INTERGROWTH-21st

International Fetal and Newborn Growth Standards for the 21st Century

The International Fetal and Newborn Growth Consortium

THE INTERGROWTH-21st NEURODEVELOPMENT PACKAGE STANDARDISATION PROTOCOL

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UNIVERSITY OF OXFORD

The INTERGROWTH-21st Project is a large, longitudinal study involving health institutions from eight geographically diverse countries. It is essential that the participating institutions follow the same data collection procedures. This protocol is designed to inform all staff involved in the neurodevelopment component of the INTERGROWTH-21st Project about the procedures for the standardisation of local assessors.

Please read this protocol carefully and refer to it throughout the study for clarification.

Abbreviations

INTER-NDA	The INTERGROWTH-21st Project Neurodevelopment Assessment
EEG	Electroencephalography
CU	The INTERGROWTH-21st Coordinating Unit

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CREDITS

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INTRODUCTION

The primary aim of the neurodevelopment component of the INTERGROWTH-21st Project is to profile multiple domains of neurodevelopment in a population of children aged 24 months, from five geographically diverse countries (Brazil, India, Italy, Kenya and the UK). For this purpose, the INTERGROWTH-21st Neurodevelopment Package was designed. The package consists of four tests that measure vision (Cardiff tests); cognition, language skills, behaviour, motor skills, attention and emotional reactivity (The INTERGROWTH-21st Project Neurodevelopment Assessment, INTER-NDA); cortical auditory processing (auditory evoked response potentials to a novelty oddball paradigm); and sleep (actigraphy and a sleep questionnaire adapted from the Brief Infant Sleep Questionnaire).[1-5]

It is essential that the neurodevelopment data collected in the tests are of the highest quality and minimally influenced by external sources of variation. The implementation of the procedures needs to be internally consistent, within and between the multiple study sites.[6] This is achieved by the standardisation of all neurodevelopment assessment procedures and equipment, which leads to maximal reliability of the child neurodevelopment indicators.[6]

Assessors were trained in the INTERGROWTH-21st Neurodevelopment Package and supplied with standardised kits, data collection devices (including the 'NeuroApp' tablet based application with integrated quality checks) and detailed operation manuals for the vision, neuropsychological, sleep and hearing assessments.[2, 3, 7-9] The training was conducted by the study coordinator following a standardised 3½ day training session. The present document describes the standardisation procedures that will be used to determine each individual neurodevelopment assessor's adherence to the protocols in the manuals.

CONCEPTUAL ISSUES

Data collection is a complex process that can be affected by the interaction of many different factors such as variation within the study subject unrelated to neurodevelopment (e.g. fatigue, hunger, etc.), and their mood or level of agitation during the assessment.[6] Moreover, if the parents are unsettled about a procedure, they may become unwilling to continue the assessment or cooperate fully. In all cases, cultural and individual sensitivities to a child's

crying and needs should be appreciated and considered when deciding how far to persist when a child is agitated.(6)

Data collection is also influenced by the setting in which the assessment is made, the accuracy and precision of the instruments used, and the method of data recording (reading and writing down), data control, data entry and data transformations before analysis. Finally, another crucial variable is the assessor; their technical abilities (i.e. language fluency, experience and reliability) will also affect the quality of the data collected.(6)

Reliability Assessment

The reliability of the data collected is determined by the accuracy and precision of the tests used, and the assessor conducting them.(6)

Accuracy

An assessor is deemed accurate if they obtain scores (with a standardised kit and administration protocol) that are consistently close to the true score. Inaccuracy (bias) occurs if there is a tendency to record scores that are consistently higher (positively biased) or consistently lower (negatively biased) than the true score. A problem with neurodevelopment assessment, as with all measurements, is that the actual or true score is unknown. For this reason, all assessors are trained to obtain scores that are as similar as possible to the scores of a single, experienced, independent, external assessor. Bias is identified by calculating the difference between the external assessor's (hereafter referred to as the "gold standard") and the local assessor's scores.(6)

