of response, but if the average seems quite flat and the RN is unexpectedly large, 60 Hz interference may have been the cause and it is not necessary to continue averaging in order to achieve a target RN of 20 nV. The bottom line is that for any average to be interpreted as *NR*, it must be subjectively flat in the latency region wherein response would reasonably be expected. If the RN is under about 20 nV at about 2000 sweeps , the *NR* interpretation can be confident. If the RN is below 30, it would be reasonable to do a second average of about 2000 sweeps and combine the two. The RN in the combined average may then achieve the 20 nV criterion. In the event of a significant discrepancy between subjective flatness and the RN value, *NR* interpretations should be reconsidered carefully, perhaps with an additional replicate average to increase the level of confidence.

Except when very close to ABR threshold, the RN has less influence on *RP* decisions than it does on *NR* decisions. *RP* decisions are based primarily on the SNR and response reproducibility. When well above ABR threshold, larges response can be identified with confidence even if the RN is above 30. At threshold, however, a quiet EEG and a low RN are necessary in order to detect a small ABR.

3.11 NOMINAL vs ACTUAL NUMBERS OF SWEEPS

The numbers of accepted sweeps in any average must be targeted to equal or minimally exceed an integer multiple of 256 sweeps. The sweep counts to avoid when stopping an average are ones that are just less than an integer multiple of 256.

When the Navpro accumulates an average while computing the RN, as is mandatory in this protocol, it displays the final average and computes the RN values after the largest available integer multiple of 256 accepted sweeps. For a given target sweep count, such as 2000 sweeps, any additional sweeps beyond the largest integer multiple of 256 are discarded in the final display and parameter listing, so they were a waste of valuable time. Setting a 2,000 sweep target would yield an actual average of 1,792 sweeps, so a target of 2048 is more effective. Similarly, a nominal '1000' sweeps is much better targeted at exactly 1024 sweeps, to avoid getting only 768, and 500 sweeps, though rarely used, should be targeted as 512 to avoid getting only 256 sweeps.

Optimal accepted sweep counts for individual, primary averages include 512, 768, 1024, 1280, 1536, 1792 and 2048. As already noted, targeting larger sweep counts than 2048 is usually better done by combining two smaller averages; for example, 4,096 sweeps is better done as two averages of 2,048 plus the combined average. A few sweeps more than these targets are not a significant problem, whereas counts that are a few sweeps short of the target can result in substantially smaller sweep counts than intended, as well as waste of up to 255 accepted sweeps-worth of test time per individual average. This may equal only about 7-8 seconds per average but in a baby with significant PHL this can easily add up to the few minutes of precious test time that could make all the difference in messaging to families or in having to schedule additional appointments to complete the ABRA.

3.12 TONEPIP ABR THRESHOLD DEFINITION

For any tonepip route (AC or BC) and frequency, the ABR threshold is the lowest level judged as *RP* (the 'upper bracket' level) for which there is a level either 5 or 10 dB lower that is judged as *NR* (the 'lower bracket' level). If the lowest *RP* level is a minimum

stimulus level (Smin), then the ABR threshold is denoted as ≤ Smin and is an upper bound of a threshold range considered 'within normal limits' (WNL) for IHP purposes. Conversely, if the highest level tested is judged as *NR* and denoted here as H, then the ABR threshold is ' > H' and H is the lower bound of a range. If H is a maximum stimulus level (Smax), the threshold cannot be specified.

In most current ABR instrumentation, including the NavPro, objective, statistical response detection criteria that are implemented and validated appropriately are not available. Implementations of Fsp and weighted averaging available in Windows EP must not be used in IHP Assessments because they are incorrectly implemented (Fsp) or insufficiently understood (weighted averaging). Therefore, ABR threshold must be estimated subjectively. The reliability of this process is improved by extensive training, ongoing decision support and a standardized and consistent protocol grounded in statistical decision theory and random process analysis.

In practice, ABR threshold is defined using the V-V' downslope as the key feature, because V-V' is usually the most detectable peak-to-trough component of the ABR waveform at stimulus levels near threshold. Note that there may not be any actual peak (local maximum) developed for wave V, nor any actual trough (local minimum) developed for wave V'. One or both of these may not necessarily appear but, even when that is the case a clear and reproducible downslope is a consistent feature of ABR presence. This variation in degree of definition of waves V and V' occurs most frequently with 0.5 kHz stimuli near threshold (**see Figure 3.12.1**).

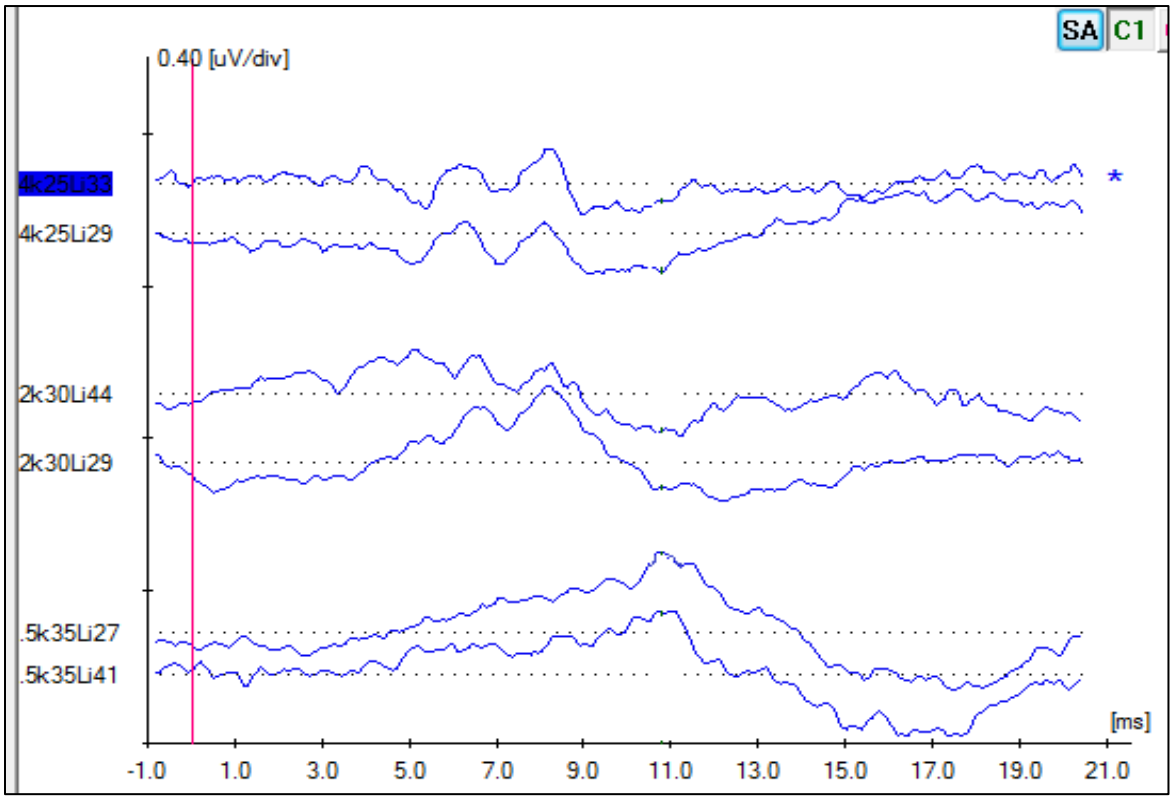


Figure 3.12.1. ***Clear ABRs for replicated averages at the minimum stimulus levels required by this protocol.***
The dBnHL levels shown are all equivalent to 25 dB Estimated Hearing Level (25 dBeHL).Note the marked increase in wave V latency and loss of fine structure, at 0.5 kHz. The primary averages of only 1024 sweeps take less than 30 second each. They are replicated because of the protocol requirement to replicate at an upper bracket stimulus level or a minimum stimulus level. The two averages at each frequency could be combined to reduce noise levels, but in this case the ABRs are so clear that the combined averages are not clinically necessary. In fact, the first 1024-sweep averages are so clear that they could be confirmed using only 512 sweeps (the absolute minimum number, used only in this confirmatory situation.

If earlier waves (eg., I or III) are clearly present but V-V' is not, an ABR threshold cannot be defined in conventional terms because historically most normative ABR threshold data are based on wave V. Moreover, absence of V-V' with present wave I implies retrocochlear pathology, for which ABR threshold inferences are inherently questionable.

3.13 ESTIMATED HEARING LEVELS

Tonepip ABR threshold estimates in dB nHL must be adjusted by the correction factors listed in Appendix I, in order to derive hearing threshold estimates in dB eHL.

The core business of ABRA is the estimation of key puretone hearing thresholds in dB HL. This is based on determination of tonepip ABR threshold estimates in dB nHL, followed by adjustments that are based on known, normative statistical relationships between tonepip ABR and VRA-based behavioural thresholds. Note the changes for AC and BC 500 Hz correction factors from the values previously listed in the 2008 IHP Assessment protocol.

ABR thresholds are generally not the same as true perceptual thresholds but they are usually good statistical correlates or predictors of them. The answers obtained in ABRA are point estimates of true puretone thresholds in a statistical 'maximum likelihood' sense, that is, in answer to the question 'given the observed ABR threshold estimate, for what value of the (unknown) true puretone threshold would the observed ABR threshold have the highest probability?'. While a more complete outcome would be a probability distribution over a range of dB HL values, the simplicity of single point estimates is popular. What should not be forgotten is that there is a range of possible true dB HL values for any given ABR threshold estimate.

The correction factors used in this protocol have been derived by statistical re-analysis of published and unpublished normative data, particularly that of Stapells and his colleagues. The corrections are similar to those used in the British Columbia Early Hearing Program, but are not identical in every case. The correction factor for a given stimulus route and frequency is based on the estimated population median difference in dB between reliable, paired ABR and VRA thresholds in large, representative groups of young infants. The overall value of the median difference (ABR minus VRA) is rounded to the nearest 5 dB, for simplicity of use. The median is more appropriate than the mean because the difference distributions at various values of the ABR threshold are systematically skew with occasional extreme values. The ancillary regression analysis testing for linear and nonlinear trend has the behavioural threshold as the dependent variable and the ABR threshold as the independent variable. The range of the independent variable must be restricted from about 30 dB nHL to about 90 dB nHL. Between those limits there is an approximately constant relationship between the two types of threshold. Below 30 dB nHL, there is no apparent relationship at all, and above about 90 dB nHL the relationship is distorted by distributional censoring of either the ABR or VRA thresholds at device intensity maxima. Extension of regression analysis below 30 dB nHL introduces systematic, segmental nonlinearity that renders a straight-line fit over the entire range of dB nHL inappropriate.

In conventional, sensory hearing loss of the type affecting first the outer hair cells then the inner hair cells as well, there is a weak tendency for the median threshold difference to decrease progressively above about 70 dB nHL.The convergence is approximately linear, but is clinically insignificant relative to other sources of bias and imprecision in behavioural threshold estimation (such as inflation of VRA thresholds due to responsiveness effects).

The IHP correction factors are valid only for the stimulus parameters and recording techniques specified in this protocol. They do not apply to estimation of hearing levels lower than the IHP target disorder limits and they cannot be assumed to apply to stimulation and recording methods that do not follow this protocol. It is important to note that publications to date purporting to address the appropriateness of IHP adjustment factors have not satisfied these criteria, nor have the data analytic methodologies used been comparatively evaluated with respect to validity, bias and precision.

3.14 THRESHOLD SEARCH & BRACKET PHASES

Each ABR threshold determination sequence can be conceptualized as a Search phase followed by a Bracket phase. In the Search phase, the goal is to reach the threshold upper bracket level very quickly. In the Bracket phase the emphasis is on response detection decision accuracy, especially a very low rate of false positive response detection at the upper bracket. It follows that stimulus level tactics, averaging tactics and response detection decisions are different in the two phases.

The Search phase is guided by the known epidemiology of PHL in newborns and infants, known properties of OAE and ABR screening tests, important results of statistical decision theory and clinical factors. The benefits of reaching an *RP* decision quickly are many, but the positive predictive value of AABR screening failure is small, especially in well babies who have no risk indicators. Thus, the Search phase typically starts at 2 kHz (arguably the single most important frequency psychoacoustically) at the Smin (because most babies tested will have hearing within normal limits) and then ascends in initially large but rapidly diminishing stimulus level step sizes. Search phase ascent in 10 dB steps (or, worse still, 5 dB steps) is usually extremely inefficient and is strongly discouraged unless there is a very strong clinical rationale.

Decision theory shows that an optimal strategy for identifying a random number distributed uniformly over the range 40 to 100 dB with only yes-no questions is a series of questions 'is it less than x?' where x approximately bisects the current range of uncertainty. This is a crude but reasonable model of the Search phase, with an ABR *RP* as the answer 'yes' and an *NR* as the 'no', after first asking whether the mystery number (the true ABR threshold) is 30 or better.

The clinical speculation that large ascending steps will awaken a sleeping baby is not valid for initial 30 dB ascent, nor for a second step of at least 20 dB. At levels above about 80 dB nHL, 10 dB steps are acceptably efficient. Close monitoring of the baby's EEG myogenic noise level and physical behaviour allows almost immediate stimulus level reduction if there are any signs of alerting.

In general, averages can be smaller and replication can be minimal in the Search phase. If after a large-step ascent there is no clear response after, say, 1024 sweeps, it is generally more efficient to go up again rather than replicate the 1024. Replication of averages should be a rarity in the Search phase, but is a routine requirement in the Bracket phase.

3.15 NUMBER OF SWEEPS & AVERAGES

It is recommended that any primary average retained for plotting should not contain less than 512 or more than 2048 accepted sweeps. For any given stimulus condition, no more than three primary averages or a total of 6144 sweeps should be used. The only reasonable exception to this maximum is a situation in which one of the primaries is clearly different from the others, such as obviously damaged by large artifact or having a much larger RN, or for which there is reason to suspect electrode or transducer problems; in those situations the suspect averages may be set aside, commented upon and not included in the 'final' combined average for the given stimulus condition.

Search Phase

For any given AC stimulus frequency and route, the usual starting condition is at an Smin, except for 4 kHz at which it is logical to start 10 dB above a previously obtained upper bracket level at 2 kHz.

The first and most critical primary average might be judged as potentially an *RP* after as few as 512 sweeps. In that case, usually there would be an immediate attempt at conversion to a true *RP* by adding another average of at least 1024 sweeps.

In contrast, the first primary average might yield a potential *NR*, for which at least 1024 sweeps are required. If it is flat or nearly so, it is usually more efficient to go up 30 dB. If the actual ABR threshold elevation were small, going up 30 dB would often give a potential *RP* after only 1024 sweeps, confirming that the loss is minor and justifying an attempt to convert the provisional *NR* to a true *NR* at the Smin. If the up-30 primary also gives a potential *NR*, which would occur in a significant hearing loss, the ascent continues. This has avoided multiple averages at the Smin when there is no indication as yet that the threshold is even near-normal. Persistent, repeated averaging at the Smin is not usually the most efficient way to prove whether hearing is WNL or not. The reason

is that the initial potential *NR* has already increased the probability of hearing loss substantially beyond that of simply failing a prior AABR.

If there is a potential *NR* at Smin and Smin+30, the next step is to go up another 20 or 30 dB. Ascent in 10 dB steps is rarely appropriate, except near Smax. Given a potential *NR* at the Smin and a potential *RP* at Smin+30 or Smin+60, going up further or pursuing conversion of a potential *RP* to a true *RP* is a judgment call that depends on multiple cues, including the perceived likelihood that a potential *RP* is real, given its size, morphology, latency and growth pattern. The ability to predict correctly most of the time whether to replicate an average or continue an ascent is a crucial clinical skill that usually grows with experience and critical self-evaluation of tactical efficiency.

