The Shrewsbury and Telford Hospital NHS Trust

Antenatal Screening for Sickle Cell and Thalassaemia
V7

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For triennial review

Version	Implementation Date	History	Ratified By	Review Date
1	May 2004	New	Labour ward forum	May 2006
2	Aug 2006			Aug 2009
3	24th May 2011	Reviewed and revised	MGG	May 2014
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1.0 Introduction

'In this guideline we use the terms 'woman' or 'mother' throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth'.

The NHS Sickle Cell & Thalassaemia Screening Programme (SCT) is the result of the Government's commitment to improve the provision of screening services in England,as outlined in the 2000 'NHS Plan' which stated that there will be 'effective and appropriate screening programmes for women and children, including a national linked antenatal and neonatal screening programme for haemoglobinopathy and sickle cell disease.'

The SCT Programme comprises of two, linked, screening programmes: sickle cell and thalassaemia screening during pregnancy; and sickle cell screening offered to all newborns in England as part of the NHS Newborn Blood Spot Screening Programme.

The UK National Screening Committee (UK NSC) set both generic and programme specific standards which aims to develop, implement and maintain high quality uniform screening. Screening Policy and standards are subject to review and development in the light of new evidence.

The Antenatal programme aims to support all women (and couples) and to make an informed choice during pregnancy and to offer timely antenatal sickle cell and thalassaemia screening.

Aetiology
Haemoglobinopathies are a group of mild or serious disorders that can occur in people who have inherited two haemoglobin gene variants. Both sickle cell diseases and thalassaemias are autosomal recessive genetic conditions of the blood that affect haemoglobin and its oxygen carrying capacity. Inheritance of an affected gene from both parents results in a disorder whilst inheritance of one abnormal gene results in a healthy carrier. Infants are at risk of inheriting these disorders if both parents are carriers and/or suffer from the disease. The most common haemoglobin disorders are sickle cell and thalassaemia.

Haemoglobinopathies are more common in people who have family origins from the malarial parts of the world; and in the UK are seen particularly amongst minority ethnic groups from Africa, the Caribbean, the Mediterranean, South East Asia, the Middle East, and the Far East but can be found (less frequently) in all ethnic groups. There have been approximately 1,000 haemoglobin gene variants identified worldwide.

There are two types of haemoglobin disorders categorized as qualitative or quantitative.

Thalassaemias are quantitative disorders which affect the quantity of haemoglobin produced. This results in partial or no cell production of the globin chains that form the structure of haemoglobin within the red blood cells. Carriers of thalassaemia have smaller red blood cells, but more of them. A full blood count (FBC) will show they have small red blood cells but a carrier should take iron medicine only if their serum iron or serum ferritin shows that they are short of iron. The two most common types are alpha and beta thalassaemia.

Alpha thalassaemia major is incompatible with extra uterine life. It occurs when both parents have the alpha zero affected gene. It is a severe anaemia that affects the fetus in utero causing Hb Barts hydrops Fetalis. The pregnancy goes normally up to about 5 months, sometimes for longer. But then the fetus stops growing properly, and the mother may develop high blood pressure. An ultrasound scan usually shows fetal hydrops and the baby is born prematurely, usually dead or dying when it is born.
Alpha plus Thalassaemia is extremely common. About 1 in 3 people who originate from Africa or the Indian sub-continent carry it. It is also common among people who originate from the Mediterranean area, the Middle East or South East Asia. Some North Europeans carry it. Some carriers are slightly anaemic. This anaemia has no effect on health or length of life. A carrier of alpha plus thalassaemia, whose partner also carries alpha thalassaemia, can have a child with a mild form of anaemia.
Alpha Zero Thalassaemia is common among people who originate from South East Asia (China, Hong Kong, Singapore, Malaysia, Indonesia, Thailand, Vietnam, Philippines), or Cyprus or Southern Turkey. It also occurs in the Northern European of Northern England and Northern Ireland. It is uncommon among other North Europeans.

