

INTERCOVID

A prospective cohort study
in pregnancy and the neonatal period



International Fetal and Newborn Growth
Consortium for the 21st Century
(INTERGROWTH-21st)

DATA COLLECTION INSTRUCTIONS

April 2020
(version 1.0)



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General Guidelines

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.

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 an '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 initialled. 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.

Study Entry Form (COV)

Form Header

 UNIVERSITY OF OXFORD	INTERCOVID Study Study Entry Form	COV Page 1 of 1
Participant Number	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Hospital/Clinic Code <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
Maternal Hospital Record No.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Visit Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Participant Number: this is the identification number assigned to each woman. The first two digits correspond to your country code, the last five digits are the unique number assigned to the participant.

Hospital/Clinic Code: Enter the code that corresponds to your hospital or clinic.

Maternal Hospital Record No.: This number is the hospital/clinic's own internal reference number for the woman; it can be used to help identify the woman and link the information on this form with her medical records.

Visit date: This is the date that the woman attended the hospital for care.

Section 1: COVID Diagnosis

1. Has virological antigen testing for COVID-19 been carried out (e.g. PCR)?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, was the result positive?	<input type="checkbox"/> yes <input type="checkbox"/> no
Date of test	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
2. Has antibody testing for COVID-19 been carried out (e.g. serology)?	<input type="checkbox"/> yes <input type="checkbox"/> no
If yes, was the result positive?	<input type="checkbox"/> yes <input type="checkbox"/> no
Date of test	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3. Does the woman have radiological signs consistent with COVID-19 infection?	<input type="checkbox"/> yes <input type="checkbox"/> no

1. Has virological antigen testing for COVID-19 been carried out (e.g. PCR)?

Place an X in the box marked 'YES' if the woman has been tested for COVID-19 using virological antigen testing, for example by PCR.

Place an X in the box marked 'NO' if the woman has not been tested for COVID-19 using a virological antigen test.

If yes was the result positive?

Place an X in the appropriate box given the test result. If she is positive for COVID-19, place an X in the box marked 'YES'. If the test result is negative for COVID-19, place an X in the box marked 'NO'.

Date of the test

Record the date of the test for COVID-19 was performed in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

2. Has antibody testing for COVID-19 been carried out (e.g. serology)?

Place an X in the box marked 'YES' if the woman has been tested for COVID-19 using antibody testing, for example by serology.

Place an X in the box marked 'NO' if the woman has not been tested for COVID-19 using an antibody test.

If yes was the result positive?

Place an X in the appropriate box given the test result. If she is positive for COVID-19, place an X in the box marked 'YES'. If the test result is negative for COVID-19, place an X in the box marked 'NO'.

Date of the test

Record the date of the test for COVID-19 was performed in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

3. Does the woman have radiological signs consistent with COVID-19 infection?

Place an X in the box marked 'YES' if the woman has radiology signs which are consistent with COVID-19 infection: this includes infiltrate, consolidation and extensive or multiple discrete opacities / ground glass areas.

Place an X in the box marked 'NO' if the woman does not have radiology signs consistent with COVID-19 infection.

4. Does the woman have any of these symptoms? Write the number of days for each symptom:			
Fever	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Cough	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Sore throat	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Headache	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Tiredness/lethargy	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Limb or joint pain	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Diarrhoea / vomiting	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Breathlessness	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Loss of smell	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Runny nose	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Flu-like symptoms	<input type="text"/>	<input type="text"/> <input type="text"/>	days
Chest pain	<input type="text"/>	<input type="text"/> <input type="text"/>	days
5. Does the woman have at least two of the symptoms listed above?			<input type="button" value="yes"/> <input type="button" value="no"/>
6. Has the woman been in close contact with someone who was COVID-19 positive?			<input type="button" value="yes"/> <input type="button" value="no"/>

4. Does the woman have any of these symptoms? Write the number of days of each symptom:

Place an X in the box if the woman displays any of the symptoms and they have recently started. For example, if the woman suffers with migraines and is currently experiencing a migraine, do not place an X next to headache. Record the number of days she had each symptom.

5. Does the woman have at least two of the symptoms listed above?

Place an X in the box marked 'YES' if two or more of the symptoms listed in Q4 are ticked.

Place an X in the box marked 'NO' if fewer than two of the symptoms listed in Q4 are ticked.

6. Has the woman been in close contact with someone who was COVID-19 positive?

Place an X in the box marked 'YES' if the woman has been in close contact with someone who has tested positive for COVID-19. This includes people she is living with or time spent in close proximity to someone who is COVID-19 positive.

Place an X in the box marked 'NO' if the woman has not been in close contact with someone who has tested positive for COVID-19. This includes people she is living with or time spent in close proximity to someone who is COVID-19 positive.

Section 2: Eligibility

7. Are any of the shaded boxes (☐) above marked with a 'X'? ☐ ☐

7. Are any of the shaded boxes (☐) above marked with a 'X'?

Place an X in the box marked 'YES' if any of the answers to questions 1, 2, 3, 5 or 6 is yes. If yes, this confirms the woman has been exposed to COVID-19. For this study she is eligible as a case.

Place an X in the box marked 'NO' if none of the answers to questions 1, 2, 3, 5 or 6 are yes. This confirms the woman has not been known to be exposed to COVID-19. For this study she is eligible as a non-case.

If the woman has been admitted to the hospital in labour or is expected to deliver during this admission, please complete a *Pregnancy and Delivery Form*, section 3 of this form and a *Neonatal Follow-up Form*.

If the woman has been admitted to hospital, referred to another level of care or quarantined and the birth is not expected now, please complete the *Maternal Referral/Admission Form*. Please also remember to complete section 3 of this form, the *Pregnancy and Delivery Form* and the *Neonatal Follow-up Form* when the birth does occur.

Section 3: Neonate

Section 3: Neonate		Infant hospital number (if the woman delivers twins, complete one form for each baby)		<input type="text"/>									
8. Was virological testing for COVID-19 carried out on the neonate (e.g. PCR)?				<input type="checkbox"/> <input type="checkbox"/>									
If yes, was the result positive?				<input type="checkbox"/> <input type="checkbox"/>		Date of test		<input type="text"/>					
9. Was antibody testing for COVID-19 carried out on the neonate (e.g. serology)?				<input type="checkbox"/> <input type="checkbox"/>		Date of test		<input type="text"/>					
If yes, was the result positive?				<input type="checkbox"/> <input type="checkbox"/>		Date of test		<input type="text"/>					

8. Infant hospital number

Enter the infant hospital number in the box provided. This will help identify the baby.

If it is a multiple birth, complete section 3 of a form for each baby ensuring you use their individual hospital numbers so each baby can be tracked at follow up visits.

9. Has virological testing for COVID-19 been carried out on the neonate (e.g. PCR)?

Place an X in the box marked 'YES' if the neonate has been tested for COVID-19 using virological antigen testing, for example by PCR.

Place an X in the box marked 'NO' if the baby has not been tested for COVID-19 using a virological antigen test.

If yes was the result positive?

Place an X in the appropriate box given the test result. If the neonate is positive for COVID-19, place an X in the box marked 'YES'. If the test result is negative for COVID-19, place an X in the box marked 'NO'.

Date of the test

Record the date of the test for COVID-19 was performed in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

10. Has antibody testing for COVID-19 been carried out on the neonate (e.g. serology)?

Place an X in the box marked 'YES' if the neonate has been tested for COVID-19 using antibody testing, for example by serology.

Place an X in the box marked 'NO' if the neonate has not been tested for COVID-19 using an antibody test.

If yes was the result positive?

Place an X in the appropriate box given the test result. If the neonate is positive for COVID-19, place an X in the box marked 'YES'. If the test result is negative for COVID-19, place an X in the box marked 'NO'.

Date of the test

Record the date of the test for COVID-19 was performed in the format dd-mm-yy, e.g. '20th May 2010' should be written '20-05-10'.

Maternal Referral/Admission Form


General instructions

Complete this form if, at any stage during her pregnancy, a woman is enrolled in the INTERCOVID Study in the antenatal period, either as:

Antenatal case: If she has been admitted or referred to hospital during antenatal care and is not expected to give birth during this admission; OR

Antenatal non-case recruited for corresponding antenatal cases: if the woman attends the hospital as above or for antenatal care.

Form Header

 UNIVERSITY OF OXFORD	INTERCOVID Study Maternal Referral/Admission Form	MRA Page 1 of 2
Participant number	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Hospital/Clinic Code <input type="text"/> <input type="text"/>
label space	Antenatal Record No.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Maternal Date of Birth	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Visit Date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Please answer all yes/no questions by placing a 'X' in the corresponding box		

Participant Number: This is the identifier given to each woman in the study and should match that on the COVID form.

Hospital/Clinic Code: Enter the code that corresponds to the hospital or clinic where the woman receives her routine antenatal care and was screened for the study.

Antenatal Record No.: This number is the hospital/clinic's own internal reference number for the woman; it can be used to help identify the woman and link the information on this form with her medical records.

