INTERGROWTH-21st

International Fetal and Newborn Growth Standards for the 21st Century

The International Fetal and Newborn Growth Consortium



PREGNANCY AND DELIVERY FORM INSTRUCTIONS

September 2009



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General Guidelines

This form is to be completed upon delivery for:

- 1. All women in the Fetal Growth Longitudinal Study (FGLS).
- 2. All women giving birth in the institution during the 12 months of the Newborn Cross-Sectional Study (NCSS).

For women in FGLS:

- To ensure that this information is captured for all women in the FGLS study, please instruct participants as they near their estimated date of delivery (EDD) that they should inform the staff at the delivery hospital upon arrival. Provide all participants with the contact details of the local research coordinator. The staff at the delivery hospital should then make arrangements for the Pregnancy and Delivery form to be completed upon delivery. One way to ensure that staff can identify a woman in FGLS is to put a sticker in their medical notes.
- Please ensure that for all women taking part in FGLS, their unique study subject numbers are transcribed onto the Pregnancy and Delivery Form. This can be made easier by keeping a constantly-updated list of all women involved in the study and their study subject numbers on a clipboard within the delivery ward.
- In addition, the local research coordinator should visit the delivery ward(s) every day to check if any women from FGLS have delivered in the last 24 hours.

For Women in NCSS:

During the time period of NCSS, the local research coordinator should arrange for a member of staff to complete this form for every single woman who delivers in the hospital, regardless of characteristics or delivery outcome. ALL WOMEN WHO DELIVER IN THE HOSPITAL DURING THE NCSS TIME PERIOD ARE AUTOMATICALLY PART OF THIS STUDY AND SHOULD HAVE THIS FORM COMPLETED. This includes women who did not have an early dating scan.

General Points

Much of the information needed for this form can be collected from the medical records. The information that is not available in the records should be obtained by direct interview with the mother or the attending staff.

The anthropometric measurements of the infant (section 10) need to be taken as soon after birth as possible (preferably within 12 hours, and absolutely no later than 24 hours after birth) by an INTERGROWTH-trained anthropometrist, following the instructions in the anthropometry handbook and the advice given during training.

When completing the form:

- 1. A ballpoint pen should be used to complete the forms and the writing should be legible.
- 2. Do not write on the forms except in the white data boxes. Where there is the option, place a 'X' in boxes that correspond to your answer. Where values need to be written, please write numbers clearly.
- 3. If there is an error made in writing, it must be crossed out, and the correct answer written outside the box and initialed. Correction fluids should not be used.
- 4. The person completing the form should fill in his/her name, signature and the date at the bottom of each form.
- 5. After completion, the form should be given to the local research coordinator for data entry at regular periods (to be decided locally).
- 6. It is up to each institution to organize the local arrangements to operationalize this process.

Completing the form

Form Header

Study Subject Number	0	1]-[Study Hospital Code	0 1 -
Maternal Hospital Record Number							·	

The unique **Study Subject Number** should be pre-printed on each form. (This part is still under discussion)

Hospital Record Number. This number may be provided by the hospital and can be used if needed to help identify the woman.

Study Hospital Code. Please obtain this number from the local research coordinator.

Please answer all yes/no questions by placing an 'x' in the corresponding box							
2.	Is the woman part of the Fetal Growth Longitudinal Stu If yes, please obtain the Study Subject Number for Longitudinal Study and alert the study coordinator	the Fetal Growth					
Sectior	11: Demographic, socioeconomic and nutritional ch	aracteristics					
3.	Age						
4.	Maternal height (cm)		cm				
5.	1st trimester or pre-pregnancy weight (kg)		kg				
6.	Has she smoked/chewed tobacco during this pregnand	sy?	yes no				
	7. if she smoked cigarettes, how many per day?						
8.	Has she used any recreational drugs during this pregna	ancy?	yes no				
	Has she had 5 or more units of alcohol per week, on av (1 unit = small glass (125ml) of wine or one bottle/can (Has she been involved in any high risk occupation and	(330ml) of beer)					
	table) Has she followed any special diets during her pregnand programme, malabsorption treatment, gluten-free diet? <i>Country specific, see attached sheet</i>		mal products, weight loss yes no				
13.	Marital status (please cross one box only)	Single	Widowed				
		Married/Cohabiting	Separated/Divorced				
14.	Total number of years of formal education						
15.	. Highest level of education she attended? (please Primary Professional/ technical training						
	cross one box only)	Secondary	University				
16.	Which of the following best describes her occupational status? (please	Housework	Skilled manual work				
	The second se	professional/technical	Unskilled manual work				
	Clerical sup	port, service or sales	Other				

1. Is the woman part of the Fetal Growth Longitudinal Study?

Please confirm whether or not the woman was part of the Fetal Growth Longitudinal Study by placing an X in the appropriate box.

2. If yes, please obtain the Study Subject Number for the Fetal Growth Longitudinal Study (FGLS)

Important: If the woman has taken part in the INTERGROWTH-21st fetal longitudinal study (FGLS) she will have a unique study subject number for that study. This number must be found from the study records and written on this form. Without it we will not be able to link this form to her other data. To make this process easier, a clipboard can be kept in the

delivery wards which lists all women taking part in FGLS and their unique FGLS study subject numbers and dates of birth. This list should be updated at least once a month.

Section 1: Demographic, socioeconomic and nutritional characteristics

3. Age (years)

Write the age of the woman in years. You are to obtain her age in completed years; that is, the age at the time of her last birthday. If you are working from medical records, you may have to calculate the age from her date of birth.

4. Maternal height (cm)

Take the woman's height using the Adult Stadiometer (Seca 242 Digital Display).

Please follow the instructions in the Anthropometry Handbook, and adhere to the advice given during training sessions.

Write the woman's height in centimetres (cm) to 1 decimal place.

Example: a height of 152.8cm should be written as 152.8cm and not rounded up to 153cm.

5. 1st trimester or pre-pregnancy weight (kg)

Take the woman's first trimester weight from her medical record. If unavailable, ask the women her approximate weight before pregnancy. If she only knows her weight in lbs you will need to convert it into kilograms.

Write the woman's weight in kilograms (kg) to 1 decimal place. Example: a weight of 60.4kg should be written as 60.4kg, not rounded down to 60kg or up to 60.5kg.

6. Has she smoked or chewed tobacco during this pregnancy?

Place a 'X' in the box marked '**YES**' if the woman reports smoking cigarettes/cigars/shisha or chewing tobacco during her pregnancy.

Place a 'X' in the box marked 'NO' if the woman HAS NOT smoked/chewed to bacco during her pregnancy.

7. If she has smoked cigarettes, approximately how many cigarettes per day?

Write the average number of cigarettes that the woman smokes per day. If her smoking habits have changed during the pregnancy, write the maximum that she was smoking at any time point. For example, if she smoked 20/day for the first 5 months and then cut down to ten, write 20.

If she has chewed tobacco, write how many times per day.

For shisha, one puff = 1/2 cigarette. A whole pipe = 15

8. Has she used any recreational drugs during her pregnancy?

Recreational drugs include heroin, methadone, cocaine, amphetamines, hallucinogens, cannabis and benzodiazepines.

Place a 'X' in the box marked '**YES**' if the woman has used ANY of the recreational drugs listed during her pregnancy

Place a 'X' in the box marked 'NO' if she HAS NOT.

