

PULSE OX STUDY DATA COLLECTION FORM



Section 1: Eligibility

Is the baby well? Yes No

If the baby is **well**, they are **eligible** for the study. Please ensure consent has been taken and continue with sections 2 – 5 below.

If the baby is **not well**, they are **not eligible** for the study. Please complete the 'Ineligibility Form', put in the participant pack and put it in the Pulse Ox collection box. Treat the baby as normal.

Section 2: Identifying Details

Baby Hospital Number

Baby NHS number

Baby date of birth ____ / ____ / ____

Time (24hr) ____ : ____

Male Female

Gestational age ____ /40 weeks

Mother's Forename _____

Mother's Surname _____

Hospital Number

Mother's NHS Number

Mother's date of birth ____ / ____ / ____

(or attach sticker)

Mother's gravida ____ parity ____

Section 3: Language

Was a translator and/or a translated version of the Information Sheet and Consent required? Yes No

If yes, specify language: _____

Section 4: Pulse Oximetry Saturations

First reading (This should be taken within 24 hours of age or before discharge)

Performed in: Delivery Suite Post Natal Unit Neonatal Unit

Performed by:

PRINT NAME: _____

Doctor Nurse Midwife Midwifery Assistant Care Assistant Neonatal nurse

Date	Time	Foot sats (%)	Right hand sats (%)	% difference	Pass/Refer

If the result is normal (i.e. **Pass**), nothing further needs to be done. Please **ensure sections 1-5 are completed**. Please put this form in the participant pack and put it in the Pulse Ox collection box.

If less than 95% in either limb or $\geq 3\%$ difference between limbs, this is a **Refer**, the baby needs to be examined/ reviewed by someone trained in neonatal examination. **Please continue with section 6 overleaf.**

Section 5: Antenatal Diagnosis

Is there a family history of congenital heart defects? Yes No

Was CHD suspected on antenatal ultrasound? Yes No

The following sections only need to be completed if the first pulse oximetry reading was <95% in either limb or $\geq 3\%$ difference between limbs i.e. a **Refer**.

Section 6: Clinical Examination

Undertaken by: Nurse/ Midwife SHO/ Registrar Consultant Other

How long did the exam take? _____ minutes

Did the baby show signs of CHD at examination? Yes No

If yes, was this murmur cyanosis abnormal pulses

Overall exam finding Normal Abnormal Details: _____

If exam is normal, a second PO reading needs to be taken. This should be taken 1-2 hours after the first reading. Please complete section 7 below.

If exam is abnormal, the baby needs to be referred straight to the Neonatal team for further investigation and management. A second PO reading does not need to be taken. Please continue with sections 9-14 overleaf.

Section 7: Second Pulse Oximetry Reading

Performed in: Delivery Suite Post Natal Unit Neonatal Unit

Performed by:

PRINT NAME: _____

Doctor Nurse Midwife Midwifery Assistant Care Assistant Neonatal nurse

Date	Time	Foot sats (%)	Right hand sats (%)	% difference	Pass/Refer

*If less than 95% in either limb or $\geq 3\%$ difference between limbs, this is a **Fail**, the baby needs to be referred to the Neonatal team for further investigation and management. Please continue with sections 8-14 overleaf.*

*If the result is normal (i.e. **Pass**), nothing further needs to be done. Please ensure all above sections are completed. Please put this form in the participant pack and put it in the Pulse Ox collection box.*

The following sections only need to be completed if the clinical examination found an abnormality or if the second pulse oximetry reading was a **Fail** and the baby has been referred to the Neonatal team for further investigation and management.

Section 8: Hyperoxia Test (only to be completed if second PO reading was a fail)

Performed by: Nurse SHO Registrar Consultant

Did saturation increase to 95% or above? Yes No

Section 9: Clinical Symptoms

If baby showed signs of CHD at birth, describe

Collapse Cyanosis Acidosis Respiratory distress

Did this baby have a respiratory illness or any illness other than CHD?

Yes No If yes details: _____

Section 10: Echocardiography

Date of echocardiography ___ / ___ / ___ Time ___ : ___ (24 Hour)

Echocardiographer: Cardiology Research Fellow Other Echocardiographer

Result: Normal Abnormal Uncertain

Details: _____

Section 11: Review of Echocardiography

Reviewed by: Cardiology Research Fellow Consultant Other

(Please tick more than one box if applicable)

Date of review ___ / ___ / ___

Result: Normal Abnormal Uncertain

Details: _____

*If there is a **disagreement between the two results** or **the result of the review is uncertain**, a second echocardiogram needs to be performed. This will be done by a Consultant Paediatric Cardiologist at Birmingham Children's Hospital*

Date of second echocardiography ___ / ___ / ___

Result: Normal Abnormal Details: _____

Please continue with sections 12-14 overleaf.