Maternal Date of Birth: Enter the woman's date of birth in the format dd-mm-yy, e.g. '17th April 1990' should be written '17/04/90. Make every effort to obtain her date of birth in full. If, however, she knows only the year or month-and-year of her birth, enter this known information and replace the unknown details with 'xx'.

Visit Date: Enter the date of this visit in the format dd-mm-yy, e.g. '20th April 2020' should be written '20/04/20.

Please answer all yes/no questions by placing a 'X' in the corresponding box.

Section 1: Pregnancy status

Section 1: Pregnancy status	
1. Is this a referral to another level of outpatient care or admission to hospital? (cross one box only)	
Referral <input type="checkbox"/>	Admission <input type="checkbox"/>
2. To which department/unit/service has she been referred or admitted? (cross one box only)	
Gynaecology <input type="checkbox"/>	Surgery <input type="checkbox"/>
Obstetric/High-risk clinic <input type="checkbox"/>	Trauma/Orthopaedics <input type="checkbox"/>
Nephrology <input type="checkbox"/>	Emergency room <input type="checkbox"/>
Nutritional <input type="checkbox"/>	Internal medicine <input type="checkbox"/>
Physiotherapy <input type="checkbox"/>	Other <input type="checkbox"/>
Psychiatry <input type="checkbox"/>	
If she has been referred or admitted for a <u>nutritional</u> problem, please indicate the diagnosis: (cross all that apply)	
3. Gestational diabetes <input type="checkbox"/>	7. Food allergy <input type="checkbox"/>
4. Overweight <input type="checkbox"/>	8. Heartburn <input type="checkbox"/>
5. Underweight <input type="checkbox"/>	9. Malabsorption syndrome <input type="checkbox"/>
6. Anaemia <input type="checkbox"/>	10. Specific dietary requirement <input type="checkbox"/>

- 1. Is this a referral to another level of outpatient care or admission to hospital?** Place an 'X' in the corresponding box. Cross one box only.

If the mother is a control and just continuing routine care, select "referral"

If the mother is being sent home to self-isolate/quarantine, select "referral".

- 2. To which department/unit/service has she been referred or admitted?**

Place an 'X' in the corresponding box. Cross one box only from the following:

- Gynaecology;
- Obstetric/High-risk clinic;
- Nephrology;
- Nutritional;
- Physiotherapy;
- Psychiatry;
- Surgery;
- Trauma/Orthopaedics;
- Emergency room;
- Internal medicine;
- Other.

Select 'Other' IF:

- the mother is a control and just continuing routine care
- if the woman is being sent home to self-isolate/quarantine
- the department/unit/service cannot be classed as one of the first 10 options

If she has been referred or admitted for a nutritional problem, please indicate the diagnosis.

Indicate the relevant diagnoses by placing an 'X' in the box next to all that apply from the list below:

3. **Gestational diabetes** (defined as any degree of glucose intolerance with onset or first recognition during pregnancy)
4. **Overweight**
5. **Underweight**
6. **Anaemia**
7. **Food allergy**
8. **Heartburn**
9. **Malabsorption syndrome**
10. **Specific dietary requirement**

Section 2: Lab information (if requested during admission/referral)

Section 2: Lab information (if requested during admission/referral)			
11. Proteinuria (by dipstick): (cross one box only)			
0 / trace	<input type="checkbox"/>	+	<input type="checkbox"/>
		++	<input type="checkbox"/>
+++	<input type="checkbox"/>	++++	<input type="checkbox"/>
			No urine test performed at this referral/admission <input type="checkbox"/>
and/or actual result (from urine sample) received from laboratory:			<input type="text"/> <input type="text"/> <input type="text"/> mg/dl
12. Urine culture: (cross one box only)			
Positive			<input type="checkbox"/>
Negative			<input type="checkbox"/>
No urine culture available			<input type="checkbox"/>
13. If positive, was antibiotic treatment given?			yes <input type="checkbox"/> no <input type="checkbox"/>
14. Lowest haemoglobin level: OR Lowest haematocrit:			
<input type="text"/> <input type="text"/> . <input type="text"/> g/dl	<input type="text"/> <input type="text"/> . <input type="text"/> %		
15. Lowest blood glucose level:			<input type="text"/> <input type="text"/> <input type="text"/> mmol/l
16. Highest blood glucose level:			<input type="text"/> <input type="text"/> <input type="text"/> mmol/l
17. Highest serum creatinine level:			<input type="text"/> . <input type="text"/> <input type="text"/> μ mol/l

Please complete **only** the results of lab tests that have been done during this referral or admission. If the tests have not been done during the referral, leave the field blank.

11. Proteinuria

Obtain the results of the urinalysis from the lab report for this referral/admission.

If proteinuria is reported from the dipstick, cross the option corresponding to the number of '+' in the box.

If proteinuria is reported in the lab results, enter the actual value in milligrams/decilitre (mg/dl) in the corresponding box. If the results are not available, leave the field blank.

12. Urine culture

Cross one box only.

Place an 'X' next to 'Positive' if the urine culture showed evidence of a urinary tract infection.

Place an 'X' next to 'Negative' if the urine culture showed no evidence of a urinary tract infection.

Place an 'X' next to 'No urine culture available' if the test was not carried out.

If 'Negative' or 'No urine culture available', leave the response to Question 13 blank, and skip to Question 14.

13. If positive, was antibiotic treatment given?

Place an 'X' in the box marked 'YES' if antibiotic treatment was given after the positive test result.

Place an 'X' in the box marked 'NO' if the positive urine culture result was not treated.

14. Lowest haemoglobin level OR Lowest haematocrit

If her haemoglobin level or haematocrit was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the lowest haemoglobin level recorded during the referral/admission, in grams/decilitre (g/dl), or the lowest haematocrit result as a percentage (%), to 1 decimal place.

If not available, leave the field blank.

15. Lowest blood glucose level

If her blood glucose level was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the lowest blood glucose level recorded during the referral/admission, in millimoles/litre (mmol/l), with no decimal places.

If not available, leave the field blank.

16. Highest blood glucose level

If her blood glucose level was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the highest blood glucose level recorded during the referral/admission, in millimoles/litre (mmol/l), with no decimal places.

If not available, leave the field blank.

17. Highest serum creatinine level

If her serum creatinine level was measured during referral/admission, obtain the results from the lab. In the corresponding box enter the highest serum creatinine level recorded during the referral/admission, in micromoles/litre ($\mu\text{mol/l}$), to 1 decimal place.

If not available, leave the field blank.

Section 3: Clinical diagnosis for this admission or referral

Important: This section refers only to diagnoses that are not directly related to pregnancy. If the diagnosis is related to pregnancy, see Section 4.

Section 3: Clinical diagnosis for this admission or referral		
Please provide the main diagnosis by referring to the medical records:		
18. Diabetes	<input type="checkbox"/> yes	<input type="checkbox"/> no
If yes, was there any evidence of diabetic ketoacidosis?	<input type="checkbox"/> yes	<input type="checkbox"/> no
19. Thyroid disease or any other endocrinological condition	<input type="checkbox"/> yes	<input type="checkbox"/> no
20. Any type of malignancy/cancer (if yes, please complete an Adverse Event Form)	<input type="checkbox"/> yes	<input type="checkbox"/> no
21. Cardiac disease	<input type="checkbox"/> yes	<input type="checkbox"/> no
22. Epilepsy	<input type="checkbox"/> yes	<input type="checkbox"/> no
23. Mental illness e.g. Clinical depression	<input type="checkbox"/> yes	<input type="checkbox"/> no
24. Symptomatic malaria	<input type="checkbox"/> yes	<input type="checkbox"/> no
25. Symptomatic malaria with parasite count	<input type="checkbox"/> yes	<input type="checkbox"/> no
26. Respiratory disease (including asthma)	<input type="checkbox"/> yes	<input type="checkbox"/> no
27. Pyelonephritis or kidney disease	<input type="checkbox"/> yes	<input type="checkbox"/> no
28. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition	<input type="checkbox"/> yes	<input type="checkbox"/> no
29. Lower urinary tract infection requiring antibiotic treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no
30. Respiratory tract infection requiring antibiotic/antiviral treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no
31. Any other infection requiring antibiotic/antiviral treatment	<input type="checkbox"/> yes	<input type="checkbox"/> no
32. Non-septic shock requiring fluid replacement or pressor agents	<input type="checkbox"/> yes	<input type="checkbox"/> no
33. Maternal trauma	<input type="checkbox"/> yes	<input type="checkbox"/> no
34. Deep vein thrombosis	<input type="checkbox"/> yes	<input type="checkbox"/> no
35. Systemic lupus erythematosus	<input type="checkbox"/> yes	<input type="checkbox"/> no
36. HIV or AIDS	<input type="checkbox"/> yes	<input type="checkbox"/> no
37. Any genital tract or sexually transmitted infection	<input type="checkbox"/> yes	<input type="checkbox"/> no
38. Sickle-cell anaemia	<input type="checkbox"/> yes	<input type="checkbox"/> no
39. Cholestasis	<input type="checkbox"/> yes	<input type="checkbox"/> no
40. Any other medical/surgical condition requiring treatment or surgery (if yes, please complete an Adverse Event Form)	<input type="checkbox"/> yes	<input type="checkbox"/> no

Please provide the main diagnosis by referring to the medical records. For each condition:

Place an 'X' in the box marked 'YES' if during this referral/admission she has been diagnosed with or treated for that condition.