9. Has she had 5 or more units of alcohol per week since during her pregnancy?

One unit of alcohol is equivalent to a small glass (125ml) of wine, a bottle/can (330ml) of beer or a 25ml measure of whisky, gin, vodka, rum, pisco, tequila, schnapps, ouzo, baijiu or similar

Place a 'X' in the box marked '**YES**' if alcohol intake has been 5 or more units per week.

Place a 'X' in the box marked 'NO' if she HAS NOT been drinking more than 5 units per week since discovering she was pregnant.

10. Has she been involved in any high-risk occupation and/or vigorous or contact sports during her pregnancy?

Here is a list of possible high-risk activities:

Place a 'X' in the box marked '**YES**' if the woman was involved in any of the high-risk activities listed above during her pregnancy.

Place a 'X' in the box marked 'NO' if she DID NOT take part in ANY activity listed above during her pregnancy.

Frequent exposure to the following chemicals or toxic substances:	Physically demanding work:	High-risk sports/vigourous excercise:
Pesticides Lead or Mercury Solvents Petrochemicals Anaesthetic gases Tetrachloroethylene	More than 7 hours standing per day More than 50 hours work per week Work involving heavy lifting or very awkward postures	Sports that involve a high risk of abdominal trauma, falls or excessive joint stress (e.g. martial arts, rugby, long- distance running or cycling, weight-lifting) Women planning to do 1 hour of vigourous exercise more than 4 times per week into the 2 nd half of pregnancy

11. Has she followed any special diets during her pregnancy, e.g. vegetarian with no animal products, weight-loss reduction program, gluten-free diet?

Vegetarian with 'no animal products' is defined as a diet that does not include any of the following foods: meat, fish, milk, cheese, yoghurt, eggs, gelatine.

Simple vegetarianism (no meat or fish) does not constitute a special diet.

A gluten-free diet is defined as no wheat, oats, barley or rye products (bread, pasta, breakfast cereals etc.)

Place a 'X' in the box marked '**YES**' if the woman follows an extreme diet.

Place a 'X' in the box marked '**NO**' if the woman does not follow an extreme diet.

12. Socioeconomic Status (country-specific) Please ask this question as stated in the forms for your centre.

13. Marital Status

Cross only the ONE box that best applies to the woman.

Place an 'X' next to $\ensuremath{\text{Single}}$ If the woman has NEVER been married and does NOT live with a partner,

Place an 'X' next to **Married/cohabiting** if the woman is married or living with a partner

Place an 'X' next to **Widow** if the woman's partner has died.

Place an 'X' next to **Separated/divorced** if the woman HAS been married but is now separated or divorced and NOT living with another partner.

14. Total number of years of formal education

In the corresponding box, please enter the total number of years that the woman attended formal education (including primary school, secondary school, post school (college and university level) and any other intermediate levels in the formal school system). This definition of school does not include Bible or Koranic school or short courses like typing or sewing. However, it does include technical or vocational training beyond primary school level, such as long-term courses in mechanics or secretarial work. One year of part-time education = 0.5 years. Round up to the nearest whole year.

Example: If she attended primary school from age 5 to 11 (6 years) and then secondary school from age 11 to 16 (5 years) then her total number of years of formal education is 11.

15. Highest level of education she attended?

Cross the ONE box that best applies to the woman.

- Primary School (Age 5-11 or similar)
- Secondary School (Age 11-16 or 11-18 in some cases)
- Professional/technical training (Vocational training/qualification e.g. Plumber/ Electrician/ Teacher training)
- University (Undergraduate or postgraduate degree e.g. Ba/BSc/Ma/MSc/MD/PhD)

16. Which of the following best describes her occupational status?

Cross the ONE box that best applies to the woman.

See the occupational classification scheme in Appendix 1 for clarification as to which occupations fall under each category.

Section 2: Medical History

Section 2: Medical history									
Prior to this pregnancy was she diagnosed with or treated for any of the following medical conditions? (cross all that apply)									
17. Diabetes	yes	no	26.	Any hematologic condition including sickle-cell anaemia or leukaemia	yes	no			
18. Thyroid disease	yes	no	27.	Epilepsy	yes	no			
19. Other endocrinological conditions	yes	no	28.	HIV or AIDS	yes	no			
20. Cardiac disease	yes	no	29.	Malaria	yes	no			
21. Hypertension/chronic hypertension	yes	no	30.	Tuberculosis	yes	no			
22. Chronic respiratory disease (including chronic asthma)	yes	no	31.	Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition	yes	no			
23. Proteinuria, kidney disease or chroni renal disease	Cyes	no	32.	Any congenital abnormality	yes	no			
24. Any type of malignancy/cancer	yes	no	33.	Other clinically relevant condition	yes	no			
25. Lupus erythematosus	yes	no							

Prior to this pregnancy, had she ever been diagnosed with or treated for any of the following medical conditions?:

Cross all boxes that apply

- 17. Diabetes (any type)
- 18. **Thyroid Disease** (any type)
- 19. **Other endocrinological conditions** (examples Addison's disease, adrenal gland disorders, hypo- or hyper-thyroidism)
- 20. **Cardiac disease** (examples arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, pericarditis, cardiomyopathy etc.)
- 21. **Hypertension/chronic hypertension with treatment** (defined as 140/90 or greater. Include in this category women who have been treated for hypertension.)
- 22. Chronic respiratory diseases (including chronic asthma). Do not include childhood asthma that is no longer present or very mild cases/allergies.
- 23. **Proteinuria or kidney disease or chronic renal disease** (The presence of excessive protein substance, chiefly albumin, in the urine)

24. Any type of malignancy/cancer

- 25. Lupus Erythematosus (a chronic inflammatory collagen disease affecting connective tissue)
- 26. Any haematologic condition including sickle cell anaemia or leukaemia. (If a woman knows that she is a heterozygous carrier of the sickle cell trait, do not exclude her)
- 27. Epilepsy (any type)
- 28. HIV or AIDS
- 29. Malaria (any episode)
- 30. Tuberculosis
- 31. Crohn's disease, Coeliac disease or ulcerative colitus or any severe malapsorption condition
- 32. Any congential abnormality or genetic disease (examples cystic fibrosis, congenital heart defects. Do not include very mild abnormalities such as extra digits, skin tags, hare lips, colobomas).
- 33. Any other clinically relevant condition (any other significant medical or surgical problem judged by the attending staff as a serious condition requiring special care, that does not fall into one of the categories above)

Section 3: Gynaecological History

Section	3: Gynaecological history									
34.	. Did she have regular (24-32 day) menstrual cycles in the 3 months prior to her pregnancy?									
35.	35. Has she used hormonal contraceptives or been breastfeeding in the 2 months prior to her current pregnancy?									
36.	36. Was this pregnancy conceived with fertility treatment?									
37.	37. First day of the last menstrual period (LMP) Date D — M M —									
38.	Was she certain of her date of LMP?				yes	no				
39.	Date of the first ultrasound scan during this pregnancy	Date	D D -	MM	— Y	Y				
40.	40. What was the CRL(crown rump length) measurement at the first ultrasound scan?									
41.	What was the BPD(biparietal diameter) measurement at the first ultrasound sc	an?			$\overline{\Box}$.		nm			
42.	Estimated gestational age at the <u>first</u> ultrasound scan			V	Veeks	Pa	ays			

34. Did she have regular (24-32 day) menstrual cycles in the 3 months prior to this pregnancy?

Regular menstrual cycles are defined as 24-32 days between the first day of one menstrual period and the first day of the next menstrual period.

Place a 'X' in the box marked '**YES**' if she DID have regular cycles in the 3 months prior to her pregnancy.

