

Clinical Guideline: Routine Pulse oximetry Screening (RoPeS) for the Early Detection of Critical Congenital Heart Disease

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Audit Standards:

All babies born in the East of England should receive pulse oximetry screening to aid timely diagnosis of critical congenital heart disease

Audit points

1. Screening performed between 4 and 8 hours of life in a hospital setting with a NNU onsite or from 2 hours of age if home birth or standalone Midwifery Led Unit.
2. Reading recorded in the baby's post-natal care record to include: pre and post ductal saturation readings including percentage difference, date and time of the readings, and a signature and designation of the health care professional performing the test.
3. Screening results have been actioned according to EoE guidance

Abbreviations

Critical congenital heart defects	CCHD
East of England	EoE
Operational Delivery Network	ODN
Maternity Clinical Network	MCN
Maternity Support Worker	MSW
Health Care Assistants	HCA
Nursery Nurses	NN
Midwifery Led Unit	MLU
Newborn Infant Physical Examination	NIPE
Neonatal Unit	NNU

1.0 Aim of Guideline:

The purpose of this guideline is to ensure that all newborn babies born in hospital, midwifery led units or at home are screened for critical congenital heart defects (CCHD) through the early recording of pre- and post-ductal oxygen saturations with a pulse-oximeter.

2.0 Scope of Guideline

The guideline applies to all neonates in neonatal units and maternity units covered by East of England Operational Delivery Network (ODN) and East of England Maternity Clinical Network (MCN) as well as those born at home and cared for by community teams. This includes the following hospitals:

EoE Neonatal ODN and EoE MCN Neonatal and Maternity Units

Norfolk and Norwich Hospital
Queen Elizabeth Hospital
Ipswich Hospital
James Paget Hospital
Luton & Dunstable Hospital
West Hertfordshire Hospitals NHS Trust
East & North Hertfordshire NHS Trust
Bedford Hospital
Addenbrooke's Hospital
Peterborough City Hospital
Princess Alexandra Hospital
Colchester Hospital
Broomfield Hospital
Hinchingbrooke Hospital
West Suffolk Hospital
Basildon Hospital
Southend Hospital
Milton Keynes Hospital

3.0 Guideline Framework

This guideline provides guidance on the routine use of pre-discharge pulse oximetry screening in the delivery suite, the postnatal ward and the community to improve the early detection of critical congenital heart disease (CCHD) in asymptomatic newborn babies and to identify babies with non-cardiac respiratory conditions. It is designed to be used by the following staff groups*:

Paediatric/Neonatal doctors
Advanced Neonatal Nurse Practitioner (ANNPs)
Nurses
Midwives
Nursery nurses
Maternity Support Workers (MSW)
Health Care Assistants (HCA)

*If appropriate competency training has been completed

4.0 Background information

Cardiovascular malformations are the leading group of congenital malformations with an incidence of 4 to 10 per 1000 live births. They account for 6-10% of all infant mortality and account for 20-40% of deaths attributable to all congenital malformations. Most of these deaths occur in the first year of life. The term congenital heart disease (CHD) encompasses a variety of lesions with a wide range of clinical importance, ranging from those with no functional or clinical significance to potentially life threatening lesions. If critical defects are not detected early, they can result in cardiovascular compromise resulting in death or significant long-term effects on neurodevelopment. Critical CHD refers to heart defects that require intervention or lead to death in the first 28 days after birth. Timely recognition of these conditions allows for the possibility of early intervention that may influence the natural history of the condition and subsequent outcome.

What is the current screening programme for heart defects in newborn babies?

All babies are currently offered screening for heart defects antenatally (antenatal ultrasound) and following birth (postnatal clinical examination).

Antenatal ultrasound – between 2014 and 2017 in the UK, **less than half** (42%) of babies with heart defects that required intervention were identified before birth (*2018 NICOR report, table 12a*). Between different health regions in the UK there is great variability in the rate of identification – between **33% in the lowest performing regions** and 62% in the highest.