Bracket Phase

An upper bracket *RP* must be based on at least two primary averages, at least one of which must have at least 1024 accepted sweeps. The absolute minimum is a potential *RP* with a least 512 sweeps followed by a confirmatory average with at least 1024.

A lower bracket *NR* (or at Smax) should not be based on less than 2048 total sweeps. These may be in a single average only if a target RN value of 20 nV or less is met, which is uncommon. Confirming an NR always involves replicates of at least 1024 sweeps. When judging replicates for a potential *NR*, the credibility of a subjectively flat record is inherently better than that of a questionable, response-like deflection. There are many ways in which a false impression of response may arise from constructive superposition of random noise but, if there is a genuine response present, a flat record would require that the random noise happened to summate in exactly the right antiphasic waveform needed to cancel out the true ABR.

3.16 THRESHOLD BRACKET STEP SIZE

For a completed ABRA, the final threshold bracket step size for all required AC frequencies must be no greater than 10 dB. If the ABR threshold estimate with that bracket is greater than 70 dB eHL, a 5 dB step size **may** be used for the final bracket. The increased precision may be relevant to accurate prescription of amplification, if the residual dynamic range is very limited. However, frequently it is challenging to make clear *RP* and *NR* decisions with steps of only 5 dB, which can cost valuable test time to little clinical benefit, and if the threshold is below 70 dB eHL the clinical benefit is negligible or zero. Therefore, 5 dB steps must **not** be used unless all core thresholds have been estimated satisfactorily to 10 dB brackets and hearing loss type(s) have been determined.

3.17 CONFIRMATION OF UPPER BRACKET RESPONSE

It is stressed that if there is any residual uncertainty about the presence of response at a threshold upper bracket level, an 'up-10' or 'up-20' check average of 1024 sweeps must be done at a level 10-20 dB above that upper bracket level, where allowable by Smax. Response presence must be confirmed in that average, in order to accept the threshold bracket as valid.

3.18 STRATEGY OF STIMULUS FREQUENCY & ROUTE

While test strategy must be responsive to many factors in the individual child and context, the following points reflect common principles of effective and efficient testing. It is assumed that cursory otoscopy indicates no canal occlusion and the baby is asleep:

- In the absence of prior IHP ABRA results, testing must begin by AC at the 2 kHz Smin of 30 dB nHL in a Referred or otherwise suspect ear. In a baby who bypassed screening because of very high risk of PHL, both ears are assumed to be suspect:

- If both ears are suspect and ear switching is practicable, pick any ear and do 2k at 30 dB. If it is *RP*, switch ears and do 2k30 in the new ear and continue. If2k 30 result in the first ear is *NR*, continue and switch later. Switching ears is usually easy in

younger infants sleeping supine with two inserts in, but when the baby is in the mother's arms special attention to positioning for ear accessibility and insert stability is needed.

- If the 2 kHz Smin is *RP*, immediate shift to 4 kHz Smin is recommended, before shifting to Smin at 0.5 kHz. Responses at 4 kHz are often very clear and confirmable quickly with smaller averages. Isolated hearing loss at high frequencies may be more common than formerly suspected and may foretell progressivity.

- BC at 2 kHz must be done as soon as possible if AC 2 kHz is *NR* at 30 and 60 dB. The immediate question is not 'what is the precise AC threshold?' but 'is this abnormality sensorineural?'. **Note that the insert need not be removed in order to apply the bone conductor by hand to the test ear mastoid. The occlusion effect is negligible for ABR thresholds in young infants. Checking BC is much easier than IHP practice has suggested historically.**

- After checking BC, If 2 kHz is *NR* at Smin and at Smin +30 dB, prompt verification of insert placement, eartip occlusion, stimulus audibility and electrode impedances is recommended.

- If the AC 2 kHz abnormality is valid and BC is also abnormal, follow the AC Search phase ascent to bracketing then switch to 0.5 kHz at the Smin for Search and bracketing, before shifting to 4 kHz. If a conductive component is found at 2 kHz, then the accuracy with which AC thresholds need to be bracketed is discretional.

- If BC at 2 kHz reveals a conductive component, a conductive component at 0.5 kHz may be assumed and its proof by 0.5 kHz BC is discretional. The converse is **not** true; if a conductive component at 0.5 kHz is proven, it cannot be assumed that abnormality at 2 kHz is conductive and absence of a sensory component at 2 kHz **must** be proven definitively.

- If AC 2 kHz is normal and 4 kHz has been completed, switch ears wherever possible if both ears have referred on screening. The immediate clinical question at that point is whether the other referred ear is normal at 2 kHz.

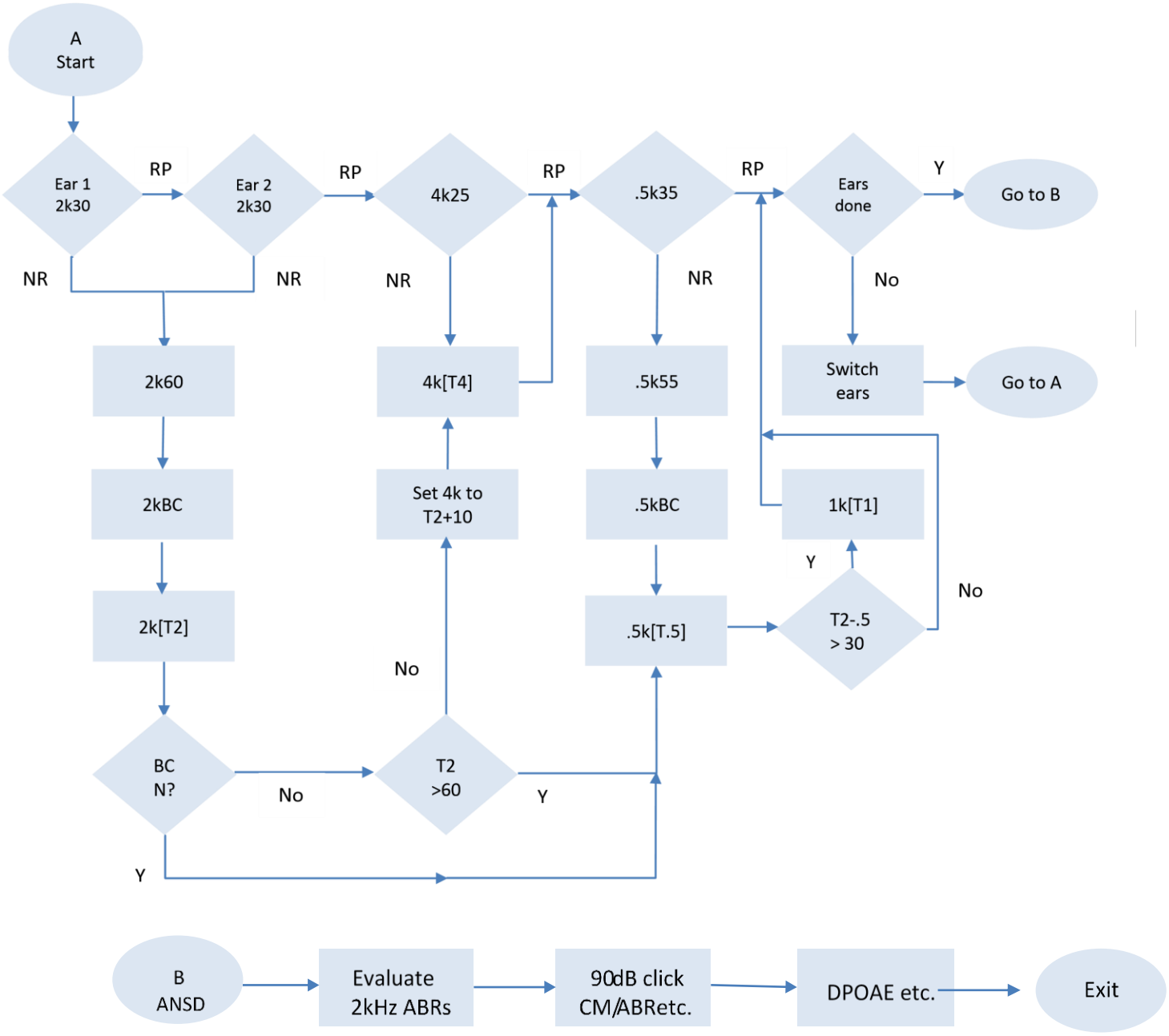
- If 2k is normal and ear switching is genuinely (as opposed to speculatively) likely to awaken the baby, go to 0.5 kHz in the first test ear at 50 dB nHL (not at the Smin). If 50 dB is NR, bracket the threshold then go to BC at 0.5 kHz. If 50 dB is RP, go to 35 dB nHL to verify normality. When the threshold elevation is minor and only at 0.5 kHz, BC is discretional.

- The BC 0.5 kHz Smin has been changed to 25 dB with a 0 dB adjustment factor, reflecting current normative data on BC ABR in young infants under one year corrected age.

- If 4 kHz is the only AC abnormality, BC testing must not be done.

- AC at 1 kHz must be done if there is a difference of 30 dB or more in the AC thresholds at 0.5 and 2 kHz in dB eHL. If the difference is less than 30 dB, testing at 1 kHz is discretional but not recommended unless **all** other ABR measurements have been completed.

Figure 3.18.1 S*ome high-efficiency ABR testing pathways.*
A complete flow diagram of all decision options for all circumstances is too complicated to be useful, so only some some common, recommended pathways are shown. Also, whole mini-sequences of testing, such as threshold bracketing, have been condensed and shown as single procedures. In the Figure, all numeric stimulus levels are in dB nHL. RP means 'Response Positive' and NR 'No Response'. The diamonds are events that have branching outcomes, whereas rectangles do not branch. A notation such as '2k[T2]' denotes threshold bracketing at 2 kHz yielding an ABR threshold value of T2, etc.


A
Start
Ear 1
2k30
RP
Ear 2
2k30
RP
4k25
RP
.5k35
RP
Ears
done
Y
Go to B
NR
NR
NR
NR
No
2k60
4k[T4]
.5k55
Switch
ears
Go to A
2kBC
Set 4k to
T2+10
.5kBC
1k[T1]
Y
No
2k[T2]
.5k[.5]
T2-.5
> 30
No
BC
N?
No
T2
>60
Y
Y
B
ANSD
Evaluate
2kHz ABRs
90dB click
CM/ABRetc.
DPOAE etc.
Exit

3.19 BC STIMULUS ARTIFACT

The amount of electromagnetic (E/M) BC stimulus artifact is variable across babies and across Audiologists. It tends to be most intrusive at 0.5 kHz because of the electroacoustic properties of the transducer and the relatively long stimulus duration at that frequency (about 10 ms). It is sometimes large at levels above about 40 dB dB nHL. Appropriate procedures to minimize BC stimulus artifact must be used. The most important steps are routing transducer leads and electrodes as far as possible from each other, keeping electrode leads close together and pointing away from the transducer, and the electrode impedance factors noted earlier.

If the AC threshold at 0.5 kHz were, say, A dB eHL then BC testing capability up to that level would be desirable. Maximum dB eHL level for BC at 0.5 kHz is about 55 dB, but stimulus artifact is often very large at that level. Artifact voltages larger than about 1 µV are inconvenient for waveform printout and if much larger than that, the artifact may trigger artifact rejection of some or all sweeps. If BC 0.5 kHz is *NR* at its Smin, the next step is to go up as high as possible, up to including A dB eHL or the level of maximum tolerable artifact, whichever is the lower. The closer the highest acceptable stimulus level is to A, the more helpful is the BC ABR in resolving conductive and sensorineural hearing loss components.

E/M artifact increases roughly three-fold in amplitude with a 10 dB increase in stimulus level, so given one average with visible artifact, its size for a higher stimulus level is predictable.

BC-evoked ABRs that are near threshold at 0.5 kHz typically have V-V' latencies of about 10 ms or more, so even a large stimulus artifact of 10 ms total duration will not necessarily render the ABR undetectable. At 2 kHz, the artifact tends to be smaller and its duration is only about 2.5 ms, so it is rarely a problem.

3.20 BC RESPONDING COCHLEA INFERENCE

BC measurements must be done with transducer placement on the mastoid of each desired test ear, using two forehead-mastoid recording channels (Fz - M1 and Fz - M2). The responding cochlea is inferred by comparing the ABRs in the channels ipsilateral and contralateral to the test ear (see example in **Figure 3.20.1** below).

In contrast to standard BC testing in adults, in infants the BC transducer must be placed on each test ear of interest. Transcranial acoustic field patterns differ in infants, the result being as if there were transcranial attenuation differences as high as 20 dB and highly variable across subjects. The exact mechanism of these differences may be dynamically very complex, but the net effect is superficially as if the bony plates of the skull were less strongly coupled in infants, to varying degree.

Using two forehead-mastoid channels, if one channel shows a clear ABR wave V-V' and the other channel does not, the response channel indicates the responding cochlea. This is a puzzling phenomenon that is not well-understood, bearing in mind that conventional wisdom is that wave V is primarily forehead-registered and the two channels have the forehead in common. Clearly, lateral difference are attributable to mastoid field effects on the net differential waveforms in each channel. This effect is most apparent at low stimulus levels and in young infants, but the detailed effects of level and age are not fully understood.

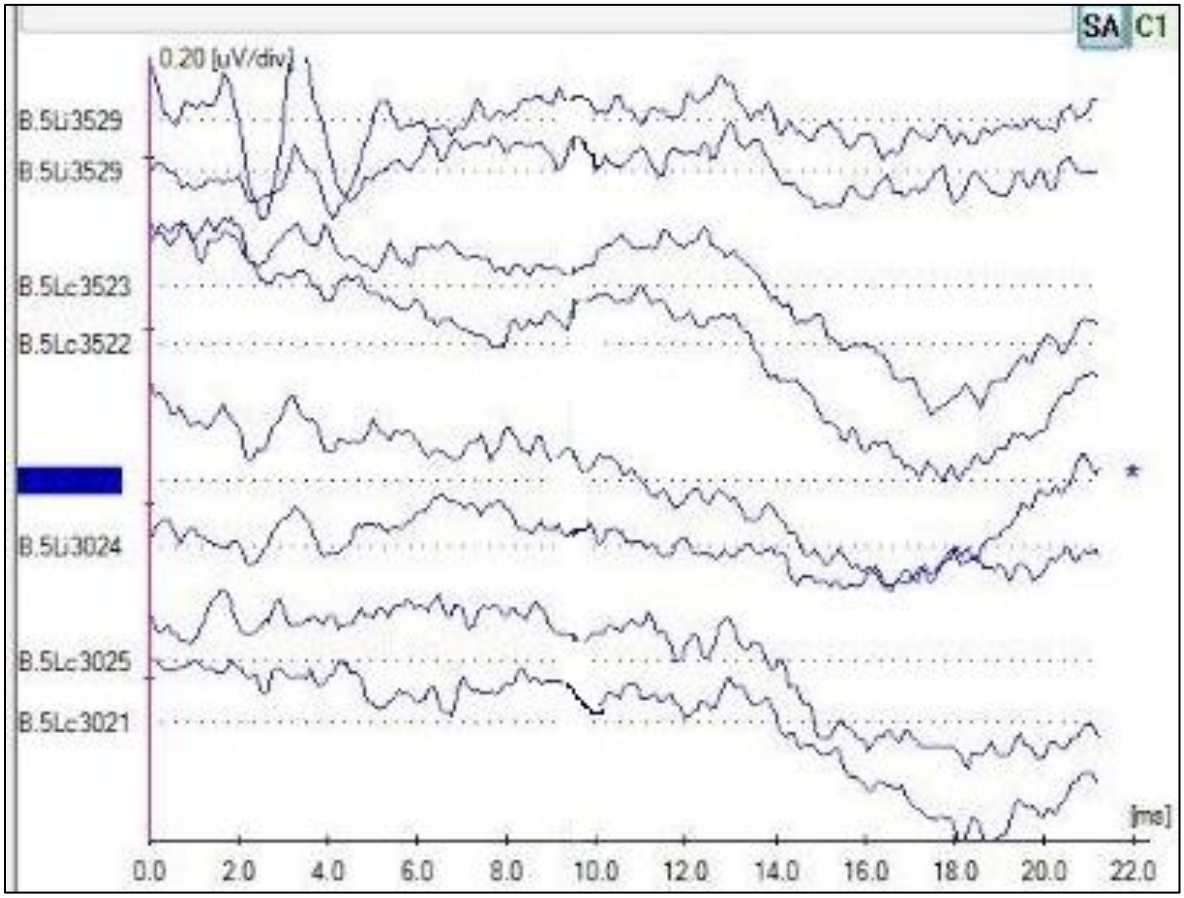


Figure 3.20.1. ***Inference of the responding cochlea in BC testing.***
Note the BC stimulus artifact in the ipsilateral trace. In this example, there is clear contralateral dominance, showing that the Right cochlea is responding preferentially. For these traces, the result would be clarified by combining the primary averages at 35 and at 30 dB. The y-scale here is only 0.2 microvolts per division, to illustrate the waveforms more clearly.