Precision

Precision can be determined in a test-retest study. A child is tested under similar conditions (same standardised kit and administration protocol) by the same assessor on two distinct occasions separated by an interval within which the child's abilities have not developed further. The differences between paired scores are quantified. An assessor is precise if, after reassessing the same child, the scores recorded are similar and do not vary widely. Perfect precision means the second assessment will result in the same scores as the first. The less precise, the larger the difference between the scores of the duplicate assessments.(6)

Precision is independent of whether the scores measured are close or not to the true score, and thus independent of accuracy. For example, if in a test-retest of an INTER-NDA item assessing a child's cognitive skills, an assessor, when scoring the child's capacity to put a spoon in a cup (INTER-NDA Item 5), forgets on both occasions to direct the objects towards the child, the child might be scored twice as 'looks confused' (response 4), thus being precise (same score) but inaccurate (not reflective of true cognitive ability).

Standardisation of Local Assessors

The standardisation of the neurodevelopment assessors is important to ensure comparability across assessors and sites. It is essential that assessors make accurate and precise assessments that yield repeatable and reproducible scores.

The neurodevelopment assessment can be divided into two aspects: (i) the administration, which comprises the correct application of the assessment items according to the instructions presented in the manuals, and (ii) the scoring, which consists of correctly evaluating and scoring the child's performance during the assessment.[2, 3, 7-9] The standardisation process must evaluate the two aspects separately to ensure the assessment is executed properly. The gold standard will visit the five study sites in order to evaluate, using the procedure described in this document, if the assessors are (i) following the standards of administration as per protocol, and (ii) scoring the children consistently, in accordance with the neurodevelopment manuals.[2, 3, 7-9]

The INTER-NDA will be evaluated in full, however, because the EEG, the actigraphy, the sleep questionnaire and the Cardiff test are already standardised measures, the gold standard will only evaluate the administration of these tests, using the Protocol Adherence Checklist (Appendix).[1, 4, 5, 10-14]

The assessments are conducted in the local language of the site and following, as closely as possible, the cultural values of the parents.

Consideration of the workload and levels of fatigue of individual, local assessors may be necessary if the standardisation process reveals that an assessor repeatedly differs from the gold standard. Retraining is also recommended in this instance. If this is unsuccessful in

improving the quality of the assessments to the required standards, an alternative assessor should be sought.

STANDARDISATION PROTOCOL

Site requirements

I. The Infant Development Coordinator and the Coordinating Unit (CU) will select the two most active assessors in each site (based on database entries) to be standardised.

II. The standardisation process will take place in the room where the neurodevelopment assessment is normally carried out, using the INTER-NDA kit and tablet-based application for neurodevelopment data collection (NeuroApp).

III. The gold standard will have:

- Two additional tablets with the NeuroApp (one for the gold standard and another for use by a local assessor).
- Printed copies of the Standardisation Protocol and the Protocol Adherence Checklist (Appendix).
- A video camera.

IV. Each site will recruit, in advance, three children aged 24 months (± 2 months) per local assessor, and three additional children aged 24 months (± 2 months) for the gold standard to assess according to the protocol in the presence of the selected local assessors, providing a total of nine children. All children will be recruited independently of the INTERGROWTH-21st sample, as the scores will only be used for the purpose of the standardisation and not for INTERGROWTH-21st related analysis or any clinical assessment.

Standardisation Process

The standardisation procedure will be conducted in two phases:

Phase I

The purpose of Phase I is to determine if the assessors' administration skills are in accordance with the protocol, using the Protocol Adherence Checklist (Appendix). Phase I will also be used as part of the scoring assessment of the INTER-NDA, by comparing the scores obtained by one assessor during two identical INTER-NDA assessments. For this to be possible, each assessor will be recorded while performing the INTER-NDA. The recordings will be watched and scored by the assessor and the gold standard. The assessor's scores will also be compared to the gold standard's scores. These comparisons allow the estimation of the test-retest (precision) and inter-observer (accuracy) reliabilities.

