Updates to NHSP guidance for post-screening diagnostic testing
Update 1: August 2015
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Introduction

This document is intended to update and extend the guidance documents originally produced by the NHSP Clinical Group and adopted by BSA. Except where stated, the guidance given in those documents continues to apply. Suggestions for further updates should be sent to the Chair of the BSA EP SIG (see the BSA web site for contact details). Further updates may be issued as required.

Update to: Guidelines for the early audiological assessment and management of babies referred from the Newborn Hearing Screening Programme. Version 3.1 July 2013.

1. Section 3.2: Staff training and expertise
   Current text: *We recommend that a robust process for auditing of results is in place, including routine and rigorous peer review of the waveforms, threshold estimation and test procedures.*
   Update: A BSA document "Principles of external ABR peer review" was released in 2014 detailing what ABR peer review should entail. Service providers, commissioners and testers should ensure that they have in place a system for the systematic external peer review of their ABR services, compliant with that document, as a component of their quality assurance infrastructure. The peer review document is available on the BSA EP SIG web pages.

2. Section 3.6: Timing of tests
   Current text: *Domiciliary assessment may be a viable alternative particularly it is difficult for the family to attend appointments.*
   Update (missing word "if" added): Domiciliary assessment may be a viable alternative particularly if it is difficult for the family to attend appointments.

3. Section 4.3 ABR stimulus start level
   Update: Since it is recommended that the better ear of a unilateral PCHI case should be tested to 20dBeHL (see section 6.1), it is an acceptable strategy to start the 4kHz test of the better ear at 30dBeHL rather than 40dBeHL in unilateral referral cases, even though many of these will turn out not to be PCHI.

4. Section 5.5 Tests for ANSD
   Current text*: If there is no response at the normal maximum permissible stimulus level to tpABR , or only abnormal waveforms at high stimulus levels (≥75dBeHL), then ANSD may be present in that ear. Tests of cochlear function are then required for that ear*.
   Update: "*abnormal waveforms at high stimulus levels*" do not include waveforms having a waveform morphology that is typically consistent with elevated hearing thresholds. Rather, an abnormal waveform is one with grossly abnormal morphology (for example no wave V in the presence of wave I or wave III), latencies or amplitudes likely to be seen in cases of ANSD or neurological dysfunction.

   Current text: *Note that along with CM testing, a click ABR test should be carried out at the same eHL level as the CM test.*
   Update: In order to avoid uncertainties relating to stimulus level in the baby's ear canal, it is

recommended that when both a click ABR (ckABR) and a CM test are conducted, the same stimulus level must be used with the same (insert) transducer. See also the updates to the Guidelines for Cochlear Microphonic Testing, below, for new guidance on the order of testing.

Update to: Guidance for Auditory Brainstem Response testing in babies Version 2.1 March 2013.

1. Section 5.10: Resolving inconclusive results
   Update: When reducing the noise by performing additional runs does not resolve an inconclusive result then a blocked stimulus run (see also section 5.15) can be helpful. This technique is particularly valuable when a likely ***RA*** or ***CR*** is recorded at the maximum available stimulus level.

2. Section 5.12: Gold Standard thresholds
   Current text: The following is accepted as meeting the Gold Standard: *where there is RA at the maximum stimulus level. The **RA** should be of good quality but 2 recordings suffice.*
   Update: The Gold Standard status for this scenario remains but the implication this has for tests at other frequencies has been changed. If an ***RA*** is obtained at one frequency (as above) yet clear responses are recorded and the threshold defined at another frequency in the same ear for the same transducer, that result should independently meet the Gold Standard. Example: An RA at maximum stimulus level is recorded at 4kHz and a response is recordable at 1kHz. Even though the 4kHz ***RA*** is gold standard, gold standard recording requirements should be met when defining the 1kHz threshold. This is to avoid the situation where the Gold Standard associated with the ***RA*** at the maximum stimulus level removes the requirement for a Gold Standard where a response is seen.

3. Section 5.14: Reporting thresholds & Appendix B: Two-Channel BC Recording
   Update: When two-channel recording is used as an alternative to masking and shows that the ipsilateral ear is responsible for the response, it is recommended that the threshold is entered into eSP and the clinical report using the qualifier (M) (as though it had been masked), and adding an appropriate clinical note. If two-channel recording does not indicate that the ipsilateral ear is responsible for the response (because it is unclear or that the contralateral ear is responsible for the response) then the qualifier (M) should not be used and a clinical note added which warns that the result is not ear-specific.