If there is response in both channels, wave V latencies are compared and the shorter latency indicates the responding cochlea. In the event of no clear latency difference, response amplitude may be used if there is a clear amplitude difference, the larger amplitude indicating the responding cochlea. If there is no clear difference of latency or amplitude, stimulus levels should be reduced in an attempt to isolate the responding side, even by going below the BC Smin if necessary. If none of these manoeuvers is successful, then it is necessary to resort to contralateral insert noise masking.

If there is response in both channels and the responding cochlea is inferred to be contralateral, the presence of response in the ipsilateral channel does **not** imply that cochlea on the stimulated side is necessarily responding. The ipsilateral waveform could be a shadow response from the contralateral cochlea. The converse is also true: if the inference is that the responding cochlea is ipsilateral, presence of a response in the contralateral channel does not imply that the contralateral cochlea is also responding.

3.21 BC CONTRALATERAL MASKING

Normative data for contralaterally masked ABR tonepip thresholds are limited for BC stimulation, one reason why in the IHP, contralateral masking is not used as the first-line approach to ensuring activation of the desired cochlea. The need for contralateral masking in tonepip ABR threshold estimation is limited to situations in which:

- Channel comparisons have not proved informative for inference of the responding cochlea in BC testing,
- Relatively rare occurrences of interaural AC threshold differences of at least 60 dB at any given frequency.

For the BC situation, wide-band insert masking at 60 dB is usually appropriate. For the situation of large interaural threshold difference, the concern is that an *RP* at a very high stimulus level in the poorer ear could result from cross-activation of the contralateral cochlea. This is only a possibility given direct extra-cranial acoustical leakage and a stimulation level exceeding about 80 dB nHL in the poorer ear, such that the effective AC stimulus to the contralateral ear is at least 20 dB nHL. This may be less problematic than it appears, because upper bracket *RP*s at high levels in ears with severe sensory losses usually show well-defined responses with relatively short latencies just above the ABR threshold, whereas contralateral responses would have latencies and waveform characteristics more typical of low dB nHLs.

3.22 ELECTROMAGNETIC 60 Hz ARTIFACT & NOTCH FILTERING

Systematic procedures must be in place to minimize contamination of averages by 60 Hz power line artifact from sources within the test area.

ABR threshold estimates can be seriously compromised by the presence of power line artifact at 60 Hz. Such artifact is usually sinusoidal with a typical period of about 17 ms. Power line artifact is most problematic for threshold measurements at 0.5 kHz, because of the artifact duration and the similar morphology of 60 Hz artifact and near-threshold ABRs at that frequency. However, large 60 Hz interference can render averages uninterpretable or unreliable for any tonepip frequency and higher harmonics of 60 Hz may be present. The best fix for 60 Hz contamination of averages is to avoid or at least minimize it by controlling its sources and pickup.

When 60 Hz artifact is present, there is often an environmental or procedural issue that can be identified and addressed. To reduce problematic near-field 60 Hz E/M radiation pickup, the baby and the ABR electrodes should be as far as possible from the closest live power outlet (used or unused) and essential power leads. Outlets that are never used should have metal cover plates. Non-essential power leads should not be plugged into outlets. Long power leads should NOT be coiled; the least-radiating configuration is planar and Z-folded like a concertina.

E/M artifact pickup generally increases, the larger the area of the loop formed by the inverting and noninverting electrode leads, the baby's head and the headbox. The electrodes should be physically arranged to run as close together as possible to the headbox. In any given test area, changing electrode lead positions and orientations may change pickup levels significantly but the absolute amount of pickup will vary from baby to baby, due to multiple factors, especially electrode impedance asymmetry.

Averages always must be inspected for possible 60 Hz artifact. Suspicion is high if a smooth, slow wave is large and clearly begins in the first 10 ms of an average. If suspected, the stimulus condition should be repeated immediately with the insert tube clamped or detached and moved away from the transducer. If the slow wave remains then it is probably not a physiologic response.

Procedures to reduce or eliminate the source of the artifact must be implemented, such as those outlined in the preceding section. If large 60 Hz artifact cannot be eliminated, the 60 Hz notch filter may be tried. The use of that filter must not be routine and must be documented. Consultation with a DTC is strongly recommended if 60 Hz artifact problems are persistent.

SECTION 4: AUDITORY NEUROPATHY SPECTRUM DISORDER (ANSD) SUB-PROTOCOL

4.01 OVERVIEW

Current evidence suggests that 7-10% of infants who have significant PHL may have ANSD. So-called 'conventional' cochlear hearing loss affects the outer hair cells (OHCs) first and at greater severities may also involve loss or damage to the inner hair cells (IHCs) and supporting structures. In contrast, ANSD is a disorder that is not known to affect OHC function but reflects abnormalities of the IHCs, their synaptic linkages to primary auditory neurons or the neurons themselves. Only the last of these alternatives is a true neuropathy, but in 15-20% of all ANSD cases there is MRI evidence of dysgenesis or agenesis of the cochlear nerve. It cannot be assumed that only one site or mechanism of ANSD expression is necessarily involved in any given individual. For a recent, detailed exposition on the pathophysiologic mechanisms of ANSD, see Appendix A: Rance & Starr (2015).

One functional result of ANSD-type pathology is a deficiency in the number and/or the temporal pattern of afferent nerve impulses elicited by sounds. Such abnormalities have a range of perceptual sequelae that are measurable psycho-acoustically in older children and adults, notably including reduced ability to detect temporal modulations of sound and difficulties with speech perception in noise that are more marked than in cases of conventional cochlear pathology with matched severity of sensitivity loss.

A further complication is that some ANSD phenotypes appear to share etiologies (such as severe perinatal hypoxia) with conventional cochlear hearing loss. Because there is no reason to assume that ANSD, conventional cochlear hearing loss and conductive hearing loss are necessarily mutually exclusive, they are referred to here as ANSD, OHC-based SHL and CHL *components*.

Mismatch between gross measures of OHC and afferent neural function is the initial hallmark of ANSD. The first necessary condition is an ABR that is absent or at least significantly depressed and/or delayed. At present, it is widely (but not universally) accepted that any elicitation of a complete ABR wave sequence at normal latencies rules out ANSD. Conversely, a completely absent ABR to a high-intensity click stimulus indicates that an ANSD component is possible but other causes include profound OHC-based PHL and mixtures of it with CHL. Between normal and absent ABR lies a spectrum of ABR abnormality within which differential diagnosis of an ANSD component can be very difficult.

The second necessary component is a measure of OHC function. The best indicator of normal OHC function is normal OAEs. CMs are an alternative tool but they are NOT equivalent to OAEs in either simplicity of interpretation or diagnostic strength. OAEs are a pure OHC phenomenon with fairly well-understood generation place characteristics, but click CM may be generated by IHCs even if the OHCs are extensively damaged; also, gross CMs at a periauricular skin electrode may arise from any part of the cochlea, not necessarily the 2-4 kHz region that normally dominates the click ABR at high levels. This raises the concern of comparing phenomena from what may or may not be different parts of the cochlea, parts that might be subject to different pathophysiology.

A major limitation of OAEs in the ANSD context is that they are reduced or abolished by even small CHLs. Therefore, while OAE presence is highly informative, OAE absence is not. When both OAEs and the ABR are absent, two possible explanations are either severe, OHC-based sensory hearing loss plus a minor conductive overlay or ANSD, so the ANSD could be missed because of the OAE absence.

In addition, there are many possibilities that are less well-defined than 'present OAE and absent ABR', such as situations of abnormal but not absent ABR and/or reduced or partial OAEs. Also, the click may be more effective at ABR elicitation that a tonepip. Therefore, it is appropriate to try high-level clicks when ABR to high-level tonepips are absent or poorly defined and an added benefit is that responses to condensation and rarefaction stimuli are easily available. For these reasons, it is appropriate to measure click ABR and CM whenever the possibility of ANSD is indicated in the course of tonepip threshold estimation. Such measurement should be deferred until tonepip ABR thresholds are completed to 10 dB bracketing. Bracketing tonepip thresholds to 5 dB is not appropriate if the ANSD sub-protocol indicates ANSD component presence.

4.02 ANSD SUB-PROTOCOL ENTRY CRITERION

The ANSD sub-protocol is ear-specific and must be done in any ear for which there is no clear ABR wave V-V' complex with a wave V latency between 5 and 10 ms at any tested level above 75 dB nHL at 2 kHz, with at least one such level having been tested. In the rare event that this condition is satisfied but there is an unequivocally normal wave V ipsilaterally to BC 2 kHz at any level, the entry into the ANSD sub-protocol is discretional.

The requirement for the ANSD protocol is ear-specific, that is, it may be required in one ear only or in both ears. The majority of ANSD is bilateral, but unilateral ANSD or asymmetric ANSD severity are not uncommon. In any given ear, as soon as presence of PHL is confirmed at any frequency, the probability of ANSD has increased from about 0.0002 in the newborn population at large through about 1% in all AABR Refers to at least 5% in all cases with confirmed PHL. But, as soon as a clear positive response is obtained with a wave V latency within normal limits well above threshold, the ANSD probability becomes close to zero. ABR threshold definition and wave V clarity and latency are often much better defined at 2 kHz than at 0.5 kHz, so a rational ANSD flag is lack of an *RP* record having a wave V latency under 10 ms at any level above 75 dB nHL at 2 kHz. This criterion is satisfied, for example, by results such as an *NR* at 80 dB, an Inc at 100 dB or an *RP* at 90 dB with wave V latency over 10 ms.

The ANSD sub-protocol may be done discretionally if the audiologist considers the tonepip response data to be anomalous, even if the criteria for mandatory entry are not satisfied, provided that so doing does not compromise efficient capture of mandatory threshold data. An example of anomalous data might be very poor suprathreshold growth of 2 kHz response amplitude over a large intensity range.

4.03 ANSD SUB-PROTOCOL TIMING

The ANSD sub-protocol usually should be deferred until after all required tonepip ABR thresholds have been established bilaterally to 10 dB bracketing. Given that there is at least severe HL or ANSD present (or both), the requirement for the ANSD protocol sometimes is established early in the initial ABRA appointment. However, it does not follow that the ANSD protocol should be entered immediately. First, unless OAEs have already been done and are normal, which is not usually the case, even complete absence of ABR at high 2 kHz tonepip levels is much more likely to have been caused by OHC-based PHL than by ANSD, so tonepip thresholds may well be valid. Second, testing at 500 Hz and 4 kHz may be clinically useful even if ANSD is present, not the least because any measurable ABR strongly suggests auditory perceptibility at the evoking stimulus level or lower. Even abnormal ABRs in ANSD can give clinically useful threshold upper bounds, and if the ABR is completely absent, the time spent confirming that for all key frequencies will be small. It follows that at least the basic threshold Search phase for 2, 4 and 0.5 kHz in each ear should be attempted first, with 10 dB AC bracketing in the event that a late wave V is recognized.

If and when AABR Referral is bilateral, neither ear tests normal and at least one ear has the ANSD Sub-Protocol indicated, then it would be unusual to complete the basic mandatory protocol in both ears within the first ABRA session. It follows that the ANSD protocol will usually be done in a second session.

4.04 ANSD TEST PROCEDURES

The following procedures must be followed in each ear for which the ANSD sub-protocol entry criteria are met. For all averages, the following (modified from 2008) parameters must be used:

Clicks, 90 dB nHL, 21.1/s, window (sweep) length 21.33 ms, 0 ms delay, bandwidth 150-2000 Hz, full page-width plotting. All primary averages must be at least 2048 sweeps each.

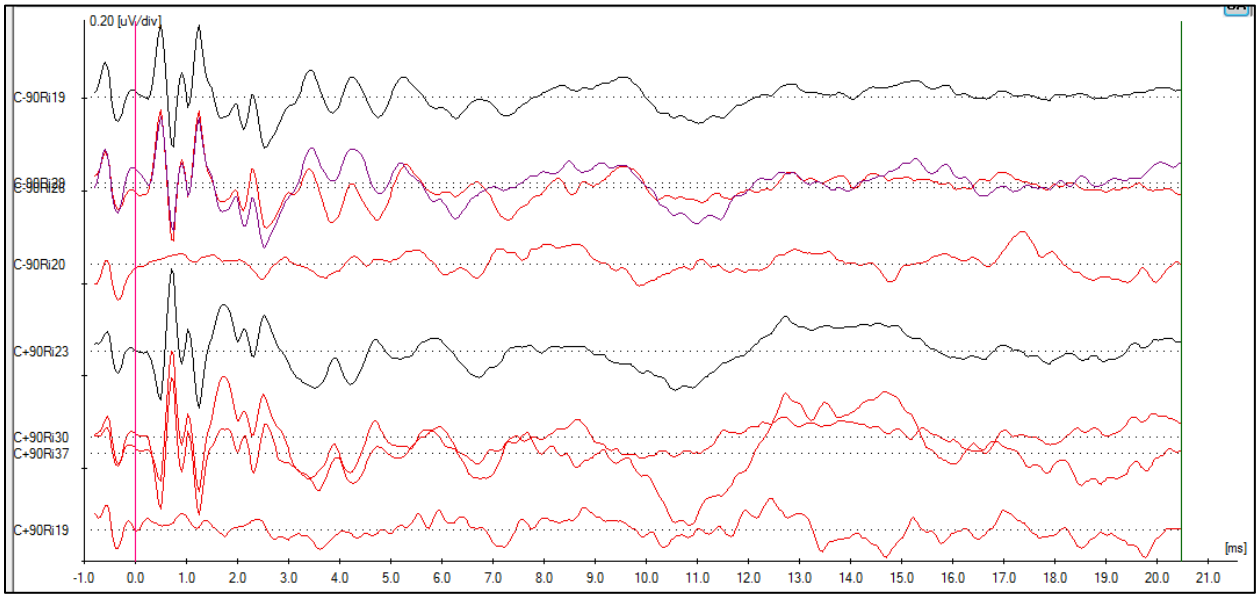
1. Two Rarefaction primary averages, denoted as *R1 and R2.*
2. One Rarefaction average with tube clamped or tube off, *Rns* (Rarefaction, no-stim).
3. Two Condensation averages, *C1 and C2*.