Place an 'X' in the box marked 'NO' if during this referral/admission she has not been diagnosed with or treated for that condition.

18. Diabetes

(any type, woman previously known to be diabetic before this pregnancy). If the woman developed diabetes during this pregnancy and had no previous history of diabetes, do not cross 'YES' here but instead refer to Question 42 ('Gestational diabetes') in Section 4.

If yes, was there any evidence of diabetic ketoacidosis?

Place an 'X' in the box marked 'YES' if there was any evidence of diabetic ketoacidosis.

Place an 'X' in the box marked 'NO' if there was no evidence of diabetic ketoacidosis.

19. Thyroid disease or any other endocrinological condition

(Examples: hypo- or hyper-thyroidism, parathyroidism (PTH), Addison's disease, adrenal gland disorders, hypophysitis). Malignant thyroid nodules should be classed as a type of malignancy/ cancer (Question 20).

20. Any type of malignancy/cancer (including leukaemia or lymphoma). If yes, complete further information in an **Adverse Event Form**.

21. Cardiac disease (Examples: arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, sarcoma, pericarditis, cardiomyopathy, etc.)

22. Epilepsy (any episode)

23. Mental illness e.g. Clinical depression (excluding mild depression without treatment). Include all forms of mental illness requiring treatment. Examples: clinical depression, schizophrenia, bipolar disorder, obsessive-compulsive disorder (OCD), generalised anxiety disorder.

24. Symptomatic malaria (any episode)

25. Symptomatic malaria with parasite count. If she has shown symptoms of malaria, only select this option if the presence of malaria has been confirmed by means of a parasite count.

26. Respiratory disease (including asthma). Other examples: chronic bronchitis, emphysema.

27. Pyelonephritis or kidney disease – pyelonephritis is an inflammation of the kidney and upper urinary tract that usually results from non-contagious bacterial infection of the bladder (cystitis) or other urinary infections.

28. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption condition

29. Lower urinary tract infection requiring antibiotic treatment (e.g. cystitis)

30. Respiratory tract infection requiring antibiotic/antiviral treatment (e.g. bacterial pneumonia)

31. Any other infection requiring antibiotic/antiviral treatment

32. Non-septic shock requiring fluid replacement or pressor agents

33. Maternal trauma (a serious or critical bodily injury, wound or shock)

34. Deep vein thrombosis

35. Systemic lupus erythematosus (a chronic inflammatory collagen disease affecting connective tissue)

36. HIV or AIDS

37. Any genital tract or sexually transmitted infection (e.g. syphilis, gonorrhoea, trichomoniasis, genital warts, condyloma acuminata, candidiasis)

38. Sickle-cell anaemia

39. Cholestasis (a condition where bile cannot flow from the liver to the duodenum)

40. Any other medical/surgical condition requiring treatment or surgery. If yes, complete further information in an **Adverse Event Form**.

Section 4: Pregnancy-related diagnosis for this admission or referral

Important: This section refers only to diagnoses that are related to pregnancy. If the diagnosis is not related to pregnancy, see Section 3.

Section 4: Pregnancy-related diagnosis for this admission or referral			
Please provide the main diagnosis by referring to the medical records:			
41. Severe vomiting requiring hospitalisation	<input type="checkbox"/> yes <input type="checkbox"/> no	52. Miscarriage or fetal death (if yes, please complete the Pregnancy and Delivery Form)	<input type="checkbox"/> yes <input type="checkbox"/> no
42. Gestational diabetes	<input type="checkbox"/> yes <input type="checkbox"/> no	53. Fetal anaemia	<input type="checkbox"/> yes <input type="checkbox"/> no
43. Vaginal bleeding	<input type="checkbox"/> yes <input type="checkbox"/> no	54. Fetal distress (abnormal fetal heart rate [FHR] or biophysical profile [BPP])	<input type="checkbox"/> yes <input type="checkbox"/> no
44. Pregnancy-induced hypertension (BP>140/90, no proteinuria)	<input type="checkbox"/> yes <input type="checkbox"/> no	55. Suspected impaired fetal growth	<input type="checkbox"/> yes <input type="checkbox"/> no
45. Preeclampsia (BP>140/90 and proteinuria)	<input type="checkbox"/> yes <input type="checkbox"/> no	56. Pelvic mass	<input type="checkbox"/> yes <input type="checkbox"/> no
46. Severe preeclampsia/Eclampsia/HELLP syndrome	<input type="checkbox"/> yes <input type="checkbox"/> no	57. Oligohydramnios	<input type="checkbox"/> yes <input type="checkbox"/> no
47. Fetal maternal haemorrhage	<input type="checkbox"/> yes <input type="checkbox"/> no	58. Polyhydramnios	<input type="checkbox"/> yes <input type="checkbox"/> no
48. Rhesus disease or anti-Kell antibodies	<input type="checkbox"/> yes <input type="checkbox"/> no	59. A condition requiring amniocentesis or fetal blood sampling (FBS)	<input type="checkbox"/> yes <input type="checkbox"/> no
49. Uterine rupture	<input type="checkbox"/> yes <input type="checkbox"/> no	60. Abruptio placentae	<input type="checkbox"/> yes <input type="checkbox"/> no
50. Prelabour premature rupture of membranes (PPROM) or Preterm labour without delivery	<input type="checkbox"/> yes <input type="checkbox"/> no	61. Clinical chorioamnionitis	<input type="checkbox"/> yes <input type="checkbox"/> no
51. PPRM or Preterm labour and delivery (if yes, please complete the Pregnancy and Delivery Form)	<input type="checkbox"/> yes <input type="checkbox"/> no	62. Any other pregnancy-related infection or condition (if yes, please complete an Adverse Event Form)	<input type="checkbox"/> yes <input type="checkbox"/> no

Please provide the main diagnosis by referring to the medical records. For each condition:

Place an 'X' in the box marked 'YES' if during this referral/admission she has been diagnosed with or treated for that condition.

Place an 'X' in the box marked 'NO' if during this referral/admission she has not been diagnosed with or treated for that condition.

41. Severe vomiting requiring hospitalisation

42. Gestational diabetes (defined as any degree of glucose intolerance with onset or first recognition during pregnancy). NB If the woman was previously known to be diabetic

before this pregnancy, do not cross 'YES' here but instead refer to Question 18 ('Diabetes, thyroid disease or any other endocrinological condition') in Section 3.

43. Vaginal bleeding

44. Pregnancy-induced hypertension (blood pressure >140/90, no proteinuria; develops after 20 weeks' gestation in a previously normotensive pregnancy)

45. Preeclampsia (blood pressure >140/90 and proteinuria)

Preeclampsia is defined as high blood pressure 140/90 mmHg or greater, or an increase of 30mmHg systolic or 15mmHg diastolic over baseline values on at least two occasions 6 or more hours apart, that develops after 20 weeks' gestation in a previously normotensive pregnancy, and proteinuria (presence of excessive protein substance, chiefly albumin, in the urine).

46. Severe preeclampsia/Eclampsia/HELLP syndrome

Severe preeclampsia is diagnosed when blood pressure is ≥ 160 mmHg systolic and/or ≥ 110 mmHg diastolic on two occasions, between 4 and 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 her cerebral conditions in a woman 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 pre-eclampsia or eclampsia and who also show signs of liver damage and abnormalities in blood clotting. It is characterised by: **H**aemolysis, **E**L (elevated) liver enzymes and **L**P (low platelet) count.

47. Fetal maternal haemorrhage

48. Rhesus disease or anti-Kell antibodies. Rhesus disease – also known as isoimmunisation or RH – can occur when the mother is Rh negative and the baby is Rh positive. The transfer of anti-Kell antibodies from the mother to the fetus across the placental barrier can cause severe anaemia by interfering with the early proliferation of red blood cells.

49. Uterine rupture. Complete uterine rupture is a catastrophic event where a full-thickness tear develops, opening the uterus directly into the abdominal cavity; it requires rapid surgical attention to safeguard maternal and infant outcomes. Occult or incomplete rupture is where a surgical scar separates but the visceral peritoneum stays intact; it is usually asymptomatic and does not require emergency surgery.

50. Prelabour premature rupture of membranes (PPROM) or Preterm labour without delivery – PPRM is rupture of the membranes before labour has begun; preterm labour is initiation of labour before 37⁺⁰ weeks.

51. PPRM or Preterm labour and delivery – PPRM is rupture of the membranes before labour has begun; preterm labour is initiation of labour before 37⁺⁰ weeks. If yes, complete the **Pregnancy and Delivery Form**.