Beta Thalassaemia major is the most severe form of thalassaemia, it results in the inability of the body to produce haemoglobin, resulting in life threatening anaemia. Children with beta thalassaemia major appear healthy at birth, but exhibit signs of failure to thrive and become severely anaemic between the age of three and 18 months. Treatment requires blood transfusions every 4-6 weeks for life as well as chelation therapy to prevent further complications such as organ damage, diabetes and other endocrine disorders arising from iron overload. Bone marrow transplantation is a treatment option.

There are other less significant thalassaemia variants, which can also be detected by antenatal screening.

Sickle Cell Disease (SCD)is a qualitative disorder affecting the oxygen carrying capacity of red blood cells. When the cells are de-oxygenated and under stress in sickle cell conditions, they can change from round flexible disc-like cells to elongated sickle or crescent moon shape. The effect of these changes is that the cells do not pass freely through small capillaries and form clusters, which block the blood vessels. This blockage prevents oxygenation of the tissues in the affected areas resulting in tissue hypoxia and consequent pain (known as sickle cell crisis pain). Repeated crises ultimately result in damage to major organs. Other clinical consequences include severe anaemia, infections, visual impairment and stroke. In its most severe form, SCD has a significant impact on morbidity and mortality. SCD comprise a group of conditions caused by the 'sickle' mutation and include a wide range of significant variants including HbSS, HbSC, HbSD Punjab, HbSb Thal (b+,b0, db, Lepore), HbSO Arab, Hb-S/HPFH.).

2.0 Aim

The aim of the antenatal programme is to identify women that need to be screened and to offer timely screening to identify women/couples who have an increased chance of having a baby with a sickle cell or thalassaemia disorder in order to facilitate informed decision making including prenatal diagnosis and any subsequent action by the end of 13 wks gestation.

3.0 Objectives

- To provide information on the benefits and risks of screening, to enable the woman and her partner to make an informed decision on whether to accept or decline the offer of screening. This information should be given in a language that they understand when available.

- To identify and offer screening to all eligible women/couples. All women need to be asked what they consider their & the baby's biological fathers family origin to be at the booking appointment.

- If the family orgin questionnaire (FOQ) indicates there is a chance of either parent being a carrier, a screening blood test is offered. All eligible women identified through the FOQ should be screened by 10^{+0} weeks gestation.

- To process and report on screening tests in a timely manner as detailed in the UK NSC working standards and the NHS Sickle Cell and Thalassaemia Screening Programme specific standards.

- To refer all women identified as having a haemoglobin variant to the haemoglobinopathy specialist nurse for specialist counselling and to offer the baby's biological father screening to estimate their risk of having a child with a haemoglobin disorder.

- To offer counselling and pre-natal diagnosis by trained counsellors to a women if the child is identified as being 'at risk' of having a haemoglobin disorder. ('At Risk' being when both parents are carriers or if the fathers status is unknown.)

- For women accepting prenatal diagnosis, 50% of prenatal diagnoses should be performed before 12^{+6} weeks.

- To provide information, support and counseling to all women with a confirmed diagnosis as the result of screening.

- To provide all health professionals involved in the screening programme an appropriate level of knowledge.

- To audit and monitor the screening process and compliance with national standards and directives.

- To provide the Quality Assurance within the screening pathway by having appropriate failsafe mechanisms in place across the whole screening pathway for risk assessment and to identify and report any adverse incidents during the screening process.

4.0 Definitions

4.1 Family Origin Questionnaire (FOQ) – is a duplicate form completed at booking and used as an initial screening tool to identify women and/or the biological father who are from a high risk family origin that determines who needs to be tested. This should be completed by the health professional and ancestry should be at least 2 generations back**,** it is particularly important for individuals with a mixed/multiple ethnic background. The top (white) copy of the form accompanies the blood sample to the lab, and the yellow bottom copy is sent to the screening midwife.

4.2 Low Prevelence – where less than 1% of bookings are screen positive. Shropshire and Telford is defined as being a low prevalence area. Low Prevelence areas use the FOQ screening tool to determine who needs to be screened.

4.3 Maternity Information System (MIS) – Badgernet is the electronic maternity system used.

4.4 Haemoglobinopathy Screening Practioner (HSP)-The HSP is employed by the Regional Genetics Service based in Birmingham. As a low prevalence area in Shropshire and Telford women are counselled regarding their screening results and the father is offered screening by the HSP.