Postnatal examination – **fails to identify up to 45%** of babies with critical congenital heart defects and up to **30% are sent home without diagnosis**. Some of these babies will die and many will have a worse outcome as a result of late diagnosis.

What will Pulse Oximetry Screening add?

Routine newborn pulse oximetry screening identifies babies with critical congenital heart defects that would otherwise have been missed by antenatal ultrasound and postnatal examination. Research has consistently shown that when **Pulse Oximetry Screening** is

added to the existing screening programme the identification rate for critical congenital heart defects increases to **between 90 and 95%**.

Pulse oximetry screening reduces mortality from critical congenital heart defects and identifies babies with other important conditions, such as respiratory disorders and sepsis. Many countries now recommend pulse oximetry screening but the UK National Screening Committee is still undecided. Despite the absence of a national recommendation, many neonatal units in the UK have introduced pulse oximetry screening. In 2017, 78 (40%) of the 193 neonatal units in the UK used pulse oximetry screening (an increase from 15 (7%) of 224 neonatal units in 2010).

5.0 Guideline Summary

All newborn babies across EoE Neonatal ODN and the EoE MCN will undergo Pulse Oximetry Screening to identify babies with congenital heart disease as well as identify babies with non-cardiac causes of low oxygen saturations. Undetected illness including potential infection, breathing difficulties, congenital heart disease and slow adaptation to ex-utero life are among the causes of low saturations. All these conditions merit neonatal review to diagnose and, if needed, to treat the underlying condition.

6.0 Details of the guideline

Measurement of oxygen saturation in newborn babies

Pulse Oximetry Screening is performed by measuring the baby's pre and post- ductal saturations. The saturation probe is applied to the **baby's right hand (provides a pre-ductal reading)** and either **foot (provides a post-ductal reading)**. For best readings tape must be applied to the right hand & either foot to hold the probe in place (see Appendix 5 for further details). It is necessary to wait until a stable good quality waveform is seen. A sustained, good signal trace with **both readings of $\geq 95\%$ and difference less than 3%** is accepted as **normal (test green)** and constitutes no concerns.

Pulse Oximetry Screening for babies born in hospital with a NNU onsite (Appendix 1 Pulse Oximetry Screening for babies born in Hospital)

- All babies born in hospitals with access to a NNU should be screened, preferably between 4 and 8 hours of life before discharge home. Ideally the screening will be conducted prior to the newborn infant physical examination (NIPE) and will be performed by a trained professional i.e., Midwifery Support Worker (MSW), Midwife, Health Care Assistant (HCA), who has received the appropriate training.
- Saturation monitors with reusable probes should be made available on the postnatal wards, delivery units, and midwife-led birth unit.
- Two saturation readings should be taken; a pre-ductal saturation (right arm) and a post-ductal saturation (either foot) – **Test one**.
- The highest consistent reading attainable in both should be recorded in the neonatal notes and should be available for the newborn examination.
- The following outcomes apply:
 - A **Pass** (test green) – both readings 95% or higher and difference less than 3%.
 - A **Fail** (test red) – either reading 89% or less, or clinical concerns.