4. One Condensation average with tube clamped or tube off, *Cns*.
5. Add R1 and R2 into combined rarefaction average denoted as *R.*
6. Add C1 and C2 into combined condensation average, *C.*
7. Add R and C into combined overall average, 'All'.
8. Subtract R from C into combined average, 'CM'

Then organize, plot and annotate the averages, in the following sequence from the top down:

R:	Best estimate of Rarefaction stimulus artifact, CM, SP and ABR all together
R1 & R2:	Superimposed at the first data point: shows reproducibility of R averages
Rns:	Reveals Rarefaction stimulus artifact
C:	Best estimate of Condensation stimulus artifact, CM, SP and ABR all together
C1 & C2:	Superimposed at first data point: shows reproducibility of C averages
Cns:	Reveals Condensation stimulus artifact
All:	Best overall estimate of the ABR; removes CM and stim artifact
CM:	Best overall estimate of CM, removes ABR if R and C ABRs are identical
R & C:	Shifted to superimpose exactly, at the first data point: this 'butterfly' plot accentuates antiphasic CM components and latency-shifting ABR components

The following Figure 4.04.1 shows an example of the relevant ANSD recordings plotted according to the described sequence:



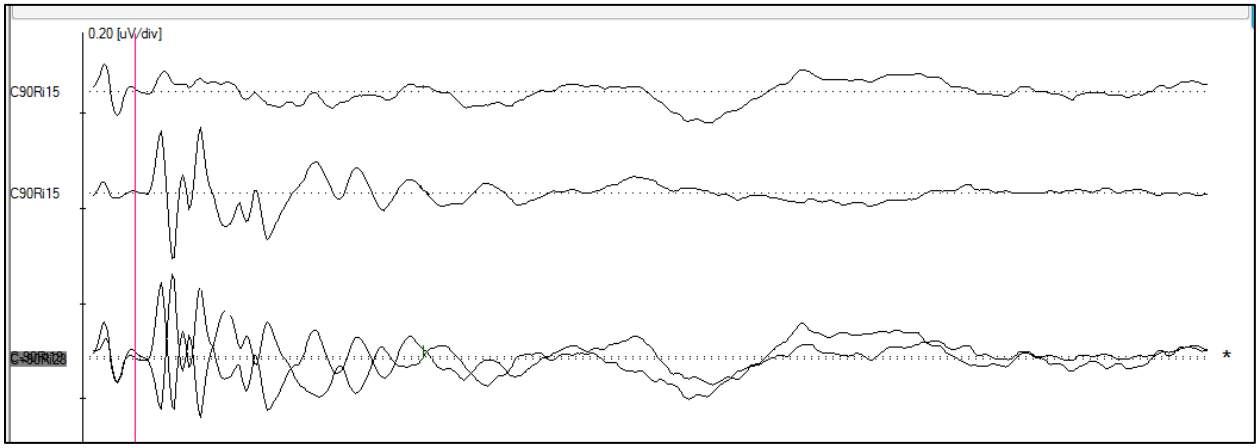


Figure 4.04.1 ***The sequence of records for the ANSD sub-protocol.***
From the top, the records are: Upper traces: The Rarefaction (R) combined average; the two R primary averages; the R tube-off; the Condensation (C) combined; the two C primaries; the C tube-off; Lower traces: the overall average of R and C; the combination R-C; the R and C combined averages superimposed at the first data point (the 'butterfly' plot).

Note the poor reproducibility of the V-V' at about 10 ms, especially for Condensation. Overall, the V is almost certainly real and the V-V' amplitude is about 0.1 µV, whereas the largest CM peak-to-peak in the R-C is about 0.25 µV. This would qualify as 'Definite ANSD component'. Notice also the slower apparently antiphasic activity in the 2-6 ms range of the butterfly. This could be continued CM, early ABR components shifted by the effect of R and C clicks on the basilar membrane activation envelope (a shift of about 0.4 ms) or a combination of the two. Additional testing would be needed to resolve the CM vs neural question, but in this case such resolution would not change the clinical outcome category. Note that the CM fast components have a frequency of about 2 kHz and would have been depressed if a low-pass filter of 1500 Hz had been used (3 kHz was used).

4.05 INTERPRETATION OF CM/ABR AVERAGES

Stimulus artifact for each polarity is revealed by the tube-off (or tube-clamped) averages. This helps to identify genuine CM components, though the artifact is brief, earlier than the CM and usually easy to distinguish from it. Click stimulus artifact is usually over within about 0.5 ms. If it is very large, the EEG preamplifier may generate 'ringing' due to the artifact impulse, interpretation is more complex and review by a DTC is recommended.

Antiphasic (mirror-image) CM components are revealed most clearly by the CM butterfly plot. Asymmetry of the CM is reflected in the curve formed by the 'butterfly wing intersection points' (nodes), which should match the All waveform over the first few milliseconds. Clear departure from zero reflect asymmetry of the CM, which is usually interpreted as SP; this may overlap with wave I (if present) after about 1.5 ms.

The record denoted as 'CM' may show high-frequency oscillation of variable duration, in the region from 0.5 through 1.5 ms. It is recommended that the maximum peak-to-trough or trough-to-peak amplitude should be recorded, along with the total number of high-frequency antiphasic segments or wing-spreads in the butterfly and their approximate overall duration. Such parameters may become useful clinically as new knowledge is acquired about CM properties in relation to ANSD subtypes, severity gradation and mixtures with other hearing loss types.

ABR components also may be present at any point after about 1.5 ms. They may or may not be different in the R and C records, both in amplitude and latency. If different, there may be partial or complete wave cancellation as well as a visual impression of phase shift in the 'All' average. Additional testing is likely to be required in order to resolve the neural components. If a wave V candidate

response waveform is clearly identifiable, the peak-to-trough amplitude should be recorded. If there is partial or total wave cancellation in the 'All' average relative to the R and C averages, the larger of the R and C wave V-V' complexes should be used.

4.06 CLICK ABR WAVEFORM & THRESHOLDS

Given that the 2 kHz tonepip ABR was absent or at best showed a small and/or late ABR wave V-V' complex above 75 dB nHL in order for the ANSD sub-protocol to be entered, a normal click ABR at 90 dB would be a rare occurrence. Far more common is a late and broad waveform that is presumptively a V-V'. If a clear and replicable such waveform is identified in response to clicks at 90 dB, the click ABR threshold must be approximated as quickly as possible by bracketing. Step size of 20 dB is sufficient but 10 dB is discretional. If there is a clear difference in wave V-V' size or Rarefaction and Condensation clicks, the polarity with the larger V-V' must be used, otherwise alternating polarity may be used for threshold. The click threshold correction to dB eHL is to subtract 10 dB. Such thresholds should be noted in any clinical report but are not entered into the HCD-ISCIS database. Clinically it can be noted that hearing in the middle or higher frequencies is X or better, where X is the approximate dB eHL of the upper bracket.

If the Rarefaction and Condensation waveforms show marked latency differences or morphology in the region of the later ABR waves (typically from about 4 to 10 ms), it may be very difficult to distinguish these waves from long CM, for example. Additional, specialized and situation-specific testing may be required and review by the Mount Sinai or CHEO DTC is strongly recommended.

Another occasional occurrence with click testing at 90 dB is an ABR waveform in the All average that shows early ABR waves with a clear delay or absence of wave V. This pattern suggests a possible retrocochlear lesion (such as an acoustic tumour or other brainstem lesion) that may not be typical of ANSD. Again, review by the Mount Sinai or CHEO DTC is strongly recommended.

4.07 DPOAE ROLE

DPOAE measurement is now discretional except as part of the ANSD sub-protocol, wherein it is mandatory. When coupled with absent ABRs, normal DPOAE amplitudes and signal-to-noise ratios exceeding about 5 dB at F2 frequencies from 2 to 4 kHz are virtually definitive for either ANSD or, more rarely, other neuropathies that compromise action potential generation in the auditory nerve. Repeatable DPOAE presence at even a single frequency of 2, 3 or 4 kHz is incompatible with absent ABR, though presence isolated to lower frequencies is not.

DPOAEs are known to originate in the OHCs specifically. As such, they can provide clear evidence of OHC functional status, though they do not offer a clear quantification of residual OHC function or a means of accurate prediction of hearing thresholds in their own right. Absence of DPOAEs an any specific F2 frequency suggests an SHL of about 40 dB or more at or near that frequency, but the overlap of DPOAE amplitude distributions for groups with and without SHL of about 30-40 dB is substantial and the distributions are quite broad.

The contribution of DPOAE testing to identification of ANSD is limited by their reduction or abolition by even minor conductive pathologies and hearing losses. DPOAEs that are clearly present are highly informative in relation to ABR characteristics, whereas DPOAEs that are absent or questionable are not. For example, an absent ABR and absent OAE cannot be reliably interpreted as uniquely indicative of severe SHL, because ANSD in combination with a minor middle ear pathology would be likely to give the same results.

Normal tympanometry suggests the absence of substantial middle ear pathology but does not rule out minor conditions that might compromise DPOAE development, so even if high-frequency tympanometry is normal, absence of OAEs does not guarantee major OHC dysfunction.

It could be argued that the specific finding of normal DPOAEs removes the need to do the CM component of the ANSD protocol. However, it is often not appropriate to do DPOAE testing before ABR testing and the measurement of CM is a helpful adjunct outcome of click ABR testing, which is necessary in any case to explore the causes of abnormal ABR waveforms and thresholds. CM is

generally less affected by minor middle ear pathology than are the DPOAE, and the combination of DPOAE and click CM/ABR results is often highly informative clinically. For these reasons, both DPOAE and click CM/ABR measurement are mandatory components of this protocol.

4.08 ACOUSTIC REFLEX (AR) ROLE

AR testing is now discretional throughout any ABRA. It might be useful in the context of ABRA only if ANSD is under investigation and even then only if tympanometry is normal. ARs are reportedly absent in most cases of an ANSD component, but the actual sensitivity of this finding is unknown and absence due to severe/profound, conventional sensory loss or significant conductive loss (the other differentials) is to be expected. Absent reflexes add little clinical information when tonepip ABRs are absent or have very high thresholds. In contrast, reflex presence is an anomaly if ABRs are absent at very high stimulus levels and should prompt critical re-evaluation of test findings, so AR testing could be seen as a crosscheck. However, it might be reasonable to assume that in the context of this protocol, such crosschecking should be considered redundant. If ANSD is considered definite, such as in a situation of normal OAEs and absent ABR, reflex testing is not useful because even reflex presence would not carry sufficient weight to change the ANSD inference.

4.09 ANSD OUTCOME CATEGORIES

It is strongly recommended that the records associated with all ANSD outcome categories except Not Suspected be anonymized and sent to the Mount Sinai or CHEO DTCs for information and review. This will allow the assembly of a provincial IHP dataset that will be used to improve ANSD category definition and protocol efficiency.

Category Determination

a. If DPOAEs present at 2, 3 or 4 kHz and click ABR V-V' < 0.1 µV : **Definite ANSD component**

b. If DPOAEs present at 2, 3 or 4 kHz and click ABR V-V' 0.1 - 0.2 µV : **Probable ANSD component**

c. If DPOAEs absent or unreliable at 2, 3 and 4 kHz, **apply table below:**

CM, pk-pk, µV	Click ABR V-V' pk-pk, µV		
	< 0.1	0.1 – 0.2	> 0.2
< 0.1	*NS*	*NS*	*NS*
0.1 - 0.2	*Probable*	*See Ratio*	*NS*
> 0.2	*Definite*	*Probable*	*See Ratio*

NS = ANSD Not Suspected

Ratio

In cells labelled 'See Ratio', calculate the amplitude ratio CM/ABR using the peak-to-peak values. If the ratio exceeds 1.5, the outcome is 'Probable ANSD component', otherwise it is 'ANSD is not suspected'.

The 'ANSD component' terminology is used to remind report recipients that ANSD, conventional (OHC) sensory and conductive hearing loss components may be present concurrently and that 'Sensory/Neural HL' does not mean simply **either** conventional sensory hearing loss **or** ANSD.

4.10 CONDUCTIVE COMPONENTS IN ANSD

When the ANSD protocol is indicated by AC 2 kHz it is very unlikely, though not impossible, that a clear ABR with normal wave V latency is obtained with BC 2 kHz at 55 dB or below. That finding implies a substantial conductive component, which renders the ANSD protocol virtually useless. A CM will not be seen to a 90 dB click with a mid-frequency conductive component of 20 dB or more. Also, it is almost certain that DPOAEs will be absent. Because these clues concerning the functionality of OHCs are not available, ANSD cannot be detected or classified with adequate reliability. Fortunately, with a normal BC ABR waveform and a correctly attributed responding cochlea, ANSD can be presumed to be absent and the ANSD sub-protocol can be treated discretionally.

If AC 2 kHz ABRs are absent at high levels and BC 2 kHz ABRs are also absent, a conductive component cannot be ruled out except by normal DPOAEs. If DPOAEs are absent, a flat tympanogram suggests a conductive component but does not prove it and does not quantify it. Alternatively, absent DPOAEs and a normal age-appropriate tympanogram strongly suggests absence of a substantial conductive component. The ANSD click CM/ABR protocol is indicated in both cases and may prove informative.

All in all, if a substantial conductive component cannot be ruled out, ANSD is unlikely to be detectable and a conventional SHL component may be overestimated. The overall interpretation will default to a severe or profound sensory/neural hearing loss with a possible or probable conductive component and ANSD not suspected. In this situation, it is desirable to wait at least 4-6 weeks and retest with tympanometry, OAEs and tonepip ABR at 2 kHz, to determine and interpretable change.

4.11 DTC CONSULTS & ADDITIONAL TESTS

It is requested that in all cases for whom the ANSD protocol is entered and the ANSD outcome category is not flat, either the Mount Sinai or the CHEO DTC should be notified by email and sent the anonymized ANSD sub-protocol printout. This notification increases the program's information bases relevant to planning, protocol and resource allocation, as well as triggering useful DTC comment on individual cases, if requested or indicated.

In complex ANSD cases, such as those with no OAE and unusual or inconsistent response morphology to rarefaction or condensation clicks, additional testing may be indicated and undertaken by referral to a DTC. Such testing may include very-high-rate (91.1/s) click ABR to suppress and delay neural components, as well as manipulations of averages to clarify CM, SP and neural response components. A common challenge is overlap and confusion among oscillatory CM, SP and the ABR.

When ANSD is present, audiometric threshold estimates are impossible or at best biased and potentially unreliable. Waiting for VRA remains an option that is far from ideal but the options are limited at present. For infants aged six months or more in whom VRA is either likely to be, or is found to be, unsuccessful, advanced Assessment may include threshold estimation using late cortical potentials (LCPs) (typically of 200-400 ms latency) in response to long tone bursts, which are far less sensitive to loss of neural synchrony than the ABR. LCP testing for threshold estimation is currently authorized for the IHP only at the Mount Sinai DTC. See, for example, He et al (2013) in Appendix A of this protocol, for information on cortical testing in children with ANSD.

4.12 EARLY MANAGEMENT

ANSD may in some cases be determined to be present under about two months corrected age, in which case repeat ABRA at about four months is usually appropriate; the ANSD sub-protocol should be prioritized at such retests. More commonly, in the IHP ANSD is initially confirmed at about 3-5 months corrected age. It is common to wait for behavioural thresholds by VRA, prior to considering

amplification. VRA should be tried at the earliest reasonable opportunity, typicall at about six months, unless there are contraindications. Agreement or discrepancy between ABR and VRA results may alter the diagnostic picture. If VRA proves to be impossible or unreliable, consideration should be given to referral to the Mount Sinai DTC, for testing with Late Cortical Potentials.

Careful communication with caregivers is required if the ANSD test outcome category is 'definite' or 'probable'. ANSD is not easy to explain, especially its relationship to 'ordinary' hearing loss, the consequent inaccuracy of the ABR and the waiting period prior to VRA and decision-making about interventions. Other issues include the variable quality of information about ANSD available on the internet, as well as the number of misconceptions that exist about the disorder, even across hearing health professionals.

