Auditory Brainstem Response (ABR) Testing in Babies: Adapted Egyptian Clinical Practice Guidelines *(ECPG)*

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The present Egyptian CPG (ECPG) represents an adapted CPG with clear outlined methodology and the related references to each guideline were cited. The contributors of these adapted ECPGs have made considerable efforts to ensure that the information upon which they are based is accurate and up to date. The publishers will be pleased to make good any omissions or rectify any mistakes brought to their attention at the earliest opportunity.

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Abbreviations

ABR	Auditory Brainstem Response
AC	Air-conduction
BC	Bone-conduction
BSA	British Society of Audiology
CM	Cochlear Microphonic
CPG	Clinical Practice Guideline
C-R	Condensation- Rarefaction
CR	Clear Response
dBnHL	Decibels normal Hearing Level
GRADE	Grading of Recommendations Assessment, Development and Evaluation
Hz	Hertz
Inc	Inconclusive
i/o	input to output
NB	Narrow Band
NHSP	Newborn Hearing Screening Programme (England)
nV	nano Volt
PTA	Pure tone Audiometry
RA	Response Absent
TB	Tone Burst
TP	Tone Pip
SNR	Signal to noise ratio
SPL	Sound pressure level

Executive Summary

Effective and consistent hearing measurement in babies is important for early intervention.

Of particular importance are guidelines to unify testing, data reporting particularly as universal hearing screening is being implemented in EGYPT

- Choice of electrodes & application Skin should be gently abraded. Appropriate options include abrasive electrode paste and cleaning stick with soft cotton material. Single use disposable electrodes are recommended. (Strong recommendation).
- Sedation is not necessary in babies under 12 weeks of age and should be used in babies under 12 months of age only in exceptional circumstances. Sleep deprivation, feeding and diaper change in most situations will lead to natural sleep and lessen activity. (Strong recommendation)
- In order to achieve frequency specificity, thresholds should be measured for at least two frequency audiometric regions:
  1. Low frequency thresholds using 0.5 kHz tone bursts or tone pips .
  2. High frequency thresholds using 2 or 4 kHz TP / TB or clicks. (Strong recommendation)
- Definition of ABR threshold It is defined (BSA, NHSP 2013) as the lowest level at which a clear response (CR) is present, with a response absent (RA) 5 - 10dB below threshold, under good recording conditions.
- Criteria for ABR response & threshold:

1-Reproducibilty of at least two response traces: visual and graphic.

2-Reproducibility of responses for all intensity i/o functions.

3-Threshold is the reproducible response at the lowest stimulus intensity reached.

(Strong recommendation)

- Calibration :
  1. Subjective stage A listening check using 50/sec RR.
  2. Reference equivalent SPL for clicks and tone pips if and when feasible.
  3. Psychoacoustic calibration control is feasible and easy and can be routinely done.

(Conditional recommendation)

- Reporting:

Results should be clearly marked using the symbols **'='**, **'≤'** or **'<='**, and **'>'** in addition to the descriptive statements, when important rehabilitation decisions are made.

(Conditional Recommendation)

Introduction, scope and audience

Introduction

Effective and consistent hearing measurement in babies is important for early intervention. Auditory Brain Response (ABR) is used to identify an accurate estimate of hearing thresholds at different frequencies. It is important to ensure good quality recordings of ABR waveforms which are obtained using earphones, inserts and bone-conduction transducers. As universal hearing screening is being implemented in EGYPT, there is a growing need to unify testing parameters and improve data reporting.

Scope:

These guidelines are for the use of ABR in assessing hearing in babies up to a corrected age of 12 weeks These guidelines aim at the achievement of the uniformity of the equipment set up, improvement in test performance and waveform interpretation. Frequency-specific information is required. It aims to define criteria by which to identity a 'clear response', 'response absent' or 'inconclusive' response when performing ABR testing in babies.