Place a 'X' in the box marked 'NO' if she DID NOT have regular cycles in the 3 months prior to her pregnancy.

35. Did she use hormonal contraceptives or been breastfeeding in the 2 months prior to her pregnancy?

Place a 'X' in the box marked '**YES**' if she DID use hormonal contraception or breastfeed in the 2 months prior to this most recent pregnancy.

Place a 'X' in the box marked '**NO'** if she HAS NOT used hormonal contraceptives and/or been pregnant and/or breastfed in the in the 2 months prior to this most recent pregnancy.

36. Was her pregnancy conceived with fertility treatment?

Place a 'X' in the box marked '**YES**' if the woman conceived using ANY FORM of with fertility treatment, including ovulation stimulation injections or similar.

Place a 'X' in the box marked '**NO**' if she conceived naturally, without any form of fertility treatment, ovulation stimulation injections or similar.

37. First day of the last menstrual period (LMP)

dd-mm-yy, e.g. 20^{th} may 2010 = 20-05-10.

Use the laminated calendar as a memory aid to help the woman remember her LMP. Write the date in the corresponding box.

38. Was she certain of the date of the LMP?

Place a 'X' in the box marked '**YES**' if the woman is CERTAIN of the date on which she began her last menstrual period.

Place a 'X' in the box marked '**NO**' if she is NOT CERTAIN or expresses any doubt over this date.

39. Date of first ultrasound scan.

First ultrasound scan is defined as any obstetric ultrasound scan after 9 weeks. If the woman had an ultrasound scan earlier than 9 weeks, take the first scan as being the first scan after 9 weeks gestation. From the notes, write down the date of the woman's first ultrasound scan (if applicable) in the format dd/mm/yy, e.g. 20^{th} May 2010 = 20/05/10. If the woman has not had an ultrasound scan during this pregnany, leave this box blank.

40. What was the CRL (Crown Rump Length) measurement at the first ultrasound?

Obtain this measurement form the medical record or ultrasonographer's notes. Enter the CRL measurement in millimeters. If this information is not available, for example if the woman did not have an early dating scan, please leave the boxes blank.

41. What was the BPD (Biparietal Diameter) measurement at the first ultrasound?

Obtain this measurement form the medical record or ultrasonographer's notes. Enter the BPD measurement in millimeters. If this information is not available, for example if only the CRL was measured at the first scan, please leave the boxes blank.

42. Estimated gestational age from <u>first</u> ultrasound scan.

From the notes, write down the gestational age estimated **by CRL in weeks and days** at the woman's first ultrasound (dating) scan. If the woman has not had an ultrasound scan during this pregnancy, leave this box blank.

Section 4: Obstetric History

Section 4: Obstetric history						
43. Number of previous pregnancies, excluding the present pregnancy (if 0, skip to Section 5)						
44. Have her last two pregnancies before this one ended in miscarriage?	yes no					
45. How many previous births has she had, excluding this birth (if 0, skip to Section 5)?						
46. Have ANY of her other babies weighed less than 2.5kg or more than 4.5kg?	yes no					
47. Have ANY of her other babies been born preterm (<37 weeks gestation)?	yes no					
48. Has she had ANY previous stillbirths or neonatal deaths?	yes no					

43. Number of previous pregnancies, excluding the present pregnancy. (If 0, skip to section 5)

Important: do not include this most recent pregnancy (that she has just delivered).

Enter the number of previous pregnancies in the box. For 0, enter 00; for 1, enter 01, etc. Include all known pregnancies, including those that ended in miscarriage or abortion.

Example, if, prior to this most recent pregnancy, she had one successful pregnancy, one abortion and one miscarriage, enter 03 in the box.

44. Have her last two previous pregnancies ended in miscarriage?

Place a 'X' in the box marked 'NO' if, prior to this pregnancy:

- she has not had a miscarriage
- > she has only had ONE miscarriage in her last two pregnancies
- she has had 2 or more previous miscarriages, BUT not in the last two consecutive pregnancies

Place a 'X' in the box marked '**YES**' if the woman's last two consecutive pregnancies HAVE resulted in miscarriage.

45. How many previous births, excluding this birth, has she had? (If 0, go to section 5)

Important: do not include this most recent birth

A birth is defined as a delivery after 24 weeks, regardless of outcome. Thus, include any still-born infants in the value.

Example: if she had 3 previous births, one of which was a stillbirth, enter 03 in the box.

46. Have ANY of her other babies weighed less than 2.5kg or more than 4.5kg?

Do not include the baby that has just been delivered.

Place a 'X' in the box marked '**YES**' if she HAS previously had a low birth weight (<2500g) or high birth weight (>4500g) baby.

Place a 'X' in the box marked '**NO**' if she has NOT previously had a low birth weight (<2500g) or high birth weight (>4500g) baby.

47. Have ANY of her other babies been born preterm (<37⁺⁰ weeks of gestation)?

Do not include the baby that has just been delivered.

<37 weeks gestation = <259 days since the last menstrual period.

Place a 'X' in the box marked '**YES**' if she HAS previously had a preterm baby.

Place a 'X' in the box marked '**NO**' if she has NOT previously had a preterm baby.

48. Have you had ANY previous stillbirths or neonatal deaths?

Do not include this most recent delivery if it was a stillbirth/neonatal death.

A stillbirth is defined as giving birth to a baby born dead after 24 weeks of gestation.

A neonatal death is defined as a death within 28 days of a live birth after 24 weeks of gestation.

Place a 'X' in the box marked '**YES**' if any of the woman's previous pregnancies have resulted in stillbirth or neonatal death.

Place a 'X' in the box marked 'NO' if she has had NO previous pregnancies resulting in stillbirth or neonatal death.

Section 5: Clinical conditions

Sectior	Section 5: Clinical conditions								
Dur	During this pregnancy was she diagnosed with, or treated for, any of the following conditions (cross all that apply)								
49.	Cardiac disease	yes	no	57.	Respiratory tract infection requiring antibiotic/antiviral treatment	yes	no		
50.	Chronic respiratory disease (including chronic asthma)	yes	no	58.	Any other infection requiring antibiotic/antiviral treatment	yes	no		
51.	Malaria	yes	no	59.	Positive syphilis test	yes	no		
52.	Mental illness e.g. depression	yes	no	60.	HIV or AIDS	yes	no		
53.	Epilepsy	yes	no	61.	Any sexually transmitted infection	yes	no		
54.	Thyroid disease or any other endocrinological condition	yes	no	62.	Any type of malignancy or cancer	yes	no		
55.	Lower urinary tract infection requiring antibiotic treatment	yes	no	63.	Any other medical/surgical condition requiring treatment or referral	yes	no		
56.	Pyelonephritis	yes	no						

In each box:

Place a 'X' in the box marked '**YES**' if the woman was EVER been diagnosed with or treated for each condition listed above during this most recent pregnancy.

Place a 'X' in the box marked '**NO'** if the woman was NEVER diagnosed with or treated for each condition listed above in any previous pregnancy.

If she is uncertain whether she has had one or more of the conditions listed during this pregnancy, consult her medical records/doctor in charge. If there is no mention of the condition, assume that she has not had it and place a 'X' in the box marked '**NO**'.