Phase I will take 2 days to complete and will be carried out at each site as follows:

A. Day 1, morning:

1. The gold standard will observe as the first local assessor (Assessor 1) administers the Neurodevelopment Package to the first child (1.1). Ensure each assessment is recorded.

    i. Assessor and gold standard: enter the biographical data of the child, including their unique study ID number, date of birth and the date of assessment, into the NeuroApp. Enter your researcher number into the field called '*Researcher Code 1*'. The field '*Researcher Code 2*' is used to indicate the phase of the standardisation procedure (not the second assessor number), therefore enter '01' into this field.

    ii. Gold standard: check that the biographical data entered by the assessor into the NeuroApp is correct before proceeding to step iii below.

    iii. The administration of the whole Neurodevelopment Package will take 45 minutes per assessor. Conduct the tests in the following order:

a. Cardiff test
b. INTER-NDA
c. Sleep watch instructions (no sleep watch will be given)
d. Sleep questionnaire
e. EEG

iv. Assessor: administer each test in front of the gold standard and enter the child's scores into the NeuroApp on the local tablet (Figure 1).

v. Gold standard: evaluate the assessor's administration using the Protocol Adherence Checklist (Appendix). At the same time as the assessor, score the child and enter their scores onto a CU tablet. This will allow the comparison of the gold standard's and assessor's scores.

2. Break for 1 hour: allow 15 minutes to clean and reset the room, and 45 minutes for a break.
3. The gold standard will then observe the second local assessor (Assessor 2), following the same procedure but with a different child (2.1).

B. Day 1, afternoon:

1. The gold standard will observe as Assessor 1 administers the Neurodevelopmental Package to the second child (1.2). Follow the same procedure as described above.
2. Break for 1 hour: allow 15 minutes to clean and reset the room, and 45 minutes for a break.
3. The gold standard will observe as Assessor 2 administers the Neurodevelopmental Package to the second child (2.2).

C. Day 2, morning:

1. The gold standard will observe as Assessor 1 administers the Neurodevelopmental Package to the third child (1.3).

2. Break for 1 hour: allow 15 minutes to clean and reset the room, and 45 minutes for a break.
3. The gold standard will observe as Assessor 2 administers the Neurodevelopmental Package to the third child (2.3).

Figure 1. Setting of Phase I, first part. The gold standard observes and records the assessor and both enter the child's scores, simultaneously, into the NeuroApp on their tablet.

D. Day 2, afternoon:

1. Each assessor will, independently, watch the recordings of the three assessments they performed. This will allow the estimation of the test-retest reliability.
    i. Assessors and gold standard: enter the biographical data of the child, including their unique study ID number, date of birth and the date of assessment, into the NeuroApp. Enter your researcher number into the field called '*Researcher Code 1*'. The field '*Researcher Code 2*' is used to indicate the phase of the standardisation procedure (not the second assessor number), therefore enter '01' into this field.
    ii. Gold standard: check that the biographical data entered by the assessors into the NeuroApp is correct before proceeding to step iii.

iii. The three videos will last 1 hour (approximately 20 minutes per video) and will be presented as follows:

   a. 1st child assessed
   b. 2nd child assessed
   c. 3rd child assessed

iv. Assessors: score each child again and enter the scores into the NeuroApp (Figure 2).

v. Gold standard: watch each video independently of the assessors (six videos in total), score the child and enter the data into the NeuroApp. This will allow the estimation of inter-observer reliability.

vi. Assessors and gold standard: when prompted, mark the Cardiff test, sleep questionnaire and EEG test as 'not completed' on the NeuroApp.

Figure 2. Setting of Phase I, second part. The local assessors watch the videos of the assessments they performed, score the child again, and enter the scores into the NeuroApp on their tablet.

Phase II

The purpose of Phase II is to determine the scoring skills of both assessors, by comparing their INTER-NDA scores with the gold standard's scores. These comparisons allow the estimation of the inter-observer reliability (accuracy). Phase II will include only the INTER-NDA part of the Neurodevelopment Package, will last 1 day and will involve the three additional children recruited especially for this phase.