Some basic, key points to be explained fo families are:

- When ANSD is present, hearing is likely to be better than that indicated by the ABR test.
- Infants with ANSD have a wide range of hearing losses, but most have some degree of loss.
- Behavioural hearing testing usually will be tried at about 6 months of age.
- Family observations of response to sounds may give useful information.
- Many children with ANSD have difficulty understanding speech, especially if there is a lot of background noise or other people talking
- The extra difficulty understanding speech happens because ANSD interferes with the timing of sound signals as they travel up the hearing nerves to the brain
- Some children (about 50%) with ANSD will benefit from amplification
- Some children with ANSD who do not get much benefit from amplification may do well with cochlear implants.
- Much information about ANSD available from the Internet is incomplete or invalid.

See Roush et al (2011) in Appendix A for a comprehensive review of audiologic management of children with ANSD. See Teagle et al (2010) on cochlear implants in ANSD. A brochure explaining the basics of ANSD in lay language for caregivers is available in the staff section of the IHP website at Mount Sinai Hospital, Toronto, (www.mountsinai/care/infant-hearing-program).

It is often quoted and written that fluctuation of hearing and possible improvement in hearing over time are common occurrences with ANSD, or even key characteristics of it. These statements are incorrect. Fluctuation of hearing levels in ANSD is not a common finding and is probably confined to specialized sub-types of ANSD. Similarly, while it is possible that hearing levels may change over time in a few cases, the actual incidence of progression or improvement is not well-understood and may be very low. The evidence to date for improvement in hearing levels is not of high quality; it should be evaluated critically in relation to individual candidacy for interventions such as cochlear implants.

4.13 DATABASE FIELD ENTRY IN THE IHP DATABASE

If ANSD is definite or probable, tonepip thresholds are likely to be positively biased and in many cases will comprise a lower bound value expressing No Response at the required maximum stimulus levels. These values must be entered in the HCD-ISCIS database frequency threshold fields as if they were valid, but must be qualified by an entry indicating ANSD as 'Not Suspected', 'Probable' or 'Definite'. PHL must be reported as 'Yes'.

4.14 POST-ABRA REFERRALS

It is the responsibility of the individual IHP Audiologist, preferably with support from a DTC, to determine the ANSD category and complete the ABRA protocol. When those steps are completed, if ANSD is definite or probable then referrals for additional investigations are discretional and are outside the scope of this protocol. It is suggested that all referrals that normally would be undertaken for an infant with non-ANSD PHL should be considered. The special concerns, particularly with definite ANSD, are primarily related to delay in definitive audiometry and the increased likelihood of agenesis or dysgenesis of the cochlear nerve(s) which are of clear relevance to amplification, CI candidature and planning of early communication development services.

SECTION 5: ANCILLARY PROCEDURES

5.01 DISTORTION PRODUCT OTOACOUSTIC EMISSION (DPOAE) TESTING

Purpose and Priority

DPOAEs reflect cochlear OHC function. They can be reliably recorded in sleeping newborns in a quiet environment. They are measured best with an f2/f1 ratio of about 1.22 and f1/f2 levels of about 65/55 dB SPL, respectively. DPOAEs yield an approximate yes/no (DPOAE absence/presence) test for significant sensory hearing loss at each f2 value tested, with an effective binary decision criterion at about 40 dB HL.

DPOAEs do not yield accurate hearing threshold estimates. The sensory hearing loss that abolishes the DPOAE is widely distributed across the infant population. Some babies who have near-normal hearing may have reduced or absent OAEs, while some babies with sensory losses of over 50 dB HL have OAEs of near-normal amplitude. OAEs may be abolished by conductive losses as small as 5-10 dB, so an unknown proportion of cases of OAE absence with apparently normal hearing may be due to conductive effects. This vulnerability to minor conductive disorders that may not be detected reliably with tympanometry limits the clinical value of DPOAEs: present DPOAEs may be very informative as a test of OHC functional status, but absent OAEs yield little diagnostic information.

In the context of initial ABRA, DPOAE measurement is now mandatory only if the indications for ANSD sub-protocol entry are met. If not, DPOAE testing is discretional but before embarking on such measurement, the Audiologist should have a clear purpose and action plan for the possible test outcomes. When ABR absence or abnormality is established at high 2 kHz levels, ANSD has substantial probability. DPOAE testing is recommended to occur after tonepip thresholds are completed and before the rest of the ANSD sub-protocol. Typically, this might occur at the end of the first ABRA session or the start of the second.

Because the primary purpose of ABRA is ABR threshold measurement, if a baby is sleeping then ABR testing is usually the immediate priority. Doing OAEs at the start of an ABRA test session is discretional but if the baby is merely drowsy, doing OAEs may interfere with falling asleep. OAEs are never a substitute for ABR thresholds, though if ABR thresholds are abandoned due to persistently poor EEG, trying OAEs may salvage at least some useful clinical information.

Procedure

DPOAE testing must adhere to this protocol, using the instrumentation, device protocol and parameters specified in Appendix I. Nominal f2 frequencies are 1, 1.5, 2, 3 and 4 kHz, with descent from 4 kHz. If the SNR (the difference between the DPOAE and noise floor levels) at every nominal f2 frequency is at least 8 dB, the test is Normal and need not be repeated. If not, DPOAEs must be replicated. Noise from the baby and environment is largest at 1 kHz and the test may be abbreviated if 1.5 kHz is obtained but 1 kHz is taking too long. Results must be plotted with replicates overlaid and Left and Right ears side by side, where feasible. Hardcopy plots and tables are retained. The 2008 IHP Protocol specified display of normative amplitude data percentile curves as part of the printout graphics, but it is now recommended that those data not be displayed because they are not useful clinically. Note that DPOAE testing above 4 kHz is not appropriate because there are no evidence-based IHP actions contingent upon such results. There are no adequate norms for ABR thresholds above 4 kHz, nor are higher frequencies within the current IHP target disorder set.

Interpretation considers absolute DPOAE and noise levels, SNRs and differences across replicates, at every f2 and for all of them collectively. Step 1 is to evaluate stimulus conditions, reflected in the upper pair of curves. These are auto-calibrated to 65 and 55 dB SPL and should be flat and level. A little droop at low frequencies is acceptable but suggests of imperfect probe fit. Major droop indicates inadequate probe fit that invalidates the test.

Step 2 is to assess replicability. Test retest differences of similar size to the average SNR at any f2 cast doubt on inference of DPOAE presence or absence. Conversely, highly reproducible profiles or smooth trends across frequency strengthen inference of DPOAE presence even if the SNRs at individual f2s are small. Step 3 is an evaluation of specific numerical values of DPOAE, noise and the difference between them, frequency by frequency, noting reflex absence, presence or indeterminacy due to excess noise. Step 4 is to assess patterns. This is a search for trends across frequencies or remarkable differences in values at single frequencies.

At each f2, the question is if the DPOAE level is real or due to noise. DPOAE amplitude and SNR are relevant. For a single f2, a conservative criterion for DPOAE presence is an SNR of at least 8 dB and a test-retest difference under 5 dB. An 8 dB criterion will yield about 1% false-positive detection whereas a 3 dB criterion would give about 10%.

When two or more adjacent frequencies show positive SNRs, each frequency adds to the probability that the DPOAE is genuine, so use a 5 dB criterion for genuine DPOAE presence at each frequency in a string of adjacent, positive differences. Normative noise floor levels have typical 99th percentile values in normal young adults when tested in a soundroom of about -8, -17 and -21 dB at 1, 2 and 4 kHz, respectively. Noise levels much greater than these limit the opportunity for an OAE to be detected reliably.

Clinical Implications

DPOAE presence for all f2 suggests grossly normal functioning of the middle ear and the cochlear OHCs. Significant conductive disorders are ruled out. OHC-based cochlear hearing loss greater than 40 dB HL is unlikely; more than 60 dB HL is virtually is ruled out. ANSD does not affect OAEs. Normal OAEs and an absent or grossly abnormal ABR to high-level 2 kHz tonepips or to high-level clicks are virtually definitive for an ANSD component, which is thereby ruled in, as noted previously.

Unfortunately, many factors other than a target PHL can obscure, reduce or abolish DPOAEs. These include a noisy environment, active baby, inadequate probe placement, eartip blockage and an array of middle ear conditions. The net result is that absence or marked reduction of DPOAEs carries little diagnostic information. Their value lies in their presence and the consistency of that presence with observed ABR characteristics. DPOAE presence with, say, a 2 kHz tonepip ABR threshold above 50 dB nHL should lead to careful review of the ABR threshold validity. More marked discrepancy raises the ANSD index of suspicion more strongly than any other test finding, but there is a large gray zone of borderline incompatibility between clear DPOAE and abnormal ABR features for which current knowledge is insufficient for interpretation.

5.02 MIDDLE EAR ANALYSIS: TYMPANOMETRY

Tympanometry is mandatory in all ABRA (see Appendix K). Tympanometric abnormality criteria are set at the 5th percentiles of age-specific normative distributions of compensated peak static admittance, where a clear peak or peaks have developed. In the case of double peaks, the larger peak is used. Admittance change without development of a genuine peak is abnormal regardless of the amount of admittance change. Caution is required in applying these criteria to young neonates, in whom canal wall collapse may lead to steep negative tails.

The clinical utility of other tympanometric measures such as peak pressure, width and gradient is unclear in infants. Reported 90% range boundaries for tympanic peak pressure are from approximately -150 to -100 daPa up to 0 to 50 daPa.

The equipment required up to and including the IHP 2008 Assessment Protocol was the Tympstar. That has now changed to include any equipment capable of providing the measures and procedures specified in this 2016 ABRA protocol, that is, the specification is now functional. Equipment other than the Tympstar must be reviewed by a DTC before implementation in ABRA.

Babies and Infants of corrected age less than six months

Tympanometry must be done with a 1 kHz probe frequency for neonates and infants under six months corrected age. The test must be repeated if the trace is noisy or if it is not clearly normal. A clearly normal tympanogram need not be repeated. The key abnormality criterion is a compensated peak static admittance of ≤ 0.6 mmho, compensated from the negative tail at -400 daPa. All tympanograms at 1 kHz must be plotted and retained on file.

Infants of corrected age six months or more

For infants aged six months or more, the probe frequency must be 226 Hz. The abnormality criterion in the range 6-12 months is a compensated peak static admittance of 0.1 mmho, compensated from the positive tail at +200 daPa. From 13-18 months, the criterion is 0.15 mmho. Above 19 months, the criterion is 0.2 mmho. At any age, a tympanogram that is noisy or not clearly normal must be repeated. Tympanograms at 226 Hz that are clearly normal need not be plotted, but they must be plotted in all other cases.

5.03 MIDDLE EAR ANALYSIS: ACOUSTIC REFLEXES

Acoustic reflex (AR) measurement is now always discretional but may be clinically contributory in the context of suspected ANSD. When an ANSD component is actually present, a clear AR is an unusual finding that should lead to careful re-evaluation of any evidence for inference of a Definite or Probable ANSD component. AR presence also has some clinical value as a crude crosscheck when AC ABR thresholds are poorly defined and suggest hearing levels over about 80 dB eHL. If such situations occur then the reliability of the ABR threshold should be re-examined and possible causes of poor threshold definition should be identified and remedied as a normal requirement of high-quality ABRA.

If ipsilateral ARs are elected to be done, a 1 kHz probe must be used for infants under six months corrected age and a 226 Hz probe for infants aged six months or more. The eliciting stimulus may be a 1 kHz tone or Broad-Band Noise (BBN), which is a protocol change from the 2008 version. BBN is the preferred stimulus because it is usually more effective than tonal stimuli for reflex elicitation, which reduces false-positive reflex absence.The BBN option is a hardkey under ‘stimulus’ on the right side of the Tympstar. The goal is not to establish an accurate reflex threshold, but to show presence or absence of reflexes at an appropriate stimulus level. The starting level should be 85 dB. In infants under six months of age, the maximum nominal level must not exceed 100 dB, because of the SPL variability across young infants due to differences in canal volume and geometry. For older infants, very small canals are uncommon and the maximum nominal stimulus level is discretional. Printouts are also discretional but are recommended because reflex waveform anomalies do occur. It is the reproducibility of the elicited waveform, not its precise morphology, that is the primary factor in response identification.

5.04 REAL-EAR-TO-COUPLER DIFFERENCE (RECD) MEASUREMENT

RECD measurements are a discretional component of ABRA. They are recommended as part of the initial ABRA process if PHL has been confirmed. The required procedure is detailed in the IHP’s ‘Protocol for the Provision of Amplification, version 2014.01, November 2014. The equipment required is now specified functionally (see Appendix A of the IHP Amplification Protocol, v 2014.01).

One rationale for adding RECDs to a completed, early initial ABRA is that rapid anatomical changes, especially in the first six months after birth, can alter actual SPLs at the cochlea for a given stimulus nominal level and thereby alter measured or estimated thresholds in an individual over time. It is also known that for a given stimulus, ear anatomy differences across individuals can cause SPL variation over a 20 dB range, especially at frequencies of 2 kHz or higher. These factors can be relevant in prescription of amplification based on ABR thresholds measured several months previously, as well as to evaluation of hearing threshold stability and relationships between ABR-based and subsequent VRA-based thresholds.

APPENDICES

APPENDIX A: REFERENCES

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APPENDIX B: ACCESSING A DESIGNATED TRAINING CENTRE (DTC) FOR CONSULTATION OR REFERRAL

Adapted from MCYS memo to Infant Hearing Program Coordinators, Spring 2015

Overview

The Designated Training Centre (DTC) structure (formerly Centre of Excellence) was put in place at the inception of the Infant Hearing Program (IHP) in 2001. DTCs provide protocol and clinical decision support, as well as training and second opinion to IHP Audiologists. The goals of DTCs are to:

- Support the timely and accurate execution of IHP protocols for assessment and the provision of amplification (including Outcome Measures);
- Help IHP Audiologists meet the IHP goals of early identification and intervention for children with permanent hearing loss. These goals align with the"1-3-6 Early Hearing Detection and Intervention (EHDI) Plan" endorsed by the Joint Committee on Infant Hearing (JCIH); and
- Serve as a clinical resource to IHP Audiologists.

The DTCs for each aspect of the IHP are as follows:

DTC	Topic Area for Support	Contact Information
Mount Sinai Hospital Toronto	ABR Counselling	Jill Witte, M.A. jwitte@mtsinai.on.ca 416-586-4800 X6130
Children's Hospital of Eastern Ontario (CHEO) Ottawa	ABR VRA CPA Counselling	Marie Pigeon, M.Sc. Pigeon_m@cheo.on.ca 613-737-7600 X2709 Pager: 613-788-1442 (for urgent ABR help)
Western University London	Amplification Outcome Measures Counselling	Marlene Bagatto, Aud.D. Ph.D bagatto@nca.uwo.ca 519-661-2111 X88949

Support is available to IHP Audiologists for a range of topics such as:

- Answering questions about IHP protocols;
- Case discussion and records review;
- Recommendations for additional testing;
- Up-front request from the IHP Audiologist for the DTC to retest a child.

WHEN to Contact a DTC for Consultation

A DTC should be contacted when an IHP Audiologist would like support, or has questions about implementing the protocols, testing, interpreting results, planning intervention, or counselling. Examples include:

- Questions/guidance related to current IHP protocols (Diagnostic Protocols, Amplification Protocol)
- Decisions about next steps (e.g., test strategy for the next visit, what is needed for complete assessment)
- Support for complex cases (e.g., medically involved child, complex audiologic profiles, rare diagnosis)
- Unsure about hearing aid recommendations, technologies or signal processing strategies for a specific child

- Determining the appropriateness of amplification (e.g., in cases of minimal/mild bilateral hearing loss, unilateral hearing loss)

HOW to Access a DTC for Consultation

Clinical decision support can be accessed by any IHP Audiologist by contacting the relevant DTC in the table above. Every effort will be made to provide feedback within 2 business days. Please refrain from leaving multiple messages for more than one DTC. In the event of vacations etc., DTCs will leave a message regarding an alternate contact at the other DTC.