5.0 Screening Pathway

Refer to the guideline ' Antenatal Screening – The Process, Review and Communication of screening results' for generic screening information on:

- Screening information given to women
- The offer and uptake of screening by 10+0 weeks
- Women who book after 20 weeks
- Women who transfer from another unit in their pregnancy
- Women who present in labour
- Women who decline screening.
- Women who miscarry/TOP

5.1 The Pathway for the review of Haemoglobinopathy screening results.

5.1.1 Screen Negative Results for the woman

- Results should be available on the electronic hospital laboratory reporting system within 3 working days of the test being taken.
- Results are reviewed by the community midwife and the woman is informed of her result at the following antenatal visit.
- The result is documented on the MIS.

5.1.2 Screen Positive Results for the woman

- The Haematology lab informs the screening midwife by phone of a screen positive result within 3 working days of the blood being received and tested by the lab.
- If a woman attends for booking and she or the biological father of the baby is a known carrier the SM should be informed directly to facilitate speedy referral to the HSP and PND if appropriate to enable early choices.
- The screening midwife completes an 'Antenatal Haemoglobinopathy Referral' form and enters the woman on the electronic screening database. The screening midwife documents the results and actions taken on the MIS.

The ‘Antenatal Haemoglobinopathy Referral’ form is emailed via a secure NHS screening email account to the HSP.

5.1.3 Testing the father of the baby indicated

The HSP contacts the woman by phone and discusses:

- The woman’s screening results
- Offer’s screening for the biological father of the baby if he is available
- Provides further information to the woman about her individual risk of having a baby with a haemoglobin disorder.

Screen Negative Results

- The haematology lab informs the HSP directly when the father’s blood has been analysed.
- The HSP contacts the woman and the father by phone as previously arranged and they are informed of the result and the inheritance probability for their baby.
- The HSP writes to the parents to confirm their results and the inheritance probability for their baby. A copy of the letter is emailed to the screening midwife and the woman’s GP.
- The screening midwife scans the correspondence in the MIS.

Screen Positive Results

- The haematology lab informs the HSP directly when the father’s blood has been analysed.
- The offer of PND for an at risk woman should be made by 12+0 weeks
- The HSP contacts the woman and the biological father by phone as previously arranged and they are informed of the result and the inheritance probability for their baby.
- The HSP discusses their options and choice regarding prenantal diagnosis (PND).
- All women/couples identified as having a pregnancy at risk will have the opportunity to discuss further the result and options for further management by expert (PEGASUS trained) counsellors with decisions clearly documented.
- The discussion should include the choices available following a confirmed diagnosis
- The HSP verbally informs the screening midwife of the fathers result and the decision the couple have made regarding PND

5.1.4 Pre Natal diagnosis is indicated.

- PND is offered if:
- The biological father of the baby is unavailable/declined screening
- The biological father of the baby has been tested and is also a carrier for a haemoglobin variant and there is a 1 in 4 risk of the baby being affected
- The pregnancy is following infertility treatment and the donor egg/sperm status is unknown
- The screening midwife documents in the MIS that PND has been offered and the decision made by the couple.

5.1.5 PND Accepted

- If a woman accepts the offer of PND she is refered by the HSP to the genetic team in Birmingham who will arrange for an appointment with the fetal medicine specialist.
- The Timeliness of PND should be by 12+6 weeks
- The results of PND should be made available by 5 working days and will be communicated to the woman by the fetal medicine team in Birmingham.

5.1.6 PND Declined

- If a woman declines any further testing her decision is documented in the MIS
- Any couple who decline further testing will be seen in the Antenatal clinic for further review and management.
- The HSP notifies the Newborn Screening Laboratory of all pregnancies that are identified as being ‘at risk’ of a haemoglobin disorder or have been confirmed through PND via an alert form inorder to link the antenatal result with the newborn screening test.

5.2 Management of Women with known haemoglobin variant – carrier.

5.2.1 Thalassaemia carrier

- It is important to monitor the woman for anaemia this is due to the smaller red blood cells that she produces (ie MCV) by FBC and ferritin levels. DO NOT give iron supplements unless her ferritin levels are low.