This will be carried out at each site in the following steps;

A. Day 3, morning:

1. The gold standard will administer the INTER-NDA to the first child (GS.1) in the presence of the two local assessors (Figure 3).

    i. Assessors and gold standard: enter the biographical data of the child, including their unique study ID number, date of birth and the date of assessment, into the NeuroApp. Enter your researcher number into the field called '*Researcher Code 1*'. The field '*Researcher Code 2*' is used to indicate the phase of the standardisation procedure (not the second assessor number), therefore enter '02' into this field. One assessor can use the local site tablet, and the other assessor can use the tablet provided by the CU for the standardisation.

    ii. Gold standard: check that the biographical data entered by the assessors into the NeuroApp is correct before proceeding to step iii.

    iii. Assessors and gold standard: enter the child's scores into the NeuroApp.

2. Break for 1 hour: allow 15 minutes to clean and reset the room, and 45 minutes for a break.
3. The gold standard will then administer the INTER-NDA to the second child (GS.2), and all will score the child following the same procedure.

B. Day 3, afternoon:

1. The gold standard will administer the INTER-NDA to the third child (GS.3), and all will score the child following the same procedure.

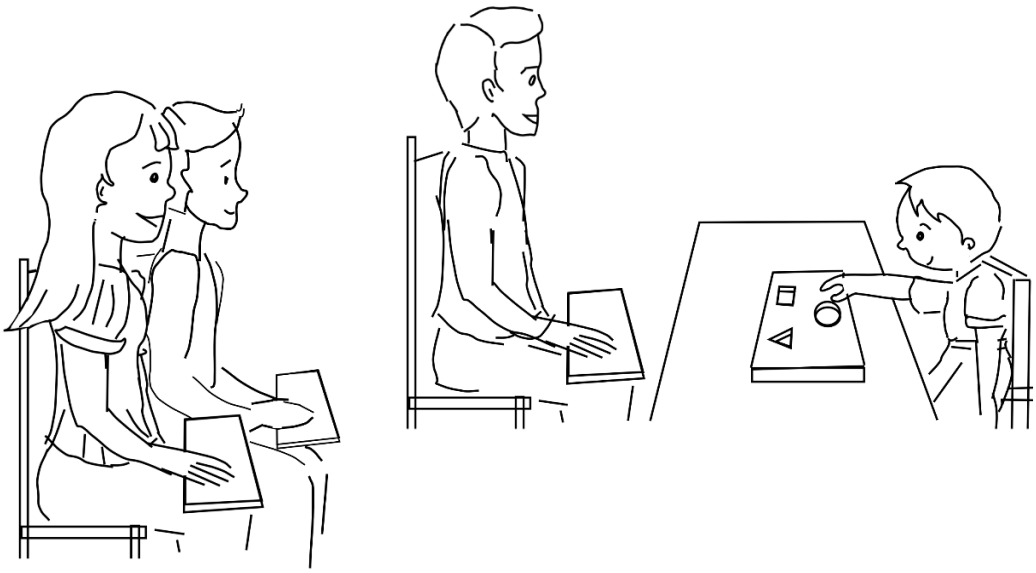

Figure 3. Setting of Phase II. The local assessors observe the gold standard, and all enter the child's scores, simultaneously, into the NeuroApp on their tablet.

DATA MANAGEMENT

The existing neurodevelopment database will be modified to incorporate multiple INTER-NDA data from a single child. These data will be stored separately from the INTER-NDA data obtained during the follow-up of the children involved in the FGLS study who have only one INTER-NDA entry per child. Each participant will be coded with a unique six digit identification number that will allow discrimination between (i) the child (ii) the country in which the standardisation is taking place, and (iii) whether the assessment is the first or the second of the same child.