52. Miscarriage or fetal death. If yes, complete the **Pregnancy and Delivery Form**.

53. Fetal anaemia (suggested by very low haematocrit or haemoglobin concentration for gestational age)

54. Fetal distress (abnormal fetal heart rate (FHR) or biophysical profile (BPP))

55. Suspected impaired fetal growth

56. Pelvic mass (enlargement or swelling in the lower abdomen or pelvic region)

57. Oligohydramnios (a decreased amount of amniotic fluid)

58. Polyhydramnios (an excessive amount of amniotic fluid)

59. A condition requiring amniocentesis or fetal blood sampling (FBS)

60. Abruptio placentae (i.e. placental abruption) refers to the partial or complete separation of the normally located placenta after the 20th week of gestation and prior to birth. The normal placenta separates from the uterus prematurely and blood collects between the placenta and the uterus.

61. Clinical chorioamnionitis (an inflammation of the fetal membranes – chorion and amnion – due to a bacterial infection)

62. Any other pregnancy-related infection or condition. If yes, complete further information in an **Adverse Event Form**.

Section 5: Medications and treatment

Section 5: Medications and treatment					
Has she been prescribed any of the following medications or treatments?					
63. Aspirin	<input type="checkbox"/>	<input type="checkbox"/>	67. Treatments for asthma	<input type="checkbox"/>	<input type="checkbox"/>
64. Antibiotics/Antivirals	<input type="checkbox"/>	<input type="checkbox"/>	68. Antipsychotics	<input type="checkbox"/>	<input type="checkbox"/>
65. Antihypertensives	<input type="checkbox"/>	<input type="checkbox"/>	69. Antidepressants	<input type="checkbox"/>	<input type="checkbox"/>
66. Prophylactic steroids for preterm labour	<input type="checkbox"/>	<input type="checkbox"/>	70. Magnesium sulphate	<input type="checkbox"/>	<input type="checkbox"/>
			71. Blood transfusion	<input type="checkbox"/>	<input type="checkbox"/>
			72. Just bed rest/observation	<input type="checkbox"/>	<input type="checkbox"/>
			73. Any other treatment	<input type="checkbox"/>	<input type="checkbox"/>

Has she been prescribed any of the following medications or treatments? For each medication or treatment:

Place an 'X' in the box marked 'YES' if she has been prescribed that medication or treatment during this referral/admission.

Place an 'X' in the box marked 'NO' if she has not been prescribed that medication or treatment during this referral/admission.

63. Aspirin

64. Antibiotics/Antivirals (e.g. penicillin)

65. Antihypertensives

66. Prophylactic steroids for preterm labour

67. Treatments for asthma

68. Antipsychotics

69. Antidepressants

70. Magnesium sulphate

71. Blood transfusion

72. Just bed rest/observation (no treatment required)

73. Any other treatment

Section 6: Final outcome

Section 6: Final outcome	
74. Final outcome of the admission: (cross one box only)	
Discharged <input type="checkbox"/>	Maternal death (complete the Pregnancy and Delivery and Adverse Event Forms) <input type="checkbox"/>
Transferred to another level of care or hospital (inform study coordinator) <input type="checkbox"/>	Left hospital or treatment against medical advice (inform study coordinator) <input type="checkbox"/>
Delivered/Miscarried (complete the Pregnancy and Delivery Form) <input type="checkbox"/>	
75. Date of discharge from hospital:	<input type="text" value="D"/> <input type="text" value="D"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/>

74. Final outcome of the admission

Place an 'X' in the corresponding box. Cross one box only from the following list:

- Discharged;
- Transferred to another level of care or hospital (inform the study coordinator);
- Delivered/Miscarried. Include in this category fetal death and miscarriage. **Complete the Pregnancy and Delivery Form in all cases.**
- Maternal death. Complete the **Pregnancy and Delivery and Adverse Event Forms**.
- Left hospital or treatment against medical advice (inform the study coordinator).

75. Date of discharge from hospital

Enter the date that the woman left the hospital/referral clinic in the format dd-mm-yy, e.g. '21st May 2020' should be written '21-05-20'.

Section 7: Next appointment

Section 7: Next appointment	
If the woman is still pregnant (even if she is still in hospital) check the date of the next ultrasound appointment.	
76. Date of the next ultrasound appointment:	<input type="text" value="D"/> <input type="text" value="D"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/>
If the woman is still in hospital please inform the study coordinator.	

76. If the woman is still pregnant (even if she is still in hospital) check the date of the next ultrasound appointment.

INTERGROWTH-21st

Implementing the INTERGROWTH-21st Preterm Postnatal Growth Standards

**International Preterm Postnatal Growth
Standards Consortium**



PREGNANCY AND DELIVERY FORM INSTRUCTIONS

December 2017



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General Guidelines

This form is to be completed upon delivery for all mothers of participants in the Early Infancy Body Composition Study (EIBCS).

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.

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 an '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 initialled. 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.

Pregnancy and Delivery Form (DEV)

Form Header

Participant study number	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Delivery Hospital Code	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
Maternal Hospital Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Infant date of birth	<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Infant Hospital Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Newborn is part of the BC study	<input type="text"/> yes <input type="text"/> no

The unique **Participant Subject Number** should be pre-printed on each form.

Delivery Hospital Code. It should be the site code (first two digits) followed by the numbers 01.

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

Infant date of birth. This should match the date recorded in question 110 of this form.

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

Newborn is part of the body composition (BC) study. Place an 'X' in the box marked 'YES' if the infant will be included in the Early Infancy Body Composition Study. If the infant was born between 32-36 gestational weeks, the newborn will be most likely part of the BC study.

Section 1: Demographic, socioeconomic and nutritional characteristics

Section 1: Demographic, socioeconomic and nutritional characteristics			
1. Maternal age	<input type="text"/> <input type="text"/> years		
2. Maternal height	<input type="text"/> <input type="text"/> <input type="text"/> cm		
3. 1st trimester or pre-pregnancy weight	<input type="text"/> <input type="text"/> <input type="text"/> kg		
4. Has she smoked/chewed tobacco during this pregnancy?	<input type="text"/> yes <input type="text"/> no		
5. If she smoked cigarettes, how many per day?	<input type="text"/> <input type="text"/>		
6. Has she used any recreational drugs during this pregnancy?	<input type="text"/> yes <input type="text"/> no		
7. On average, how many units of alcohol per week has she had during this pregnancy? (1 unit = small glass (125ml) of wine or one bottle/can (330ml) of beer; see table)	<input type="text"/> <input type="text"/> units		
8. Has she been involved in any high risk occupation and/or vigorous sport during this pregnancy?	<input type="text"/> yes	<input type="text"/> no	see table
9. Has she followed any special diets during this pregnancy? (e.g. vegetarian with no animal products, weight loss programme, malabsorption treatment, gluten-free)	<input type="text"/> yes	<input type="text"/> no	see table
10. Current marital status	Single <input type="text"/>	Widowed <input type="text"/>	
(cross one box only)	Married/Cohabiting <input type="text"/>	Separated/Divorced <input type="text"/>	
11. Total number of years of formal education	<input type="text"/> <input type="text"/> years		
12. Highest level of education she attended	Primary <input type="text"/>	Professional/ technical training <input type="text"/>	
(cross one box only)	Secondary <input type="text"/>	University <input type="text"/>	
13. Which of the following best describes her occupational status?			
(cross one box only)	Housework <input type="text"/>	Skilled manual work <input type="text"/>	
	Manager/professional/technical <input type="text"/>	Unskilled manual work <input type="text"/>	
	Clerical support, service or sales <input type="text"/>	Other <input type="text"/>	

1. Maternal age (years)

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

2. 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.

3. 1st trimester or pre-pregnancy weight (kg)

Take the woman's first trimester weight from her medical record. If unavailable, ask the woman 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.

4. 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 an 'X' in the box marked 'NO' if the woman HAS NOT smoked/chewed tobacco during her pregnancy.

5. 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

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

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

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

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

7. On average, how many units of alcohol per week has she had during this pregnancy?

Write the average number of units of alcohol that the woman has been drinking per week.

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

8. 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 an 'X' in the box marked 'YES' if the woman was involved in any of the high-risk activities listed below during her pregnancy.

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

Frequent exposure to the following chemicals or toxic substances:	Physically demanding work:	High-risk sports/vigorous exercise:
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 vigorous exercise more than 4 times per week into the 2 nd half of pregnancy

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

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

10. **Marital Status**

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

Place an 'X' next to **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.

11. **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.