5.2.2 Sickle Cell Carrier (Trait)

- Women who are sickle cell carriers are more prone to urinary tract infection and anaemia in pregnancy.
- In labour, sickle cell carriers are more prone to fetal distress therefore continuous electronic fetal monitoring is indicated.
- Sickle cell crisis can happen in the presence of severe dehydration and hypoxia even in women who are only carriers and are not affected by a disorder. Therefore maintaining adequate hydration is important

5.3 Management of Women with a known haemoglobin disorder

5.3.1 Sickle cell - Refer to BSH (British Society for Haematology) guideline ' Guidelines for the Management of Sickle Cell disease in Pregnancy' – August 2021, to make an individualised care plan

5.3.2 Thalasaemia -Refer to RCOG Green top Guideline no 66 'Management of Beta Thalassaemia in Pregnancy' – March 2014, to make an indicvidualised care plan.

6.0 Screening Failsafes for Haemoglobinopathy Screening

A screening failsafe process should be in place to ensure we can identify and prevent any screening safety incidents.

- At booking the midwife gives written and verbal information about sickle cell and thalassaemia screening. It will be explained that to determine if screening is indicated the family origin questionnaire (FOQ) is completed to identify whether the woman and the baby's biological father have a family origin that is considered to be more 'at risk'. (Go back at least 2 generations).
- The top copy (white),of the completed FOQ accompanies the blood sample to the lab. If the woman declines screening then a completed FOQ will still need to be sent to the haematology lab.
- The bottom copy (yellow) of the FOQ is sent to the screening midwife following booking. The screening midwife checks that it has been completed correctly and that screening has been completed.
- Any sample that reaches the lab without an FOQ / the FOQ is not completed – the haematologist contacts the screening team who provide the missing information in order that the woman is screened appropriately.
- Each week the haematologist monitors the number of antenatal samples that have not had a completed FOQ and the screening midwife is notified.
- Each week the screening midwife monitors the number of women tested and the number of FOQ's received. Also the number of incomplete FOQ's and the area and midwife responsible. This information is cascaded to the appropriate area manager.

7.0 Missed Screening

Safety concerns and incidents in screening services need special attention because of the characteristics of screening. Staff should be encouraged to report quality concerns so that action is taken to reduce and improve the service.

Screening safety incidents include:

- Any unintended or unexpected incident, act of commission or acts of omission that occur in the delivery or screening that could have or did lead to harm.
- Harm or risk of harm if the person eligible for screening are not offered screening.

Serious Incidents

- Where individuals, public or staff would suffer avoidable harm or death if the root cause is unresolved.
- The likelihood of significant damage to the reputation of the organization involved.

In the event of a missed screen refer to the Public Health England (PHE) Guidance 'Managing Safety Incidents in NHS Screening Programmes' published 2015, updated 14th July 2023.

- Report the incident on 'Datix', the Trust incident reporting system.
- Inform the screening midwife.
- The Screening Midwife will complete a Screening Incident Assessment Form (SIAF) to collect information on the suspected incident.
- The SIAF will be sent to the PHE Screening Quality Assurance Service and the Screening and Immunisation Team for North Midlands (Shropshire and Staffordshire)
- The incident will be reviewed by PHE, QA to distinguish whether it is a 'screening safety incident' or a 'serious incident'.
- The incident will be reviewed at the weekly 'Maternity Risk Meeting'.
- The incident investigation will follow the Trust Risk Management Policy and PHE Guidance.

A duty of candour should be completed for any individual affected/impacted by a screening safety incident.

8.0 Training

Training and updating will be delivered in accordance with the SATH Maternity Services Training Needs Analysis. The current programme of the training that is being provided are kept by the Lead Midwife for Education.