49. Cardiac disease (any type)

- 50. Chronic respiratory disease (including chronic asthma) Do not include mild asthma not requiring treatment or temporary use of an inhaler due to seasonal allergies.
- 51. Malaria (any type)
- 52. **Mental illness** (examples: depression, bipolar disorder, schizophrenia, general anxiety disorder). Do not include mild depression not requiring treatment.
- 53. Epilepsy (any type of seizure/episode)
- 54. **Thyroid disease or any other endocrinological condition** (examples Addison's disease, adrenal gland disorders, hypo- or hyper-thyroidism)

55. Lower urinary tract infections requiring antibiotic treatment

- 56. **Pyelonephritis** defined as an inflammation of he kidney and upper urinary tract that usually results from non-contagious bacterial infection of the bladder (cystitis) or other urinary infections.
- 57. Respiratory tract infection requiring antibiotic/antiviral treatment
- 58. Any other infections requiring antibiotic/antiviral treatment.
- 59. Positive syphilis test
- 60. HIV or AIDS

- 61. Any sexually transmitted infections. (Examples: gonorrhea, Chlamydia)
- 62. Any type of malignancy or cancer.
- 63. Any other medical/surgical condition requiring treatment or referral

Section 6: Pregnancy specific conditions

Sectio	Section 6: Pregnancy related complications							
Dur	ing this pregnancy was she diagnose	d with,	or treated for, a	any of the f	following conditions (cross all tha	it apply)		
64.	Severe vomiting requiring hospitalisation	yes	no	71.	Severe preeclampsia/ Eclampsia/HELLP syndrome	yes	no	
65.	Gestational diabetes	yes	no	72.	Rhesus disease	yes	no	
66.	Vaginal bleeding before 15 weeks	yes	no	73.	Preterm labour	yes	no	
67.	Vaginal bleeding at 15-27 weeks	yes	no	74.	Fetal distress	yes	no	
68.	Vaginal bleeding after 27 weeks	yes	no	75.	Suspected impaired fetal growth or small for gestational age	yes	no	
69.	Pregnancy-induced hypertension	yes	no	76.	Any other pregnancy related condition requiring treatment or referral	tion _{yes}	no	
70.	Preeclampsia	yes	no					
77.	Lowest haemoglobin level (if available)		<15 weeks	g/dl	15-27 weeks >	27 weeks	• g/dl	

During this pregnancy was she diagnosed with or treated for any of the following conditions (cross all that apply)

64. Severe vomiting requiring hospitalization

- 65. **Gestational diabetes** is a condition in which women without previously diagnosed diabetes exhibit high blood glucose levels during pregnancy.
- 66. Vaginal bleeding before 15 weeks
- 67. Vaginal bleeding at 15-27 weeks
- 68. Vaginal bleeding after 27 weeks
- 69. **Pregnancy-induced hypertension** high blood pressure 140/90 or greater that develops after 20 weeks gestation in a previously normotensive pregnancy.
- 70. **Preeclampsia** Preeclampsia is defined as high blood pressure 140/90 or greater, or an increase of 30mmHg systolic or 15 mmHg diastolic over baseline values on at least two occasions six or more hours apart that develops after 20 weeks gestation in a previously normotensive pregnancy, and proteinuria.

71. Severe preeclampsia/Eclampsia/HELLP syndrome

Severe preeclampsia is diagnosed when blood pressures are \geq 160 mmHg systolic and/or \geq 110 mmHg diastolic on two occasions, at least 4 hours but not more than 168 hours apart, or if the first measurement was immediately followed by treatment with an antihypertensive, either of these scenarios being associated with the presence of proteinuria.

Eclampsia is defined as the occurrence of convulsions and/or coma unrelated to toher cerebral conditions in women with signs and symptoms of pre-eclampsia. Seizures are of grand mal type and may first appear before labour, during labour or up to 48 hours postpartum.

HELLP syndrome is a group of symptoms that occur in pregnant women who have preeclampsia or eclampsia and who also show signs of liver damage and abnormalities in blood clotting. It is characterised by: Haemolysis, **EL** (elevated) liver enzymes and **LP** (low platelet) count.

- 72. **Rhesus Disease** also known as RH- isoimmunisation can occur when the mother is Rh negative and the baby is Rh positive.
- 73. Preterm labour. Initiation of labour before 37+0 weeks (both with and without delivery)
- 74. Fetal distress (antepartum)
- 75. Suspected impaired fetal growth or small for gestational age
- 76. Any other pregnancy related condition requiring treatment or referral

77. Lowest haemoglobin level (if available).

For each of the following gestational ages enter the lowest Hb result (if available). If not available, leave blank.

- <15 weeks
- 15-27 weeks
- >27 weeks

Section 7: Nutritional supplements/medications

Sectio	Section 7: Nutritional supplements / Medications								
Dur	During this pregnancy, has she routinely taken any of the following supplements?								
78.	Iron	yes	no	81.	Food supplements	yes	no		
79.	Folic acid	yes	no	82.	Multi-vitamins/minerals	yes	no		
80.	Calcium	yes	no						
Dur	ing this pregnancy, has she taken an	y of the	following medi	cations?					
83.	Routine aspirin	yes	no	87.	Insulin	yes	no		
84.	Any antibiotics or antivirals (except those used for PROM)	yes	no	88.	Prophylactic steroids for preterm labour	yes	no		
85.	Antibiotics used for PROM	yes	no	89.	Any other treatment	yes	no		
86.	Non-steroidal anti-inflammatories	yes	no						

During this pregnancy, has she routinely taken any of the following nutritional supplements? (please cross as many as apply)

Cross 'Yes' for those supplements that the woman has taken routinely and 'No' for those that she has not. Routinely is defined as for more than one month. For example, do not cross 'YES' for a woman who has received a one-off supplement of iron.

- 78. Iron
- 79. Folic acid
- 80. Calcium
- 81. Food supplements
- 82. Multi-vitamins/minerals

During this pregnancy, has she routinely taken any of the following medications? (please cross as many as apply)

Cross 'Yes' for those treatments that the woman has been given routinely and 'No' for those that she has not. Routinely is defined as for more than one month. For example, do not cross 'YES' for a woman who has taken aspirin for occasional headaches.

- 83. Routine aspirin
- 84. Any antibiotics or antivirals (except those used for PROM) e.g. penecillin
- 85. Antibiotics used for PROM (e.g. prophylactic antibiotics)
- 86. Non-steroidal anti-inflammatories e.g. ibuprofen
- 87. Insulin
- 88. Prophylactic steroids for preterm labour
- 89. Any other treatment

Section 8: Delivery

Sectio	n 8: Delivery			
90.	Onset of labour (cross one box only)			92. Mode of delivery (cross one box only)
Sp	ontaneous Induced N	o Labour		Vaginal spontaneous Assisted breech or breech extraction
91.	Did she have pre-labour rupture of membranes (PROM)?	yes	no	Vaginal assisted (e.g. Caesarean section forceps, vacuum)
lf la	bour was induced or a caesarean se	ction wa	s performed pl	ease cross all indications that apply
93.	Vaginal bleeding	yes	no	103. Suspected impaired fetal growth or yes no
94.	Fetal death	yes	no	104. Post term (>42 weeks gestation)
95.	Pregnancy-induced hypertension	yes	no	105. Rhesus disease yes no
96.	Preeclampsia	yes	no	106. HIV or AIDS yes no
97.	Severe preeclampsia/ Eclampsia/HELLP Syndrome	yes	no	107. Any sexually transmitted infections yes no
98.	Breech presentation	yes	no	108. Any infections requiring ves no
99.	Fetal distress	yes	no	109. Maternal request yes no
100	. Failure to progress	yes	no	110. Any other maternal reason yes no
101	. Cephalo-pelvic disproportion	yes	no	111. Any other fetal reason yes no
102	. Prelabour rupture of membranes (PROM)	yes	no	112. Previous caesarean section yes no

90. Onset of labour

Spontaneous is defined as the spontaneous initiation of labour even if she has any augmentation later during labour.

