

SOP: 2-year follow up visit – Bayley and medical examination

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Please read the appendix to make sure that you have all the information required in the eCRF.

1.0 SafeBoosC, Bayley and medical examination

At 2 years of corrected age, the development of the child must be assessed with the Bayley Scales of Infant and Toddler Development (Bayley-II or III) and a medical examination.

The SafeBoosC accepts Bayley II and III but each centre must use only one version.

1.1 Who should be assessed?

All infants who are alive at corrected age 23-25 months

If the parents are unable to attend the SafeBoosC follow-up clinic an attempt should be made to assess the child in her/his home environment.

Importantly, a child whose test was started but not completed successfully because

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of behaviour problems, fatigue or an acute illness should be re-booked 2 months later.

1.2 When should the child be assessed?

- All children should be invited to the follow-up visit as soon as possible after (but not before) the child reaches a corrected age of 23 months. (This is to ensure that a potentially required second appointment can be arranged as soon as possible).
- If, despite best efforts, a centre cannot complete an assessment by the end of the 25th month, attempts to locate and test the child should continue. **We prefer to have a late assessment than to have no assessment at all.**

2.0 Bayley assessment

The test should be conducted as described in details in the Bayley II or III manual.

If the child has no obvious developmental delay, the examiner should use the child's corrected age to select the initial item set.

If cognitive delay is suspected, the examiner should use clinical judgment when selecting the initial item set.

2.1 Bayley II

For the second edition of Bayley we ask for Mental Developmental Index (MDI) and Psychomotor Developmental Index (PDI)

The scoring index for each item should be calculated as described in the manual.

Keep the original Bayley records on site.

2.2 Bayley III

For the third edition of Bayley we ask for Cognitive Developmental Index (CDI), Language Developmental Index (LDI), and Motor Developmental Index (MDI).

The scoring index for each item should be calculated as described in the manual.

Keep the original Bayley records on site.

2.3 What if the child cannot be assessed because of impairment?

If for some reason a full Bayley cannot be conducted we kindly ask you to give the mental developmental index (MDI for Bayley II), Cognitive developmental index and language developmental index (CDI and LDI for Bayley III) highest priority.

If the child cannot conduct one or more of the sections in the Bayley II or III because of impairment they should receive a score of 48 – and a comment should be included in the eCRF.

2.4 What if the child cannot be assessed because of other reasons?

A new visit should be offered if the child fails to conduct the whole or part of the Bayley or medical examination due to fatigue, acute illness or other reasons).

If the parents do not want to come again, they should be offered a home visit. If they do not want this either – a note stating why the different parts of the Bayley and medical examination was not performed.

3.0 The medical examination

The medical examination should always take place after the Bayley test.

The items in this section is based on *Report of a BAPM/RCPCH Working Group*

Classification of health status at 2 years as a perinatal outcome

Version 1.0; 8 January 2008

3.1 Basic growth measurements

The child is weighed (kg) and the height (cm) and head circumference (cm) is measured.

3.2 Auditive function

This evaluation is based on information from the parents and observation of the child. The impairment is categorized in two sections.

- 1) Severe hearing impairment – not corrected by hearing aids
- 2) Hearing impairment that can be corrected by hearing aids

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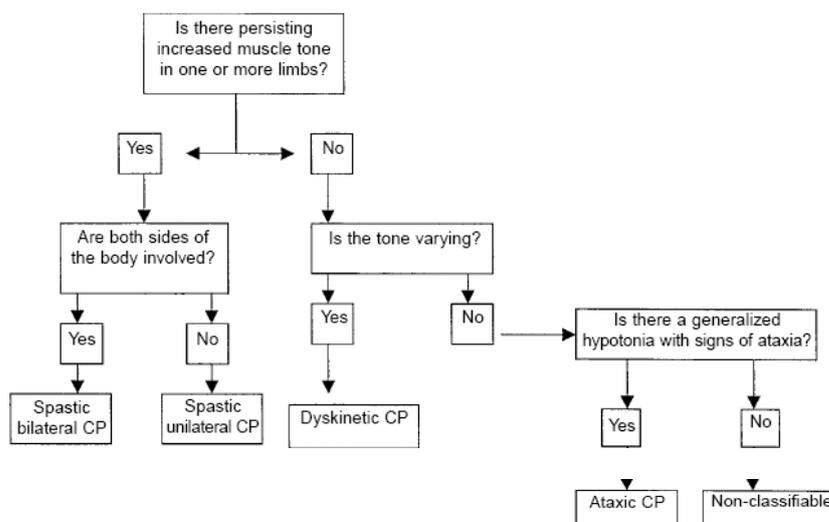
3.3 Vision

This evaluation is based on information from the parents and observation of the child. Impairment is categorized in two sections.