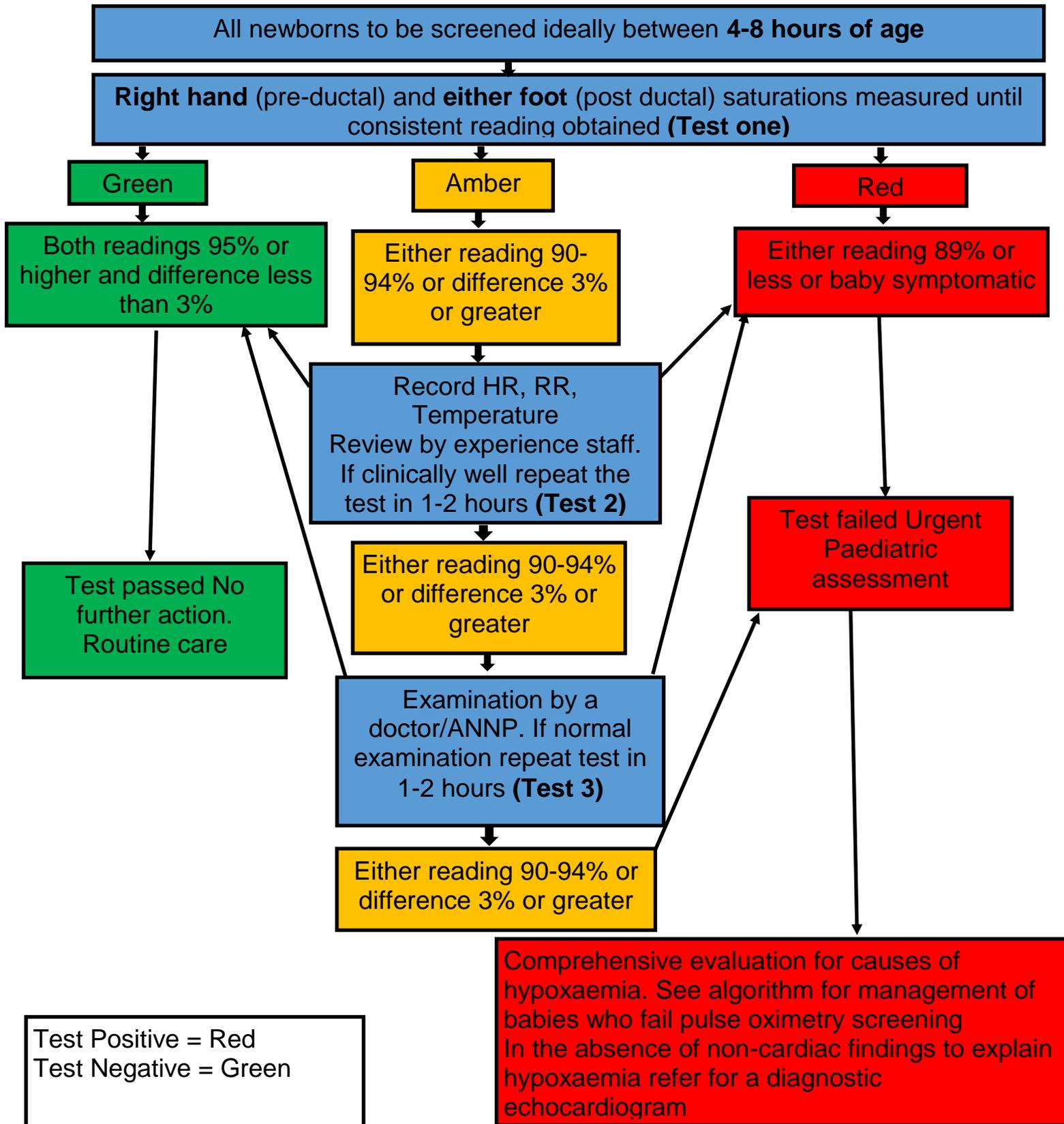
- A **Borderline** (test amber) – either reading 90-94% or difference of 3% or greater.
- For a pass, no further action is required, other than recording the saturations in the medical notes.
- Babies who **fail** screening (test red) will be referred to the neonatal/paediatric team for urgent assessment.
- If the result is borderline (test amber), and the baby is clinically well with normal observations, the test should be repeated in 1 to 2 hours by a pulse oximetry screener – **Test two**.
- If the result is again borderline (test amber), a trained neonatal/paediatric clinician should examine the baby.
- If this examination is normal, the test should be repeated in 1-2 hours – **Test three**.
- Anything but a clear pass (test green) in **Test three** requires urgent senior paediatric assessment and investigation.
- Passing the screening does not rule out a congenital heart defect, and an abnormal cardiac examination should always be investigated
- Oxygen saturations should be checked in any baby where there is a clinical concern regardless of whether or not they have previously passed the test.