Target audience:

Audiologists for proper performance and interpretation of ABR. ENT specialists for proper interpretation of ABR results.

Methods

Methods of development

Stakeholder Involvement: Individuals who were involved in the development process. Included the above-mentioned Audiology Chief Manager, Audiology Executive Manager, Assembly Board, Grading Board and Reviewing Board.

Information about target population experiences were **not applicable** for this topic.

Search Method

Electronic database searched:
Pubmed, Google scholar, Cochrane and Embase

Keywords

ABR, clicks, tone burst, frequency specific audiological assessment, hearing assessment in babies

The adaptation cycle passed over: set-up phase, adaptation phase (Search and screen, assessment: currency, content, quality & /decision/selection) and finalization phase that included revision and external reviewing.

Time period searched: 2003 to 2019

Results

Three national audiologists reviewed the guidelines available. Guidelines from the British Society of Audiology (BSA) gained the highest scores as regards currency, contents and quality.
It was graded GRADE by twenty one experts and reviewed by three expert reviewers to improve quality, gather feedback on draft recommendations.
The external review was done through a rating scale as well as open-ended questions.

Setting: Primary, secondary and tertiary care centers & hospitals, and related specialties.

Interpretation of strong and conditional recommendations for an intervention

Audience	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action; only a small proportion would not. Formal decision aides are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Most individuals in this situation would want the suggested course of action, but many would not
Clinicians	Most individuals should receive the intervention. Adherence to the recommendation could be used as a quality criterion or performance indicator.	Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences. Decision aides may be useful in helping individuals make decisions consistent with their values and preferences.
Policymakers	The recommendation can be adopted as policy in most situations.	Policy-making will require substantial debate and involvement of various stakeholders.

WHO handbook for guideline development – 2nd ed.
Chapter 10, page 129

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to Decision frameworks (GRADE Working Group 2013)

Grade	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Recommendations,

The following statements and flowchart were adapted from the Guidelines from (**Auditory Brainstem Response (ABR) Testing in Babies, BSA 2019 due for review 2024**) which received the highest scores as regards the currency, contents, and quality.

Accepted statements	
Modified statements	
Added statements	

Recommendations statements

Clinical Question	Action recommendation	Evidence Quality	Strength of recommendation	Reference	Study Type
1. Patient preparation 1.1 Test environment	Threshold ABR tests should be performed in a sound-proofed room or environment which meets the same standards as PTA. Levels of electrical interference should be sufficiently low such that the signal baseline is not adversely affected.	Very Low	Strong	1,2	Literature review
1.2 Precautions against cross-infection	All local procedures should follow proper hygiene procedures upon use of equipment and electrodes.	Very Low	Strong	3,4	Literature review
Sedation	Sedation is not necessary in babies under 12 weeks of age and considered in babies under 12 months of age only in exceptional circumstances. Sleep deprivation, feeding, Diaper change in most situations will lead to natural sleep and lessen activity	Very Low	Strong	4	Literature review
1.3 Choice of electrodes & application	Skin should be gently wiped with (wet) gauze, Caution with abrasive materials. Appropriate options: cleaning stick with soft cotton material. Single use disposable electrodes.	Very Low Very Low	Conditional Strong	1 4,5	Expert opinion Literature Review

	The impedance, as measured between each electrode pair should be under 5000 ohms and similar across electrodes. The ABR system must not be switched on or off with the patient attached.	Moderate Very Low	Strong Strong	20 5,6	Randomized experimental study Literature review
2. Stimulus parameters 2.1Polarity	Alt polarity to minimize the stimulus artifact. C-R clicks when CM collection is needed	High	Strong	8,9	Randomized experimental study
2.2 Timing	Click: 100µs Tone pip: 2 -1-2 cycles or 5-cycle Blackman Narrow band (pip-like) chirps (NBchirp)	Very Low Low	Strong Conditional	3,4,5 10	Literature review Observational Study
2.3 Rate	Rates 45.1-49.1/s	Moderate	Strong	11,20	Non randomized experimental study