9.0 Monitoring/audit

The antenatal and Newborn Screening Programmes are audited in line with the National Screening Committee standards. The following National Screening Key Performance Indicators (KPI's) for the sickle cell and thalassaemia programme are audited on a quarterly basis and submitted to NHS England by the screening midwife:

- **ST1** - All eligible women accepting an offer of screening are tested and a have a screening result.
Acceptable level: ≥ 95.0%
Achievable level: ≥ 99.0%

- **ST2** - The proportion of women having antenatal sickle cell and thalassaemia screening for whom a conclusive screening result is available by 10 weeks' gestation.
Acceptable level: ≥ 50.0%
Achievable level: ≥ 75.0%

- **ST3**- The proportion of antenatal sickle cell and thalassaemia samples submitted to the laboratory which are supported by a completed Family Origin Questionnaire (FOQ).
Acceptable level: ≥ 90.0%
Achievable level: ≥ 95.0%

- **ST4a** - The timely offer of prenatal diagnosis (PND) to women at risk of having an affected infant
No threshold set yet

- **ST4b -** The timely offer of prenatal diagnosis (PND) to couples at risk of having an affected infant
No threshold set yet

In addition the following auditable standards are submitted to NHS England annually by the screening midwife :

SCT-S04: Test turnaround time – the number of results reported on or before 3 working days.
Acceptable level: ≥ 90.0%
Achievable level: ≥ 95.0%

SCT-S06: Proportion of PND tests perfomed before or at 12+6 weeks gestation.
Acceptable level: ≥ 50.0%
Achievable level: ≥ 75.0%

SCT-S07: Proportion of women receiving results for their PND before or after 5 working days
Acceptable level: ≥ 70.0%
Achievable level: ≥ 90.0%

The screening programme is audited annually and an Annual audit report is submitted to the Regional Screening Quality Assurance Team is presented to the Trust. An action plan is developed based on the audit report findings.

10.0 References:

- PHE NHS Sickle Cell and Thalassaemia Screening Programme Standards 2019, updated 24th July 2023
- PHE Sickle Cell and thalassaemia screening pathway requirements specification. 21st June 2021
- NHS Sickle Cell and Thalassaemia Screening Overview January 2018
- Antenatal and Newborn Screening programmes: NHS Sickle Cell and Thalassaemia Screening- Handbook for Laboratories. Updated July 2018
- BSH (British Society for Haematology) guideline ' Guidelines for the Management of Sickle Cell disease in Pregnancy' – August 2021
- RCOG Green top Guideline no 66 'Management of Beta Thalassaemia in Pregnancy' – March 2014
- Public Health England (PHE) Guidance 'Managing Safety Incidents in NHS Screening Programmes' published 2015, updated 14th July 2023

Appendix 1: **Antenatal Care Pathway – For Screening for Sickle cell and Thalassaemia**

At Booking, from 6 weeks – Selective screening for Sickle cell and Thalassaemia based on family origin
Written and verbal information is given, including the NSC leaflet 'Screening Tests for you and your baby'.
Screening is discussed and the offer documented in the maternity information system.
Family origin questionnaire completed (ask at least 2 generations back) to determine who requires screening

Screening not indicated as of low risk family origin
Antenatal Booking Blood and FOQ forms completed
(Top white copy to the lab with blood sample and bottom yellow copy to the SM.)
Explaination given to woman why screening is not indicated.

Screening Accepted/Indicated
Antenatal Booking Blood and FOQ form completed (Top white copy to the lab with blood sample and bottom yellow copy to the SM.)
Bloods should be taken with consent by 10+0 weeks.
The woman is informed how she will receive her result.
Document when bloods taken in the MIS

Screening Declined
Document her decline in the MIS
Complete the FOQ and document screening declined (Top white copy to the lab with blood sample and bottom yellow copy to the SM)
Re-offer screening again later in pregnancy