Clinical decision support may result in a recommendation for a referral to the DTC for additional testing. If the IHP Audiologist wishes a second assessment at a DTC, then the following administrative procedures should be followed:

1. The IHP Audiologist discusses with the family their plan to seek expert support at a DTC and once they have obtained parent/caregiver permission, notifies their Regional IHP Coordinator.
2. The IHP Audiologist sends the relevant anonymized chart information (e.g., ABR tracings, hearing aid verification, outcome measures) by fax, e-mail or courier to the appropriate DTC following a discussion about the request.
3. The IHP Audiologist/IHP Coordinator makes the necessary arrangements for the second assessment with the DTC. The DTC contacts and counsels the family, establishes the appointment and notifies the IHP/Audiologist and Co-ordinator

The IHP Audiologist has the option of attending the second assessment to co-test with the DTC Audiologist if they wish. The DTC discusses the results with the IHP Audiologist in order to best support him/her to continue providing services to the child and family.

Please note that this type of ‘consultative referral’ has replaced the concept of ‘Second Opinion’ referral to a DTC initiated by an IHP Audiologist. The term ‘Second Opinion referral’ is now restricted to a specific type of referral that is driven by the child’s family or caregiver, not by the primary IHP audiologist, but for which the Audiologist and coordinator have acquiesced following consultation with a DTC. In distinction, ordinary Consultative referral is part of the continuum of services offered by DTCs to support IHP Audiologists in their care of the child. Expert peer Audiologists at DTCs are part of the child’s team and are intended to enhance the care of the child, not to replace it. The process for obtaining a second opinion is described in a separate document.

In addition, note that case records made available to a DTC by the primary audiologist for consultative referral will not be included in any subsequent IHP Standard Practise Review (see Appendix D) of that audiologist, given that the audiologist has proactively sought clinical decision support and is encouraged to do so to enhance quality of care.

APPENDIX C: PROCEDURE FOR ACCESSING SECOND OPINION SUPPORT FROM A DESIGNATED

TRAINING CENTRE

Adapted from MCYS memo to Infant Hearing Program Coordinators, Spring 2015

Overview

The goal of second opinion support is to provide a mechanism to facilitate timely and accurate assessment and intervention (amplification) services for children with permanent hearing loss in the IHP. Through second opinion support, a clinical impression of an IHP case from a source independent of the managing IHP Audiologist but who has an in-depth understanding of IHP protocols and procedures is obtained. The purpose is to determine whether further assessment or clinical review is required for the child at the Designated Training Centre (DTC) relevant to the issue to be evaluated (i.e., diagnostics or amplification). A report will be provided to the IHP Audiologist and the Regional Coordinator that describes the impression of the case and follow-up recommendations for the family and, in some cases, the Audiologist.

Administrative Procedures

The procedure for pursuing a second opinion varies depending on who initiates it. Second opinions can be initiated by a parent/caregiver of the IHP child or by a non-IHP service provider. In any scenario, the appropriate Designated Training Centre (DTC) must be contacted for evaluation of the case. These are as follows:

Designated Training Centre (DTC)	Topic Area for Review	Contact Information
Children's Hospital of Eastern Ontario (CHEO) Ottawa	Diagnostics (ABR, VRA, CPA)	Marie Pigeon, M.Sc. Pigeon_m@cheo.on.ca 613-737-7600 Ext. 2709 Pager: 613-788-1442 (for urgent ABR help)
Mount Sinai Hospital Toronto	Diagnostics (ABR)	Jill Witte, M.A. jwitte@mtsinai.on.ca 416-586-4800 Ext. 6130
Western University London	Provision of Amplification	Marlene Bagatto, Aud.D. Ph.D bagatto@nca.uwo.ca 519-661-2111 Ext. 88949

It is critical that patient files have all relevant patient and family information (e.g., name, address, phone number) removed so that the child and family cannot be identified by the DTC (Personal Health Information Protection Act, 2004). Clinically relevant information should remain visible (e.g., gender, date of birth, other medical issues) so that a thorough review can be completed.

The following describes the procedure for pursuing a second opinion for an IHP child.

Step 1: Regardless of who initiates the second opinion request, the Regional Coordinator must be notified. If a parent initiates the request through their IHP Audiologist, the IHP Audiologist notifies their Regional Coordinator. A non-IHP Service Provider will often request a second opinion after discussion of a case with the IHP Audiologist. The IHP Audiologist will contact their Regional Coordinator.

Step 2: Regional Coordinator contacts the appropriate DTC to inform them of the request, describes the situation and arranges to have the necessary items of the patient chart reviewed.

Step 3: Deidentified patient chart is sent to the appropriate contact person at the relevant DTC. Individual DTCs may

request specific chart information depending on the nature of the second opinion. The anonymized information can be sent by fax, email or courier to the DTC contact person.

Step 4: DTC reviews the relevant clinical information to determine whether:

a. More clinical or contextual information from the IHP Audiologist is needed prior to making recommendations;
b. Further assessment/review is not warranted and a report will be issued; or
c. Arrangements will be made for the family to be seen by the DTC.

During this process, the Regional Coordinator, IHP Audiologist, the family and person who requested the second opinion (if different from those already mentioned) will be kept informed of the status of the review.

Step 5: A report will be provided to the Regional Coordinator and the IHP Audiologist. The Coordinator will review the report with the family and non-IHP service provider (if initiated request) and follow-up with recommended next steps from the DTC.

Notes

Please note the removal of second opinion by an IHP Audiologist that was included in the previous Second Opinion Protocol (2010). A consultative referral has replaced this concept as it is part of a continuum of services offered by DTCs to support IHP Audiologists in their care of the child (see Appendix B). Expert peer Audiologists at DTCs are part of the child's team and are intended to support and enhance the care of the child by the primary audiologist, not to replace it.

In addition, note that case records made available to a DTC by the primary audiologist for consultative referral will not be included in any subsequent IHP Standard Practise Review (see Appendix D) of that audiologist, given that the audiologist has proactively sought clinical decision support and is encouraged to do so to enhance quality of care.

APPENDIX D: CLINICAL RECORDS AND STANDARD PRACTICE REVIEWS

CLINICAL RECORDS

Clinical records of ABRA function as the required primary audiologic clinical record, as a source of information for interactions with a DTC and as the source material for IHP standard practice reviews and adverse event audits. The hardcopy clinical records should include the following items:

- All retained ABR averages, identified by correct tag strings that include key stimulus specifiers and the Residual Noise value. Averages must be formatted, organized, printed and annotated as specified throughout this protocol. Notes related to any major departure from this protocol should be included.
- Related parameter lists that include stimulus ear, type, route, frequency and intensity, numbers of accepted and rejected sweeps, together with the list specifying the exact order of acquisition of all primary averages (new requirement). Assessments must be dated and the Audiologist identified.
- The suite of special averages defined as part of the ANSD sub-protocol.
- DPOAE plots with Left and Right Ear side by side and replications overlayed, plus the associated tables.
- Tympanograms and related parameters, replicated and plotted where required.
- Acoustic reflex plots and related paramaters, where elected.
- The submitted IHP Assessment report and any other audiologic clinical report that references the ABRA records and their interpretation.

STANDARD PRACTICE REVIEWS

The IHP is required to establish and document that ABRA services are being delivered in adherence to this protocol and that such delivery yields the required audiologic information in a timely, accurate and complete manner. To that end, a standard practice review (SPR) process is obligatory. The SPR is applicable to all IHP audiologists who are authorized to provide ABRA services with IHP funding. It is a part of the overall Continuous Quality Improvement (CQI) program of the IHP. As such, the SPR is not adversarial in nature but is intended to provide both evidence of ABRA-related service quality and an opportunity to identify practice challenges that may benefit from additional audiologist supports or procedural adjustments. It is intended that the SPR should function as an aid to improved practice quality, a stimulus for strengthening a culture of critical self-evaluation of clinical practices and a facilitator of protocol and practice evolution and learning. Processes such as the SPR are routine in most high-quality newborn hearing screening and follow-up programs.

The SPR process will be initiated in calendar 2016 as a long-term monitoring process, following up from the April 2016 distribution of this revised ABRA protocol to all IHP audiologists who provide ABRA services. Over the course of fiscal 2016-17, the rate of reviews will ramp up to a long-term goal that each and every ABRA provider will be reviewed at least once every three years.

The Standard Practice Review process has the following steps:

- MCYS selects reviewees using stratified random sampling from the pool of IHP ABRA providers.
- MCYS notifies the Regional Coordinator concerned who, in turn, informs the audiologist selected.
- The Coordinator and audiologist select THREE ABRA cases, each of which had ABRA testing by the

audiologist on or after the 'go-live' date of this protocol (scheduled for May 2, 2016). One of the chosen cases should be a baby with normal ABR; the other two cases should identify hearing loss, preferably with one being conductive and the other being 'Permanent Hearing Loss.

- Any audiologist who cannot satisfy these case criteria, such as might be due to low caseload, must contact the DTC representative in order to establish an alternative case selection.
- The complete ABRA records of the selected cases are de-identified, assigned an identification code and couriered to the DTC specified by MCYS.
- A companion email copy noting the child ID code, Date of Birth, Risk Indicators, screening results and dates is sent to the DTC to flag the immminent materials.
- Every item of documentation required for the SPR should routinely be present in the audiology chart, as a requirement of this protocol and of generally accepted practices for standard-of-care clinical records. The documentation should not be altered or updated in any way in the period from receipt of notification of the SPR through to submission of the documents.
- The DTC expert reviews the records in relation to the Key Performance Indicators listed later in this Appendix. Additional input or clarification may be sought, if the submitted materials are incomplete, in which case the audiologist must respond in a timely manner.
- A summary report is sent by the DTC to the audiologist and Regional Coordinator. The report identifies KPI areas, if any, that may require attention or adjustment of practice and specifies the desired adjustment. The report document is tabular and focused upon specific process elements; it specifically does not include any overall category rating of test quality or protocol adherence.
- If any area of major divergence from the protocol is found, the DTC may contact the audiologist directly and seek to resolve the issue promptly and collaboratively. Given the diversity of possible scenarios, this process will be case-specific.
- Audiologists should contact the DTC directly and promptly if any clarification or discussion of the DTC report is desired.
- In the event that the audiologist and DTC are unable to agree upon and follow a mutually acceptable and timely process to resolve a practice issue raised in the review, the DTC will so inform the Regional Co-ordinator. It is the Co-ordinator's responsibility to ensure that the audiology services they fund satisfy the terms and conditions specified in the service agreement with MCYS.
- The DTCs will summarize statistically the findings of all their SPRs annually in a report to MCYS. Individual audiologists will not be identified in any such resports.

KEY PERFORMANCE INDICATORS (KPIs)

The following lists identify the indicators that will form the main basis for the SPRs. It is understood that there are many procedural components of high-quality ABRA that are not specifically identified as KPIs. An example is the decision to implement the ANSD sub-protocol. However, because of the relative rarity of such an event, it could not serve as a generally relevant KPI, despite its importance in a specific context. KPIs are characterized by their general relevance, clarity and the ease and validity with which they can be measured.

- Departures from this protocol with and without documented justification.
- Appropriateness of artifact rejection data.
- Correctness of all stimulation, recording and printout parameters.
- Efficiency of stimulus frequency and level selections and order.
- Appropriate use of ear switching and bone conduction testing.
- Use of necessary and sufficient number and size of averages.
- Annotation and correctness of response judgements.
- Completion and timeliness of all mandatory components.
- Appropriateness of all clinical inferences and categories.
- Consistency between measurements and clinical reports.
- Appropriateness of test strategy across multiple test sessions.

DPOAE TESTING

- Acceptability of autocalibrated stimulus levels.
- Correctness of integrated inference from DPOAE levels, noise levels, replicability and frequency pattern.
- Consistency between measurements and reports.

TYMPANOMETRY

- Use of correct probe frequency for baby age.
- Appropriateness of tympanogram classification.
- Consistency between measurements and reports.

APPENDIX E: SUMMARY OF KEY NAVPRO STIMULATION AND RECORDING PARAMETERS

PROTOCOL FILES	See detailed SETUP procedure notes following this summary Table.	
ELECTRODE SITES	Noninverting: High midline forehead, referenced to Inverting for Channel 1: Left mastoid Inverting for Channel 2: Right mastoid Common: Lateral forehead > 3 cm from Noninverting electrode	
CHANNELS	Air Conduction: Single channel ipsilateral to stimulated ear Bone Conduction: Two channel, ipsi and contra to stimulated ear	
FILTERS		
HIGH-PASS ('LOW')	Tonepip thresholds	30 Hz
	All click recordings	150 Hz
LOW-PASS ('HIGH')	Tonepip thresholds	1500 Hz
	All click recordings	2000 Hz
NOTCH FILTER	Off, except as a last resort when 60 Hz artifact is severe.	
ARTIFACT REJECT	**On, with rejection level adjusted to achieve 5-10% rejection in quiet EEG.**	
AMPLIFIER GAIN	150,000	
AVERAGING	**1024-2048 accepted sweeps per average, 1 to 3 averages per condition, plus combined averages discretionally. 512 sweeps may be used solely for mandatory replication of a clear upper bracket response.**	
EPOCH LENGTH	21.33 ms	
ANALYSIS OFFSET	Zero	
RESIDUAL NOISE TARGET	**≤25 nanovolts, required for Response-Negative judgment.**	
STIMULI		
TONEPIPS	Linear ramp (Trapezoidal envelope), 2-1-2 cycle rise/plateau/fall times. Alternating polarity. Repetition rate 39.1/s.	
CLICKS	100 µs drive voltage pulse duration Alternating, condensation, rarefaction polarity as specified. Repetition rate 21.1/s	
MASKING	Ipsilateral: None. Contralateral: discretional 60 dB broad-band noise.	
STIMULUS TRANSDUCER CALIBRATION OFFSETS	`See Appendix F for IHP Navpro Stimulus Transducer Calibration. See Appendix G for detailed procedure for IHP NavPro Protocol Setup	

APPENDIX F: IHP NAVPRO STIMULUS TRANSDUCER CALIBRATION

All IHP Navigator Pros must be set up identically, as specified in this protocol. The two Evoked Potential application software versions in current use in the IHP are AEP 6.2, a 32-bit legacy version that runs under Windows XP, and the current version AEP 7.2, which is a 64-bit version that runs under Windows 7. Windows XP is technically obsolete, is no longer supported by Microsoft and can no longer be purchased on a new or replacement laptop. All new systems purchased by the IHP are the Win 7 AEP 7.2 version.

From the user's perspective, the two key setup activities for ABR testing are (a) stimulus transducer calibration adjustment to set the required IHP values, which are different from the factory-installed defaults, and (b) configuring and storing the device protocols for the tonepip AC and BC tests as well as the click tests used in the ANSD sub-protocol (Appendix G).

Whichever software is installed on any given NavPro, correct stimulus calibration settings are essential in order to use that NavPro for IHP ABRA. It is necessary to be able to view the stored calibration values in order to confirm that they are correct, and for new systems the factory installed values need to be changed. The stored values are not dB SPL values but are internal 'offset' values that produce the desired SPLs for 0 dB 'dial' to equal 0 dB nHL for the specific stimuli to be used in ABRA. See the Tables below.