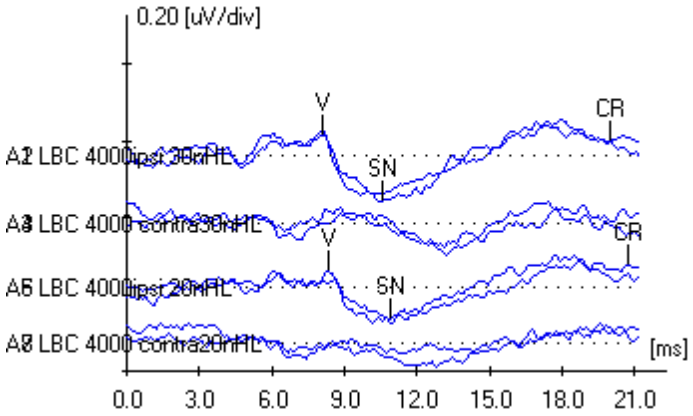
4. Section 5.5: Notch filter
   Current text: *This will not be required under normal recording conditions and with good electrode practice as 50Hz mains artefact should be absent or minimal. If mains artefact levels are high it is better to identify and remove the source of the problem rather than rely on the use of the notch filter, which may distort or attenuate the slower components of the recorded ABR waveform. However if there is an unusual and exceptional degree of mains interference which cannot be eliminated the temporary use of a notch filter is preferable to raising the high pass filter or abandoning the test. When a notch filter is used this must be noted in the clinical report.*
   Update: This will not be required under normal recording conditions and with good electrode practice as 50Hz mains artefact should be absent or minimal. If mains artefact levels are high it is better to identify and remove the source of the problem rather than rely on the use of the notch filter. However if there is an unusual and exceptional degree of

mains interference which cannot be eliminated the temporary use of a notch filter is preferable to raising the high pass filter or abandoning the test. When a notch filter is used this must be noted in the clinical report. The available evidence is that notch filtering does not distort the newborn ABR, with the exception of testing at 500 Hz where waveform distortion has been observed and could compromise waveform interpretation. At 500 Hz therefore the notch filter must not be used.

5. Section 5.8: Masking
   Update: As a practical guide, the following table may be helpful. It is based on the Noise Calculator spreadsheet 2013b and assumes the non-test ear is normal.
   Masking the ABR: consider the need for masking when using stimuli at or above the following levels (in dBnHL) for babies of 0 to 8 weeks corrected age (consult the spreadsheet for other ages)
   Note: the stimulus levels for chirps are 5dB lower than shown below

Transducer	Click	500Hz	1000Hz	2000Hz	4000Hz
TDH	65	75	75	65	75
Insert	60	75	75	70	75
BC	20	15	15	25	20

6. Appendix B: Two-Channel BC Recording
   Update: The following example shows typical waveforms in a case where the BC stimulus generates the ABR via the ipsilateral ear. The contralateral waveforms have a lower amplitude and longer latency wave V so in this case it is safe to ascribe the responses to the left ear without recourse to masking.



   Order of waveforms (top to bottom): 30dB ipsi; 30dB contra; 20dB ipsi; 20dB contra.

7. Appendix E: Objective measures for ABR interpretation in babies.
   Update: Following an update to the software for the Interacoustics Eclipse system (version 4.4.2.x or later), the current guidance relating to Fmp and residual noise for the Eclipse is no longer valid. Direct comparisons between Eclipse 4.2 and 4.4 systems simultaneously recording ABRs has led to the following new advice (advice for the Biologic NavPro is unchanged):

   Fmp >7 for the Eclipse (v4.4.2.x or later)in both replicated waveforms using the NHSP recommended settings support the conclusion that the response probably exceeds the 3:1 condition component of the NHSP ***CR*** criteria.

Residual noise values may be used as a guide of when to stop averaging if the outcome of the test appears to be a candidate for ***RA*** status. The recommended target value for the Interacoustics Eclipse (v4.4.2.x or later) is 15nV.

Thus for both Fmp/Fsp and residual noise, the criteria for the Interacoustics Eclipse and Biologic NavPro are now the same.