12. 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)

13. 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					
14. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>	23. Any hematologic condition including sickle-cell anaemia or leukaemia	<input type="checkbox"/>	<input type="checkbox"/>
15. Thyroid disease	<input type="checkbox"/>	<input type="checkbox"/>	24. Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>
16. Other endocrinological conditions	<input type="checkbox"/>	<input type="checkbox"/>	25. HIV or AIDS	<input type="checkbox"/>	<input type="checkbox"/>
17. Cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>	26. Malaria	<input type="checkbox"/>	<input type="checkbox"/>
18. Hypertension/chronic hypertension	<input type="checkbox"/>	<input type="checkbox"/>	27. Tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>
19. Chronic respiratory disease (including asthma)	<input type="checkbox"/>	<input type="checkbox"/>	28. Crohn's disease, coeliac disease, ulcerative colitis or any severe malabsorption	<input type="checkbox"/>	<input type="checkbox"/>
20. Proteinuria, kidney disease or chronic renal disease	<input type="checkbox"/>	<input type="checkbox"/>	29. Any congenital abnormality	<input type="checkbox"/>	<input type="checkbox"/>
21. Any type of malignancy/cancer	<input type="checkbox"/>	<input type="checkbox"/>	30. Any other clinically relevant condition	<input type="checkbox"/>	<input type="checkbox"/>
22. Lupus erythematosus	<input type="checkbox"/>	<input type="checkbox"/>			

Prior to this pregnancy, had she ever been diagnosed with or treated for any of the following medical conditions? Cross all boxes that apply

14. **Diabetes** (any type)
15. **Thyroid Disease** (any type)
16. **Other endocrinological conditions** (examples - Addison's disease, adrenal gland disorders, hypo- or hyperthyroidism)
17. **Cardiac disease** (examples - arrhythmias, murmurs, valve diseases, atherosclerosis, atrial fibrillation, pericarditis, cardiomyopathy etc.)
18. **Hypertension/chronic hypertension with treatment** (defined as 140/90 or greater. Include in this category women who have been treated for hypertension.)
19. **Chronic respiratory diseases (including chronic asthma).** Do not include childhood asthma that is no longer present or very mild cases/allergies.

20. **Proteinuria or kidney disease or chronic renal disease** (The presence of excessive protein substance, chiefly albumin, in the urine)
21. **Any type of malignancy/cancer**
22. **Lupus Erythematosus** (a chronic inflammatory collagen disease affecting connective tissue)
23. **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)
24. **Epilepsy** (any type)
25. **HIV or AIDS**
26. **Malaria** (any episode)
27. **Tuberculosis**
28. **Crohn's disease, Coeliac disease or ulcerative colitis or any severe malabsorption condition**
29. **Any congenital 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).
30. **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									
31. Did she have regular (24-32 day) menstrual cycles in the 3 months prior to this pregnancy?								yes	no
32. Has she used hormonal contraceptives or been breastfeeding in the 2 months prior to this pregnancy?								yes	no
33. Was this pregnancy conceived with fertility treatment?								yes	no
34. First day of the last menstrual period (LMP)				<div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">D</div>	–	<div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div>	–	<div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div>	
35. Was she certain of her date of LMP?								yes	no
36. Date of the first ultrasound scan during this pregnancy				<div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">D</div>	–	<div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div>	–	<div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div>	
37. What was the CRL (crown rump length) measurement at the first ultrasound scan?						<div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div>	.	<div style="border: 1px solid black; padding: 2px;"> </div>	mm
38. What was the BPD (biparietal diameter) measurement at the first ultrasound scan?						<div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div>	.	<div style="border: 1px solid black; padding: 2px;"> </div>	mm
39. Estimated gestational age at the first ultrasound scan						<div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div>	wks	<div style="border: 1px solid black; padding: 2px;"> </div>	days

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

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

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

Place an '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 an '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.

33. Was her pregnancy conceived with fertility treatment?

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

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

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

dd-mm-yy, e.g. 20th 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.

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

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

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

36. 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. 20th May 2010 = 20/05/10. If the woman has not had an ultrasound scan during this pregnancy, leave this box blank.

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

Obtain this measurement from 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.

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

Obtain this measurement from 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.

39. Estimated gestational age from first 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	
40. Number of previous pregnancies, excluding the present pregnancy (if 0, skip to Section 5)	<input type="text"/>
41. Number of previous miscarriages	<input type="text"/>
42. Number of previous births, excluding this birth (if 0, skip to Section 5)?	<input type="text"/>
43. Have ANY of her other babies weighed less than 2.5kg or more than 4.5kg?	yes <input type="text"/> no <input type="text"/>
44. Have ANY of her other babies been born preterm (<37 weeks' gestation)?	yes <input type="text"/> no <input type="text"/>
45. Has she had ANY previous stillbirths or neonatal deaths?	yes <input type="text"/> no <input type="text"/>

40. 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.

41. Number of previous miscarriages

Enter the number of previous miscarriages in the box. For 0, enter 00; for 1, enter 01, etc. Do not include any terminations.

42. 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.

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

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

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

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

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

Section 5: Clinical conditions

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

In each box:

Place an '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 an '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 an 'X' in the box marked '**NO**'.

46. **Cardiac disease** (any type)

47. **Chronic respiratory disease (including chronic asthma)** Do not include mild asthma not requiring treatment or temporary use of an inhaler due to seasonal allergies.

48. **Malaria** (any type)

49. **Mental illness** (examples: depression, bipolar disorder, schizophrenia, general anxiety disorder). Do not include mild depression not requiring treatment.

50. **Epilepsy** (any type of seizure/episode)

51. **Thyroid disease or any other endocrinological condition** (examples - Addison's disease, adrenal gland disorders, hypo- or hyper-thyroidism)

52. **Lower urinary tract infections requiring antibiotic treatment**

53. **Pyelonephritis** defined as an inflammation of the kidney and upper urinary tract that usually results from non-contagious bacterial infection of the bladder (cystitis) or other urinary infections.

54. **Respiratory tract infection requiring antibiotic/antiviral treatment**
55. **Any other infections requiring antibiotic/antiviral treatment.**
56. **Positive syphilis test**
57. **HIV or AIDS**
58. **Any sexually transmitted infections.** (Examples: gonorrhea, Chlamydia)
59. **Any type of malignancy or cancer.**
60. **Any other medical/surgical condition requiring treatment or referral**

Section 6: Pregnancy specific conditions

Section 6: Pregnancy related complications					
During this pregnancy was she diagnosed with, or treated for, any of the following conditions (cross all that apply)					
61. Severe vomiting requiring hospitalisation	yes	no	68. Severe preeclampsia/ Eclampsia/HELLP	yes	no
62. Gestational diabetes	yes	no	69. Rhesus disease	yes	no
63. Vaginal bleeding before 15 weeks	yes	no	70. Preterm labour	yes	no
64. Vaginal bleeding between 15-27 weeks	yes	no	71. Fetal distress	yes	no
65. Vaginal bleeding after 27 weeks	yes	no	72. Suspected impaired fetal growth or SGA	yes	no
66. Pregnancy-induced hypertension	yes	no	73. Any other pregnancy related condition	yes	no
67. Preeclampsia	yes	no	requiring treatment or referral		
<div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <15 weeks 74. Lowest haemoglobin level (if available) <input type="text"/> <input type="text"/> . <input type="text"/> g/dl </div> <div style="text-align: center;"> 15-27 weeks <input type="text"/> <input type="text"/> . <input type="text"/> g/dl </div> <div style="text-align: center;"> >27 weeks <input type="text"/> <input type="text"/> . <input type="text"/> g/dl </div> </div>					

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

61. **Severe vomiting requiring hospitalization**
62. **Gestational diabetes** is a condition in which women without previously diagnosed diabetes exhibit high blood glucose levels during pregnancy.
63. **Vaginal bleeding before 15 weeks**
64. **Vaginal bleeding at 15-27 weeks**
65. **Vaginal bleeding after 27 weeks**
66. **Pregnancy-induced hypertension** high blood pressure 140/90 or greater that develops after 20 weeks gestation in a previously normotensive pregnancy.
67. **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.
68. **Severe preeclampsia/Eclampsia/HELLP syndrome**

Severe preeclampsia is diagnosed when blood pressures are ≥ 160 mmHg systolic and/or ≥ 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 other 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 pre-eclampsia 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.

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

Section 7: Nutritional supplements / Medications					
During this pregnancy, has she routinely taken any of the following supplements? (cross all that apply)					
75. Iron	<input type="checkbox"/> yes	<input type="checkbox"/> no	78. Food supplements	<input type="checkbox"/> yes	<input type="checkbox"/> no
76. Folic acid	<input type="checkbox"/> yes	<input type="checkbox"/> no	79. Multi-vitamins/minerals	<input type="checkbox"/> yes	<input type="checkbox"/> no
77. Calcium	<input type="checkbox"/> yes	<input type="checkbox"/> no			
During this pregnancy, has she taken any of the following medications? (cross all that apply)					
80. Routine aspirin	<input type="checkbox"/> yes	<input type="checkbox"/> no	83. Non-steroidal anti-inflammatories	<input type="checkbox"/> yes	<input type="checkbox"/> no
81. Any antibiotics or antivirals (except those used for PROM)	<input type="checkbox"/> yes	<input type="checkbox"/> no	84. Insulin	<input type="checkbox"/> yes	<input type="checkbox"/> no
82. Antibiotics used for PROM	<input type="checkbox"/> yes	<input type="checkbox"/> no	85. Prophylactic steroids for preterm labour	<input type="checkbox"/> yes	<input type="checkbox"/> no
			86. Any other treatment	<input type="checkbox"/> yes	<input type="checkbox"/> 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.

75. **Iron**
76. **Folic acid**
77. **Calcium**
78. **Food supplements**
79. **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.