On both Win XP and Win 7 systems, to access the Transducer Calibration drop-down option you must first open a patient (a real case or a new 'Test' case) in either the data collection or data review windows. On Win XP devices with AEP 6.2, to view and/or change the stored calibration offsets, you simply go into **Setup** and select the **Transducer Calibration** option. On Win 7 devices with AEP 7.2, when you enter **Setup, in** the dropdown list the **Transducer Calibration** option normally will be inaccessible (greyed out), so you select **Switch Profile**, **Administrator** and enter the P**assword** 'AEP' (all caps). On re-entering **Setup**, the **Transducer Calibration** option should now be accessible and you must view the Table entries and change them to the correct IHP values, where necessary.

WARNING!

The NavPro protocol setup procedures are similar for Win XP AEP 6.2 and Win 7 AEP 7.2 and details are given in the following Appendix (G). **However, with Win 7 AEP 7.2 you must NOT delete any of the factory installed test protocols, even though they are of no interest to IHP users. If certain of the factory-installed protocols are inadvertently deleted, you will not be able to access the Transducer Calibration settings, even as an Administrator!** It appears that to gain access to the calibrations in that situation, the least that must be done is a complete de-install and re-install of the AEP software by the NavPro distributor. It also appears that this may not succeed in activating the calibration option and more drastic measures such as Win 7 re-installation also may be necessary! **The bottom line is: with Win 7 AEP 7.2, never mess with the factory protocols – simply set up and save the required IHP device protocols (which will be appended to the factory list automatically) and then use them.**

ABR NavPro CALIBRATION file offsets for IHP nominal 0 dB nHL at dial 0 dB

These values are numbers specified by the IHP that are intended to produce appropriate stimulus levels, such that dial values approximate dB nHL values. The numbers are NOT actual values of dB SPL ppe; the current values are internal offsets that yield actual SPLs or force levels in dB ppe at IHP nominal 0 dB nHL that match those recommended by Stapells.

Air Conduction				
Frequency	*TDH49 Calib*	*ER3A Calib*	*ER3A dBSPL*	*ER3A Stapells*
500 Hz	25	25	22	22
1000 Hz	23	25	25	25
2000 Hz	26	22	20	20
4000 Hz	29	26	26	26
Clicks	35	35		
Bone Conduction				
Frequency	*B71 Calib*	*Actual dB Force*	*Stapells dB Force*	
500 Hz	64	67	67	
2000 Hz	61	49	49	

APPENDIX G: IHP NAVPRO AEP PROTOCOL SETUP

IHP Protocol Setup is straightforward for Audiologists who have read the NavPro User Manual and familiarized themselves with how the device operates. This is customary and is necessary not only for protocol setup but also for effective and efficient clinical operation, as well as conferring greater ability to handle any unanticipated equipment issues successfully on the spot. The protocol setup should take about one hour and the main steps are described in the following text. An alternative is to arrange for the IHP protocols setup to be carried out by Electromedical Instruments, typically for a reasonable fee.

AEP SETUP

If you are now ready to begin the setup, double click the AEP icon to open the program. If the Open Patient window appears, close that window.

SETUP DISPLAY PARAMETERS
In the Main Menu shown at the top of the screen on startup:

Select **Setup/Default Display Parameters**
For **Waveform Grouping:** check **Match**
This groups displayed averages by stimulus level, but leaves a small vertical space between their baselines, vertically separating the Tags for individual traces. The Tag is the text string that identifies the key test parameters associated with each trace. The 8-character Tags are set up to a very specific, standard format, incorporating key information such as the test Ear, Frequency, Level and Residual Noise level. Example: 2k30Li23, denoting a 2 kHz tonepip stimulus at 30 dBnHL in the Left ear, ipsilateral channel recording, with a final Residual Noise level of 23 nanovolts. The format is slight different for BC ABR, an example being B2Lc4528, denoting bone conduction, 2 kHz, Left ear, contralateral recording channel, 45 dBnHL, RN of 28 nV. Earlier versions of AEP on Win XP systems used an RN to two decimal places, but this ran into the beginning of the waveform, was completely unnecessary precision, and was corrected on later versions of the AEP software.

For **Alternating Polarity Wave Display:** check **Alt**
This is the standard setting for tonepip ABR thresholds. Note that for the ANSD sub-protocol, when it is required, you will override the Alt by using the **Polarity** option on the **Stimulus** tab in the **Collection Protocol Setup** screen (see later) to display the Rarefaction and Condensation click responses.

For **Stimulus Blocking Appearance:** check **Show response**
This is a better option than a flat line in the stimulus region, because the stimulus artifact waveform and size can be informative. Large artifacts can cause the preamplifier to produce a 'ringing' response-like waveforms, may alert you to poor electrode contact or poor positioning of transducer and electrode leads, and artifact display is especially important in the ANSD sub-protocol.

For **Display Scale**: check **Specific Scale, 0.4 µV (See note!)**
For newer NavPros running AEP 7.2, the display screen has a wider format and a Specific Scale of **0.2 µV per division** is required to restore the waveform appearance (aspect ratio) familiar to users of older AEP systems under Win XP. **Do not ever use Auto-Specific Scaling! It leads to scale variation from trace to trace and makes visual assessment of a set of waveform virtually impossible.**

Automatic Collecting Wave Display:
Panel Selection
The data collection screen contains two Panels, side by side, that display acquired averages.. A vertical separator can extend one panel or the other by click and drag, but for normal data collection, both panels should be left fully displayed. **The position of the vertical separator affects the x-axis scaling and for display and printout of tonepip ABR records it is important that the left and**

right panels, which usually display the results for individual ears side-by-side, have the same horizontal scaling. For the ANSD sub-protocol, it is preferable to display each record with full panel and page width, in order to be able to resolve the CM nd early neural components easily.

Check: **Ear Panel Same** to display the Left Ear on the Left panel and the Right Ear on the Right Panel.

Automatic Collecting Wave Display:
The screen display is slightly different from that shown in the AEPUM manual.
AEP, VEMP & P300: Check **Ipsi**

Latency Grid: On Waveform Baseline: Blank
Hit **OK**

SETUP USER PREFERENCES

From the main menu, select **Setup/User Preferences**
These preferences will normally be preset to manufacturer defaults. They should be reviewed and, if necessary, changed to the following selections:

For **Frequency Duration Units**: check **cycles**
For **Amplifier Units**: check **Gain**

Tone Burst Default Duration and Ramp
For **ALL frequencies:** Set **Rise/Fall: 2.00 , Plateau: 1.00 , Ramp: Linear**
Check **Open the…**and check **Prompt Exit**
Hit **OK**

SETUP TRANSDUCER CALIBRATION

From the main menu, select SETUP/TRANSDUCER CALIBRATION
See the important information in Appendix F about access to the Transducer Calibration drop-down option under Win 7 AEP 7.2.

Select **Insert Earphones**
Verify that **Manufacturer Defaults** and **Use Defaults** are **blank,** and if not, set them to **blank.**
Insert the following values in the nHL table: **500 Hz, 1 kHz, 2 kHz, 4 kHz to 25, 25, 22, 26.**
Leave all other values unchanged.

Select **Bone Oscillator**
Verify that **Manufacturer Defaults** and **Use Defaults** are **blank,** and if not, set them to **blank.**
Insert the following values in the nHL table: **500 Hz, 2 kHz to 64, 61.**
Leave all other values unchanged.

Select Headphones
Verify that **Manufacturer Defaults** and **Use Defaults** are **blank,** and if not, set them to **blank.**
Insert the following values in the nHL table: **500 Hz, 1 kHz ,2 kHz, 4 kHz to 25, 23, 26, 29.**
Leave all other values unchanged.

The manufacturer's default value for click stimuli is already correct, so leave it unchanged.

Exit **Transducer Calibration** by hitting **OK**, to apply your changes. Re-enter the **Insert Earphones** and **Bone Oscillator** displays and verify that your changes have been implemented. Exit again with **OK.**

Note that the IHP does not endorse the accuracy of ABR threshold testing or the validity of these calibration values for any other stimuli than precisely those routes, frequencies and tonepip envelopes specified in this document. For threshold estimation, IHP specifically does not endorse the use of Blackman envelopes and use of tonepip frequencies lower than 500 Hz.

IHP ABR TEST PROTOCOL SETUP

You will need to setup **seven** distinct test protocols. The instructions that follow are the safest and quickest way to do it. Essentially, what you do is set up completely and save a new 'master' IHP protocol, then you edit only a few fields in a specific sequence, to develop the complete set of IHP protocols.

Please note carefully each parameter value and text string in the following notes; some of them may not be what you anticipate, due to new system features and modifications to IHP protocols. As you work through these instructions, the level of detail given will decrease, in the light of your increasing familiarity with the procedures.

Open the AEP application. If it opens in the **Open Patient** window, **Close** that window to reveal the Main Menu at the top of the screen. Select **Setup/Collection Protocols.**
In the **Collection Protocol Setup** screen, click the down arrow by **Protocol Name**. You will see a drop-down list of pre-installed Bio-logic protocols. **DO NOT DELETE ANY OF THSE PROTOCOLS!**

Select protocol **ABR (2 Channel, Right Ear, 21.33 ms window)**
Select **Save As**
In **Protocol Save As** enter the new protocol name as **AEP: IHP Insert 2 kHz 30 dBnHL**
Hit **OK**
Note that we have not included the setup ear in the protocol name. This is a generic IHP 2 kHz minimum stimulus level protocol and you simply choose the test ear before data collection.

Select **Recording.** You are now in the **Recording** parameter setup screen.
Enter or verify the following parameters:
Test Type: **AEP** Epoch Time: **21.33** # Points: **512** Pre/Post Time: **0.0** Blocking: **0.0**

Maximum# of Averages: **3072**
Note that while the recommended maximum number of sweeps per primary average is 2048, the default stop count is set to 3072, to allow uninterrupted continuation if you are very close to a satisfactory response detection judgment at 2048 and will probably not need another 2048 and combination into a net 4096 combined average.

Save Impedance Test Values: **check** Noise Level Stop Criterion: **check, 25 nV**
Fsp Calculation: **blank**
Note that the Fsp calculation is not correctly implemented in this device and should never be used to aid response detection judgment.

Select **Save**

Select **Stimulus.** Enter or verify the following parameters:
Transducer: **Insert Earphones** Insert delay: **0.80** Ear: **Right** Stim Rate: **39.1**
Polarity: **Alternating** Trigger In: **blank** Intensity: **30 dBnHL** Intensity Step: **5**

Continuous Stimulus: **blank** Trigger Out Pulse: **blank**
Stimulus Type: **Tone burst** Frequency: **2000** Ramp: **Linear** Plateau (cycle): **1.00** Rise/Fall (cycle): **2.00**
Masking type: **none**
Select **Save**

Select **Amplifier** Enter or verify the following parameters:
Channel Number: **Channel 1 Channel 2** Enable: **Check Check**
Gain: **150000 150000**
Artifact Reject: **check, 15.83 check, 15.83** (value is automatic)
Low Filter: **30 30** High Filter: **1500 1500** Notch Filter: **blank blank**
Input 1: **Fz Fz** Input 2: **A1 A2**

Now you must set up EXACTLY AS FOLLOWS the Tags for the averages; this is very important. DO NOT INSERT ANY SPACES in Tags. There is a string character limit and there is only just room for the information required on actual waveforms.

Select **Edit Tag 1** You are now in **Edit Tag Setup**
Remove any and all **Channel 1 Tag** entries from the Left-hand **Channel 1 Tag** window, by highlighting any entries and hitting **Remove**.
In the **Tag Options** list, Select **User Text** and hit **Add**
In the text window, type **2k (with NO SPACES)** and hit **OK**
Select **Intensity** and hit **Add**
Select **Ear Abbr** and hit **Add**
Select **Ipsi or Contra Abbr** and hit **Add**
Select **Noise Estimate** and hit **Add**
Your selections should now appear in sequence in the **Channel 1 Tag** window as:
User Text
Intensity
Ear Abbr
Ipsi or Contra Abbr
Noise Estimate
Ignore the contents of the **Channel 1 Sample Tag** in the **Edit Tag Setup** screen
Hit **OK**

Back in the **Amplifier** window, the Channel 1 **Sample Tag** should read as: **2k30Rc?**
The **?** signifies the **Noise Estimate**, which only acquires real values for actual waveforms.
Now you are back in the **Amplifier** window and must select **Edit Tag 2.** You are back in **Edit Tag Setup.**
Remove any and all **Channel 2 Tag** entries from the **Channel 2 Tag** window.
In the **Tag Options** list, Select **User Text** and hit **Add**
In the text window, type **2k (with NO SPACES)** and hit **OK**
Select **Intensity** and hit **Add**
Select **Ear Abbr** and hit **Add**
Select **Ipsi or Contra Abbr** and hit **Add**
Select **Noise Estimate** and hit **Add**
Your selections should now appear in sequence in the **Channel 2 Tag** window as:
User Text
Intensity
Ear Abbr
Ipsi or Contra Abbr
Noise Estimate

Ignore the contents of the **Channel 2 Sample Tag** in the **Edit Tag Setup** screen
Hit **OK**
Back in the **Amplifier** window, The Channel 2 **Sample Tag** should read as: **2k30Ri?**
Select **Save**
Select **Make Default** and select **OK** in the verification window.
Your 2 kHz protocol is now appended to the protocol list and will load on system startup as the default. You will use **IHP Insert 2kHz 30 dBnHL** as the toneburst ABR 'master' protocol, which you edit to create the other protocols.

Now Exit from AEP to the desktop. Restart the AEP program.
To create the Insert 500 Hz protocol:
In **Collection/ Protocol Setup,** select protocol: **AEP:IHP Insert 2 kHz 30 dBnHL** (already the default).
Select **Save As** and rename the protocol as: **AEP:IHP Insert 500 Hz 35 dBnHL.**
Hit **OK.**
Select **Stimulus** Change **Intensity** to **35 dBnHL** Change **Frequency** to **500**
Select **Save**
Select **Amplifier**
Select **Edit Tag 1**
Highlight **User Text** in the **Channel 1 Tag** window and hit **Remove**
Highlight **User Text** in the **Tag Options** window, hit Add, input the string:**.5k** and hit **OK**
Highlight **User Text** in the **Channel 1 Tag** window, then hit **Move Up four times**.
Hit **OK**
In **Amplifier**, the Channel 1 **Sample Tag** window should contain: **.5k35Rc?**
Hit **Save**

Select **Edit Tag 2**
Repeat the procedure just used for **Edit Tag 1**
The Channel 2 **Sample Tag** window should contain: **.5k35Ri?**
Select **Save**
The Insert 500 Hz protocol will be added to the list.
It is assumed that at this point you understand the basic protocol editing and Tag Setup process. These will not be described in such detail in the following text.