Induced is defined as the initiation of uterine contractions before the spontaneous onset of labour, with the aim of accomplishing vaginal delivery.

No labour refers to the woman when she has an elective caesarian section without labour

If the reply is either Induced or No Labour, please ensure that you complete questions 89-110.

If the reply is Spontaneous, you do not need to complete questions 89-110.

91. Did she have pre-labour rupture of membranes (PROM)

Prelabour Rupture Of Membranes (PROM) (sometimes described as 'premature rupture of membranes') is the point diagnosis of the rupture of the sac membranes prior to labour/start of painful contractions, independently of gestational age.

Place a 'X' in YES if she had prelabour rupture of membranes

Place a 'X' in NO if she did not have prelabour rupture of membranes

92. Mode of delivery

Please cross ONE box that best applies

Vaginal spontaneous is defined as delivery that did not require any special intervention. Episotomy is considered a normal delivery.

Vaginal assisted is defined as delivery assisted with forceps or vacuum. Vacuum extraction uses a suction cup that is placed over the baby's head, which allows the physician to pull the child through the birth canal.

Assisted breech or breech extraction

Caesarian Section (including elective, intrapartum and emergency C-sections)

If labour was induced or a caesarian section was performed please cross indications that apply.

Please take the indications directly from the medical records. In cases of uncertainty, check with the attending midwife/doctor. Please cross as many indications as apply.

For each indication:

Pace a 'X' in the box marked '**YES**' if the indication is written in the medical record as a main reason for induction or caesarian.

Pace a 'X' in the box marked 'NO' if the indication is NOT written in the medical record as a main reason for induction or caesarian.

93. Vaginal bleeding

94. Fetal death (or suspected fetal death)

95. Pregnancy-induced hypertension (see definition p. 13)

- 96. Preeclampsia (see definition p.13)
- 97. Severe Preeclampsia/Eclampsia/HELLP syndrome (see definition p.14)
- 98. Breech presentation (feet first)

99. Fetal Distress

- 100. **Failure to progress** (this diagnosis given to a woman who does labor does not follow a normal pattern and is severely prolonged)
- 101. **Cephalo-pelvic disproportion** (when the baby's head is too big to fit through the mother's pelvis)
- 102. Prelabour reupture of membranes (PROM)

- 103. Suspected impaired fetal growth or small for gestational age
- 104. Post term (>42 weeks)
- 105. Rhesus disease
- 106. HIV or AIDS
- 107. Any sexually transmitted infections (example: Herpes)
- 108. Any infection requiring antibiotic/antiviral treatment
- 109. Maternal request
- 110. Any other maternal reason
- 111. Any other fetal reason
- 112. Previous caesarian section

Section 9: Newborn Outcomes and Care

Section 9: Newborn outcomes and care	
113. Date of deliver	118. Apgar score at 5 minutes
114. Time of delivery H H (24hr clock) I15. Number of babies	119. Newborn status at <u>birth (</u> cross one box only)
If more than 1 baby, complete another Pregnancy and Delivery form, (section 9 to 12 only). 116. Gestational age at birth	Alive Intrapartum death Antepartum death
based on the best obstetric wks days	120. Newborn sex Male Female
For women in the FGLS study, if the gestational age at birth is <37 weeks please contact study coordinator for the <i>Preterm</i> <i>Postnatal Follow-up Study</i>	121. Was the newborn admitted to intensive care or any special care unit?
117. Fetal presentation at delivery (cross one box only) Cephalic Breech Other	122. Total amount of days spent in intensive care or special care unit (if less than 24hrs please enter 1 day)

113. Date of Delivery

Please write the date of delivery in the format dd-mm-yy. For example the 20th May 2010 should be written 20-05-10.

114. Time of Delivery (24 hour clock)

Please write the time of delivery using the 24 hour clock, for example 8:15pm is written as 20:15

115. Number of babies

Please write the number of babies that the woman delivered (whether alive or not).

If this was a multiple pregnancy, continue this form by completing the details of the first baby to be delivered. Then, get a new form, complete the header with the same study subject number, and complete sections 8, 9, 10, 11 and 12 for the second baby delivered. If more than 2 babies were delivered, repeat this process for each additional birth.

116. Gestational age at birth (based on best obstetric estimate)

Please obtain the *best obstetric estimate* (also known as clinical estimate) of the gestational age at birth. The best clinical obstetric estimate is based on all clinical and ultrasound data that were available to the attending staff (as they interpret it) and should be written in the medical records. Write the estimated gestational age at birth in weeks and days. Important: If the mother was in the Fetal Growth Longitudinal Study (FGLS) and her baby is born at >26⁺⁰ and <37⁺⁰ weeks gestation, please contact the local research coordinator for the PPFS study and begin a new PPFS booklet for the baby. The Preterm Study Entry form (PSE) should be completed 48-72 hours after birth, or before hospital discharge, whichever is sooner.

117. Fetal presentation at delivery

Cephalic (Head first) Breech (Feet first) Other (Any other fetal presentation at delivery, e.g. Arm first)

118. Apgar score at 5 minutes

Please write the Apgar score (range 1-10) at 5 minutes in the corresponding box.

Apgar Scoring			
Apgar Sign	2	1	0
Heart Rate (pulse)	Normal (above 100 beats per minute)	Below 100 beats per minute	Absent (no pulse)
Breathing (rate and effort)	Normal rate and effort, good cry	Slow or irregular breathing, weak cry	Absent (no breathing)
Grimace (responsiveness or "reflex irritability")	Pulls away, sneezes, or coughs with stimulation	Facial movement only (grimace) with stimulation	Absent (no response to stimulation)
Activity (muscle tone)	Active, spontaneous movement	Arms and legs flexed with little movement	No movement, "floppy" tone
Appearance (skin coloration)	Normal color all over (hands and feet are pink)	Normal color (but hands and feet are bluish)	Bluish-gray or pale all over

119. Newborn status at birth

Place a 'X' in the box that corresponds to the newborn's status at birth.

120. Newborn sex

Please place a 'X' in the box that corresponds to the infant's sex.

If the sex is undifferentiated or undeterminable, please leave blank and complete a **congenital abnormality form.**

121. Was the newborn admitted to intensive care or any special care unit?

Place a 'X' in the box marked YES if the newborn was admitted to intensive care, special care, or any other non-routine form of care.

Place a 'X' in the box marked NO if the newborn was not admitted to intensive care, special care, or any other non-routine form of care and skip to question 121.

122. Total amount of days spent in intensive care or special care unit (if less than 24 hours, please enter 1 day)

Enter the total number of days spent in intensive care, special care, or any other form of non-routine care, rounded to the next whole day. For example, if the infant spent 1 day and 6 hours in the NICU, write 2 in the box.