80. **Routine aspirin**

81. **Any antibiotics or antivirals (except those used for PROM)** e.g. penicillin

82. **Antibiotics used for PROM** (e.g. prophylactic antibiotics)

83. **Non-steroidal anti-inflammatories** e.g. ibuprofen

84. **Insulin**

85. **Prophylactic steroids for preterm labour**

86. **Any other treatment**

Section 8: Delivery

Section 8: Delivery			
87. Onset of labour (cross one box only)		89. Mode of delivery (cross one box only)	
Spontaneous <input type="checkbox"/>	Induced <input type="checkbox"/>	No Labour <input type="checkbox"/>	
88. Did she have pre-labour rupture of membranes <input type="checkbox"/> yes <input type="checkbox"/> no		Vaginal spontaneous <input type="checkbox"/>	Assisted breech <input type="checkbox"/>
		Vaginal assisted (e.g. forceps, vacuum) <input type="checkbox"/>	Caesarean section <input type="checkbox"/>
If labour was induced or a Caesarean section was performed, please cross all indications that apply			
90. Vaginal bleeding	<input type="checkbox"/> yes <input type="checkbox"/> no	100. Suspected impaired fetal growth or SGA	<input type="checkbox"/> yes <input type="checkbox"/> no
91. Fetal death	<input type="checkbox"/> yes <input type="checkbox"/> no	101. Post term (>42 weeks gestation)	<input type="checkbox"/> yes <input type="checkbox"/> no
92. Pregnancy-induced hypertension	<input type="checkbox"/> yes <input type="checkbox"/> no	102. Rhesus disease	<input type="checkbox"/> yes <input type="checkbox"/> no
93. Preeclampsia	<input type="checkbox"/> yes <input type="checkbox"/> no	103. HIV or AIDS	<input type="checkbox"/> yes <input type="checkbox"/> no
94. Severe preeclampsia/ Eclampsia/HELLP	<input type="checkbox"/> yes <input type="checkbox"/> no	104. Any sexually transmitted infections	<input type="checkbox"/> yes <input type="checkbox"/> no
95. Breech presentation	<input type="checkbox"/> yes <input type="checkbox"/> no	105. Any infections requiring antibiotics/antivirals	<input type="checkbox"/> yes <input type="checkbox"/> no
96. Fetal distress	<input type="checkbox"/> yes <input type="checkbox"/> no	106. Maternal request	<input type="checkbox"/> yes <input type="checkbox"/> no
97. Failure to progress	<input type="checkbox"/> yes <input type="checkbox"/> no	107. Any other maternal reason	<input type="checkbox"/> yes <input type="checkbox"/> no
98. Cephalo-pelvic disproportion	<input type="checkbox"/> yes <input type="checkbox"/> no	108. Any other fetal reason	<input type="checkbox"/> yes <input type="checkbox"/> no
99. Prelabour rupture of membranes (PROM)	<input type="checkbox"/> yes <input type="checkbox"/> no	109. Previous Caesarean section	<input type="checkbox"/> yes <input type="checkbox"/> no

87. 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 Caesarean 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.

88. 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 an 'X' in YES if she had prelabour rupture of membranes

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

89. Mode of delivery

Please cross ONE box that best applies

Vaginal spontaneous is defined as delivery that did not require any special intervention. Episiotomy 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

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

If labour was induced or a Caesarean 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:

Place an 'X' in the box marked '**YES**' if the indication is written in the medical record as a main reason for induction or Caesarean section.

Place an 'X' in the box marked '**NO**' if the indication is NOT written in the medical record as a main reason for induction or Caesarean section.

90. Vaginal bleeding

91. Fetal death (or suspected fetal death)

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

93. Preeclampsia (see definition p.13)

94. Severe Preeclampsia/Eclampsia/HELLP syndrome (see definition p.14)

95. Breech presentation (feet first)

96. Fetal Distress

97. Failure to progress (this diagnosis given to a woman who does labour does not follow a normal pattern and is severely prolonged)

98. Cephalo-pelvic disproportion (when the baby's head is too big to fit through the mother's pelvis)

99. Prelabour reupture of membranes (PROM)

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

Section 9: Newborn Outcomes and Care

Section 9: Newborn outcome and care	
110. Date of delivery	<div> <div><input type="text"/></div> <div><input type="text"/></div> <div>–</div> <div><input type="text"/></div> <div><input type="text"/></div> <div>–</div> <div><input type="text"/></div> <div><input type="text"/></div> </div>
111. Time of delivery (24h clock)	<div> <div><input type="text"/></div> <div><input type="text"/></div> <div>:</div> <div><input type="text"/></div> <div><input type="text"/></div> </div>
112. Number of babies	<div> <div><input type="text"/></div> <div><input type="text"/></div> </div>
If more than 1 baby, complete another Pregnancy and delivery form (sections 3 to 5 only)	
113. Gestational age at birth (best obstetric estimate)	<div> <div><input type="text"/></div> <div><input type="text"/></div> <div>wks</div> <div><input type="text"/></div> <div>days</div> </div>
114. Apgar score at 5 minutes	<div> <div><input type="text"/></div> <div><input type="text"/></div> </div>
115. Newborn sex	<div> <div>Male</div> <div><input type="checkbox"/></div> <div>Female</div> <div><input type="checkbox"/></div> </div>
116. Fetal presentation at delivery (cross one box only)	<div> <div>Cephalic</div> <div><input type="checkbox"/></div> <div>Breech</div> <div><input type="checkbox"/></div> <div>Other</div> <div><input type="checkbox"/></div> </div>
117. Was the newborn admitted to intensive care or any special care unit?	<div> <div><input type="checkbox"/></div> <div>yes</div> <div><input type="checkbox"/></div> <div>no</div> </div>
118. Total number of days spent in intensive/special care unit (if <24h, enter 1 day)	<div> <div><input type="text"/></div> <div><input type="text"/></div> <div>days</div> </div>
119. Age at gavage onset	<div> <div><input type="text"/></div> <div><input type="text"/></div> <div>days</div> </div>
120. Age at full oral feeding onset	<div> <div><input type="text"/></div> <div><input type="text"/></div> <div>days</div> </div>
121. Enteral feeding was suspended/reintroduced	<div> <div><input type="checkbox"/></div> <div>yes</div> <div><input type="checkbox"/></div> <div>no</div> </div>

110. 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.

111. 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

112. 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 9, 10, 11, 12 and 13 for the second baby delivered. If more than 2 babies were delivered, repeat this process for each additional birth.

113. **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.

114. **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

115. **Newborn sex**

Please place an 'X' in the box that corresponds to the infant's sex.
If the sex is undifferentiated or undeterminable, please leave blank.

116. **Fetal presentation at delivery**

Cephalic (Head first)

Breech (Feet first)

Other (Any other fetal presentation at delivery, e.g. Arm first)

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

Place an '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 an '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.

118. **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.

119. **Age at gavage onset**

Enter the postnatal age (in complete days) at which gavage feeding was first introduced. It includes gavage feeding administered via an oro-gastric or naso-gastric tube either intermittently or continuously.

120. **Age full oral feeding onset**

Enter the postnatal age (in complete days) at which full oral feeding was first started, excluding non-nutritive sucking (mother pumps first and then places the baby to the breast).

121. **Enteral feeding was suspended/reintroduced**

Place an 'X' in the box marked YES if enteral feeding had to be suspended (initiating or reinitiating parenteral feeding) and later reintroduced before hospital discharge.

Has the newborn been diagnosed with/treated for any of the following conditions?					
122. Respiratory distress syndrome	yes	no	135. Seizures	yes	no
123. Transient tachypnea of the newborn	yes	no	136. Hypoglycaemia	yes	no
124. Pneumonia/Bronchiolitis	yes	no	137. Periventricular haemorrhage/leukomalacia	yes	no
125. Apnea of prematurity	yes	no	138. Hypotension requiring inotropics/steroids	yes	no
126. Bronchopulmonary dysplasia	yes	no	139. Anaemia (requiring transfusion)	yes	no
127. Meconium aspiration with respiratory distress	yes	no	140. Patent ductus arteriosus (requiring pharmacological treatment or surgery)	yes	no
128. No enteral feeding for more than 24 hours	yes	no	141. Any gastro-intestinal surgery	yes	no
129. Hypoxic-ischaemic encephalopathy	yes	no	142. Any other condition requiring surgery	yes	no
130. Polycythaemia	yes	no	143. Endocrine abnormalities	yes	no
131. Hyperbilirubinemia requiring transfusion	yes	no	144. Inborn errors of metabolism	yes	no
132. Kernicterus	yes	no	145. Any other serious condition	yes	no
133. TORCH or any other intrauterine infections	yes	no	146. Congenital abnormality (late diagnosis)	yes	no
134. 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).