2.4 Frequency Specific ABR	0.5, 1, 2 or 4kHz. Thresholds may be measured for at least two frequency audiometric regions: Low frequency thresholds using 0.5khz High frequency thresholds using TP / TB 2, 4 khz or clicks	High High	Strong Strong	12,13, 14,15	Randomized experimental studies
3.TRANSDUCER 3.1 Earphones	• Should be able to deliver a stimulus up to 140dBSPL peak (107dBnHL for clicks) without distortion. • Supra-aural or insert earphones (*e.g.* type ER-3A). • Insert phones should not be used > maximum levels given in (BSA, HNSP 2013). • Supra-aural earphones should be centered over the ear canal to avoid collapse of ear canal due to excess pressure.	Very Low	Strong	1-6	Literature review
3.2 Bone vibrator	• Should be able to deliver a stimulus up to 60dBnHL (50dBnHL at 0.5 kHz) without waveform distortion. • Placement: on mastoid 1 finger's width above the electrode + finger pressure on BC vibrator. • Placement on temporal bone posterior to the upper part of pinna if it gets close to electrode. Effective level of stimulus changes with age (BSA, NHSP2013) may be used. Relaxed and sleeping baby is important.	Very Low High	Strong Strong	16 17	Literature review Randomized experimental study
4. Data collection and analysis					

4.1 Amplifier artifact rejection level	±3 to ±10μVg peak-to-peak.	High	Strong	18	Randomized experimental study
4.2 Amplifier filters	Low frequency 30Hz- 50Hz . High frequency 1500Hz	High	Strong	20	Randomized experimental study
4.3Use of digital filters	• Smoothing of averaged waveform • 50-1000hz • Notch filter	High	Strong Recommendation-against	19	Randomized experimental study
4.4 Window length & averaging	• Click, NB chirp & 2kHz / 4kHz tone pip : 20ms • 0.5kHz / 1kHz tone pip : 25 ms	High	Strong	18	Randomized experimental study
	Number of sweeps averaged per replication: • 1500 -2000 click & NB chirp, or • 2000- 3000 for TP ABR • If response is clear stop averaging	High	Strong	18	Randomized experimental study
4.5 Display	• wave V upwards • Ensure small waveforms near threshold are visible. • automatic display gain.	Very Low	Strong	1,2	Literature review

<table>
<tr>
<td>4.6 Masking</td>
<td>
Masking of the contralateral ear when stimulus level is high to cross to the other cochlea and produce a response.
Consider masking when stimuli are at or above the following levels (in dBnHL) for babies of 0 to 8 weeks corrected age assuming the other ear is normal
<table>
<tr><td>Transducer</td><td>Click</td><td>0.5kHz</td><td>1kHz</td><td>2kHz</td><td>4kHz</td></tr>
<tr><td>Supra Aural</td><td>65</td><td>75</td><td>75</td><td>65</td><td>75</td></tr>
<tr><td>Insert</td><td>60</td><td>75</td><td>75</td><td>70</td><td>75</td></tr>
<tr><td>BC</td><td>20</td><td>15</td><td>15</td><td>25</td><td>20</td></tr>
</table>
</td>
<td>High

High</td>
<td>Strong

Strong</td>
<td>21

22</td>
<td>Randomized experimental study

Meta-analysis</td>
</tr>
<tr>
<td>4.7 Criteria for accepting the presence of a response</td>
<td>
Visual interpretation.
Replication of waveforms
Decision criteria for the result at each stimulus level

CR: clear response present

RA: Response absent, or

Inc: Inconclusive

<u>Criteria for CR</u>

1- High correlation between replications, waveforms should show the expected characteristics of amp, latency & morphology.
2- The size/amplitude of the response as judged from the wave III/V should be a minimum of 40nV and at least 3 times the background noise level
3- The waveform should be judged over the whole time window excluding any stimulus artifact.
4- Waveforms should be compared with those at other stimulus levels to confirm that they follow the expected changes with stimulus
</td>
<td>Very Low