Was the newborn diagnosed with or tre	ated for	any of the follow	ving conditions before hospital discharge?
123. Respiratory distress syndrome	yes	no	134. Necrotising enterocolitis, stage 2 or yes no greater
124. Transient tachypnea of the newborn	yes	no	135. Seizures ves no
125. Apnea of prematurity	yes	no	136. Hypoglycaemia
126. No oral feeds for more than 24hrs	yes	no	137. Intraventricular haemorrhage grade 2 yes no or greater/ periventricular haemorrhage/leukomalacia
127. Bronchopulmonary dysplasia	yes	no	138. Hypotension requiring ionotropic yes no treatment or steroids
128. Retinopathy of prematurity	yes	no	139. Anaemia (requiring transfusion)
129. Meconium aspiration with respiratory distress	yes	no	140. Patent ductus arteriosus (requiring yes no pharmacological treatment or surgery)
130. Hypoxic-ischaemic encephalopathy	yes	no	141. Polycythaemia yes no
131. Hyperbilirubinaemia	yes	no	142. Any other serious condition yes no
132. TORCH or any other intrauterine infections	yes	no	143. Congenital abnormality (complete a ves neonatal abnormality form)
133. Neonatal sepsis	yes	no	

Was the newborn diagnosed with or treated for any of the following conditions before hospital discharge?

Please take the diagnoses directly from the medical records. In cases of uncertainty, check with the attending neonatologist. Please cross as many neonatal diagnoses as apply.

For further clarification on the definitions of the diagnoses, or information for when interacting with the neonatologist, please see Appendix 2 (this will be updated once the definitions are received from the Neonatal Group).

- 123. Respiratory distress syndrome
- 124. Transient tachypnea of the newborn
- 125. Apnoea of prematurity
- 126. No oral feeds for more than 24 hours
- 127. Broncopulmonary dysplasia
- 128. Retinopathy of prematurity
- 129. Meconium aspiration with respiratory distress
- 130. Hypoxic-ischemic encephalopathy
- 131. Hyperbilirubinemia

- 132. TORCH and/or other intrauterine infections
- 133. Neonatal sepsis
- 134. Necrotising enterocolitis, stage 2 or greater
- 135. Seizures
- 136. Hypoglycemia
- 137. Intraventricular haemorrhage grade 2 or greater, or periventricular hemorrhage/leukomalacia
- 138. Hypotension requiring ionotrophic treatment or steroids
- 139. Anaemia (requiring transfusion)
- 140. Patent ductus arteriosus (requiring pharmacological treatment or surgery)
- 141. Polycythaemia
- 142. Any other serious condition
- 143. Congenital abnormality. Please complete a Neonatal Abnormality form.

		-		
Section 10: Newborn anthr	opometry (please carry	out as soon as possib	le, no later than 24	hours after birth)
144. Date of measuremer	nt		145. Time of measu	rement (24 hr clock)
D	D – M M – Y	Y		н н М
I st set of anthropometric n	neasurements	Repeat measurer	ments, if required	Repeat measurements, if required
146. Weight		kgs	kgs	kgs
147. Length	• cm		cm	•
148. Head circumference			cm	

Section 10: Newborn Anthropometry

Section 10: Newborn anth	ropometry (continued)			
2 nd set of anthropometric measurements		Repeat measurements, if required	Repeat measurements, if required	
149. Weight	kgs	kgs	kgs	
150. Length	cm	• cm	• cm	
151. Head circumference		cm	cm	

For advice on carrying out the measurements in this section, please consult the INTERGROWTH-21st Anthropometry Handbook.

- 144. **Date of measurement** written in the format day-month-year. Example 20th May 2010 is written as 20-05-10.
- 145. **Time of measurement** written using the 24-hour clock. Example 5:15 in the morning is written as 5:15 whereas 5:15 in the afternoon is written as 17:15.

1st **Set of Measurements** (Observer A takes the role of lead observer and takes the following measurements using the study equipment and following the guidelines).

146. Weight

147. Length

148. Head circumference

2nd Set of Measurements (Now it is time for Observer B to take over the role of lead observer and takes the following measurements using the study equipment and following the guidelines)

- 149. Weight
- 150. Length

151. Head circumference

If one or more of the measurements differ by more than the maximum allowable difference (see Anthropometry Manual p...) each observer should repeat the measurement(s) again and record on the form in the second box. If the difference is still greater than the maximum allowable difference, a third repetition should be carried out. If, after three times, the discrepancy is still too big, stop the process there and ensure all values are recorded on the form.

Section 11: Newborn Outcomes

Section 11: Newborn outcomes	
152. Newborn status at hospital discharge	153. Date of hospital neonatal hospital discharge or date of death
Alive Alive but referred to a Dead higher level of care	

152. Newborn status at hospital discharge

Place an X in the box that corresponds to the newborn status at discharge.

153. Date of neonatal discharge (or date of death)

If the infant is discharged from hospital (i.e. no longer requires any special care) but the mother remains in hospital/special care, the date of neonatal discharge is the date that the baby leaves special care, even if it remains in hospital so as to be with the mother. Please write the date in the format dd-mm-yy. For example, 20th May 2010 should be written 20-05-10.

Section 12: Feeding Practices

154. What was the main mode of feeding at hospital discharge? (cross one box only)

This question relates to the main mode of feeding in the 24 hours prior to hospital discharge.

Please use the definitions below:

Section 12: Nutritional practices				
154. What was the main mode of feeding in the 24hrs prior to hospital discharge? (cross one box only)				
Exclusive breast milk	Combination Feeding Predominant breast milk	Partial breast milk	Exclusive formula	

Feeding practice	Requires that the infant receive:	Allows that the infant receive:	Does not allow the infant to receive:
Exclusive breast milk	Human breast milk (including milk expressed or from a wet nurse) as the sole source of nourishment	ORD, drops, syrups (vitamins, minerals, medicines)	Anything else (in particular, non human milk, food-based fluids)
Predominant breastfeeding	Human breast milk (including milk expressed or from a wet nurse) as the predominant source of nourishment	Certain liquids (water and water- based drinks, fruit juice and ritual fluids, and ORD, drops, syrups (vitamins, minerals, medicines)	Anything else (in particular, non human milk, food-based fluids)
Partial breast milk	Human breast milk (including milk expressed or from a wet nurse)	Any other liquids including non- human milk (formula) and water-based drinks/soups. ORD, drops, syrups (vitamins, minerals, medicines)	N/A
Exclusive formula	Infant formula (made from non-human milk) fed from a bottle with a nipple/teat as the sole source of nourishment. This includes all types of infant formula.	ORD, drops, syrups (vitamins, minerals, medicines)	Anything else (in particular breast milk)

Section 13: Maternal Outcomes

Section 13: Maternal outcomes			
155. Was the mother admitted to intensive care of	or any special care uni	t after delivery?	yes no
156. If yes total n	umber of days (if less	than 24 hours, please enter as 1 day)	days
157. Maternal status at hospital discharge	Alive	Alive but referred to a higher level of care	Dead

155. Was she admitted to intensive care or any special care after delivery?

Place a 'X' in **YES** if the mother was admitted to any 'special care.' Special care is defined as any form of care that is non-routine following delivery. Do not include those who were kept in the recovery room following caesarian section if this is the routine practice in your institution. Include those that gave birth in a high-risk delivery ward and were kept there following delivery for more than 2 hours. Answer question 154.

Place a 'X' in **NO** if the mother continued with the routine postnatal procedure. Go to question 155.

156. Total amount of days she was in intensive care or special care.

Please write the number of days that the woman spent in special care, rounded to the nearest whole day.