To create the Insert 1 kHz protocol
Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30 dBnHL**
Select **Save As** and rename the protocol as **AEP:IHP Insert 1 kHz 35 dBnHL.** Hit **OK.**
Select **Stimulus.** Change **Intensity** to **35 dBnHL** and **Frequency** to **1000.** Hit **Save.**
Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2,** changing the **User Text** to:**1k**
Sample Tags 1 and 2 in the **Amplifier** window should read: **1k35Rc?** And **1k35Ri?**
Now select **Save**

To create the Insert 4 kHz protocol
Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30 dBnHL**
Select **Save As**. Rename the protocol as **AEP:IHP Insert 4 kHz 25 dBnHL.** Hit **OK**
Select **Stimulus.** Change **Intensity** to **25 dBnHL** and **Frequency** to **4000.** Hit **Save.**
Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2,** changing the **User Text** to:**4k**
The **Sample Tags 1 and 2** should now show: **4k25Rc?** and **4k25Ri?**
Now select **Save**

To create the BC 2 kHz protocol
Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30 dBnHL**
Select **Save As.** Rename the protocol **AEP:IHP BC 2 kHz 30 dBnHL** Hit **OK**
Select **Stimulus.** Set **Transducer** to **Bone Oscillator.** Hit **Save**
Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2,** change the **User Text** to **B2** and move **Ear Abbr** and **Ipsi and Contra Abbr** in front of **Intensity**. These changes are necessary to keep the BC tag length to a minimum while retaining all required information. The **Sample Tags** should show **B2Rc30?** and **B2Ri30?**
Now select **Save**

To create the BC 500 Hz protocol
Go to **Collection Protocol Setup** and select **AEP:IHP BC 2 kHz 30dBnHL**
Select **Save As** and rename the protocol **AEP:IHP BC 500 Hz 25 dBnHL.** Hit **OK.**
Select **Stimulus** and change **Frequency** to **500**. Hit **Save**.
Select **Amplifier** and **Edit Tag 1** and **Edit Tag 2,** changing **User Text** to **B.5**
The **Sample Tags** should now show **B.5Rc25?** and **B.5Ri25?**
Now select **Save**

To create a 'master' ANSD protocol
Go to **Collection Protocol Setup** and select **AEP:IHP Insert 2 kHz 30dBnHL**
Select **Save As** and rename the protocol **AEP:IHP Insert Click 30 dBnHL.** Hit **OK.**
Select **Stimulus**
Stimulus Type: Click Stimulus Rate: 21.1 **Intensity Step: 5**
Click Duration: 100 **Masking Type: None**
Select **Save**
Select **Recording** Change the **Noise level stop criterion** to **20 nV** (note the change in value)
Select **Save** Select **Amplifier**
High Filter: both 2000 **Low Filter: both 150**
Note the change in high filter cutoff to 2 kHz, to allow better registration of the true CM waveform. We have tried 3 kHz, but this allows unnecessary 'grass' into the recording.

Edit the Tags, with the **User Text** as **C** (with NO SPACES!) and also **Add** the **Polarity Abbr** option immediately below **User Text,** then **Intensity, Ear Abbr, Ipsi or Contra Abbr,** and **Noise Estimate**.
The **Sample Tags** in the **Stimulus** window should read: **Ca30Rc?** and **Ca30Ri?**
Select **Save**
Your IHP collection protocol set is now complete.

To run protocols with TDH 39 earphones
At the point of data collection, Select the relevant **Insert** protocol and change the **Transducer** in **Stimulus.**
Exit the Stimulus window with OK, not with Save! Your transducer change will be applied only for the protocol you are using.

REPORT SETUP
In order to enter Report Setup, you will have to have at least one client entered. You may create a 'test' client for this purpose.
You will need to customize your report. The AEP User Manual is quite clear about this process. You can build a report from scratch by first selecting a blank report template and then populating the blank by dragging the desired items from the tree on the right. Alternatively, you can select a template from the drop-down list and edit it by adding, moving or deleting items. We recommend using **ABR-1** and modifying it.

Deleting and Moving Fields on the Template
You remove unwanted individual report objects by clicking on them; they will then be boxed and you hit delete.
You manipulate sets of objects by positioning the cursor, holding down the left click button and dragging a box around the entire set of items you want to delete or drag, then releasing the left button. The object set will be multiple-boxed. You hit **Delete** to remove the set or you position the cursor over the boxed set, left-click and
drag the set. Do this to delete the **Latencies** set and the **Interlatencies** set.

While many other report items are redundant because they are not changed throughout IHP testing, we have not yet succeeded in selecting and integrating the few important items from the manufacturer's default Stimulus Parameters, Recording Parameters and Amplifier Parameters sets in order to reduce clutter and save trees.

Setup/Report Layout/Edit Facility Name? This allows you to customize your facility name.
Modifying Report Field Labels Many of the field labels are unnecessarily long. If you wish, you can change the field labels, including the Header, by right-clicking on the item you want to change, then hitting **Properties** and **Text**, etc.
Saving Template Changes
See the AEP User Manual instructions. The IHP Report Template should be stored as **IHPABR.ert**

DATA COLLECTION
The Main Test Screen is quite intuitive. You have two waveform Display Panels and two EEG View displays at bottom right.
Panels
The Left and Right panels show whatever you have selected in **Default Display**
Setup, namely **Ear-Panel Same** or **Ear-Panel Opposite.** We strongly recommend that you leave the vertical panel separator in its default central position. It is sometimes useful to view both ears simultaneously, for waveform identification. More importantly, changing the panels changes the report panel x-axes, as noted earlier.
Control Panel
Set to Ipsi for testing with inserts and to Both for testing by bone conduction.
EEG View
The **EEG View** displays show you both recording channels. The protocols will always allow you to see the **Channel 1 (Left Mastoid)** EEG on the Left and **Channel 2 (Right Mastoid)** EEG on the Right, if you wish to do so. You may not be interested in both EEGs, although the ability to see them both may be informative in terms of problems such as 60 Hz artifact or myogenic artifact, which may allow you to adjust electrodes or to the positioning of the baby, to achieve best EEG bilaterally. This is highly relevant in BC recordings!
Normally, during data acquisition you will focus on the Ipsilateral EEGChannel, which will be the Left or Right display, depending on the stimulated ear. You can move the EEG vertical splitter bar to give the maximum view of the ipsilateral EEG Channel, or you can leave both displayed and simply watch the ipsi channel more closely.

Miscellaneous Operating Notes

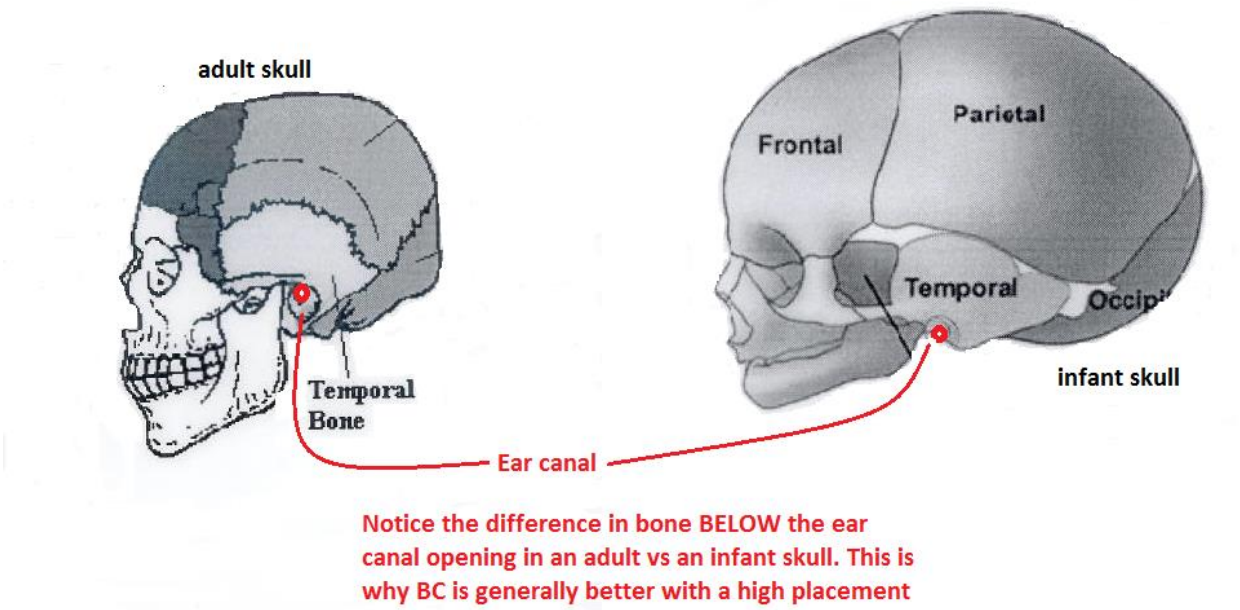
Sweep Count
The sweep count is updated every 256 sweeps, not continuously. The Noise Estimate is similarly updated.

Polarity
In the ANSD sub-protocol, you will be collecting replicated Rare and Cond primary averages.
While the system will automatically display the Rare and Cond sub-averages of an alternating – polarity run on hitting the appropriate icon at the top of the Collection screen, this option should NOT be used, for two reasons. First, splitting out the Rare and Cond sub-averages can accentuate correlation between them caused by high-amplitude EEG episodes (that are not high enough to be rejected). This can complicate interpretation of relationships between Rare and Cond averages. Second, the split-out Rare and Cond averages plot a light gray **on the report** and are not as easy to read as separate Rare and Cond averages. **Therefore, you should adjust the polarity in the Stimulus screen before acquisition of Rare and Cond averages.**

APPENDIX H: CLINICAL TIPS FOR A HAND-HELD BONE OSCILLATOR

When hand-holding the bone oscillator for BC ABR, proper placement and consistent pressure are important. The following tips are recommended:

- Ensure the oscillator is flat against the temporal bone.
- Place the oscillator high on the temporal bone rather than low, as in the image below.
- Ensure even pressure is applied. If the baby is being held during the test, instruct the caregiver to keep the baby still (i.e., no rocking or other motion) during BC recordings



Source: Audiology Department, Children's Hospital of Eastern Ontario

APPENDIX I: IHP MINIMUM STIMULUS LEVELS & ABRA THRESHOLD CORRECTIONS FOR dB eHL

	AIR CONDUCTION				BONE CONDUCTION	
Frequency (Hz)	0.5k	1k	2k	4k	0.5k	2k
Minimum Level (dB Dial)	35	35	30	25	25 <1 yr 30 ≥1 yr	30
Correction Factor (dB)*	-10	-10	-5	0	0	-5

CHANGES TO THRESHOLD CORRECTIONS AND IHP MINIMUM TEST LEVELS

The correction factors for 500 Hz AC and BC have been adjusted to reflect recent data and to approximate more closely the BC Early Hearing Program values.

The IHP minimum levels are now set at dial values that correspond to 25 dB eHL after correction, for all stimulus conditions. These levels are consistent with a target impairment equivalent to 30 dB HL or greater at any frequency in the set [0.5, 1, 2, 4 kHz].

* For AC ABR threshold estimates greater than 70 dB dial, if 5 dB final step size is used for the threshold bracket then the absolute value of the Adjustment should be reduced by 5 dB at any frequencies. The rationale is that with a 10 dB step size, the possibility of response presence at a level 5 dB lower (untested) is included in the statistical adjustment for bias, whereas with a 5 dB step there is no such possibility, because the 5 dB lower level was now demonstrated to be No Response.

Examples: 2k 80 dBnHL (RP), 70 (NR): EHL = 80-5 = 75 dB eHL 2k 80 dBnHL (RP), 75 (NR): EHL = 80-(5-5) = 80 dB eHL
*where (RP) and (NR) represent definite response detection outcomes (see Protocol text).

For any AC ABR threshold, it is discretional to reduce the absolute value of the Adjustment by 5 dB, if the response at the lowest level considered Response Positive is minimal AND the EEG noise level is very low (such as a Residual Noise Level below 20 nV). The rationale is that with exceptionally quiet EEG, the ability to identify small, near-threshold responses is increased, and if such a response is seen, the negative offsets normally used are likely to be on average excessive.

Examples: AC 500 Hz 60 dBnHL (RP), 50 (NR): EHL = 60 -10 = 50 dB eHL AC 500 Hz 60 dBnHL (RP, small, very low noise, e.g., 18 nV), 55 (NR): EHL = 60 –(10-5) = 55 dB eHL

Because current correction factors typically reflect only the mean or median values of the normative difference between ABR thresholds and measured behavioural thresholds in the same subjects, and both measures are subject to random error, it is statistically possible that valid RP outcomes might occur at dBeHL levels that are judged NR by BC, implying negative air-bone gaps. This occasional finding is to be expected, and the lower of the two thresholds should be assumed to be correct.

APPENDIX J: BIOLOGIC SCOUT DPOAE PROTOCOL SETUP

SCOUT DPOAE SETUP

Double-click the **Scout** shortcut icon on the desktop.
Setup/Select protocol: type **1-4 kHz Diagnostic Test.** Hit **OK.**

Setup/Display Parameters

Spectrum Ranges
Upper Frequency Limit (kHz): 10 **Decibel Range (dB): 100**
Autoscale Frequency: check **Bar Plot Spectral Data: blank**

DP-Gram Analysis Range
Maximum Level (dB): 70 **Minimum Level (dB): -30**
Maximum Frequency (Hz): 16000 **Minimum Frequency (Hz): 250**
Reference Data: do not use.

Setup/Collection Parameters **Protocol Name: 1-4 kHz Diagnostic Test**
Frequencies and Levels **Frequency Begin: 4000** **Frequency End: 1000**
F2/F1 Ratio: 1.22 **Points per Octave: 2**
L1 Level dB: 65 **L2 Level dB: 55**

Stopping Criteria
Min DP amplitude (dB): -5 **Noise Floor (dB): -17**
S/N Ratio: 8 **Point Time Limit (sec): 20**
Sample Size: 1024 **Number of Tests: 1**
Minimum # Samples 50.

Hit **OK**
Hit **Yes** in response to the **Save?** question. Save as the **Default Protocol.**

Scout report printing format

The DPOAE report should display the Left and Right Ears side-by-side, with the replicate measurements superimposed in each graphical panel. This is done as follows:

Open the **folder** icon.
You are in **'Open Scout Patient Data File'**
Highlight the required test files, which will usually be contiguous
In **Multiple File Selection View**, check **Right/Left side by side**, or check **Superimposed** if replicates for only one ear are being printed
Select **Open**
You will now be at a **Print Preview** screen.

APPENDIX K: MIDDLE-EAR ANALYSIS TECHNICAL SUMMARY

TYMPANOMETRY

Infants Under Six Months Corrected Age

Tympanometry must be done using a **1 kHz** probe frequency, with repetition when not clearly normal.

The key abnormality criterion is a compensated peak static admittance of <= 0.6 mmho, compensated from the **negative** tail at -400 daPa.

Infants Six Months and Over Corrected Age

- Tympanometry must be done using a **226 Hz** probe frequency, with repetition when not clearly normal.
- The key abnormality criterion in the age range 7-12 months is a compensated peak static admittance of 0.1 mmho, compensated from the **positive** tail at +200 daPa. From 13-18 months, the criterion is 0.15 mmho. From 19 months on, the criterion is 0.2 mmho.
- Tympanometry criteria are set at the 5^{th} percentiles of age-specific normative distributions. In the case of double peaks, the larger peak is used. Admittance change without development of a genuine peak is abnormal regardless of change size. Caution is required in applying these criteria to young neonates, in whom canal wall collapse may lead to steep negative tails.
- The clinical utility of other measures such as peak pressure, width and gradient is unclear in infants. Reported 90% range boundaries for TPP are from approximately (-150 to -100) up to (0 to 50) daPa.

MIDDLE-EAR MUSCLE REFLEXES (ACOUSTIC REFLEXES, ARs)

ARs are always discretional but their measurement is recommended as a limited crosscheck in situations of suspected ANSD. If a significant ANSD component is present, ARs are usually absent, but the quantitative evidence for such a finding is limited. ARs may be elicited by a 1 kHz tone or a broad-band noise (BBN) stimulus; the latter is preferable because BBN stimuli are more effective than tones for reflex elicitation, thereby reducing false-negative reflex absence. The AR is measured ipsilaterally using a 1 kHz probe frequency. Stimulus level should start at 85 dB and increase in 5 dB steps up to no greater than 100 dB. Note that for a given nominal level, real-ear SPLs in young infants may be up to 20 dB greater than in adults. Reflex presence is usually defined by a repeatable, clear, negative deflection, though biphasic and even positive deflections sometimes occur. Printout is discretional but is recommended if the AR is given substantive clinical weight in overall interpretation of test findings.

End of ABRA protocol Version 2016.01, April 04, 2016

END OF PROTOCOL