All participants will be coded with a study number beginning by '99'. This number will serve as a marker to identify that the child is part of the standardisation study and not the FGLS follow-up. This means the results will be sent to the NDA Standardisation database and not the NDA FGLS database. The third digit will be either '1' or '2', depending on whether this is the first or second assessment of the child. Please note that the children in Phase I will be

assessed twice whereas the children in Phase II will only be assessed once. The standardisation phases are indicated in the '*Researcher Code 2*' field in the NeuroApp (instructions on page 18). The fourth digit will always be '0'. The fifth and sixth digits will be unique to each child in the standardisation study and are ordered depending on the country in which the standardisation occurred, i.e. numbers 01 to 19 will be assigned to children based in the UK, 20 to 39 will represent children based in Italy, 40 to 59 for the children in India, 60 to 79 for the children in Kenya, and finally, 80 to 99 will represent the children based in Brazil. Each child will participate in either Phase I or Phase II, not both. For example:

- 99-1002 and 99-2002: these correspond to the first and second INTER-NDA assessments of participant 02 based in the UK and participating in Phase I of the standardisation (i.e. only Phase I involves two assessments of the same child, producing two study numbers per child).

- 99-1060 and 99-2060: these correspond to the first and second INTER-NDA assessments of participant 60 based in Kenya and participating in Phase I of the standardisation.

- 99-1041: this corresponds to the assessment of participant 41 based in India and participating in Phase II of the standardisation (i.e. Phase II has one assessment, producing only one study number per child).

The participant study number together with '*Researcher Code 2*' field will be used to identify the assessments. As shown in the examples above, children participating in Phase I will be allocated two study numbers which will differ only by the third digit (assessment '1' or '2'), and these will be linked with two '*Researcher Code 1*' numbers, representing the two assessors scoring the child. Hence, for every child in Phase I, there will be four entries in the database (Table 1).

Table 1. Database format for Phase I.

Child No. 1	**Assessment 1**	**Assessment 2**
Researcher	Database entry 1 (Researcher 1, Child 1, Assessment 1)	Database entry 2 (Researcher 1, Child 1, Assessment 2)
Gold Standard	Database entry 3 (Gold Standard, Child 1, Assessment 1)	Database entry 4 (Gold Standard, Child 1, Assessment 2)

The third digit of the study number assigned to Phase II participants will always be '1' since there is only one assessment per child in this phase. The study number will be linked to three '*Researcher Code 1*' numbers, representing the three assessors scoring the child. Hence, for every child in Phase II, there will be three entries in the database (Table 2).

Table 2. Database format for Phase II.

Child No. 1	**Assessment 1**
Researcher 1	Database entry 1 (Researcher 1, Child 1, Assessment 1)
Researcher 2	Database entry 2 (Researcher 2, Child 1, Assessment 1)
Gold Standard	Database entry 3 (Gold Standard, Child 1, Assessment 1)

The assessor will enter the following details into the biography page of the NeuroApp:

- *FGLS Number*: the participant study number.
- *Date of birth*: the date of birth of the child.
- *Date of assessment*: the date on which the assessment is being performed.
- *Researcher Code 1*: the assessor's researcher number.
- *Researcher Code 2*: the phase of the experiment, i.e. Phase I or II, as '01' or '02', respectively.

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Appendix: The Protocol Adherence Checklist

The INTERGROWTH-21st Project
Neurodevelopment Assessment Package

Protocol Adherence Checklist

NDA-PAC

Participant ID No.	☐☐ - ☐☐☐☐☐	**Researcher code: Expert**	☐☐
Child Date of Birth	D D M M Y Y	**Researcher code: Assessor**	☐☐
Visit Date	D D M M Y Y		

Please rate the performance of the assessor in adhering to the INTERGROWTH-21st Neurodevelopment Assessment Protocol during the administration of the following items. For the purpose of this exercise, complete adherence is defined as adherence to all aspects of the protocol as stated in the operation manual of the INTER-NDA; partial adherence is defined as adherence to half or more aspects, but not all aspects, of the protocol as stated in the operation manual of the INTER-NDA and limited adherence is defined as adherence to less than half of the aspects of the protocol as stated in the operation manual of the INTER-NDA as adjudged by the expert assessor.