Pulse oximetry Screening Pathway for babies born at home or in standalone MLU's (Appendix 2 Pulse Oximetry Screening Pathway for babies born at home or in standalone MLU's)

- Pulse oximetry screening for babies born at home would usually be undertaken by the attending midwife **prior to leaving the home or MLU** after delivery and not at the NIPE that is done at a later stage.
 - Each team should have its own portable pulse-oximeter with reusable probes.
 - Screening for babies born at home or in a standalone MLU should ideally be performed from **2 hours** after birth or sooner if there is clinical concern
 - Two saturation readings should be taken; a pre-ductal saturation (right arm) and a post-ductal saturation (either foot) – **Test one**
 - The highest, consistent reading attainable in both will be recorded in the neonatal notes and will be available for the newborn examination.
- The following outcomes apply:
- A **Pass** (test green) – both readings 95% or higher and difference of less than 3%
 - A **Fail** (test red) – either reading 89% or less, or baby symptomatic
 - A **Borderline** (test amber) – either reading 90-94% or difference 3% or greater
 - Babies who **fail screening** (test red) should be referred to the neonatal/paediatric team for urgent assessment.
 - A **borderline** (test amber) result should also be discussed with the on-call neonatal/paediatric registrar, and if both midwife and registrar have no clinical concerns, the test can be repeated in 1 to 2 hours – **Test two**
 - If the baby does not pass (red/amber) **Test two**, or the examination is abnormal, or there are other clinical concerns, the baby should be referred to the neonatal/paediatric registrar (depending on trust pathway) for immediate assessment in hospital.
 - Oxygen saturations should be checked in any baby where there is a clinical concern regardless of whether or not they have previously passed the test.
 - Passing the screening does not rule out a congenital heart defect and an abnormal cardiac examination should always be investigated.

Appendix 1

Pulse Oximetry Screening for babies born in Hospital with a NNU onsite



Appendix 2

Pulse Oximetry Screening for babies born at home or standalone MLU

All babies **born at home** or in **Stand Alone Midwifery Led Units** should undergo pulse oximetry screening, performed by the attending midwife/maternity support worker (MSW)
Screening should ideally be performed from **2 hours after birth**, unless there is a **cause for clinical concern**

Right hand (pre-ductal) and **either foot** (post ductal) saturations measured until consistent reading obtained (**Test one**)

Green

Both readings 95% or higher and difference less than 3%

Test passed No further action. Routine care

Amber

Either reading 90-94% or difference 3% or greater

Record HR, RR, Temperature
Discuss with on-call neonatal/paediatric registrar.
If both midwife/MSW and doctor have no clinical concerns, repeat the test in 1-2 hours (**Test 2**)