Update to: Guidelines for Cochlear Microphonic Testing Version 2.0. September 2011

See also the update notes above relating to tests for ANSD

1. Current text: (lines 80-90) *Where the AC 4kHz tpABR threshold is significantly raised (>75dBeHL) and there are no recordable BC 4kHz tpABR responses for that ear it is recommended to switch to ckABR (i.e. a broad band stimulus) to determine if any AC responses can be recorded up to the maximum recommended stimulus level available. This is because absent tpABR responses at 4kHz cannot exclude an island of better hearing 85 which could generate an ABR and CM in a "conventional" cochlear hearing loss. However in some cases it may be possible to record a low frequency (e.g. 1kHz) tpABR and this must be considered when interpreting the CM (see the notes in the section on interpretation, below). In practical terms therefore if CM testing is being considered it is necessary to first perform a ckABR up to the maximum permitted stimulus level (if required) in addition to tpABR*.
   Update: The decision to conduct tests for ANSD should be based on ABR absence at the maximum recommended stimulus level or, in the case of a recordable ABR at or above 75dBeHL, an abnormal ABR morphology (for example no wave V in the presence of wave I or wave III) regardless of stimulus type. Any evidence of a recordable ABR of normal morphology (normal for the stimulus used) makes the likelihood of ANSD very low. Regardless of the presence or absence of ANSD, testing at a lower frequency (e.g. 1 kHz) will be useful in addition to testing at 4 kHz so it is logical to proceed from tpABR at 4 kHz to tpABR at 1 kHz and only if both show absent or abnormal responses (see below) should we then consider ANSD.

2. Current text: (lines 90-95) *ANSD should be considered when a click ABR is not present at the maximum permissible stimulus level or is present but abnormal at or above 75dBeHL. ABR waveforms should be considered abnormal if they have unexpected (even for a baby with hearing loss) latencies, amplitude or morphology (e.g. missing peaks).*
   Update: "*abnormal at or above 75dBeHL*" applies to click or tone pip ABRs and does not include waveforms having a waveform morphology that is typically consistent with elevated hearing thresholds. Rather, an abnormal waveform is one with grossly abnormal morphology (for example no wave V in the presence of wave I or wave III), latencies or amplitudes likely to be seen in cases of ANSD or neurological dysfunction.

3. Update (order of tests): ANSD can be confirmed only with the following combination of findings: (a) a recordable CM which disappears upon clamping of the insert tube (or a recordable TEOAE) and (b) an absent or abnormal morphology (see above) ckABR for the same stimulus and transducer.
   It may not be necessary to conduct both a ckABR and a CM test and the two tests do not have to be conducted in a fixed order. The following examples illustrate the two possible test strategies:

Example 1: Where a ckABR is conducted prior to CM testing: if the ckABR shows a clear response of normal morphology (albeit at a high stimulus level, consistent with a severe high frequency sensory neural hearing loss) then no CM testing is needed – this is not a case of ANSD. If a ckABR is absent or has abnormal morphology then CM testing is needed.
Example 2: Where a CM test is conducted prior to ckABR testing: if the CM is absent (and any current or previous OAE testing also shows no evidence of hair cell activity) then there is no evidence of ANSD and a ckABR is not needed to confirm the absence of ANSD. If the CM is present then ckABR testing is needed to interpret the significance of the recorded CM.

4. Current text: ("Methods & test parameters" lines 129-130): *The recommended method is to use separate replicated runs of condensation and rarefaction polarity clicks at 80 dBnHL.*
   Update: The recommended method is to use separate replicated runs of condensation and rarefaction polarity clicks at 80 or 85 dBnHL. In order to avoid uncertainties relating to stimulus level in the baby's ear canal, it is recommended that both the ckABR and the CM test are conducted at the same stimulus level with the same (insert) transducer.

5. Update: It is not satisfactory to perform a ckABR with the recording parameters recommended for CM testing. It is likewise not ideal to derive the CM from the ckABR waveform even though some ABR systems will show separate polarity waveforms when an alternating polarity stimulus is used. Refer to the CM guidance and ABR guidance documents for appropriate stimulus and recording parameters for CM and ABR tests respectively. Because the recommended timebases for CM and ckABR tests differ considerably it is recommended to plot them on separate charts to aid interpretation (the size and aspect ratio of the waveforms may then be optimised). The time base for CM testing should be 8ms to 10ms but it is usually advantageous to specify a time base (window or recording epoch) that begins at minus 1ms, i.e. 1ms prior to stimulus onset, allowing the stimulus artifact to be seen and therefore distinguished from any genuine CM response. A 10ms time base would therefore start at -1ms and end at 9ms.

6. Update: The "show flat line" option for the NavPro blocking period appearance should not be used for CM testing as it is important to visualise any stimulus artifact in order to distinguish it from any valid CM.

Update to: Guidelines for the Assessment and Management of Auditory Neuropathy Spectrum Disorder in Young Infants Version 2.2 August 2013:

Section 2 "Initial Assessment": updates to the Cochlear Microphonic guidelines above also apply to the ANSD guidelines.