High</td>
<td>Strong recommendation

Strong recommendation</td>
<td>1,2

22</td>
<td>Literature review

Meta-analysis</td>
</tr>
</table>

	level. Criteria for ***RA*** the waveforms must be appropriately flat, no evidence of a response and the average gap (noise) between a pair of optimally superimposed waveforms should be less than or equal to 25nV. If the result does not meet the criteria for either a (***CR***) or (***RA***), the result should be marked as inconclusive (***Inc***). Inconclusive waveforms should not contribute to the derivation of threshold.	High Moderate	Strong recommendation Strong	22 22	Meta-analysis Meta-analysis
5. Threshold 5.1. Definition of ABR threshold	ABR threshold is defined in (BSA, NHSP 2013) as the lowest level at which a clear response (***CR***) is present, with a response absent (***RA***) 5 - 10dB below threshold, under good recording conditions. Alternately criteria for ABR response & threshold: may be defined as visual and graphic reproducibility of responses for all intensity i/o function where threshold is the reproducible response at the lowest stimulus intensity attained. I/O intensity may start at low stimulus levels unless there are good reasons to do otherwise. stimulus level may change in10db steps. Larger steps may be better in some occasions according to babies ' sleep	High	Strong	22	Meta-analysis

5.2. Reporting thresholds (including those which are not gold standard)	Results should be clearly marked using the symbols '=', '≤' or '<=', and '>' in addition to the descriptive statements, when important rehabilitation decisions are made **'='** means clear ***response*** at threshold (***CR*** at 5-10dB above & ***RA*** 5-10db below). **'<='** means ***CR*** at threshold but not tested below this level. **'>'** means ***RA*** at 80dB, but not tested above this level. ● If no 'confirmatory' ***CR is*** obtained at 5 or 10dB above threshold, ***report threshold = lowest CR obtained***. ● If no ***CR*** is obtained above a RA result, ***report threshold > highest RA*** ● If an ***RA*** response is obtained but not within 10dB of the lowest ***CR report threshold as <=lowest CR and > highest RA;*** .	Very Low Very low	Conditional conditional	*2.3* 2	Literature review Expert opinion

6.Calibration	• Subjective stage A listening check using 50/sec RR • Reference equivalent SPL for clicks and tone pips	Low	Conditional	23	Observational study
7.Artifacts Recording & system checks	• Weekly check • Use normal protocol on a pillow (dummy) • Blocked stimulus run and compare to a normal waveform • If artefactual response are observed: determine source – contact manufactures	Low	Strong	23	Observational study

Research needs

There is a need to conduct randomized controlled trials (RCTs) to determine the efficacy of the short statement versus the full array of ABR testing.
There is a need to conduct RCTs for verification of the efficacy of ABR testing guidelines.

Monitoring and evaluating the impact of the guideline

Monitoring/ Auditing Criteria: to assess guideline implementation or adherence to recommendations.
Clinicians should be able to:

- Acquire a full history from the patient or parents.
- Ensure the acquisition of a two frequency audiogram (low frequency tone burst and high frequency click).
- Ensure the acquisition of two fence intensity regions (low intensity at 30 dBnHL and a higher fence at 60 dBnHL).
- Inform the parents with outcome of ABR test and the follow up needed.
- Give advice on measures needed if hearing loss was reported and the need for repetition at 3 and 6 months of age.

Updating of the guideline

Updating Procedure:
Any recommendation of this guideline will be updated when new evidence that could potentially impact the current evidence base for this recommendation is identified. If no new reports or information are identified for a particular recommendation, the recommendation will be revalidated. The focus will be on recommendations supported by very-low- or low certainty evidence and where new recommendations or a change in the published recommendations may be needed.