Either reading 90-94% or difference 3% or greater

Red

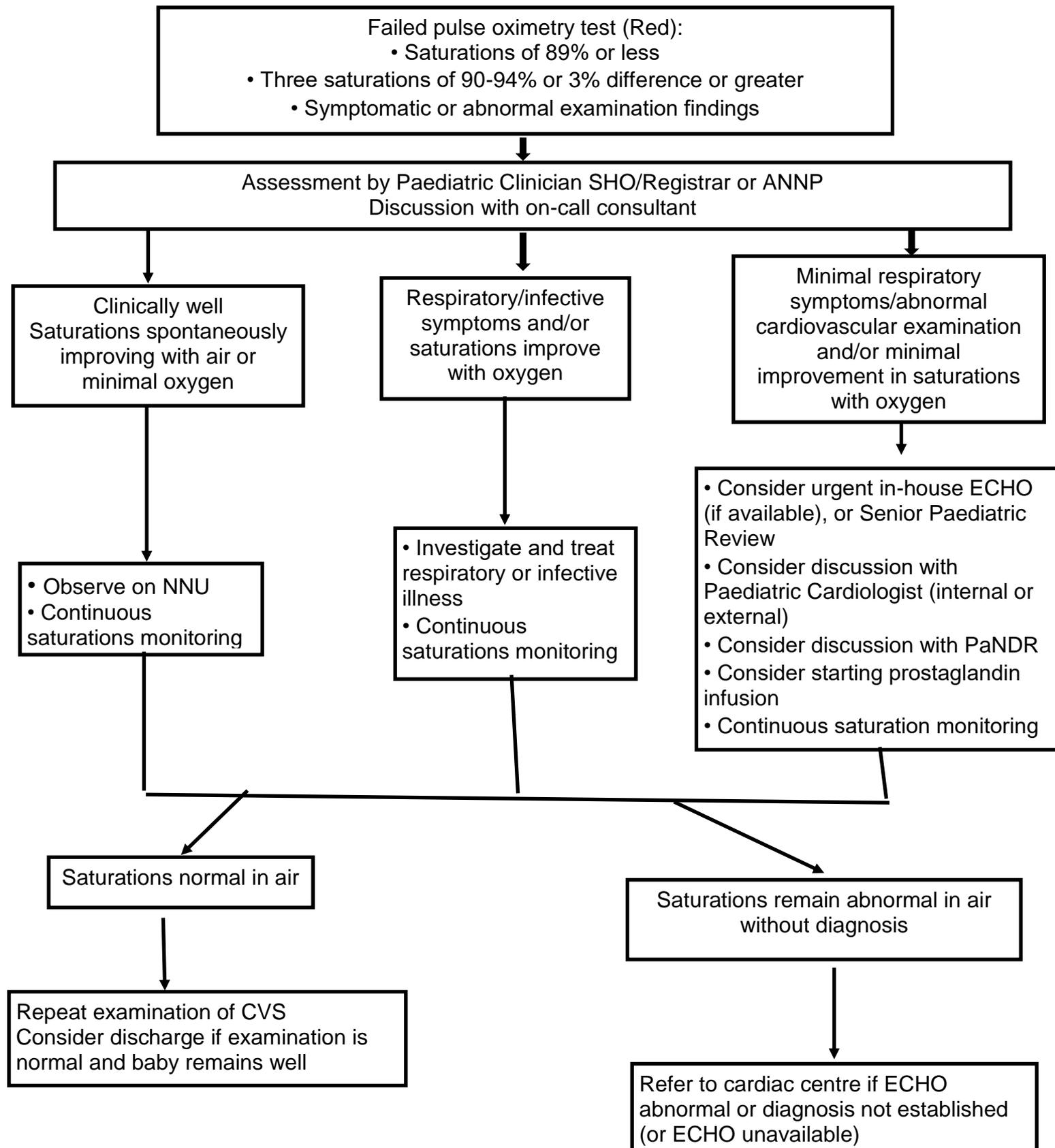
Either reading 89% or less or baby symptomatic

Refer to neonatal/local paediatric team for urgent assessment

Test Positive = Red
Negative = Green

Note: Passing the screening does not rule out a congenital heart defect, and an abnormal cardiac examination should always be investigated (even if the baby has passed the screening)

Investigations for babies who fail Pulse Oximetry Screening (Test positive)



Appendix 4

Healthcare information: How to perform pulse oximetry screening

Checking Oxygen Saturation (SpO₂) Measurement in a Baby

1) Explain to parents that you are going to check the baby's blood oxygen level and that it will not hurt the baby. Give parents the parent information leaflet on neonatal pulse oximetry screening. Explain to parents the process as you are doing the test and the outcomes afterwards (see Appendix 6). Offer the parents the chance to ask questions about the screening and about the results.