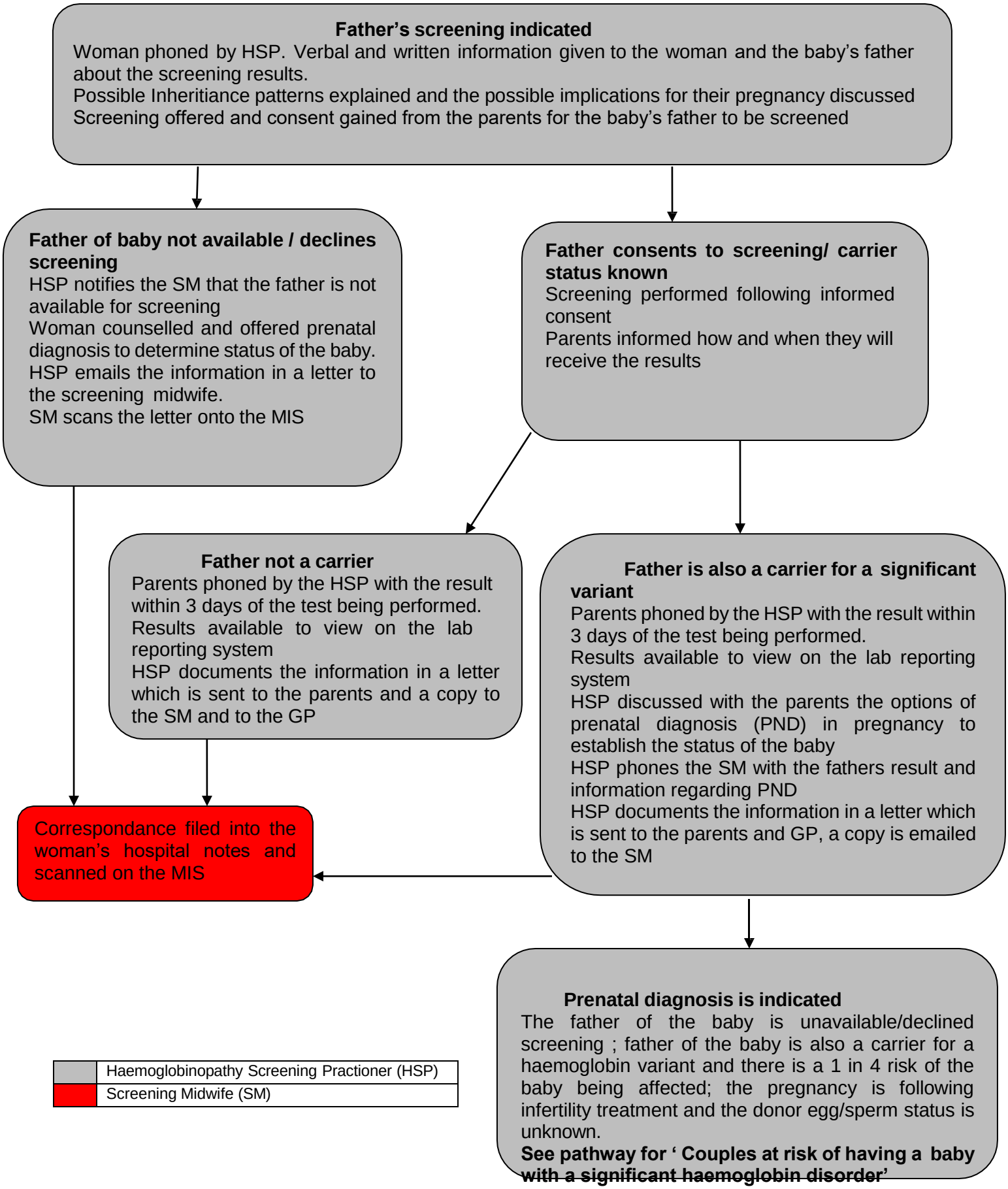
No Significant variant/carrier status
Result available on lab electronic reporting system within 3 working days.
Results documented in the MIS
Woman informed of her result at her next antenatal appointment

Carrier Detected
Haematology lab phones the SM with the result within 3 working days of the blood being received in the lab.
The SM emails a referral to the HSP with the woman's results and requests the biological fathers screening
The results are available on the lab electronic reporting system and a hard copy of the result is sent to the SM.
The SM documents the results on the MIS and the actions taken.