122. **Respiratory distress syndrome**

123. **Transient tachypnea of the newborn**

124. **Pneumonia/Bronchiolitis**

125. **Apnoea of prematurity**

126. **Broncopulmonary dysplasia**
127. **Meconium aspiration with respiratory distress**
128. **No oral feeds for more than 24 hours**
129. **Hypoxic-ischemic encephalopathy**
130. **Polycythaemia**
131. **Hyperbilirubinemia requiring transfusion**
132. **Kernicterus**
133. **TORCH and/or other intrauterine infections**
134. **Sepsis**
135. **Seizures**
136. **Hypoglycemia**
137. **Periventricular hemorrhage/leukomalacia**
138. **Hypotension requiring inotropic treatment or steroids**
139. **Anaemia (requiring transfusion)**
140. **Patent ductus arteriosus (requiring pharmacological treatment or surgery)**
141. **Any gastro-intestinal surgery**
142. **Any other condition requiring surgery**
143. **Endocrine abnormalities**
144. **Inborn errors of metabolism**
145. **Any other serious condition**
146. **Congenital abnormality**

Section 10: Newborn Anthropometry

Section 10: Newborn anthropometry			
147. Birthweight	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> kg	150. Date of measurement	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
148. Length at birth	<input type="text"/> <input type="text"/> <input type="text"/> cm		
149. Head Circumference at birth	<input type="text"/> <input type="text"/> <input type="text"/> cm	151. Time of measurement	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
(please obtain the anthropometry preferably within 12 hours, and no later than 24 hours, after birth)			

The anthropometric measurements of the infant need to be taken as soon as possible after birth (preferably within 12 hours, and no later than 24 hours after birth), following the instructions in the Anthropometry Handbook and adhering to the advice given during training sessions.

147. **Birthweight (g)**

148. **Length at birth (cm)**
149. **Head Circumference at birth (cm)**
150. **Date of measurement** written in the format day-month-year. Example 20th May 2018 is written as 20-05-18.
151. **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.

Section 11: Morbidities/treatments during hospitalisation

Section 11: Morbidities/treatments during hospitalisation														
152. Has the newborn received respiratory support?				<input type="checkbox"/> yes <input type="checkbox"/> no	Has the newborn been given any of the following:									
153. If yes, number of days in respiratory support until discharge (round up to the next whole day)				<input type="text"/> <input type="text"/> <input type="text"/> days	155. Corticosteroids postnatally					<input type="checkbox"/> yes <input type="checkbox"/> no				
154. If on respiratory support, type of respiratory support.					156. Surfactant replacement therapy					<input type="checkbox"/> yes <input type="checkbox"/> no				
Mechanical ventilation				<input type="checkbox"/>	157. Diuretics					<input type="checkbox"/> yes <input type="checkbox"/> no				
Nasal C-PCP/high flow				<input type="checkbox"/>	158. Antibiotics					<input type="checkbox"/> yes <input type="checkbox"/> no				
Oxygen hood				<input type="checkbox"/>	159. Antipyretics					<input type="checkbox"/> yes <input type="checkbox"/> no				
					160. Methylxanthines					<input type="checkbox"/> yes <input type="checkbox"/> no				
Has the newborn been diagnosed with/treated for any of the following conditions?														
161. Intraventricular haemorrhage				<input type="checkbox"/> no <input type="checkbox"/> yes	→ Grade I	<input type="checkbox"/>	Grade II	<input type="checkbox"/>	Grade III	<input type="checkbox"/>	Grade IV	<input type="checkbox"/>		
162. Necrotising enterocolitis				<input type="checkbox"/> no <input type="checkbox"/> yes	→ Stage I	<input type="checkbox"/>	Stage IIa	<input type="checkbox"/>	Stage IIb	<input type="checkbox"/>	Stage III	<input type="checkbox"/>		
163. Retinopathy of prematurity				<input type="checkbox"/> no <input type="checkbox"/> yes	→ Stage I	<input type="checkbox"/>	Stage II	<input type="checkbox"/>	Stage III	<input type="checkbox"/>	Stage IV	<input type="checkbox"/>	Stage V	<input type="checkbox"/>

152. **Has the newborn received respiratory support?**
Place an 'X' in the box marked 'YES' if the newborn has received, AT ANY TIME, respiratory support.
153. **If yes, number of days in respiratory support until discharge (round up to the next whole day)**
Write the number of days that the newborn was in respiratory support up to the day of hospital discharge. Round up the nearest whole day. Examples: 12 hours should be recorded as 1 day; 36 hours should be recorded as 2 days.
154. **If on respiratory support, type of respiratory support.**
Cross only the ONE box that best applies to the type of respiratory support received by the newborn.

Has the newborn been given any of the following:

Cross all boxes that apply

155. **Corticosteroids postnatally**
156. **Surfactant replacement therapy**
157. **Diuretics**
158. **Antibiotics**

159. **Antipyretics**

160. **Methylxanthines**

Has the newborn been diagnosed with/treated for any of the following conditions?

161. **Intraventricular haemorrhage**

If the answer is YES, place an X in the box corresponding to the grade of the intraventricular haemorrhage.

162. **Necrotising enterocolitis**

If the answer is YES, place an X in the box corresponding to the grade of the necrotising enterocolitis.

163. **Retinopathy of prematurity**

If the answer is YES, place an X in the box corresponding to the grade of the necrotising retinopathy of prematurity.

Section 12: Newborn Outcomes

Section 12: Newborn outcomes	
164. Newborn status at hospital discharge Alive <input type="checkbox"/> Alive but referred <input type="checkbox"/> Dead <input type="checkbox"/> to another hospital	165. Date of hospital discharge or date of neonatal death D D - M M - Y Y

164. **Newborn status at hospital discharge**

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

165. **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 13: Feeding Practices at hospital discharge

Section 13: Newborn nutritional practices at hospital discharge			
166. What was the main mode of feeding in the 24 hours prior to hospital discharge? (cross one box only)			
Exclusive <input type="checkbox"/> breastmilk	Combination feeding Predominant <input type="checkbox"/> Partial <input type="checkbox"/> breastmilk breastmilk		Exclusive <input type="checkbox"/> No oral feeds <input type="checkbox"/> formula (IV fluids only)

166. **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:

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) ORD, drops, syrups	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	(vitamins, minerals, medicines)	Anything else (in particular breast milk)

Section 14: Maternal Outcomes

Section 14: Maternal outcomes			
167. Was the mother admitted to intensive care or any special care unit after delivery?	<div>yes</div> <div>no</div>		
168. If yes, total number of days: (if less than 24 hours, please enter as 1 day)	<div></div> <div></div> <div></div>		
169. Maternal status at hospital discharge: (cross one box only)	<div>Alive</div> <div></div>	<div>Alive but referred to another hospital</div> <div></div>	<div>Dead</div> <div></div>

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

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

168. 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.

169. Maternal status at hospital discharge

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

Comments

167. Comments (please identify the question that the comment refers to with a *q* followed by the question number; example: "q146. head circumference at birth not available in medical records")

This section allows you to enter comments specific to questions in the form. Please be brief, and identify the question that the comment refers to with a *q* followed by the question number; example: "q146. head circumference at birth not available in medical records".

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 Ophthalmol* 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 ≤ 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 ≥ 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 severe sepsis, or marked gastrointestinal hemorrhage

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

REFERENCE

Gastrointestinal disorder: In Robertson's Text book of Neonatology (3rd ed). 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. New York: 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 H₂O
 - B) Hct 21%–30%
Receiving <35% supplemental hood oxygen
On CPAP or mechanical ventilation with mean airway pressure <6 cm H₂O
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, occlusomotor disturbances, dental dysplasia and mental deficiency.

REFERENCE

Guidelines for detection, management and prevention of hyperbilirubinemia in term and late preterm 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.

REFERENCE

Charles Scriver, Beaudet A.L, Valle D, Sly, WS, Vogelstein, B Kinzler. K.W. The online Metabolic and molecular bases of inherited disease. New York: McGraw Hill 2001.

Infant Follow-up Form (COV)

Form Header

Participant Study Number	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Delivery Hospital Code	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
Maternal Hospital Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Infant date of birth	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
Infant Hospital Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date of this visit	<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>

Participant Study Number. This is the identification number assigned to the woman. The first two digits correspond to your country code, the last five digits are the unique number assigned the participant.

Delivery Hospital Code. It should be the site code (first two digits) followed by the numbers 01.

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

Infant date of birth. Enter the infant's date of birth in the format dd-mm-yy. For example, the 20th May 2010 should be written 20-05-10.

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

Section 1: Status of the neonate

Section 1: Status of the infant			
1. Status of the infant	Alive <input type="checkbox"/>	Dead <input type="checkbox"/>	→ If dead, date of death <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>
Since the last study examination, how many days has the infant spent in any of the following;			
2. High dependency unit/NICU (any hospital)	<input type="text"/> <input type="text"/> days	5. Another special care unit	<input type="text"/> <input type="text"/> days
3. Intermediate dependency unit	<input type="text"/> <input type="text"/> days	6. At home	<input type="text"/> <input type="text"/> days
4. Low dependency unit/Nursery	<input type="text"/> <input type="text"/> days	7. TOTAL NUMBER OF DAYS since last study examination	<input type="text"/> <input type="text"/> days
8. If the infant has been discharged since the last visit, date of hospital discharge			<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>

1. Status of the infant

Place a 'X' in the box marked 'ALIVE' if the infant is currently alive.

Place a 'X' in the box marked 'DEAD' if the infant died.

If dead, date of death. If the infant died, enter the date of death in the format dd-mm-yy. For example, the 20th May 2010 should be written 20-05-10.

Since the last study examination, how many days has the infant spent in any of the following;

Enter the total number of days spent in each of the following since the last study examination or since birth (in case of the first follow-up visit), 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.