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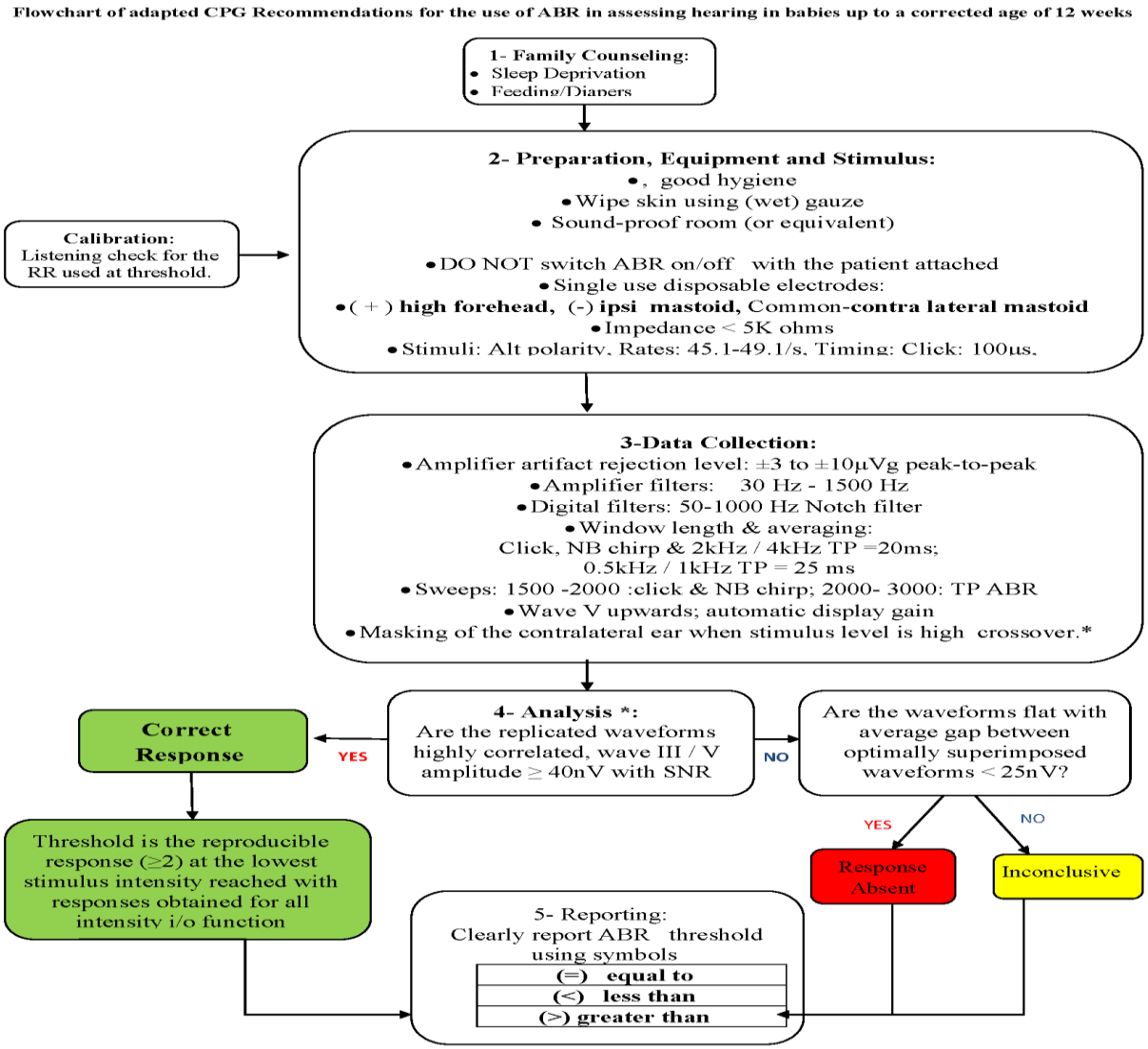
Annexes

Editorial Independence:

- This guideline was developed without any external funding.
- All the guideline development group members have declared that they do not have any competing interests.