Section 12: Admission Summary

Number of days on Postnatal unit? _____ days

Number of days on Neonatal unit? _____ days

Section 13: Discharge Details

Home Cardiac Unit Other Details: _____

If home, date of discharge ____ / ____ / ____ Time of discharge (24hr) ____ : ____

If cardiac unit, number of days on unit _____ days

Section 14: Death Details

Death Date of death ____ / ____ / ____ Time of death (24hr) ____ : ____

Cause of Death: Cardiac Non-cardiac

If cardiac: Post-operative Other If other, please specify: _____

If non-cardiac, please specify: _____

PULSE OX STUDY

CONGENITAL HEART DEFECT CASE REPORT FORM

Date of Diagnosis ____ / ____ / ____

How was the CHD detected and confirmed?

- Pulse oximetry at birth then echocardiogram
- Clinical examination at birth then echocardiogram
- Post-mortem
- Later echocardiogram by paed cardiologist
- Congenital anomaly registry

Type of CHD?

- Aortic (valve) stenosis Persistent (patent) ductus arteriosis
- Atrial septal defect Tetralogy of Fallot
- Coartation of aorta Total anomalous pulmonary venous connection
- Complete arterioventricular septal defect Transposition of great arteries
- Hypoplastic left heart syndrome Ventricular septal defect
- Interruption of aortic arch
- Other (specify) _____

Has the baby had cardiac surgery? Yes No Planned

If yes, when was the surgery ____ / ____ / ____

Type of surgery? _____

Death Date of death ____ / ____ / ____ Time of death (24hr) ____ : ____

Cause of Death: Cardiac Non-cardiac

If cardiac: Post-operative Other

If non-cardiac, please specify: _____

(For Midwife use only)
Form Identification

Mother Hospital Number:

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Mother's Initials _____

Date Received _____

Date Entered _____



Pulse Oximetry Study Acceptability Questionnaire

Soon after your baby was born s/he was given a Pulse Oximetry test to see if there was a problem with the heart.

This involved putting a sensor on the baby's hand and foot to measure the oxygen levels (how 'pink' the baby was).

We would like you to answer some questions about the test and about yourself.

All your answers will be confidential and will **not** affect your treatment or your baby's treatment.

When are you filling in the questionnaire?

Date	Month	Year

For each question, please tick the box which best represents your views or fill in your answer.

Before your baby was born, the midwife gave you a leaflet on the Pulse Oximetry test.

How satisfied are you with:

	Very satisfied	Satisfied	Neither	Dissatisfied	Very dissatisfied
1. The information in the leaflet on what the PO test involved?					
2. The information in the leaflet on heart disease in new born babies?					
3. The information in the leaflet on what would happen if the PO test showed there might be a problem?					

Before the test was done, how satisfied were you with:

4. The opportunities you had to discuss the PO test before you gave consent to have it?					
5. The opportunities you had to change your mind about having the test?					

Having the PO measure taken

Please say how much you agree with these statements

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
6. Overall I was happy with the way the test was done.					
7. My baby was very comfortable when the test was done					
8. I felt very stressed while the test was being done.					
9. I am very confident that the test was done properly					
10. I was sure results of the test were correct					

After the PO test was done, how satisfied were you with:

	Very satisfied	Satisfied	Neither	Dissatisfied	Very dissatisfied
11. The way you the doctor or nurse gave you the results?					
12. The information you were given on what would happen next?					
13. The opportunities you had to discuss the results?					

General feelings about the PO test

	Yes definitely	Probably	Don't know	Probably not	Definitely not
14. Do you think it was important for your baby to have the test?					
15. Do you think it is important for all babies to have the test?					
16. Do you think the doctors and nurses would have found any heart problem without the test?					
17. Would you recommend the test to someone else?					

18. What do you think the Pulse Oximetry test showed? Please tick one box only

There is <u>no</u> problem with my baby's health	
My baby has a minor <u>heart</u> condition	
My baby has a minor health condition, but not a <u>heart</u> condition	
My baby has a serious <u>heart</u> condition	
My baby has a serious health condition, but not a <u>heart</u> condition	
Don't Know	
Other (please state)	

The following questions ask you about your views on Heart Disease in babies.