Affected mother identified
Haematology lab phone the result to the SM within 3 working days of the blood being received in the lab.
The SM emails a referral to the HSP with the woman's results and requests the fathers screening
The results are available on the lab electronic reporting system
And a hard copy of the result is sent to the SM.
The SM documents the results on the MIS and the actions taken.
Woman referred for consultant care and appointment generated

	Community Midwife
	Screening Midwife (SM)
	Haemoglobinopathy Screening Practioner (HSP)

Father screening indicated- see separate pathway
Woman phoned by the HSP within 24 hrs of receiving the referral
Woman informed of her result and arrangements made for a face to face consultation to discuss implications of result and to request fathers screening


Father's screening indicated
Woman phoned by HSP. Verbal and written information given to the woman and the baby's father about the screening results.
Possible Inheritiance patterns explained and the possible implications for their pregnancy discussed
Screening offered and consent gained from the parents for the baby's father to be screened
Father of baby not available / declines screening
HSP notifies the SM that the father is not available for screening
Woman counselled and offered prenatal diagnosis to determine status of the baby.
HSP emails the information in a letter to the screening midwife.
SM scans the letter onto the MIS
Father consents to screening/ carrier status known
Screening performed following informed consent
Parents informed how and when they will receive the results
Father not a carrier
Parents phoned by the HSP with the result within 3 days of the test being performed.
Results available to view on the lab reporting system
HSP documents the information in a letter which is sent to the parents and a copy to the SM and to the GP
Father is also a carrier for a significant variant
Parents phoned by the HSP with the result within 3 days of the test being performed.
Results available to view on the lab reporting system
HSP discussed with the parents the options of prenatal diagnosis (PND) in pregnancy to establish the status of the baby
HSP phones the SM with the fathers result and information regarding PND
HSP documents the information in a letter which is sent to the parents and GP, a copy is emailed to the SM
Correspondance filed into the woman's hospital notes and scanned on the MIS
Prenatal diagnosis is indicated
The father of the baby is unavailable/declined screening ; father of the baby is also a carrier for a haemoglobin variant and there is a 1 in 4 risk of the baby being affected; the pregnancy is following infertility treatment and the donor egg/sperm status is unknown.
See pathway for ' Couples at risk of having a baby with a significant haemoglobin disorder'
Haemoglobinopathy Screening Practioner (HSP)
Screening Midwife (SM)

Appendix 3 **Pathway for couples at risk of having a baby with a significant haemoglobin disorder**

Prenatal diagnosis is indicated

The father of the baby is unavailable/declined screening ; father of the baby is also a carrier for a haemoglobin variant and there is a 1 in 4 risk of the baby being affected; the pregnancy is following infertility treatment and the donor egg/sperm status is unknown.

Prenatal Counselling

The woman and the baby's father (if available) are seen by the HSP from Birmingham by 12+0 weeks of pregnancy
Information about the possible inheritance pattern for their baby is discussed and further information regarding the specific disorder that the baby may be affected with is explained
The options that are available for them are given and discussed
Both verbal and written information is given regarding PND

Prenatal Diagnosis Declined

The HSP phones the SM following the woman's decision.
The HSP sends a 'At Risk Pregnancy' Alert to the newborn screening lab inorder to link the newborn screening results with the mother
The HSP emails a letter to the SM confirming the offer and decision made a copy is sent to the GP and the woman

The SM generates a neonatal alert for the neonatologist following delivery
A consultant appointment is generated

Prenatal Diagnosis is Accepted

The HSP phones the SM regarding the parents decision regarding PND
The woman is informed how she will receive the result following PND

The HSP liases with the fetal medicine
to arrange an appointment for PND within 3 days and by 12+6 weeks.
The decision is documented on the MIS The woman is informed how and when she will receive the PND results

No Haemoglobin Disorder confirmed

The woman is informed of her PND result within 5 working days
The result of her PND is documented on the MIS and the SM is informed

Haemoglobin Disorder Confirmed

The woman is informed of her PND result within 5 working days An appointment is offered for the couple to discuss the results and to consider their options
The result of her PND are documented on the MIS.

Decision to end pregnancy

Refer as appropriate and inform the bereavement midwife
The SM informs the HSP
Will need postnatal consultant follow-up

Continuing with Pregnancy

For consultant care and delivery
Support as appropriate
'At risk pregnancy' alert to the Newborn Screening Lab , Neonatal Alert Complete

	Other specialist = Consultant
	Fetal medicine specialist
	Haemoglobinopathy Screening Practioner (HSP)
	Screening Midwife (SM)