2) Place the flat sides of the probe on opposing sides of the baby's **right hand to check the pre-ductal saturations**. To get a good trace the probe 'faces' must be opposite one another with '**red emitter light**' being on top. Now measure the **post ductal saturations** by placing the saturations probe on either foot (**Fig.1**)

3) Use Posey wrap to secure the probe - it is much less likely to pick up a safe and reliable trace if held in place by hand (**Fig. 2**). Once connected turn on the power.

4) Allow time for a stable reading to appear. This may take up to 30-60 seconds to settle. Always wait for a good trace as shown below (**Fig 3 and 4**).



Figure 1: The probe 'faces' are placed opposite one another with red emitter light being on top



Figure 2: Use a posey to secure the probe



Figure 3: Good trace
 Action: Pass, reassure parents



Figure 4: Good trace with low saturations
 Action: Inform neonatal team urgently

Test 1:

- If both readings are **equal to or more than 95% and difference of less than 3%** has been present for 20s (steady reading) with the baby breathing air, the baby has **'passed'** the test with a normal result (**green**). No further action is required providing the baby remains well.
- If **either reading shows saturations of 89% or less, or if the baby is symptomatic** then contact the neonatal/paediatric team for an urgent review. The baby has **'failed'** the test (**red**).
- If the saturations are between 90 - 94% or the difference is 3% or more then **providing the baby is clinically well**, the test can be repeated in 1-2 hours (see **Test 2** of the pathway).

Test 2:

- If both readings are **equal to or more than 95% and difference less than 3%**, the baby has passed the test (**green**). No further action is required providing the baby remains well.
- If **either reading shows saturations of 89% or less, or if the baby is symptomatic** then contact the neonatal/paediatric team for an urgent review. The baby has **'failed'** the test (**red**).
- If the saturations remain between 90 - 94% or the difference is 3% or more then contact the neonatal/paediatric team for an urgent review. If the examination by the neonatal/paediatric team is normal, then the test can be repeated in 1-2 hours, **providing the baby remains well** (see **Test 3** of the pathway)

Test 3:

- If both readings are equal to or more than 95% and the difference is less than 3%, the baby has passed the test (**green**). No further action is required **providing the baby remains well**.
 - If the saturations remain between 90-94% or the difference is 3% or more, then the **test is positive(red)**. Call for an urgent paediatric/neonatal review.
- 5) Clean probe with detergent wipes.
 - 6) Document oxygen saturation levels in the baby notes, date, time and sign.

7) Babies should not be discharged home without a documented normal oxygen saturation level

Appendix 5

FAQ About Pulse Oximetry Screening

Why does the routine baby check miss up to 50% of congenital heart disease?

The signs of congenital heart disease are not always present in the first few hours of life, or even absent in the first few days after birth. This is because of the transition of circulation from fetal to ex-utero circulation, which involves pressure changes between the chambers of the heart and lungs. The earlier the examination is performed while this transition is taking place, the less accurate is routine clinical examination.

Some babies are identified as having heart murmurs on the routine NIPE, which may represent these pressure changes in the heart chambers and lungs and hearing flow of blood through the heart or blood vessels. This can resolve without any intervention. Not all babies with a heart murmur have congenital heart disease.

Why should we measure oxygen saturation in the first place?

The ductus arteriosus, a connection between the aorta and the pulmonary artery which is commonly called the 'duct', allows blood to communicate between the left and the right sides of the heart while the baby is still in the uterus and the lungs are not working properly. Babies in the uterus get their oxygen via the placenta. This duct also allows mixing of blood between the left and right sides of the heart in a group of congenital heart conditions called duct-dependent congenital heart conditions.

Closure of the duct, which is a natural phenomenon after birth, can result in sudden deterioration including collapse and even death in babies with duct-dependent congenital heart conditions. Pulse oximetry screening is a way of potentially detecting such an abnormality in the face of a normal examination. Therefore screening could facilitate early diagnosis of a significant cardiac condition, thereby reducing potential morbidity and mortality.