This is not a test of how much you know.

On a scale of 1 to 5, please circle the number that represents your views.

19. How much would heart disease affect a baby's life?

No effect at all 1 2 3 4 5 Severe effect

20. How long do you think heart disease would last if not treated?

A very short time 1 2 3 4 5 Forever

21. How much do you think treatment helps a baby with heart disease?

Not at all 1 2 3 4 5 Extremely helpful

22. How well do you feel you understand heart disease in babies?

Do not understand at all 1 2 3 4 5 Understand very clearly

The following questions are about how you feel about yourself.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
23. I hardly ever expect things to go my way					
24. I always look on the bright side					

Below are a number of statements which people have used to describe themselves. Tick the box to indicate how you feel right now, that is at this moment

Not at all Somewhat Moderately Very much so
SO

25. I feel calm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. I am tense	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. I feel upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. I am relaxed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. I feel content	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. I am worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Read each statement below and tick the answer that comes closest to how you have been feeling in the past week. Please don't take too long over your replies. Tick only one box for each statement

31. I still enjoy the things I used to enjoy:

Definitely as much
Only a little

Not quite so much
Hardly at all

32. I can laugh and see the funny side of things:

As much as I always could
Definitely not so much now

Not quite as much now
Not at all

33. I feel cheerful:

Not at all
Sometimes

Not often
Most of the time

34. I feel as if I am slowed down:

Nearly all of the time
Sometimes

Very often
Not at all

35. I have lost interest in my appearance:

Definitely
I may not take quite as much care

I don't take as much care as I should
I take as much care as ever

36. I look forward with enjoyment to things:

As much as I ever did
Definitely less than I used to

Rather less than I used to
Hardly at all

37. I can enjoy a good book or radio or TV programme:

Often
Not often

Sometimes
Very seldom

Thank you for answering these questions

Please use the space below to add any ideas you have on what we could do to improve the Pulse Oximetry test procedure for parents, or any other comments you would like to make

(For office use only)
Form Identification

Mother Hospital Number:

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Date Received

Date Entered



Pulse Oximetry Study Follow-up Acceptability Questionnaire

Soon after your baby was born s/he was given a Pulse Oximetry test to see if there was a problem with the heart. This involved putting a sensor on the baby's hand and foot to measure the oxygen levels (how 'pink' the baby was).

We are contacting you again because we would be interested in what your views are now, a year after your baby was born.

All your answers will be confidential and will **not** affect your treatment or your baby's treatment.

For each question, please tick the box which best represents your views or fill in your answer.

When you have completed the questionnaire please return it in the envelope provided

When are you filling in the questionnaire?

Date	Month	Year

Thinking back to when the PO test was done, how satisfied are you now with:

	Very Satisfied	Satisfied	Neither	Dissatisfied	Very Dissatisfied
1. The way you the doctor or nurse gave you the results?					
2. The information you were given on what would happen next?					
3. The opportunities you had to discuss the results?					

General feelings about the PO test

	Yes Definitely	Probably	Don't know	Probably not	Definitely not
4. Do you think it was important for your baby to have the test?					
5. Do you think it is important for all babies to have the test?					
6. Do you think the doctors and nurses would have found any heart problem without the test?					
7. Would you recommend the test to someone else?					

Below are a number of statements which people have used to describe themselves. Please tick the box to indicate how you feel right now, that is at this moment

	Not at all	Somewhat	Moderately so	Very much so
8. I feel calm				
9. I am tense				
10. I feel upset				
11. I am relaxed				
12. I feel content				
13. I am worried				

Finally, how you feel about your baby's health now at the present time

	Not at all	A little bit	Moderately	Quite a bit	A great deal
14. Do you think your baby is healthy?					
15. Do you ever think there is something seriously wrong with your baby?					
16. Do you worry a lot about your baby's health?					
17. Is it hard for you to believe a doctor or health visitor when they tell you there is nothing to worry about?					
18. If a disease is brought to your attention (e.g. on the TV, radio, newspapers or by someone you know) do you worry about your baby having it?					

Please use this space to add any ideas you have on what we could have done to improve the Pulse Oximetry test for you, or any other comments you would like to make

Thank you very much for answering these questions

Please return your questionnaire in the envelope provided