- 1) Severe visual impairment: blind or can only perceive light or light reflecting objects (– usually this will equate to a legal definition of “blind”).
- 2) Visual impairment: moderately reduced vision but better than severe visual impairment.

3.4 Gross motor function – assessment of CP and GMFCS-level

Cerebral palsy is diagnosed if the child had a nonprogressive motor impairment characterized by abnormal muscle tone and decreased range or control of movements. The cerebral palsy must be categorized according to the figure below.



Surveillance of Cerebral Palsy: a European Collaboration *SCPE*

GMFCS-level

If the child has CP, the GMFCS-level must be categorized according to the 5 levels below.

- Level 1 Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk between 18 months and 2 years of age without the need for any assistive mobility device
- Level 2 Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees. Infants may pull to stand and take steps holding on to furniture

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- Level 3 Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs
- Level 4 Infants have head control but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone
- Level 5 Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll

4.0 Children who do not show up for the 2 year follow up visit

For children who do not want to participate or do not show up at the scheduled 2 year follow up visit, we ask for a categorization of the neurodevelopmental status based on best available information (informal observation, parental information, or medical records). The categories are:

- No neurodevelopmental impairment
- Mild neurodevelopmental impairment
- Moderate neurodevelopmental impairment
- Severe neurodevelopmental impairment

or

- `no impairment´ based on the best available information.

Lost to follow up should only be checked in the eCRF, if it is impossible to reach contact with the parents and if the medical record does not contain the information mentioned above.

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Appendix A: Information required in the eCRF

Bayley		
The child was assessed with the Bayley test	Yes	*No
*If no Why not	Comment	
Date of the Bayley test	Date	
Bayley edition	II III	If Bayley II go to Bayley II score If Bayley III go to Bayley III score

Bayley II score	
PDI If the child did not complete the sub item because of Impairment score=48. If the test was not completed due to other reasons score must be 999. Always comment if you score 999 or 48!	Number Comment Number
MDI If the child did not complete the sub item because of Impairment score=48. If the test was not completed due to other reasons score must be 999. Always comment if you score 999 or 48!	Comment Number

Bayley III score	
Cognitive Index score If the child did not complete the sub item because of Impairment score=48. If the test was not completed due to other reasons score must be 999. Always comment if you score 999 or 48!	Number Comment Number
Language Index score If the child did not complete the sub item because of Impairment score=48. If the test was not completed due to other reasons score must be 999. Always comment if you score 999 or 48!	Comment Number
Motor Index score If the child did not complete the sub item because of Impairment score=48. If the test was not completed due to other reasons score must be 999. Always comment if you score 999 or 48!	Comment Number

Medical Examination

Basic growth measurements		
Head circumference	cm	
Height	cm	
Weight	kg	
Auditive function		
Does the child have any hearing impairment? *If yes	*Yes	No
Severe hearing impairment *If yes	*Yes	No
Can the hearing impairment be corrected with hearing aids	Yes	No
Vision		
Does the child have any visual impairment? *If yes	Yes*	No
Please check in one of the categorizes		
Severe visual impairment: Blind or can only perceive light or light reflecting objects (– Usually this will equate to a legal definition of “blind”).	X	
Moderate visual impairment: Moderately reduced vision but better than severe Visual impairment.	X	

Cerebral Palsy

Does the child have cerebral palsy? *If yes - please categorize and score	*Yes	No
GFMCS-level		
Spastic unilateral	X	
Spastic bilateral	X	
Dyskinetic	X	
Ataxic	X	
Non-classifiable	X	
GFMCS-level		
Gross motor function classification system	Number	(Limits 1-5)

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Children who do not show up for the 2-year follow up visit

The following information is based on: (Please add the Xs)	X X X	Parental information Medical records Informal observation
Only one X No neurodevelopmental impairment Mild neurodevelopmental impairment Moderate neurodevelopmental impairment Severe neurodevelopmental impairment or `No impairment` based on the best available information. Please give a reason for the chosen category	X X X X	X Comment
The child was lost to follow up This item should only be checked in the eCRF, if it is impossible to reach contact with the parents and the medical record does not contain the information mentioned above		X