Combining pulse oximetry screening with existing screening methods, antenatal screening and the routine NIPE, could detect up to 92% of critical CHD cases.

Research studies have also showed that measuring oxygen saturation in the postnatal period can also help in the earlier diagnosis of other non-cardiac conditions eg infection, breathing difficulties etc before worsening of the baby's clinical condition.

Why measure oxygen saturation on the hand and foot?

Babies with congenital heart disease may have more normal saturations in the hands than in the feet. All babies require oxygen saturation measurement in the right upper limb (pre-ductal) and the right foot (post-ductal). A value of < 95% in either reading or a difference of $\geq 3\%$ between pre and post ductal readings, even if these measurements are both >95%, is suggestive of significant underlying heart or lung problems such as right to left shunting.

What are the causes of low oxygen saturations in babies?

Undetected illness including potential infection, breathing difficulties, congenital heart disease and slow adaptation to ex utero life are among the causes of low saturations. All these conditions merit neonatal review to diagnose and, if needed, to treat the underlying condition.

Appendix 6

FAQ Performing Pulse Oximetry Screening

What do I do if the trace is poor?

Choose a time when the baby is settled to do the test. This will optimise the chances of getting a good trace. If the baby is unsettled or crying, wait until the baby is settled to perform the test.

Make sure that the probe is attached to the baby's hand and foot as shown in the picture above. Reposition the probe if required. Ensure that the baby's skin is dry and warm.

What do I do if the test is negative, but the baby appears unwell?

If, at any point during the test, you think the baby appears unwell (respiratory distress, mottled, blue, unresponsive, floppy) then call for an urgent paediatric/review immediately.

What do I tell the parents if the baby passes the test (Test green)?

If the baby passes the test, then it means that the baby's oxygen levels are within normal limits and no further pulse oximetry is necessary at this point. Passing the test is very reassuring but it does not always mean that there is no problem. A small proportion of babies who pass the test (about 1 in every 8000) may still have a serious heart condition, therefore it is still important for the parents to know that and inform a health care professional if they are worried about their baby.

What do I tell the parents if the baby does not pass the first test (Test 1)?

About **3 babies in every 1000 (0.3%)** tested will have very low oxygen levels (saturation of <89%) on the first test which means that they will be seen by a doctor or specialist nurse used to looking after babies straight away (**red**). They will examine the baby and may do tests to try to find out why the levels are so low (including checking for a heart problem). About **3 in every 100 (3%)** babies **will not pass the test first time** but the oxygen levels will only be slightly low (saturation of 90-94%). We know that the lungs of some babies adapt to being born at a slower rate than others – this is normal, and these babies are healthy. Because we know this, if the baby's saturation levels are only **slightly reduced** in the first test and the baby **appears healthy** then we will repeat the test a second time about 1 to 2 hours later (**Test 2**). It's important to reassure parents that **9 out of 10 babies will pass Test 2** and **these babies will be treated as healthy (green)**. The baby's oxygen levels need to be normal before going home and so very occasionally this will lead to a slight delay in the baby's discharge (1 to 4 hours).

What do I tell the parents if a baby does not pass Test 2?

Those who do not pass **Test 2 (red/amber)** will be seen by a doctor or specialist nurse used to looking after babies. They will examine the baby and may do tests to try to find out why the levels are low (including checking for a heart problem). If clinical examination is normal, and the baby remains well, then the test can be repeated a third time 1-2 hours later (**Test 3**).

What do I tell the parents if a baby does not pass Test 3?

Those babies who do not pass **Test 3** will need a further paediatric/neonatal review and further investigations. This may include admission to the neonatal unit for further investigations. If the baby passes the test, then no further tests are required at that point, providing the baby remains well. The baby can be discharged home.

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Rationale why Trust is unable to adhere to the document:	
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Date:	Date:
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