2. **High dependency unit/NICU**

3. **Intermediate dependency unit**

4. **Low dependency unit/Nursery**

5. **Another special care unit**

6. **At home**

7. **TOTAL NUMBER OF DAYS since the last study examination**

8. **If the infant has been discharged since the last visit, date of hospital discharge.**
Enter the date of discharge if the infant has been discharged since the last visit. Write the date in the format dd-mm-yy. For example, the 20th May 2010 should be written 20-05-10.

Section 2: Status of the mother

Section 2: Status of the mother			
9. Where is the mother? (cross one box only)	Still in hospital <input type="checkbox"/>	At home/with family <input type="checkbox"/>	Dead <input type="checkbox"/>

9. **Where is the mother?**

Place a X in the box marked 'STILL IN HOSPITAL' if the mother is currently hospitalized.

Place a X in the box marked 'AT HOME/WITH FAMILY' if the mother was discharged.

Place a X in the box marked 'DEAD' if the mother died.

Section 3: Feeding Practices

Section 3: Feeding Practices	
<p>10. Which of the following liquids has the infant been given since the last study examination (cross all that apply)</p> <p>Breast milk <input type="checkbox"/> Soy based formula <input type="checkbox"/></p> <p>Breast milk with fortifiers <input type="checkbox"/> Hydrolysed formula <input type="checkbox"/></p> <p>Standard infant formula <input type="checkbox"/> Any other special formula <input type="checkbox"/></p> <p>Preterm/post-discharge formula <input type="checkbox"/> Animal milk <input type="checkbox"/></p> <p>High energy formula <input type="checkbox"/> Water based drinks/fruit juice <input type="checkbox"/></p>	<p>11. Which method(s) were used? (cross all that apply)</p> <p>Breastfeeding <input type="checkbox"/></p> <p>Oral feeding <input type="checkbox"/></p> <p>Tube feeding <input type="checkbox"/></p> <p>Parenteral nutrition including dextrose infusion <input type="checkbox"/></p> <p>12. Number of days of parenteral nutrition since birth or the last study examination <input type="text"/> <input type="text"/> days</p>

10. **Which of the following liquids has the infant been given since the last study examination (cross all that apply)**

Place a 'X' in all the boxes that apply.

11. **Which method(s) were used? (cross all that apply)**

Place a 'X' in all the boxes that apply.

12. **Number of days of parenteral nutrition since birth or the last study examination.**

Enter the total number of days in which the infant was given parenteral nutrition since birth (in case of the first follow-up visit) or since the last study examination, rounded to the next whole day. For example, if the infant received parental nutrition for 1 day and 6 hours, write 2 in the box.

Section 4: Neonate anthropometry

NB Information required for this section must be obtained following the anthropometry protocol (<https://globalhealthtrainingcentre.tghn.org/intergrowth-21st-course-maternal-fetal-and-newborn-growth-monitoring/>)

Section 4: Infant Anthropometry	
13. Date of measurement	<input type="text" value="D"/> <input type="text" value="D"/> - <input type="text" value="M"/> <input type="text" value="M"/> - <input type="text" value="Y"/> <input type="text" value="Y"/>
14. Time of measurement	<input type="text" value="H"/> <input type="text" value="H"/> : <input type="text" value="M"/> <input type="text" value="M"/>
15. Weight	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> <input type="text"/> kg
16. Length	<input type="text"/> <input type="text"/> . <input type="text"/> cm
17. Head Circumference	<input type="text"/> <input type="text"/> . <input type="text"/> cm

13. **Date of measurement.** Enter the date of measurement in the format dd-mm-yy. For example, the 20th May 2020 should be written 20-05-20.
14. **Time of measurement.** Enter the time of measurement using the 24-hour clock. For example, '8:15pm' should be written as '20:15'.
15. **Weight** (in kilograms (kg), to 3 decimal places)
16. **Length** (in centimetres (cm), to 1 decimal place)
17. **Head circumference** (in centimetres (cm), to 1 decimal place)

Section 5: Morbidities/treatments

Section 5: Morbidities/treatments					
Since the last study examination, has the infant started or continued treatment for any of the conditions which required appointment(s) with a health care provider?					
18. Pneumonia/Acute respiratory infection/ Bronchiolitis	<input type="checkbox"/> yes	<input type="checkbox"/> no	30. Febrile episodes	<input type="checkbox"/> yes	<input type="checkbox"/> no
19. Blindness	<input type="checkbox"/> yes	<input type="checkbox"/> no	31. Sepsis/meningitis	<input type="checkbox"/> yes	<input type="checkbox"/> no
20. Otitis media	<input type="checkbox"/> yes	<input type="checkbox"/> no	32. Infectious disease (e.g. measles, malaria)	<input type="checkbox"/> yes	<input type="checkbox"/> no
21. Hearing problems	<input type="checkbox"/> yes	<input type="checkbox"/> no	33. Metabolic disorders	<input type="checkbox"/> yes	<input type="checkbox"/> no
22. Cardiovascular problems	<input type="checkbox"/> yes	<input type="checkbox"/> no	34. Seizures	<input type="checkbox"/> yes	<input type="checkbox"/> no
23. Skin problems	<input type="checkbox"/> yes	<input type="checkbox"/> no	35. Chronic renal failure	<input type="checkbox"/> yes	<input type="checkbox"/> no
24. Stoppage of enteral feeding for more than 3 consecutive days	<input type="checkbox"/> yes	<input type="checkbox"/> no	36. Neurological disorders	<input type="checkbox"/> yes	<input type="checkbox"/> no
25. Gastro-esophago-pharyngeal reflux	<input type="checkbox"/> yes	<input type="checkbox"/> no	37. Hydrocephalus	<input type="checkbox"/> yes	<input type="checkbox"/> no
26. Other feeding problems	<input type="checkbox"/> yes	<input type="checkbox"/> no	38. Endocrine abnormalities	<input type="checkbox"/> yes	<input type="checkbox"/> no
27. Persistent vomiting	<input type="checkbox"/> yes	<input type="checkbox"/> no	39. Malignancy	<input type="checkbox"/> yes	<input type="checkbox"/> no
28. Diarrhoea	<input type="checkbox"/> yes	<input type="checkbox"/> no	40. Injury/trauma	<input type="checkbox"/> yes	<input type="checkbox"/> no
29. Short bowel syndrome	<input type="checkbox"/> yes	<input type="checkbox"/> no	41. Any other serious condition	<input type="checkbox"/> yes	<input type="checkbox"/> no
			(please specify)	<input type="text"/>	

Since the last study examination, has the infant been diagnosed with/treated for any of conditions which required appointment(s) with a health care provider?

For each condition:

Place a 'X' in the box marked 'YES' if the infant was diagnosed with or received any treatment for that condition.

Place a 'X' in the box marked 'NO' if the infant was not diagnosed with and received no treatment for that condition.

18. **Pneumonia/Acute respiratory infection/Bronchiolitis**

19. **Blindness**

20. **Otitis media**

21. **Hearing problems**

22. **Cardiovascular problems**

23. **Skin problems**

24. **Stoppage of enteral feeding for more than 3 consecutive days**

25. **Gastro-esophago-pharyngeal reflux**

26. **Other feeding problems**

27. **Persisting vomiting**

- 28. **Diarrhoea**
- 29. **Short bowel syndrome**
- 30. **Febrile episodes**
- 31. **Sepsis/meningitis**
- 32. **Infectious disease (e.g. measles, malaria)**
- 33. **Metabolic disorders**
- 34. **Seizures**
- 35. **Chronic renal failure**
- 36. **Neurological disorders**
- 37. **Hydrocephalus**
- 38. **Endocrine abnormalities**
- 39. **Malignancy**
- 40. **Injury/trauma**
- 41. **Any other serious condition (please specify).** Specify every other serious condition not included in the list provided.

Since the last study examination which treatments have been given?

For each medication or treatment:

Place a 'X' in the box marked 'YES' if the infant has been prescribed that medication or treatment since the last study examination.

Place a 'X' in the box marked 'NO' if the infant has not been prescribed that medication or treatment since the last study examination.

- 42. **Analgesics**
- 43. **Antacids**
- 44. **Haematinics**
- 45. **Anticonvulsants**
- 46. **Antiemetics**
- 47. **Anti-inflammatory agents**
- 48. **Antibiotics**
- 49. **Antipyretics**
- 50. **Antitussive or expectorant drugs**

51. **Blood transfusions**

52. **Bronchodilators**

53. **Diuretics**

54. **Glucocorticoids**

55. **Oxygen**

Section 6: Next examination

Section 6: Next examination									
Please now arrange the next follow-up examination									
56. Date of the next study appointment or hospital examination	<table border="1"><tr><td>D</td><td>D</td><td>–</td><td>M</td><td>M</td><td>–</td><td>Y</td><td>Y</td></tr></table>	D	D	–	M	M	–	Y	Y
D	D	–	M	M	–	Y	Y		

56. **Date of the next appointment or hospital examination.** Enter the date of the next study appointment in the format dd-mm-yy. For example, the 20th May 2020 should be written 20-05-20.

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