Annex 1: Guideline Flowchart



Annex 2: <u>Tables of appraisal of selected guidelines:</u> Currency (table 1), Content (table 2) and Quality (table 3) of the selected guidelines.

Table 1 Currency

No.	Guideline Name	Year of Publication	The Organization	Age Demography
1	Threshold estimation by the tone evoked auditory brainstem response: A literature meta-analysis	2000	Canadian Journal of Speech-Language Pathology and Audiology BY University of British Columbia	Adult and infant/ child
2	Practice guidelines: Principles of external peer review of auditory electrophysiologic measurements	2018	British Society of Audiology	Newborn
3	Guidelines 9C: Recommended standards for Short latency auditory evoked potentials: American neurophysiological guidelines	2008	American Clinical Neurophysiology Society	Adult, neonates, infants and children
4	Recommended Procedure: Auditory Brainstem Response (ABR) Testing in Babies	2019	British Society of Audiology	Newborn
5	Year 2019 Position Statement: Principles And Guidelines For Early Hearing Detection And Intervention Programs	2019	The Joined Committee On Infant Hearing	Infants
6	Guidelines for the early audiological assessment and management of babies referred from the Newborn Hearing Screening Program: Version 3.1	2013	The UK NHC and NHS screening programs	Newborns

Table 2 Content

	Guideline 1 British Columbia 2000	Guideline 2 BSA 2018	Guideline 3 American Clinical Neurophysiology Society 2008	Guideline 4 BSA 2019	Guideline 5 JCIH 2019	Guideline 6 NHSP 2013
Credibility	7	8	7	9	8	8
Observability	7	8	8	9	8	8
Relevance	8	6	8	9	8	8
Relative advantage	8	8	7	9	8	7
Easy to install and understand	7	7	8	9	8	8
Compatibility	7	8	7	9	8	7
Testability	8	5	7	9	8	8
Total score	48	50	48	72	64	54

Table 3 Quality

Domain	Guideline 1 British Columbia 2000	Guideline 2 BSA 2018	Guideline 3 American Clinical Neurophysiology Society 2008	Guideline 4 BSA 2019	Guideline 5 JCIH 2019	Guideline 6 NHSP 2013
Transparency	A	A	A	A	A	A
Conflict of interest	B	A	NR	A	B	A
Development group	A	A	B	A	A	A
Systematic review	A	B	C	A	A	A
Grading of evidence	B	A	B	A	B	B
Recommendations	A	A	A	A	A	A
External review	B	B	C	A	A	B
Updating	C	A	C	A	A	B

Annex 3: The risks and benefits of added and/or modified statements

The statement to be adapted: action	**Benefits**	**Risk/Harm**
Skin should be gently wiped with (wet) gauze , abrasions avoided	No possibility of skin injury or skin reaction	No risk or harm
Sleep deprivation, feeding, Diaper change in most situations will lead to natural sleep and lessen activity	No possible complications from sedatives No special or additional safety precautions needed	No risk or harm
Thresholds should be measured for at least two frequency audiometric regions: Low frequency thresholds using 0.5khz High frequency thresholds using TP or TB 2 or 4 khz or clicks	Allows low & high frequency threshold assessment for two region audiometric representation Reduces test time	No harm Potential risk of missing mid frequency HL
Criteria for ABR response & threshold: 1-Reproducibilty of at least two response traces: visual and graphic 2-Reproducibility of responses for all intensity i/o function 3-Threshold is the reproducible response at the lowest stimulus intensity reached	Simplified criteria Matches all response descriptions in the selected guideline Lessens confusion Allows clear , easy & unified reporting of results	No harm or risk
Clinician listening check for the RR used at threshold. Reference dBSPLpe/ eq if and when feasible	Psychoacoustic calibration control is feasible and easy and can be routinely done	No harm or risk