157. Maternal status at hospital discharge

Cross the box that best applies to the status of the mother at hospital discharge

PLEASE CHECK EACH FORM FOR MISSING VALUES CAREFULLY BEFORE SIGNING THE LAST PAGE AND PASSING THE FORM TO THE DATA ENTRY AND QUALITY CONTROL UNIT

Appendix 1. Occupational classification scheme

Housework (including care of child(ren)/care of elderly relative)

Manager/Professional/Technical

- Chief executives, senior officials and legislators and associated professionals
- Administrative and commercial managers and associated professionals
- Health professionals and associated professionals
- Teaching professionals and associated professionals
- Business and administration professionals and associated professionals
- Information and communications technology professionals and technicians
- Legal, social and cultural professionals
- Production and specialized services managers
- Hospitality, retail and other services managers
- Science and engineering professionals

Clerical/Sales/Services

- General and keyboard clerks
- Customer services clerks
- Numerical and material recording clerks
- Other clerical support workers
- Service and sales workers
- Personal service workers
- Sales workers
- Personal care workers e.g. care home worker
- Protective services workers

Skilled Manual Worker

- Market-oriented skilled agricultural, forestry, fishing and hunting workers
- Subsistence farmers, fishers, hunters and gatherers
- Craft and related trades workers
- Building and related trades workers, excluding electricians
- Metal, machinery and related trades workers
- Handicraft and printing workers
- Electrical and electronic trades workers
- Food processing, wood working, garment and other craft and related trade workers
- Stationary plant and machine operators
- Assemblers
- Drivers and mobile plant operators

Unskilled Manual Worker

- Cleaners and helpers
- Agricultural, forestry and fishery labourers
- Labourers in mining, construction, manufacturing and transport
- Food preparation assistants
- Street and related sales and service workers
- Refuse workers and other elementary workers

Other

- Student
- Redundancy/unemployed

Appendix 2. Definitions Of Neonatal Morbidities

Transient Tachypnea of Newborn (TTN)

TTN is a parenchymal lung disorder characterized by pulmonary edema resulting from delayed resorption and clearance of fetal alveolar fluid.

The onset of TTN is usually at the time of birth and within two hours after delivery with tachypnea being the most prominent clinical feature. Characteristic findings on chest radiograph support the diagnosis and include increased lung volumes, and prominent vascular markings, with fluid in the interlobar fissure. In order to make the diagnosis, other conditions (such as pneumonia, respiratory distress syndrome, pneumothorax, etc) must be ruled out.

Symptoms of TTN usually last for 12 to 24 hours, but may persist as long as 72 hours in severe cases. Infants rarely require supplemental oxygen, but if required they usually respond to oxygen therapy. When oxygen is needed, usually concentrations less than 40 percent are sufficient to achieve adequate oxygenation.

REFERENCE

Guglani, L et al. "Transient Tachypnea of the Newborn." Pediatr. Rev. 2008; 29;e59-e65

Respiratory Distress Syndrome (RDS)

An infant is determined to have respiratory distress syndrome if each of the following is true:

Requires O2 at 6 hours of life continuing to age 24 hours

Demonstrates clinical features within age 24 hours

Has need for respiratory support to age 24 hours, AND

Has an abnormal chest x-ray within age 24 hours consistent with surfactant deficiency

OR

Has received surfactant therapy within the first 24 hours of life

REFERENCE

Fanaroff AA, Stoll BJ, Wright LL, et al; NICHD Neonatal Research Network. Trends in neonatal morbidity and mortality for very low birth weight infants. Am J Obstet Gynecol 2007; 196:147.e1-147.e8

Bronchopulmonary Dysplasia (BPD)

1) Chronic supplemental oxygen needs for >28 days (28 days oxygen need based BPD)

OR

2) Chronic supplemental oxygen needs at either PMA of 36 weeks or discharge from hospital whichever come first (36 weeks Oxygen need based BPD)

REFERENCE

Pascal M. Lavoie, Chandra Pham, Kerry L .Jang. Heritability of Bronchopulmonary Dysplasia, defined according to consensus statement of National Institute of Health.Pediatrics.2008; 122:479-485.

Meconium Aspiration Syndrome

Meconium Aspiration Syndrome (MAS) is defined as respiratory distress in an infant born through meconium stained amniotic fluid (MSAF), whose symptoms cannot be otherwise explained. This disorder may be life threatening complicated by respiratory failure, pulmonary air leaks and persistent pulmonary hypertension.

REFERENCE

Fanaroff AA. Meconium aspiration syndrome: historical aspects. J Perinatol.2008; 28:3-7

Retinopathy of Prematurity (ROP)

ROP a developmental vascular retinopathy occurs only in the incompletely vascularized retina of premature infants, leading to a wide range of outcomes from normal vision to blindness. For a diagnosis of ROP to be documented we need a confirmed diagnosis by an ophthalmologist in the notes according to the staging criteria below;

Staging of ROP:

Stage1: Demarcation line separating the avascular retina anteriorly from the vascularized retina posteriorly, with abnormal branching of small vessels immediately posterior.

Stage 2: Intraretinal ridge; the demarcation line has increased in volume, but proliferative tissue remains intraretinal.

Stage 3: Ridge with extraretinal fibrovascular proliferation.

Stage 4: Partial retinal detachment

Stage 5: Total retinal detachment.

REFERENCES

International Committee for the classification of Retinopathy of Prematurity "The international classification of Retinopathy of Prematurity Revisited" Arch Ophtalmol 2005;123:991-999.

M.Subhani, Adriann Coombs, Pamela Weber, Corina Gerontis. Screening guidelines for Retinopathy of Prematurity: The needs for revision in Extremely Low Birth Weight Infants.Pediatrics.2001; 107:656-659

Periventricular Leukomalacia

Damage to the deep white matter (WM) in the centrum semiovale is the main characteristic feature of PVL. The damage may vary from punctuate areas of hemorrhage & necrosis to more extensive injuries including cystic changes, scarring, hypomyelination / demyelination, and even hemorrhagic infarction of the white matter.

REFERENCE

De Vries LS, Eken P, Dubowitz LMS. The spectrum of leukomalacia using cranial ultrasound. Behav Brain Res 1992;49:1-6

Apnea of Prematurity

Clinically significant apnea in infants is defined as breathing pauses that last for > 20 seconds or for > 10 seconds if associated with bradycardia (e.g. < 80 beats per minute) or oxygen desaturation (e.g. O2 saturation of < 80-85%).

REFERNECE

Finer N, Higgins R, Kattwinkel J, Martin RJ. Summary Proceedings From the Apnea-of-Prematurity Group. Pediatrics 2006;117;S47-S51.

Hypoxic Ischemic Encephalopathy (HIE)

Hypoxic Ischemic Encephalopathy (HIE) of the newborn is "a clinically defined syndrome of disturbed neurological function in the earliest days of life in the term infant, manifested by difficulty with initiating and maintaining respiration, depression of tone and reflexes, sub normal level of consciousness and often seizures.

REFERENCE

Nelson KB, Leviton A. How much of neonatal encephalopathy is due to birth asphyxia? Am J Dis Child 1991

Birth Asphyxia

Apgar score \leq 5 or a continued need for resuscitation at 10 minutes OR

Acidosis (defined as any occurrence of umbilical-cord, arterial, or capillary pH of <7.00 or base deficit of \geq 16 mmol per liter) within 60 minutes after birth.

Moderate-to-severe encephalopathy (indicated by lethargy, stupor, or coma) and either hypotonia, abnormal reflexes (including oculomotor or pupillary abnormalities), an absent or weak suck, or clinical seizures.

Abnormal background activity of at least 30 minutes' duration or seizures on amplitudeintegrated electroencephalography.