I. Cardiff Tests of Vision

	Visual acuity			Contrast sensitivity		
	Complete adherence	Partial adherence	Limited adherence	Complete adherence	Partial adherence	Limited adherence
1. Explaining procedure & cautioning mother against pointing to pictures	☐	☐	☐	☐	☐	☐
2. Child at 50 cms	☐	☐	☐	☐	☐	☐
3. Child & assessor's eyes at same level	☐	☐	☐	☐	☐	☐
4. Presentation of cards correctly	☐	☐	☐	☐	☐	☐
5. Presentation of cards quickly	☐	☐	☐	☐	☐	☐
6. If 2/2 correct moves to next level	☐	☐	☐	☐	☐	☐
7. If 1/2 correct, repeats level	☐	☐	☐	☐	☐	☐
8. If 0/2 correct, drops level	☐	☐	☐	☐	☐	☐

II. Measurement of Cortical Auditory Processing

	Complete adherence	Partial adherence	Limited adherence
1. Correct placement of 8 electrodes & front ends	☐	☐	☐
2. Correct & complete set-up and pre-checks	☐	☐	☐
3. Explaining procedure to mother & child	☐	☐	☐
4. Correct placement of cap	☐	☐	☐
5. Placement of reference electrodes on mastoid	☐	☐	☐
6. Checking signals & adjusting electrodes if necessary	☐	☐	☐
7. Motivating child to keep cap on	☐	☐	☐

III. Sleep Assessment

1. Administration of sleep questions	☐	☐	☐
2. Set up of sleep watch	☐	☐	☐
3. Correct instructions to mother regarding sleep watch	☐	☐	☐

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Participant ID No. ☐☐ - ☐☐☐☐☐ **Researcher code: Expert** ☐☐

Child Date of Birth D D M M Y Y **Researcher code: Assessor** ☐☐

Visit Date D D M M Y Y

Please rate the performance of the assessor in adhering to the INTERGROWTH-21st Neurodevelopment Assessment Protocol during the administration of the following items. For the purpose of this exercise, complete adherence is defined as adherence to all aspects of the protocol as stated in the operation manual of the INTER-NDA; partial adherence is defined as adherence to half or more aspects, but not all aspects, of the protocol as stated in the operation manual of the INTER-NDA and limited adherence is defined as adherence to less than half of the aspects of the protocol as stated in the operation manual of the INTER-NDA as adjudged by the expert assessor.

IV. The INTER-NDA

	Complete adherence	Partial adherence	Limited adherence
1. Item 1 - uses 5 red cubes, 3 trials, demonstration before each trial			
2. Item 2 - 4 cubes of different colours placed in a line, assessor does not name colours, 1 trial			
3. Item 3 - 1 demonstration, 1 trial, conceptually correct scoring (stacking & pointing accepted)			
4. Item 4 - holds hand out for 5 seconds			
5. Item 5 - correct placement of objects - handles facing child, cup & spoon not adjacent, 5 trials			
6. Item 6 - 5 trials, no demonstration, shapes near child, holds board, puts shapes back discretely			
7. Item 7 - 5 trials, no demonstration, shapes near child, rotates board on table, holds board			
8. Item 9 - 1 demonstration, 1 trial, tests both hands			
9. Item 11 - 5 trials, no demonstration, relatively slow pointing movement so child can follow			
10. Item 12 - allows time for self-symbolic play before suggestion & demonstration			
11. Item 13 - 2 trials, demonstrate if not spontaneous, involve mother if necessary			
12. Item 14 - 2 trials, demonstrate if not spontaneous, involve mother if necessary			
13. Item 15 - 5 trials, demonstration before each trial, start at upper part of paper			
14. Item 16 - 5 trials, displaces bracelet relatively slowly, tests both sides			
15. Item 20 - 1 demonstration, 1 trial, tests both hands			
16. Item 30 - uses opportunities during assessment, uses culturally appropriate combinations, informs mothers about purpose & rationale of item			
17. Assessor's interaction with the child (good verbal & nonverbal communication, sets child at ease, builds rapport, accomodates needs of the child)			
18. Assessor's interaction with the mother/caregiver (explains tests, builds rapport, involves mother in testing providing instructions to prevent compromising test)			

Name of expert researcher	
Signature	