REFERENCE

Denis V. Azzopardi, Brenda Strohm, A. David Edwards, Leigh Dyet, Henry L. Halliday, Edmund Juszczak, Olga Kapellou, Malcolm Levene, Neil Marlow, Emma Porter, Marianne Thoresen, Andrew Whitelaw and Peter Brocklehurst for the TOBY Study Group. Moderate Hypothermia to Treat Perinatal Asphyxial Encephalopathy. N Engl J Med 361;14:1349-1358

Postnatal Infection (Sepsis)

Neonatal sepsis is a clinical syndrome of systemic illness accompanied by bacteremia occurring in the first month of life.

Late onset sepsis defined as 1 or more positive blood cultures obtained after 3 days of age from infants with clinical features of sepsis

Since culture positive sepsis is relatively rare, a physician documented episode of sepsis would suffice.

REFERENCES

Infectious disease: In Gomella TL, Cunningham MD(eds): a LANGE Clinical manual. Neonatology: Management, procedures, on Call Problems Diseases and Drugs.5th ed. McGraw Hill, 2004.p434-440.

M Gary Karlowickz, E Stephen Buescher Fulminant Late Onset Sepsis in a intensive neonatal care unit, 1987-1997, and the impact of avoiding empiric vancomycin therapy. Pediatrics.2000; 106:1387-1390

Intraventricular Hemorrhage (IVH)

A diagnosis of IVH should be based on a documentation of IVH based on Ultrasonographic findings conducted by a qualified ultrasonographer/ultrasonologist.

Intraventricular hemorrhage is graded by the classification of Papile et al on ultrasonographic examination as follows:

Grade1: Blood in the periventricular germinal matrix regions or germinal matrix hemorrhage.

Grade2: Blood within the lateral ventricular system without ventricular dilatation.

Grade3: Blood acutely distends the lateral ventricles.

Grade4: Blood within ventricular system and parenchyma

REFERENCE

Papile LA, Burstein J, Burstein R, Koffler H. Incidence and evolution of subependymal and intraventricular hemorrhage: a study of infants with birth weights less than 1,500 gm. J Pediatr 1978;92(4):529-34.

Necrotizing Enterocolitis (NEC)

A diagnosis and staging of Necrotizing enterocolitis (NEC) should be based on a clinical documentation by treating clinician based on the following criteria:

Stage1: Suspected

*History of perinatal stress

*Systemic signs of ill health: temperature instability, lethargy, apnea

*Gastrointestinal manifestations: poor feeding, increased volume of gastric aspirates, vomiting, mild abdominal distension, faecal occult blood (no fissure)

Stage2: Confirmed

*Any of the features of stage 1 plus:

*persistent occult, or gross gastrointestinal bleeding, marked abdominal distension

*abdominal radiograph: intestinal distension, bowel wall oedema, unchanging bowel loops, pneumatosis intestinalis, portal vein gas.

Stage3: Advanced

*Any of features of stages 1 or 2 plus:

*Deterioration in vital signs, evidence of shock or severs sepsis, or marked gastrointestinal hemorrhage

*Abdominal radiograph shows any of features of stage 2 plus pneumoperitoneum

REFERENCE

Gastrointestinal disorder: In Roberton's R Text book of Neonatology (3rded). Churchill Livingstone. 1999, p752.

Polycythemia

Polycythemia in term infant is the presence of a venous hematocrit more than 65% or a venous hemoglobin concentration in excess of 22 gm/dl.

REFERENCE

Phibbs RH:Neonatal polycythemia. In Rudolph AB (ed): Pediatrics, 16th ed. Newyork: Appleton Century Crofts, 1997.

Anemia requiring transfusion

There is no consensus on definition of Anemia of Prematurity.

Shown below is the criteria for transfusion taken from US and Canadian collaborative study. Patients are transfused in a volume of 15ml/kg, administered over 2-3 hours.

TABLE 1. Transfusion Criteria

A) Hct 31%–35%
Receiving >35% supplemental hood oxygen
Intubated on CPAP or mechanical ventilation with mean
airway pressure $>6-8$ cm H ₂ O
B) Hct 21%–30%
Receiving <35% supplemental hood oxygen
On CPAP or mechanical ventilation with mean airway
pressure $< 6 \text{ cm H}_2\text{O}$
Significant apnea and bradycardia (>9 episodes in 12 h or 2
episodes in 24 h requiring bag and mask ventilation) while
receiving therapeutic doses of methylxantines
Heart rate >180 beats/min or respiratory rate >80 breaths/
min persisting for 24 h
Weight gain <10 g/d observed over 4 d while receiving
>100 kcal/kg/d
Undergoing surgery
C) Hct <21%
Asymptomatic with reticulocytes <1%
D) Transfuse at any hematocrit value if hypovolemic shock
develops
E) Do not transfuse
To replace blood removed for laboratory tests
For low Hct alone

CPAP indicates continuous positive airway pressure; Hct, hematocrit.

Table 1 adapted from Donato et al. Pediatrics. 2000;105(5):1066-72.

REFERENCE

Donato H, Vain N, Rendo P, Vivas N, Prudent L, Larguía M, Digregorio J, Vecchiarelli C, Valverde R, García C, Subotovsky P, Solana C, Gorenstein A. Effect of early versus late administration of human recombinant erythropoietin on transfusion requirements in premature infants: results of a randomized, placebo-controlled, multicenter trial. Pediatrics. 2000;105(5):1066-72.

Acute Bilirubin Encephalopathy

A clinical syndrome in the presence of severe hyperbilirubinemia, of lethargy, hypotonia, and poor suck, which may progress to hypertonia (with opisthotonus and retrocollis) with a high-pitched cry and fever and eventually to seizures and coma.

Chronic Bilirubin Encephalopathy

The clinical sequelae of acute encephalopathy with athetoid cerebral palsy with or without seizures, developmental delay, hearing deficit, occlumotor disturnances, dental dysplasia and mental deficiency.

REFERENCE

Guidelines for detection, management and prevention of hyperbilirubinemia in term and late preternm newborn infants (35 or more week's gestation).Canadian Pediatric Society. Pediatr Child Health.2007; 12:1-12

Hypotension in Neonates

Hypotension is a blood pressure (B.P) >2 standard deviations below normal for age. For infants who are <30 weeks gestation, a mnemonic that is helpful in remembering BP is that the mean BP should be at least the same number as gestational age. For example, a 23 week infant should have a mean BP of 23 mmHg.

REFERENCE

Hypotension and shock in Gomella TL, Cunningham MD (eds): a LANGE clinical manual, Neonatology: 5th ed. McGraw Hill 2004

Hypoglycemia

A normal range for neonatal hypoglycemia has not been properly defined, and there is controversy over safe blood glucose concentration. The World Health Organization designates a blood glucose "operational threshold"<2.6 mmol/L or 46.8 mg/dl as requiring treatment and make no distinction between preterm and term infants.

REFERENCE

Division of Child Health and Development and Maternal and Newborn Health/Safe Motherhood, Hypoglycemia of the Newborn. Review of the literature. World Health Organization.Geneva.1997.1-55

Inborn Error of Metabolism

Inborn errors of metabolism comprise a large class of genetic diseases involving disorders of metabolism. The majority are due to defects of single genes that code for enzymes that facilitate conversion of various substances (substrate) into others (products). In most of the disorders, problems arise due to accumulation of substances which are toxic or interfere with normal function, or to the effects of reduced ability to synthesize essential compounds. Inborn errors of metabolism are now often referred to as congenital metabolic diseases or inherited metabolic diseases, and these terms are considered synonymous.

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